

be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 15, 2005.

**Julie M. Hagensen,**

*Acting Regional Administrator, Region 10.*

■ Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart WW—Washington

■ 2. Section 52.2470 is amended by adding paragraph (c)(88) to read as follows:

##### § 52.2470 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

(88) On March 1, 2004, the Washington State Department of Ecology submitted amendments to WAC Ch. 173–434, Solid Waste Incinerator Facilities, as revisions to the Washington State implementation plan.

(i) Incorporation by reference.

(A) The following new and revised sections of WAC Ch. 173–434, Solid Waste Incinerator Facilities: WAC 173–434–020, Applicability and Compliance; –030, Definitions; –110, Standards of

Performance [except (1)(a)]; –130, Emission Standards [except (2)]; –160, Design and Operation; –170, Monitoring and Reporting; –190, Changes in Operation; and –200, Emission Inventory, State effective January 22, 2004.

(B) Remove the following provisions from the current incorporation by reference: WAC 173–434–050, New Source Review (NSR); –070, Prevention of Significant Deterioration (PSD); and –100, Requirement of BACT, State effective October 18, 1990.

■ 3. Section 2.2.434 of § 52.2479 is revised to read as follows:

##### § 52.2479 Contents of the federally approved, State submitted implementation plan.

\* \* \* \* \*

### WASHINGTON STATE IMPLEMENTATION PLAN FOR AIR QUALITY; STATE AND LOCAL REQUIREMENTS

#### [Table of Contents]

2.2.434	WAC 173–434	Solid Waste Incinerator Facilities
	173–434–010	Purpose [10/18/90]
	173–434–020	Applicability and Compliance [1/22/04]
	173–434–030	Definitions [1/22/04]
	173–434–090	Operation and Maintenance Plan [10/18/90]
	173–434–110	Standards of Performance, except (1)(a) [1/22/04]
	173–434–130	Emission Standards, except (2) [1/22/04]
	173–434–160	Design and Operation [1/22/04]
	173–434–170	Monitoring and Reporting [1/22/04]
	173–434–190	Changes in Operation [1/22/04]
	173–434–200	Emission Inventory [1/22/04]
	173–434–210	Special Studies [10/18/90]

[FR Doc. 05–15439 Filed 8–3–05; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP–2005–0208; FRL–7727–5]

#### Tebuconazole; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of tebuconazole in or on soybeans; poultry, meat; poultry, fat; poultry, meat byproducts; hog, meat; hog, fat; hog, meat byproducts; and eggs. This action is in conjunction with EPA's granting of an emergency exemption under section

18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes maximum permissible levels for residues of tebuconazole in or on these food commodities. The tolerances will expire and are revoked on December 31, 2009.

**DATES:** This regulation is effective August 4, 2005. Objections and requests for hearings must be received on or before October 3, 2005.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0208. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. 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:

Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:

703-308-9367; e-mail address: *sec-18-mailbox@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 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 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 on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

### II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the fungicide tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol), in or on soybean at 0.1 parts per million (ppm); and (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite in or on poultry, meat at 0.1 ppm; poultry, fat at 0.1 ppm; poultry, meat byproducts at 0.1 ppm; hog, meat at 0.1 ppm; hog,

fat at 0.1 ppm; hog, meat byproducts at 0.1 ppm; and eggs at 0.1 ppm. These tolerances will expire and are revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18-related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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. . . .”

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### III. Emergency Exemption for Tebuconazole on Soybeans and FFDCA Tolerances

The States of Minnesota and South Dakota, as lead State agencies in what is essentially a “national” section 18 request for all soybean growing States, have petitioned the Agency requesting an emergency exemption for tebuconazole to control soybean rust under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On November 10, 2004, the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (USDA/APHIS) confirmed the presence of *Phakopsora pachyrhizi*, the pathogen that causes soybean rust, on soybean leaf samples taken from two plots associated with a Louisiana State University research farm. Soybean rust has been designated as a biosecurity threat and therefore it is important that control measures be available for the disease. EPA has authorized under FIFRA section 18 the use of tebuconazole on soybeans for control of soybean rust in Minnesota, South Dakota, and all the other States that have requested an exemption for this use. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebuconazole in or on soybean. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although the tolerances will expire and are revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybeans; poultry, meat; poultry, fat; poultry, meat byproducts; hog, meat; hog, fat; hog, meat byproducts; and eggs after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier

if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether tebuconazole meets EPA's registration requirements for use on soybeans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of tebuconazole by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Minnesota and South Dakota to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebuconazole, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### IV. Aggregate Risk Assessment and Determination of Safety

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 the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. For purposes of this section 18 emergency exemption, the only residue of concern is tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) in crops and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-

triazole-1-yl-methyl)-pentane-3,5-diol metabolite in edible animal tissues. EPA has sufficient data to assess the hazards of tebuconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol), in or on soybean at 0.1 ppm and (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite in or on poultry, meat at 0.1 ppm; poultry, fat at 0.1 ppm; poultry, meat byproducts at 0.1 ppm; hog, meat at 0.1 ppm; hog, fat at 0.1 ppm; hog, meat byproducts at 0.1 ppm; and eggs at 0.1 ppm.

#### A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. 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. A 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. A UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. A uncertainty factor of 10X was used for extrapolation from LOAEL to NOAEL from the developmental neurotoxicity (DNT) study in rats. A special FQPA safety factor was not applied because the health endpoint being used as the basis for regulation for all subpopulations is an adverse effect on young animals in a developmental neurotoxicity study.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ( $RfD = NOAEL / UF$ ). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) =  $NOAEL / \text{exposure}$ ) is calculated and compared to the LOC.

The linear default risk methodology ( $Q^*$ ) is the primary method currently used by the Agency to quantify carcinogenic risk. The  $Q^*$  approach assumes that any amount of exposure will lead to some degree of cancer risk. A  $Q^*$  is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as  $1 \times 10^{-6}$  or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ( $MOE_{\text{cancer}} = \text{point of departure} / \text{exposures}$ ) is calculated. A summary of the toxicological endpoints for tebuconazole used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TEBUCONAZOLE FOR USE IN DIETARY EXPOSURE ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Hazard and Exposure Based Special FQPA Safety Factor*	Study and Toxicological Effects
Acute dietary (females 13+)	LOAEL = 8.8 mg/kg/day UF = 1,000 Acute RfD = 0.0088 mg/kg/day	FQPA SF = 1X aPAD = acute RfD = 0.0088 mg/kg/day	Developmental Neurotoxicity Study - Rat Offspring toxicity LOAEL = 100 ppm based on decreases in body weights and decreases in absolute brain weights. No NOAEL was determined.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TEBUCONAZOLE FOR USE IN DIETARY EXPOSURE ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Hazard and Exposure Based Special FQPA Safety Factor*	Study and Toxicological Effects
Acute dietary (general population)	LOAEL = 8.8 mg/kg/day UF = 1000 Acute RfD = 0.0088 mg/kg/day	FQPA SF = 1X aPAD = acute RfD = 0.0088 mg/kg/day	Developmental Neurotoxicity Study - Rat Offspring toxicity LOAEL = 100 ppm based on decreases in body weights and decreases in absolute brain weights. No NOAEL was determined.
Chronic dietary (all populations)	LOAEL = 8.8 mg/kg/day UF = 1,000 Chronic RfD = 0.0088 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD = 0.0088 mg/kg/day	Developmental Neurotoxicity Study - Rat Offspring toxicity LOAEL = 100 ppm based on decreases in body weights and decreases in absolute brain weights. No NOAEL was determined.
Dermal (short-term, intermediate-term, long-term)	LOAEL = 8.8 mg/kg/day; dermal equivalent dose is estimated using a 23.1% dermal absorption factor	MOE = 1,000 (10X for interspecies, 10X for intraspecies, and 10X for extrapolation from LOAEL to NOAEL)	Developmental Neurotoxicity Study - Rat Offspring toxicity LOAEL = 100 ppm based on decreases in body weights and decreases in absolute brain weights. No NOAEL was determined.
Inhalation (any time period)	LOAEL = 8.8 mg/kg/day; inhalation absorption is assumed equivalent to oral absorption	Occupational MOE = 1,000 (10X for interspecies, 10X for intraspecies, and 10X for extrapolation from LOAEL to NOAEL)	Developmental Neurotoxicity Study - Rat Offspring toxicity LOAEL = 100 ppm based on decreases in body weights and decreases in absolute brain weights. No NOAEL was determined.
Cancer	Group C - possible human carcinogen and recommended that for the purpose of risk characterization the reference dose (RfD) approach be used for quantification of human risk		

\*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

#### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.474) for the residues of tebuconazole, in or on a variety of raw agricultural commodities. Meat, and milk tolerances have also been established for the combined residues of tebuconazole and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite. Risk assessments were conducted by EPA to assess dietary exposures from tebuconazole in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.00–2.02) analysis evaluated the individual food

consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute assessment was a refined assessment using a combination of tolerances as listed in 40 CFR 180.474, maximum residues from field trials, distributions of field trial data, distributions of Pesticide Data Program (PDP) monitoring data, percent crop treated, default DEEM processing factors and the results of processing studies, all incorporated into an analysis conducted with the DEEM-FCID program. The resulting exposure estimates were compared to the acute population adjusted dose (aPAD) for tebuconazole of 0.0088 milligrams/kilogram body weight/day (mg/kg bwt/day).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM-FCID, Version 2.00–2.02 analysis

evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity.

The chronic dietary exposure assessment used tolerance level residues as listed in 40 CFR 180.474, mean residue values from field trials and from PDP monitoring, and estimates of percent crop treated with tebuconazole. These data were used with the chronic analysis module of the DEEM-FCID software. As with the acute assessment, processing factors from registrant studies as well as default DEEM processing factors were used. The resulting exposure estimates were compared to the cPAD for tebuconazole of 0.0088 mg/kg bwt/day.

iii. *Cancer.* The Agency classified tebuconazole as a possible human carcinogen and recommended that for the purpose of risk characterization, the

RfD approach should be used for quantification of human risk.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that 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 such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: PCT data were used in the chronic assessment for garlic (40% crop treated), peanuts (35% crop treated), and wheat (5% crop treated).

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a

period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, 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 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 lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for tebuconazole 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 tebuconazole.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW (screening concentration in ground water), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a

Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOC) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to tebuconazole, they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of tebuconazole for acute exposures are estimated to be 39 parts per billion (ppb) for surface water and 0.4 ppb for ground water. The EECs for chronic non-cancer exposures are estimated to be 23 ppb for surface water and 0.4 ppb for ground water. For chronic/cancer assessments, the 36-year average from PRZM/EXAMS is 19 ppb.

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).

Non-dietary, non-occupational (residential), exposures are not expected from the proposed use of this section 18 request on soybeans. However, a few

residential use patterns are present on the labels of several registered end use products. Non-agricultural use sites include ornamental plants, shrubs, vines, trees and flowers, plus wood protection treatments, and other preservative/additive uses. Short-term dermal and inhalation exposures to residential handlers are possible with the use of residential home and garden products. Residential short-term postapplication exposure from these home and garden products is also possible. Additionally, residential postapplication exposure to wood products previously treated with tebuconazole are possible.

For residential handlers, the exposure scenarios that should result in the highest exposure potentials include use of hose-end sprayers and pump sprayers. These two scenarios were assessed using the application rate for shrubs, since it should encompass the largest possible treatment exposure area and amount of product used. A low pressure hand wand scenario was used as a surrogate for the pump sprayer scenario, since no unit exposure data exist for this scenario. The watering can/bucket scenario was not assessed, since it should result in much less exposure. Since the toxicological endpoint is the same for short-term dermal and inhalation exposures, the risk estimates are combined in this assessment. The combined exposures resulted in MOEs ranging from 1,500 to 3,200, and therefore, do not exceed EPA's level of concern, i.e. all MOEs greater than or equal to 1,000.

Residential short-term postapplication exposures from ornamental plants, shrubs, vines, trees and flowers previously treated with tebuconazole were not assessed, because the residential handler exposure and risk estimates for the uses resulted in risk estimates that do not exceed EPA's level of concern, and postapplication exposures should be considerably less.

Residential postapplication exposure to wood products previously treated with tebuconazole are not quantified, because the exposure is expected to be negligible; i.e., the nature of the use patterns would result in very low, if any exposure that would impact aggregate risk. All wood products are commercially treated, and then most of these wood products are intended for uses (e.g., door jams, sills) that should not result in dermal or oral exposures in residential settings.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA 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 tebuconazole and any other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebuconazole 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/>.

However, the Agency does have concern about potential toxicity to 1,2,4-triazole and two conjugates, triazolylalanine and triazolyl acetic acid, metabolites common to most of the triazole fungicides. To support the extension of existing parent triazole-derivative fungicide tolerances, EPA conducted an interim human health assessment for aggregate exposure to 1,2,4-triazole. The exposure and risk estimates presented in this assessment are overestimates of actual likely exposures and therefore, should be considered to be highly conservative. Based on this assessment, EPA concluded that for all exposure durations and population subgroups, aggregate exposures to 1,2,4-triazole are not expected to exceed EPA's level of concern. This assessment is presented in the April 22, 2005 **Federal Register** (70 FR 2028) (FRL-7702-4) notice for another triazole fungicide, tetraconazole. This assessment should be considered interim due to the ongoing series of studies being conducted by the U.S. Triazole Task Force (USTTF). Those studies are designed to provide the Agency with more complete toxicological and residue information for free triazole. Upon completion of the review of these data, EPA will prepare a more sophisticated assessment based on the revised toxicological and exposure data bases.

#### C. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCFA 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 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal susceptibility.* The data from prenatal developmental toxicity studies provided no indication of increased quantitative susceptibility of mice, rats, or rabbits following *in utero* exposure to tebuconazole. In the prenatal developmental toxicity studies in mice, rats, and rabbits, the NOAELs for developmental toxicity were comparable to or higher than the NOAELs for maternal toxicity. There was, however, indication of increased qualitative susceptibility. In all three species, maternal toxicity was minimal at the LOAEL (consisting of increases in hematological findings in mice, increased liver weights in rats, and decreased body weight gain/food consumption in rats) and did not increase substantially in severity at higher doses; there was more concern for the developmental effects at each LOAEL, which included increases in runts and increased fetal loss in mice, increased skeletal variations in rats, and increased fetal loss and frank malformations in rabbits. Additionally, more severe developmental effects (including frank malformations) were seen at higher doses in mice (100 mg/kg/day), rats (120 mg/kg/day), and rabbits (100 mg/kg/day). In the 2-generation reproduction study, NOAELs/LOAELs were the same for offspring and parental systemic toxicity. In the developmental neurotoxicity study, increases in qualitative and quantitative susceptibility were seen in rats; maternal toxicity was seen only at the high dose of 65 mg/kg/day (decreased body weights, body weight gains, and food consumption, prolonged gestation with mortality, and increased number of dead fetuses), with a NOAEL of 22 mg/kg/day, while offspring toxicity (including decreased body weight and brain weight) was seen at all doses (LOAEL = 8.8 mg/kg/day).

3. *Conclusion.* The toxicity data base for tebuconazole is complete, and includes developmental toxicity studies in three species (mouse, rat, and rabbit), a reproductive toxicity study in the rat,

acute and subchronic neurotoxicity studies in rats, and a developmental neurotoxicity study in the rat. The exposure data are complete or estimated based on data that reasonably accounts for potential exposures in occupational and residential settings. Available data indicate greater sensitivity of the developing organism to exposure to tebuconazole, as demonstrated by increases in qualitative sensitivity in prenatal developmental toxicity studies in rats, mice, and rabbits, and by an increase in both qualitative and quantitative sensitivity in the developmental neurotoxicity study with tebuconazole. Clear NOAELs for developmental toxicity were seen in available prenatal developmental toxicity studies; these NOAELs are higher than those used in the current risk assessment. Although there was a NOAEL for maternal animals in the available developmental neurotoxicity study, there was no NOAEL for effects in the offspring. As the offspring LOAEL from this study is the lowest dose at which effects were seen following exposure to tebuconazole, this endpoint was selected for use in the current risk assessment, for both acute and chronic dietary exposure. Residual uncertainty due to the lack of a NOAEL in this study is accounted for by using a factor of 10X to extrapolate from the LOAEL seen in the study to a NOAEL. Thus, although the effects seen in the offspring in the DNT study occurred at doses below those causing effects in maternal animals, these effects are being used as the basis for the acute and chronic endpoints, and are thus accounted for in the current risk assessment. Any residual uncertainty regarding the lack of a NOAEL in the developmental

neurotoxicity study is accounted for by including an additional uncertainty factor of 10X for extrapolation from the LOAEL seen in the study to a NOAEL. Thus, any residual uncertainty regarding toxicity to offspring has been accounted for in the risk assessment, and an additional special FQPA uncertainty factor is not required.

#### *D. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 Liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be

taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to tebuconazole in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of tebuconazole on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to tebuconazole will occupy 14% of the aPAD for the U.S. population, 7% of the aPAD for females 13 years and older, 25% of the aPAD for infants less than 1 year old, and 53% of the aPAD for children 1 to 2 years old. In addition, despite the potential for acute dietary exposure to tebuconazole in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of tebuconazole in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TEBUCONAZOLE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.0088	14%	39	0.4	266
Children (1-2 years old)	0.0088	53%	39	0.4	41
Females (13 years and older)	0.0088	7%	39	0.4	245

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tebuconazole from food will utilize 7% of the cPAD for the U.S. population, 15% of the cPAD for all infants less than 1 year old and 16% of

the cPAD for children 1 to 2 years old. Based on the use pattern, chronic residential exposure to residues of tebuconazole is not expected. In addition, despite the potential for chronic dietary exposure to tebuconazole in drinking water, after

calculating DWLOCs and comparing them to conservative model EECs of tebuconazole in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TEBUCONAZOLE

Population Subgroup	cPAD mg/ kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0088	7%	23	0.4	285
All Infants (less than 1 year old)	0.0088	15%	23	0.4	74
Children (1-2 years old)	0.0088	16%	23	0.4	74

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).

Tebuconazole 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 food and water and short-term exposures for tebuconazole.

A short-term aggregate risk assessment based on exposure from inhalation and dermal routes was considered and performed for adults only. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in an aggregate MOE of 1,300. This aggregate MOE does not exceed the Agency's level of concern for aggregate

exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of tebuconazole in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO TEBUCONAZOLE

Population Subgroup	Aggregate MOE (Food + Residen- tial)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
General U.S. Population	1,300	1,000	23	0.4	280

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

Though residential uses of tebuconazole are registered, intermediate-term dermal and inhalation exposures to residential handlers are not expected with the use of residential home and garden products.

5. *Aggregate cancer risk for U.S. population.* Tebuconazole has been classified as a Group C possible human carcinogen, non-quantifiable. Consequently, the standard chronic dietary exposure analysis and risk assessment using the cPAD serves as the assessment for cancer. Since carcinogenic risk for tebuconazole is addressed with the cPAD, cancer risk from the proposed use on soybeans is not expected to be of concern.

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 tebuconazole residues.

## V. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) 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](mailto:residuemethods@epa.gov).

### B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRLs) for tebuconazole on soybeans. Therefore, there are no international harmonization issues associated with this action.

## VI. Conclusion

Therefore, the tolerance is established for residues of the fungicide tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol), in or on soybean at 0.1 ppm; and (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol

metabolite in or on poultry, meat at 0.1 ppm; poultry, fat at 0.1 ppm; poultry, meat byproducts at 0.1 ppm; hog, meat at 0.1 ppm; hog, fat at 0.1 ppm; hog, meat byproducts at 0.1 ppm; and eggs at 0.1 ppm.

## VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.



### *A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2005-0208 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 October 3, 2005.

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 VII.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 the docket ID number OPP-2005-0208, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request

via e-mail to: [opp-docket@epa.gov](mailto: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).

### **VIII. Statutory and Executive Order Reviews**

This final rule establishes time-limited tolerances under section 408 of the FFDCA. 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 FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances 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 the 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.

### IX. 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: July 28, 2005.

**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 180.474 is amended by revising paragraph (b) to read as follows:

#### **§ 180.474 Tebuconazole; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* (1) Time-limited 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 connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Barley, grain .....	2.0	6/30/08
Barley, hay .....	20.0	6/30/08
Barley, straw .....	20.0	6/30/08
Garlic .....	0.1	12/31/05
Soybean .....	0.1	12/31/09
Sunflower, oil .....	0.4	12/31/05
Sunflower, seed .....	0.2	12/31/05
Wheat, hay .....	15.0	6/30/08
Wheat, straw .....	2.0	6/30/08

(2) Time-limited tolerances are established for the combined residues of the fungicide tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-ethyl)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Eggs .....	0.1	12/31/09
Poultry, fat .....	0.1	12/31/09
Poultry, meat .....	0.1	12/31/09
Poultry, meat byproducts .....	0.1	12/31/09
Hog, fat .....	0.1	12/31/09
Hog, meat .....	0.1	12/31/09
Hog, meat byproducts .....	0.1	12/31/09

\* \* \* \* \*

[FR Doc. 05-15440 Filed 8-3-05; 8:45 a.m.]

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### FEDERAL MARITIME COMMISSION

#### 46 CFR Parts 501 and 502

[Docket No. 05-01]

#### Agency Reorganization and Delegations of Authority

**AGENCY:** Federal Maritime Commission (FMC).

**ACTION:** Final rule; corrections.

**SUMMARY:** This document corrects the regulations in §§ 501.26(a)(8), 502.271(f)(1), and 502.401 of 46 CFR Parts 501 and 502 of the Final Rule published on February 15, 2005. These revisions to the regulations are non-substantive and no public comments on the Final Rule are necessary.

**DATES:** Effective August 4, 2005.

### FOR FURTHER INFORMATION CONTACT:

Amy W. Larson, General Counsel, Federal Maritime Commission, 800 North Capitol Street, NW., Room 1018, Washington, DC 20573-0001, (202) 523-5740, E-mail: [GeneralCounsel@fmc.gov](mailto:GeneralCounsel@fmc.gov).

**SUPPLEMENTARY INFORMATION:** On February 15, 2005, the Federal Maritime Commission ("FMC" or "Commission") adopted a Final Rule to amend its regulations in 46 CFR Part 501 to reflect the reorganization of the agency that took effect on August 23, 2004. This Rule also made nomenclature changes in certain CFR units to reflect changes in relevant Commission bureau names. This revision corrects errors in the regulations, which were not detected in the course of preparing the Final Rule for publication. The revisions are non-substantive in nature, therefore, no public comments on the Final Rule are necessary.

Therefore, for the reasons set forth above, the following sections in the regulations of Parts 501 and 502 have been amended.

### List of Subjects

#### 46 CFR Part 501

Administrative practice and procedure, Authority delegations (Government agencies), Organization and functions (Government agencies), Seals and insignia.

#### 46 CFR Part 502

Administrative practice and procedure, Claims, Equal access to justice, Investigations, Lawyers, Maritime carriers, Penalties, Reporting and recordkeeping requirements.

### PART 501—THE FEDERAL MARITIME COMMISSION—GENERAL

■ 1. The authority citation for part 501 continues to read as follows:

**Authority:** 5 U.S.C. 551-557, 701-706, 2903, and 6304; 31 U.S.C. 3721; 41 U.S.C. 414 and 418; 44 U.S.C. 501-520 and 3501-3520; 46 U.S.C. app. 876, 1111, and 1701-1720; Reorganization Plan No. 7 of 1961, 26 FR 7315, August 12, 1961; Pub. L. 89-56, 70 Stat. 195; 5 CFR Part 2638; Pub. L. 89-777, 80 Stat. 1356; Pub. L. 104-320, 110 Stat. 3870.

#### **§ 501.26 [Corrected]**

■ 2. Amend § 501.26(a)(8), by removing the words "Bureau of Consumer Complaints and Licensing," and adding, in their place, the words "Bureau of Certification and Licensing."

### PART 502—RULES OF PRACTICE AND PROCEDURE

■ 3. The authority citation for part 502 continues to read as follows: