

MRLs for tribenuron methyl on several plant commodities. However, no Canadian or Mexican MRLs for tribenuron methyl have been proposed or established for barley, hay; oat, forage; oat, hay; wheat, forage; or wheat, hay.

C. Response to Comments

A comment was received from a private citizen supporting the Agency's updating of pesticide regulations.

V. Conclusion

Therefore, tolerances are established for residues of tribenuron methyl, methyl-2-[[[4-methoxy-6-methyl-1,3,5-triazin-2-yl)methylamino]carbonyl]amino)sulfonyl]benzoate on barley, hay at 0.4 ppm; oat, forage at 0.05 ppm; oat, hay at 0.05 ppm; wheat, forage at 0.3 ppm; and wheat, hay at 0.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final 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 9, 2000) do not apply to this final rule. In addition, this final 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: July 31, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.451 is amended by alphabetically adding the following entries to the table in paragraph (a) to read as follows:

§ 180.451 Tribenuron Methyl; Tolerances for Residues.

(a) * * *

Commodity	Parts per million
Barley, hay	0.4
Oat, forage	0.05
Oat, hay	0.05
Wheat, forage	0.3
Wheat, hay	0.5

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0097; FRL-8376-2]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on apple, wet pomace; asparagus; bean, succulent; bean, dry seed; beet, garden, tops; beet, garden, roots; brassica, leafy greens, subgroup 5B; coffee, green bean; coffee, roasted bean; corn, field, grain; corn, field, forage; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, kernel plus cob with husks removed; corn, sweet, forage; corn, sweet, stover; cotton, undelinted seed; cotton, gin byproducts; Fruit, pome, group 11; fruit, stone, group 12, except cherry; grain, aspirated fractions; hop, dried cones; lychee; mango, postharvest; okra; onion, bulb, subgroup 3-07A; onion, green, subgroup 3-07B; plum, pre- and post-harvest; turnip, roots; turnip, tops; soybean, forage; soybean, hay; soybean, seed; sunflower, seed; sunflower, meal; sunflower, refined oil; and vegetable, cucurbit, group 9. Bayer CropScience LP and Interregional Research Project No. 4 (IR4) have requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2008. Objections and requests for hearings must be received on or before October 14, 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-2005-0097. 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: Tracy Keigwin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6605; e-mail address: keigwin.tracy@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather 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-2005-0097 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 October 14, 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-2005-0097, 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 May 18, 2005 (70 FR 28527) (FRL-7708-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP) 6F4668, 0F6086, 0E6091, 0F6129, 1F6289, 4E6842, and 4F6854 by Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petitions requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, in or on food commodities: Fruit, pome, group 11 at 0.05 parts per million (ppm) (PP 6F4668); bean, succulent at 0.1 ppm (PP 0F6086); bean, dry seed at 0.1 ppm (PP 0F6086); cotton, undelinted seed at 2.0 ppm (PP 0F6086); cotton, gin byproducts at 16 ppm (PP 0F6086); asparagus at 0.01 ppm (PP 0E6091); coffee, green bean, at 0.1 ppm (PP 0E6091); coffee, roasted bean, at 0.2 ppm (PP 0E6091); garlic, dry bulb at 0.1 ppm (PP 0E6091); onion, dry bulb at 0.1 ppm (PP 0E6091); corn, field, grain at 0.01 ppm (PP 0F6129); corn, field, forage at 3.0 ppm (PP 0F6129); corn, field, stover at 3.0 ppm (PP 0F6129); corn, pop, grain at 0.01 ppm (PP 0F6129); corn, pop, stover at 3.0 ppm (PP 0F6129); corn, sweet, kernel plus cob with husks removed at 0.5 ppm (PP 0F6129); corn, sweet, forage at 6.0 ppm (PP 0F6129); corn, sweet, stover at 5.0 ppm (PP 0F6129); soybean, seed at 0.01 ppm (PP 0F6129); soybean, forage at 0.01 ppm (PP 0F6129); soybean, hay at 0.05 ppm (PP 0F6129); fruit, stone, group 12, except cherry at 1.0 ppm (PP 1F6289); hop, dried cones at 30.0 ppm (PP 4E6842); soybean, seed at 0.06 ppm (PP 4F6854); soybean, forage at 17 ppm (PP 4F6854); soybean, hay at 45 ppm (PP 4F6854); soybean, hulls at 0.06 ppm (PP 4F6854); and grain, aspirated

fractions at 15 ppm (PP 4F6854). Bayer CropScience also proposed to add a postharvest use on cherries at the current 0-day pre-harvest tolerance level of 4.0 ppm. That notice referenced a summary of the petitions prepared by Bayer CropScience LP, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C. Note that the tolerances proposed for the food commodities listed under PP 0E6091 were import tolerances.

Additionally, in the same Notice of filing, EPA announced the filing of PPs 9E6045, 9E6046, 9E6048, 0E6103, 0E6117, 0E6153, 0E6158, and 0E6212 from Interregional Research Project No. 4 (IR4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petitions requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, in or on food commodities: Turnip, tops at 8.0 ppm (PP 9E6045); turnip, roots at 0.4 ppm (PP 9E6045); hops at 5.0 ppm (9E6046); vegetable, cucurbit, group 9 at 0.1 ppm (PP 9E6048); mango, postharvest at 0.2 ppm (PP 0E6103); fruit, stone, group 12, except cherry at 1.0 ppm (PP 0E6117); sunflower, seed at 0.05 ppm (PP 0E6153); sunflower, refined oil at 0.2 ppm (PP 0E6153); sunflower, meal at 0.2 ppm (PP 0E6153); okra at 1.0 ppm (PP 0E6158); and lychee at 1.5 ppm (PP 0E6212). That notice referenced a summary of the petitions prepared by the IR-4, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

In the **Federal Register** of April 12, 2006 (71 FR 18746) (FRL-7773-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of PPs 6E7036 by Interregional Research Project No. 4 (IR4), 681 U.S. Highway 1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, in or on the food commodity asparagus at 0.05 ppm. That notice referenced a summary of the petition prepared by IR-4, which is available to the public in the docket, <http://www.regulations.gov>. No comments

were received in response to this Notice of Filing.

In the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL-8133-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of PP 6E7097 by Interregional Research Project No. 4 (IR4), 681 U.S. Highway 1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, in or on food commodities vegetable, bulb, group 3 at 1.3 ppm; Brassica, leafy greens, subgroup 5B at 2.5 ppm; beet, garden, roots at 0.7 ppm; and beet, garden, leaves at 5.0 ppm. That notice referenced a summary of the petition prepared by IR-4, which is available to the public in the docket, <http://www.regulations.gov>. No comments were received in response to this Notice of Filing.

Based upon review of the data supporting the petitions, EPA has modified the level and/or the tolerance expression for all commodities except the following: Pome fruit; bean succulent, cotton, undelinted seed; corn, sweet kernel plus cob with husks removed; sunflower, seed; sunflower, meal; sunflower, oil; brassica, leafy greens subgroup 5B; and beet, garden root. The reason for these changes is explained in Unit IV.D.

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...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in

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 for the petitioned-for tolerances for residues of tebuconazole.

A. Toxicological Profile

The toxicological profile for tebuconazole can be found in the final rule published in the **Federal Register** of May 14, 2008 (73 FR 27748-27756, FRL-8364-6). Refer to this **Federal Register** document, available at <http://www.regulations.gov> for a detailed discussion of the toxicological profile of tebuconazole.

B. Toxicological Endpoints

The toxicological endpoints for tebuconazole can be found in the final rule published in the **Federal Register** of May 14, 2008 (73 FR 27748-27756, FRL-8364-6). Refer to this **Federal Register** document, available at <http://www.regulations.gov>, for a detailed discussion of the toxicological endpoint selection for tebuconazole.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tebuconazole, EPA considered exposure under the petitioned-for tolerances, including other pending petitions, as well as all existing tebuconazole tolerances in (40 CFR 180.474). EPA assessed dietary exposures from tebuconazole 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, anticipated residues for bananas, grapes, raisins, nectarines, peaches and peanut butter were derived using the latest USDA Pesticide Data Program (PDP) monitoring data from 2002-2006. Anticipated residues for all other registered and proposed food commodities were based on field trial data. Projected percent crop treated estimates were used for apples, apricots, cherries, hops, plums and sweet corn. For the remaining crops, 100% crop treated was assumed. Available

processing data were used to refine anticipated residues for apples/pears (dried and juice), apricots (dried), cherry (juice), coffee (roasted bean), grapes (juice), plums (prunes/prune juice) and peanut (oil). For all other processed commodities, DEEM (ver. 7.81) default processing factors were assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the same assumptions as stated above for acute exposure (Unit III.C.1.i).

iii. *Cancer.* As explained in the **Federal Register** of May 14, 2008 (73 FR 27748–27756, FRL–8364–6), the chronic risk assessment is considered to be protective of any cancer effects; therefore, a separate quantitative cancer dietary risk assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency assumed PCT for grapes; grape, raisins; nectarines; oats; peaches;

and peanuts. The PCT for each crop is as follows: Grapes: 25%; grape, raisin: 25%; nectarine: 25%; oats: 2.5%; peach: 20%; and peanuts: 45%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency used projected percent crop treated (PPCT) information for tebuconazole on apple (44% acute assessment, 41% chronic assessment); apricot (56% acute assessment, 43% chronic assessment); cherry (pre-harvest: 42% acute assessment, 37% chronic assessment); cherry (post-harvest: 100% acute assessment, 66% chronic assessment); corn, sweet (22% acute assessment, 14% chronic assessment); hop (64% acute assessment, 64% chronic assessment); plum, pre- and post-harvest (26% acute assessment, 24% chronic assessment); and turnip tops (68% acute assessment, 44% chronic assessment).

EPA estimates PPCT for a new pesticide use by assuming that its actual PCT during the initial 5 years of use on a specific use site will not exceed the recent PCT of the market leader (i.e., the one with the greatest PCT) on that site. An average market leader PCT, based on three recent surveys of pesticide usage, if available, is used for chronic risk assessment, while the maximum PCT from the same three recent surveys, if available, is used for acute risk assessment. The average and maximum market leader PCTs may each be based on one or two surveys if three are not available. Comparisons are only made among pesticides of the same pesticide types (i.e., the leading fungicide on the use site is selected for comparison with the new fungicide). The market leader PCTs used to determine the average and the maximum may be each for the same

pesticide or for different pesticides since the same or different pesticides may dominate for each year. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data.

An estimated PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment, and an estimated PPCT, based on the maximum PCT of the market leaders, is appropriate for use in acute dietary risk assessment. This method of estimating PPCTs for a new use of a registered pesticide or a new pesticide produces high-end estimates that are unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the PPCTs could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors have been considered for tebuconazole on the seven crops, resulting in adjustments to the initial estimates for three crops to account for lack of confidence in projections based on less than three observations, old data and/or data based on expert opinion.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis, or conservative estimates based on information from agricultural experts. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to

which tebuconazole may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tebuconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tebuconazole. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of tebuconazole for acute exposures are estimated to be 78.5 parts per billion (ppb) for surface water and 1.56 ppb for ground water. The EDWCs for chronic, non-cancer are estimated to be 44.9 ppb for surface water and 1.56 ppb for ground water. The EDWCs for chronic, cancer exposures are estimated to be 32.3 ppb for surface water and 1.56 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 78.5 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment (which is protective of any possible cancer effects), the water concentration value of 44.9 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Tebuconazole is currently registered for uses that could result in residential exposures. Short-term dermal and inhalation exposures are possible for residential adult handlers mixing, loading, and applying tebuconazole products outdoors to ornamental plants. Short- and intermediate-term dermal post application exposures to adults during golfing and children playing on treated wood structures are also possible. Children may also be exposed via the incidental oral route when playing on treated wood structures. Long-term exposure is not expected. As a result, risk assessments have been completed for residential handler scenarios as well as residential post application scenarios.

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."

Tebuconazole is a member of the triazole-containing class of pesticides. Triazole-derived pesticides can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). Refer to EPA's recent tolerance rulemaking on tebuconazole in the **Federal Register** of May 14, 2008 (73 FR 27748-27756, FRL-8364-6), for more information on this risk assessment.

D. Safety Factor for Infants and Children

In the **Federal Register** of May 14, 2008 (73 FR 27748-27756, FRL-8364-6) the Agency published a Final rule establishing tolerances for residues of tebuconazole in or on various food commodities. When the Agency conducted the risk assessments in support of that tolerance action, it also assessed dietary exposure to tebuconazole assuming that all of the tolerances in this action were in place. Accordingly, EPA relies on the decision on the FQPA safety factor for infants and children as set out in that action. Refer to EPA's recent tolerance rulemaking on tebuconazole, available at <http://www.regulations.gov>, for a detailed discussion and selection of a safety factor for infants and children for tebuconazole. For the reasons explained there, EPA reduced the FQPA safety factor to 3X for all potential exposure scenarios.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate safety factors (SFs). EPA calculates the aPAD and cPAD by dividing the point of departure (POD) by all applicable uncertainty factors (UFs). For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and

residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

Below, EPA has summarized the conclusions from its recent tolerance rulemaking on tebuconazole which took into account exposure to tebuconazole from the food commodities covered by the tolerances in this action. Refer to EPA's recent tolerance rulemaking on tebuconazole, available at <http://www.regulations.gov>, for a detailed discussion of EPA's safety determinations.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tebuconazole will occupy 53% of the aPAD for the population group (all infants less than 1 year old) receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tebuconazole from food and water will utilize 4% of the cPAD for the U.S. population and 11% of the cPAD for the most highly exposed population group (infants less than 1 year old).

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Tebuconazole is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to tebuconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the short-term aggregate MOE from dietary exposure (food + drinking water) and non-occupational/residential handler exposure for adults using a hose-end sprayer on ornamentals is 400. The short-term aggregate MOE from dietary exposure and exposure from golfing is 1,800. The short-term aggregate MOE to children from dietary exposure and exposure from wood surfaces treated at the above ground use rate is 530. The short-term aggregate MOE to children from dietary exposure and exposure to wood surfaces treated at the below ground use rate is 230. The combined and aggregate MOEs for wood treated for below ground uses exceed the Agency's LOC of 300, and indicate a potential risk of concern. However, the MOE of 230 is based on unrealistic assumptions and EPA has concluded that aggregate

exposure does not pose a risk of concern.

4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Tebuconazole is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to tebuconazole.

Since the POD, relevant exposure scenarios and exposure assumptions used for intermediate-term aggregate risk assessments are the same as those used for short-term aggregate risk assessments, the short-term aggregate risk assessments represent and are protective of both short- and intermediate-term exposure durations.

5. *Aggregate cancer risk for U.S. population.* Although tebuconazole is classified as a Group C Carcinogen-Possible Human Carcinogen, the Agency has concluded that the chronic RfD is protective of the cancer effects.

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 tebuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate gas chromatography/nitrogen phosphorus detection and liquid chromatography/mass spectrometry/mass spectrometry (GC/NPD and LC/MS/MS) methods are available for enforcing tolerances for tebuconazole and its metabolites in plant commodities, livestock matrices and processing studies. The methods have been adequately validated by an independent laboratory in conjunction with a previous petition. 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 Codex, Canadian and Mexican maximum residue limits (MRLs) for residues of tebuconazole in or on a variety of plant and livestock commodities. The tolerance definition for residues in plants is tebuconazole, per se, for Codex, Canada, and Mexico.

For livestock commodities, the tolerance expression is for the combined residues of tebuconazole and HWG 2061 in the United States and Canada, and tebuconazole, per se, for Codex. Where possible, the proposed tolerance levels have been harmonized with the MRLs from Canada, Mexico, and Codex. With regard to the pome fruit tolerance, the Agency recommended tolerance of 0.05 ppm differs from the Codex MRL of 0.5 mg/kg. Harmonization of the pome fruit tolerances is not possible because U.S. data were derived using long pre-harvest intervals (PHIs) of 75-129 days while Italian data were derived using maximum PHIs of 14 days. With regard to the cucurbit vegetable tolerance, the Agency recommended tolerance of 0.09 ppm for vegetable, cucurbit, group 9, differs from the Codex MRL of 0.2 mg/kg on cucumber and 0.02 mg/kg on summer squash. The Agency notes that some of the cucumber data from Spain were derived from trials conducted in greenhouses. Although the application rate used for the Spanish trials was similar to the trials conducted in the United States, it is quite normal for greenhouse trials to give higher residues. If the greenhouse trials are ignored, then the remaining Codex data are in the 0.02 – 0.04 range, consistent with the U.S. data and tolerance. In short, the higher Codex MRL for cucumber accommodates the greenhouse use.

C. Response to Comments

The Agency received a comment from a citizen of New Jersey. The commenter questioned the necessity of using taxpayer money through the agency of the Interregional Research Project No. 4 to develop pesticides, challenged the appropriateness of conducting some of the tebuconazole field trials outside of the United States, expressed concern over whether specific warnings were given to residents of New Jersey prior to conducting field trials in that State, and worried that students at Rutgers University may have been injured in the tebuconazole toxicological tests on animals that were performed at that facility.

In response, as to the commenter's concern with field trials that were conducted in countries other than the United States, EPA notes that frequently field trials are conducted in other countries as well as in the United States so that EPA can understand the range of pesticide residues that may be present on a food. EPA received several applications for tebuconazole import tolerances and it is appropriate that the field trials would be conducted in the countries where the pesticide was to be

used. Additionally, some tebuconazole import tolerances were proposed with foreign data, and then a U.S. use was proposed and U.S. data submitted. None of the other comments address the findings made in this action regarding the establishment of a tolerance. Nonetheless, EPA provides the following information regarding the comments. IR-4 was established by the USDA to help minor acreage; specialty crop producers obtain EPA tolerances and new registered uses of pesticides. As to whether warnings were given to residents of New Jersey regarding field trials, EPA would point out that experimental field trials are subject to EPA regulations at 40 CFR part 172. EPA also has regulations governing the toxicological data testing laboratories that are designed to insure data quality (40 CFR part 160). Federal jurisdiction concerning the safety of workers in testing laboratories would be under the Occupational Safety and Health Administration in the U.S. Department of Labor. EPA has responded to similar comments from this commenter on previous occasions. Refer to 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), and 69 FR 63083 (October 29, 2004).

D. Revisions to Petitioned-for Tolerances

Based upon review of the data supporting the petitions, EPA determined that the proposed tolerances should be revised as follows: Cotton, gin byproducts at 25.0 ppm; asparagus at 0.05 ppm; coffee, green bean at 0.15 ppm; coffee, roasted bean, at 0.3 ppm; onion, bulb, subgroup 3-07A at 0.2 ppm; corn, field, grain at 0.05 ppm; corn, field, forage at 4.0 ppm; corn, field, stover at 3.5 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 3.5 ppm; corn, sweet, forage at 7.0 ppm; corn, sweet, stover at 6.0 ppm; turnip, tops (limited to east of the Rockies) at 7.0 ppm; turnip, roots at 0.5 ppm; beet, garden, tops at 7.0 ppm; beet, garden, root at 0.70; hop, dried cones at 35.0 ppm; vegetable, cucurbit, group 9 at 0.09 ppm; mango, postharvest at 0.15 ppm; plum, pre- and post-harvest at 1.0 ppm; okra at 1.2 ppm; lychee at 1.6 ppm; soybean, seed at 0.08 ppm; soybean, forage at 25 ppm; soybean, hay at 50 ppm; and grain, aspirated fractions 16.0 ppm. A separate tolerance is required for apple, wet pomace at 0.1 ppm. No tolerance is required for soybean hulls. A tolerance of 1.3 ppm is required for onion, green, subgroup 3-07B. The tolerance proposed by IR-4 for hops (PP 9E6046) is covered by the registrant proposed tolerance for hops, dried cones (PP 4E6842). EPA revised

most of these tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP). For the proposed tolerances on asparagus; corn, field, grain; and by translation corn, pop grain the tolerance could not be set lower than the limit of quantitation (LOQ) of the enforcement analytical method, which was 0.05 ppm for tebuconazole. For corn, field, forage, the proposed tolerance was raised to 4.0 ppm based on the maximum residue level in the field trials.

Additionally, IR-4 petitioned for a tolerance on bulb vegetables group 3 as that crop group was defined at the time of the petition (6E7097). In the **Federal Register** of December 7, 2007 (72 FR 69150–69158) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920–28930) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. As part of this action, EPA expanded and revised bulb vegetables group 3. Changes to crop group 3 (bulb vegetables) included adding new commodities, creating subgroups for bulb and green onions, and changing the name of one of the representative commodities from “onion, dry bulb” to “onion, bulb”. The Bayer proposed tolerance for garlic (bulb) and onion (bulb) with no U. S. registration was superseded by the proposed tolerance for bulb vegetables. The proposed tolerance on bulb vegetables group 3 was determined to be inappropriate because the residues were found to be more than a factor of 5x. Thus, separate tolerances were set for the crop subgroups, onion, bulb, subgroup 3-07A at 0.2 ppm, and onion, green, subgroup 3-07B at 1.3 ppm.

EPA concludes it is reasonable to revise the petitioned-for tolerance so that they agree with the recent crop grouping revisions because (1) although the new crop groups/subgroups include several new commodities, the added commodities are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk; and tebuconazole exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action; and (2) the representative commodities for the revised crop groups/subgroups have not changed.

Finally, the proposed tolerance for hops, domestically grown, in PP 4E6046, was superseded by the proposed tolerance for hops, dry cone (based on data for imported hops) in PP 4E6842, since the latter proposed tolerance is higher, 30.0 ppm. The proposed tolerance for asparagus (domestic) at 0.2 ppm, in PP 6E7036, superseded the proposed tolerance for imported asparagus at 0.1 ppm, in PP 0E6091. The tolerances for inadvertent residues of tebuconazole in soybeans planted in rotation with treated wheat in PP 0F6129, were superseded by the proposed tolerance for soybean following a direct treatment of tebuconazole in PP 4F6854.

V. Conclusion

Therefore, tolerances are established for residues of the fungicide tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, in or on food commodities apple, wet pomace at 0.1 ppm; asparagus at 0.05 ppm; bean, succulent at 0.1 ppm; bean, dry seed at 0.1 ppm; beet, garden, tops at 7.0 ppm; beet, garden, roots at 0.70 ppm; brassica, leafy greens, subgroup 5B at 2.5 ppm; coffee, green bean at 0.15 ppm; coffee, roasted bean at 0.3 ppm; corn, field, grain at 0.05 ppm; corn, field, forage at 4.0 ppm; corn, field, stover at 3.5 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 3.5 ppm; corn, sweet, kernel plus cob with husks removed at 0.5 ppm; corn, sweet, forage at 7.0 ppm; corn, sweet, stover at 6.0 ppm; cotton, undelinted seed at 2.0 ppm; cotton, gin byproducts at 25.0 ppm; Fruit, pome, group 11 at 0.05 ppm; fruit, stone, group 12, except cherry at 1.0 ppm; grain, aspirated fractions at 16.0 ppm; hop, dried cones at 35.0 ppm; lychee at 1.6 ppm; mango, postharvest at 0.15 ppm; okra at 1.2 ppm; onion, bulb, subgroup 3-07A at 0.2 ppm; onion, green, subgroup 3-07B at 1.3 ppm; plum, pre- and post-harvest at 1.0 ppm; soybean, forage at 25 ppm; soybean, hay at 50 ppm; soybean, seed at 0.08 ppm; sunflower, seed at 0.05 ppm; sunflower, meal at 0.2 ppm; sunflower, refined oil at 0.2 ppm; vegetable, cucurbit, group 9 at 0.09 ppm; turnip, roots at 0.5 ppm; and turnip, tops at 7.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petitions 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 final rule has been exempted from review under Executive Order 12866, this final 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 9, 2000) do not apply to this final rule. In addition, this final 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: July 29, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.474 is amended by revising the introductory text of paragraph (a)(1), by alphabetically adding the following commodities to the table in paragraph (a)(1); by removing the text from paragraph (b) and reserving the paragraph designation and heading; and by adding a new paragraph (c).

§ 180.474 Tebuconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for the residues of the fungicide, tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on the following commodities:

Commodity	Parts per million
* * * * *	*
Apple, wet pomace	0.1
Asparagus	0.05
* * * * *	*
Bean, succulent	0.1
Bean, dry seed	0.1
Beet, garden, roots	0.70
Beet, garden, tops	7.0

Commodity	Parts per million
Brassica, leafy greens, subgroup 5B	2.5
Coffee, green bean ¹	0.15
Coffee, roasted bean ¹	0.3
Corn, field, grain	0.05
Corn, field, forage	4.0
Corn, field, stover	3.5
Corn, pop, grain	0.05
Corn, pop, stover	3.5
Corn, sweet, kernel plus cob with husks removed	0.5
Corn, sweet, forage	7.0
Corn, sweet, stover	6.0
Cotton, undelinted seed	2.0
Cotton, gin byproducts	25.0
Fruit, pome, group 11	0.05
Fruit, stone, group 12, except cherry	1.0
Grain, aspirated fractions	16.0
* * * * *	*
Hop, dried cones	35.0
Lychee	1.6
Mango, postharvest	0.15
* * * * *	*
Okra	1.2
Onion, bulb, subgroup 3-07A	0.2
Onion, green, subgroup 3-07B	1.3
* * * * *	*
Plum, pre- and post-harvest	1.0
* * * * *	*
Soybean, forage	25
Soybean, hay	50
Soybean, seed	0.08
Sunflower, seed	0.05
Sunflower, meal	0.2
Sunflower, refined oil	0.2
Vegetable, cucurbit, group 9	0.09
* * * * *	*

¹There are no U.S. registrations as of 7/31/2008.

* * * * *

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

(c) *Tolerances with regional registrations.* Tolerances with regional registrations for the residues of the fungicide, tebuconazole, alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on the following commodities:

Commodity	Parts per million
Turnip, roots	0.5
Turnip, tops	7.0

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0564; FRL-8374-4]

Thifensulfuron Methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thifensulfuron methyl in or on barley, hay; oat, forage; oat, hay; wheat, forage, and wheat, hay. E.I. DuPont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2008. Objections and requests for hearings must be received on or before October 14, 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-2007-0564. To access the electronic docket, go to <http://www.regulations.gov>, and search for the docket ID number. 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:

Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: