

Commodity	Parts per million
Grass forage, fodder, and hay crop group 17, straw .....	4.0
* * * * *	* * * * *

[FR Doc. 2010-1610 Filed 1-26-10; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2009-0276; FRL-8808-6]

#### Triticonazole; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of triticonazole in or on grain, cereal, group 15, except rice, and grain, cereal, fodder, forage and straw, group 16, except rice. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective January 27, 2010. Objections and requests for hearings must be received on or before March 29, 2010, 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-2009-0276. All documents in the docket are listed in the docket index available at <http://www.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:** Tawanda Maignan, Registration

Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8050; e-mail address: [Maignan.Tawanda@epa.gov](mailto:Maignan.Tawanda@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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods & Guidelines" on the left-side navigation menu.

###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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-2009-0276 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 March 29, 2010.

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-2009-0276, 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 Facility'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 August 19, 2009, (74 FR 41900) (FRL-8426-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7420) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.583 be amended by establishing tolerances for residues of the fungicide triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on grain, cereal, group 15, except rice, and grain, cereal, forage, fodder and straw, group 16, except rice, at 0.05 and 0.10 parts per million (ppm), respectively. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has modified both the crop group terminology, and tolerance levels for

grain, cereal, group 15, except rice, at 0.01 ppm, and the crop group terminology (only) for grain, cereal, forage, fodder and straw, group 16, except rice, at 0.10 ppm. These tolerances replace previously established individual tolerances for barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw at 0.05 ppm. The reason for these changes is explained in Unit IV.C.

### 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 triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol on grain, cereal, group 15, except rice, at 0.01 ppm, and grain, cereal, forage, fodder and straw, group 16, except rice, at 0.10 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the

sensitivities of major identifiable subgroups of consumers, including infants and children.

Triticonazole has low acute toxicity, is not a skin, eye, or respiratory irritant, or a dermal sensitizer. Non-acute toxicity studies show that the liver (rat, mouse, dog) and adrenals (rat, dog, rabbit) are target organs across species. Adverse body weight changes (rat, dog, rabbit, mouse) and clinical signs (rat, dog, mouse) also were observed in multiple species. In the developmental and reproductive toxicity studies, adverse effects were seen at the same dose level in the offspring and parental animals, and the offspring were not qualitatively more susceptible compared with adults. In the rat subchronic study, decreased thymus weights were reported at a dose level (~2,300 milligrams/kilogram/day (mg/kg/day)) two times higher than the limit dose (1,000 mg/kg/day). Triticonazole was negative for mutagenicity, and the cancer classification is "Not Likely to Be Carcinogenic to Humans" based on a lack of evidence of carcinogenicity in the two guideline studies conducted on rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by triticonazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document "Triticonazole. Human Health Risk Assessment for Proposed Seed Treatment Use on Cereal Grains (Crop Group 15) Including Barley, Field Corn, Oats, Popcorn, Rye, Sorghum Grain, Sweet Corn, Triticale, and Wheat (Excluding Rice); and Forage, Fodder, and Straw of Cereal Grains (Crop Group 16), Excluding Rice," at pages 34 to 36 in docket ID number EPA-HQ-OPP-2009-0276.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account

uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for triticonazole used for human risk assessment can be found at <http://www.regulations.gov> in the document "Triticonazole. Human Health Risk Assessment for Proposed Seed Treatment Use on Cereal Grains (Crop Group 15) Including Barley, Field Corn, Oats, Popcorn, Rye, Sorghum Grain, Sweet Corn, Triticale, and Wheat (Excluding Rice); and Forage, Fodder, and Straw of Cereal Grains (Crop Group 16), Excluding Rice," at pages 15 to 16 in docket ID number EPA-HQ-OPP-2009-0276.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to triticonazole, EPA considered exposure under the petitioned-for tolerances as well as all existing triticonazole tolerances in 40 CFR 180.583. EPA assessed dietary exposures from triticonazole 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 U.S. Department of

Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance level residues of triticonazole were found in all commodities and that all commodities consumed were 100% crop treated. Anticipated residues and/or percent crop treated (PCT) information were not used.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance level residues in all commodities, and 100% crop treated for all treated commodities. Anticipated residues and/or PCT information were not used.

iii. *Cancer.* Triticonazole is classified as “not likely to be carcinogenic to humans” based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. There is no evidence that triticonazole is carcinogenic to humans, therefore an exposure assessment to evaluate cancer risk is not needed.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for triticonazole. Tolerance level residues and/or 100% crop treated were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for triticonazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of triticonazole. 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>.

The estimated drinking water concentrations (EDWCs) used in the dietary risk assessment were provided by OPP’s Environmental Fate and Effects Division and incorporated directly into the dietary assessment. The EDWCs used in the dietary assessment were modeled using the surface water model, Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS). For the acute point estimate, the PRZM-EXAMS 1-in-10 year annual maximum EDWC was used. For the chronic point estimate, the PRZM-EXAMS 1-in-10 year annual mean EDWC was used. PRZM-EXAMS EDWCs were used because they were higher (and therefore more protective) than the groundwater model’s, (Screening Concentration in Groundwater

model (SCI-GROW’s)) EDWC. Based on the PRZM/EXAMS, the EDWCs of triticonazole for acute exposures are 75.5 parts per billion (ppb) for surface water and 5.7 ppb for ground water, and chronic exposures for non-cancer assessments are estimated to be 32.8 ppb for surface water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 75.5 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 32.8 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). Triticonazole is currently registered for the following uses that could result in residential exposures: Residential and commercial turfgrass, golf courses, and sod farms. EPA quantitatively assessed the risk from residential exposure to children from children’s incidental oral post-application scenarios (hand to mouth, mouthing grass, and soil ingestion). Children and adults may also have post-application dermal exposure but dermal toxicity studies with triticonazole did not identify any adverse effects from such exposure.

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.”

EPA has not found triticonazole to share a common mechanism of toxicity with any other substances, and triticonazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that triticonazole does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

Triticonazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in

plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice; some induce thyroid tumors in rats; and some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA’s procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

Triticonazole and other triazole-containing pesticides can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including triticonazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency’s complete risk assessment is found in the propiconazole reregistration docket at <http://www.regulations.gov>, Docket

Identification (ID) Number EPA-HQ-OPP-2005-0497.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for triticonazole includes rat and rabbit developmental toxicity studies and a two generation reproduction study in rats. There is no evidence of increased susceptibility following *in utero* and/or postnatal exposure in the developmental toxicity studies in rats or rabbits, and in the 2-generation rat reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for triticonazole is complete with the exception of a newly required immunotoxicity study. In accordance with 40 CFR Part 158 toxicity data requirements, an immunotoxicity study (Harmonized guideline 870.7800) is required for triticonazole. In the absence of specific immunotoxicity studies, EPA has evaluated the available triticonazole toxicity data to determine whether an additional uncertainty factor is needed to account for potential immunotoxicity. The toxicological database for triticonazole does not indicate that the immune system is the primary target organ. Decreased thymus weight was observed in only one species (rat) at the highest dose tested (~2x the limit dose of 1,000 mg/kg/day); these findings may be due to secondary effects of overt systemic toxicity. Based on this evidence, EPA does not believe that conducting immunotoxicity testing will result in a point of departure lower than those already selected for triticonazole risk assessment, and an additional uncertainty factor is not needed to account for potential immunotoxicity.

ii. There are no indications that triticonazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that triticonazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure database. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to triticonazole in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers.

#### *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 SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable 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.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the combined acute dietary exposure from food and water to triticonazole will occupy < 1% of the aPAD for (females 13 to 49 years old), the population subgroups receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to triticonazole from food and water will utilize 1.4% of the cPAD for all infants (< 1 year old), the subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of triticonazole is not expected.

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). Triticonazole is currently registered for use(s) 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 triticonazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of: 1,100 for children 1 to 2 years old, and 1,100 for all infants < 1 year old. Because the level of concern is for MOEs below 100, these MOEs are not 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). Triticonazole is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure to triticonazole through food and water with intermediate-term exposures for triticonazole.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of: 780 for children 1 to 2 years old, and 740 for all infants < 1 year old. Because the level of concern is for MOEs below 100, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Triticonazole is classified as "not likely to be carcinogenic to humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. Thus, triticonazole is not expected to pose a cancer risk.

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 triticonazole residues.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (liquid chromatography/mass spectrometry (LC/MS), and liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) methods (Method 148.02) is available to

enforce the tolerance expression. These methods 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 no established Codex or Mexican maximum residue levels (MRLs)/tolerances for triticonazole on wheat or barley. Triticonazole is registered as a seed treatment in Canada for oats, barley, and wheat, and has established MRL levels at 0.01 ppm on barley, oats, and wheat and for livestock commodities at 0.05 ppm. The Canadian MRLs on barley, oats, and wheat are in harmony with the United States' 0.01 ppm tolerance level for grain, cereal, group 15, except rice. Additionally, no U.S. tolerances have been established on livestock commodities. No harmonization issues exist in connection with the proposed use on turf.

**C. Revisions to Petitioned-for Tolerances**

EPA determined the tolerances for grain, cereal, group 15, except rice, should be established at 0.01 ppm, based on a harmonization concern with Canada, and residue data which supported this tolerance level. Thus the proposed tolerance level of 0.05 ppm was deemed excessive. Upon establishing the grain, cereal, group 15, except rice, tolerance at 0.01 ppm, the individual tolerances established for barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw at 0.05 ppm are being removed from 40 CFR 180.583(a).

**V. Conclusion**

Therefore, tolerances are established for residues of triticonazole, (1RS)-(E)-5-[[4-chlorophenyl)methylene]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on grain, cereal, group 15, except rice, at 0.01 ppm, and grain, cereal, forage, fodder and straw, group 16, except rice, at 0.10 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, entitled *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: January 19, 2010.

**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 180.583 is amended by revising the table in paragraph (a) to read as follows:

**§ 180.583 Triticonazole; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Grain, cereal, forage, fodder and straw, group 16, except rice .....	0.10
Grain, cereal, group 15, except rice .....	0.01

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[FR Doc. 2010-1614 Filed 1-26-10; 8:45 am]  
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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0675; FRL-8805-3]

**Oxirane, 2-Methyl-, Polymer with Oxirane, Dimethyl Ether; Tolerance Exemption**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.