

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.

X. Submission to Congress and the Comptroller General

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: September 18, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.364 is amended by revising the introductory text of paragraph (a) and alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) *General.* Tolerances are established for residues of glyphosate (N-phosphomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on the following food commodities:

Commodity	Parts per million
* * * * *	* * *
Animal feed, nongrass, group	400
* * * * *	* * *
Grass, forage, fodder and hay, group	300
* * * * *	* * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0199; FRL-7200-6]

Triticonazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1 H-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. Aventis CropScience USA requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Subsequent to the filing of this petition, Bayer Corporation acquired Aventis CropScience to form Bayer Crop Science. Therefore, the registrant is now Bayer Crop Science.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0199, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0199 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select “Laws and Regulations,” “Regulations and Proposed Rules,” and then look up the entry for this document under the “**Federal Register**—Environmental Documents.” You can also go directly to the **Federal Register** listings at <http://www.federalregister.gov/>

www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0199. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of March 14, 2002 (67 FR 11476) (FRL-6825-1), EPA issued a notice pursuant to section 408 of the FFDCa, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 9F6051) by Aventis Crop Science USA, 2 TW Alexander Drive, Research Triangle

Park, NC 27709. This notice included a summary of the petition prepared by Aventis CropScience USA, the registrant. Subsequent to the filing of this petition, Bayer Corporation acquired Aventis CropScience to form Bayer Crop Science. Therefore, the registrant is now Bayer Crop Science. There were no comments received in response to the notice of filing.

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-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw at 0.05 parts per million (ppm).

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...."

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).

III. Aggregate Risk Assessment and Determination of Safety

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. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCa, for a tolerance for residues of triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, on barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by triticonazole are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity in rodents-rat	NOAEL = M: 2, F: 22.3 mg/kg/day LOAEL = M: 19.8, F: 1183.5 mg/kg/day based on M: Increases in the incidence of adrenocortical fatty vacuolation in males receiving \geq 250 ppm, F: Hair loss, decreased food efficiencies, adrenocortical fatty vacuolation, zona reticularis degeneration, centriacinar hepatocytic fatty vacuolation, and more severe anisocytosis and spherocytosis in females receiving \geq 12,500 ppm.
870.3200	28-Day dermal toxicity-rat	NOAEL = Dermal and systemic: 1,000 mg/kg/day (limit dose). LOAEL = Were not identified.
870.3700	Prenatal developmental in rodents-rat	Maternal NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based on reduction in mean body weight gain from GD 12-16. Developmental NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based on treatment-related increases in unilateral and bilateral supernumerary ribs.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in nonrodents-rabbit	Maternal NOAEL = 25 mg/kg/day LOAEL = 50 mg/kg/day based on decreased body weight gain, reduced food consumption, and mortality. Developmental NOAEL = 50 mg/kg/day LOAEL = 75 mg/kg/day based on cranial variations, abortion, and increased pre- and post-implantation losses.
870.3800	Reproduction and fertility effects-rat	Parental/Systemic NOAEL = 37.5 mg/kg/day LOAEL = 250 mg/kg/day based on reduced body weights of the F ₀ females and the F ₁ males and females, F ₀ maternal mortality, and microscopic lesions in the adrenal gland of F ₀ and F ₁ males and females. Reproductive NOAEL = 37.5 mg/kg/day LOAEL = 250 mg/kg/day based on decreased fertility of the F ₁ animals, reduced F ₁ and F ₂ pup survival, and reduced F ₁ and F ₂ pup body weight.
870.4100	Chronic toxicity dogs	NOAEL = 25 mg/kg/day LOAEL = 150 mg/kg/day based on decreased absolute body weights of females, decreased weight gain by males and females, and treatment-related toxicity to the eye, liver, and adrenals.
870.4200	Carcinogenicity rats	NOAEL = M: ≥ 203.6, F: 38.3 mg/kg/day LOAEL = M: Adverse effects were not observed, F: 286.6 mg/kg/day based on decreased body weight and body weight gain, adrenal cortical and liver toxicity.
870.4300	Carcinogenicity mice	NOAEL = M: 17.4; F: 20.1 mg/kg/day LOAEL = M: 202.2, F: 209.5 mg/kg/day based on decreased body weight gain and liver toxicity. No significant increase in the incidence of neoplastic lesions. No evidence of compound-induced carcinogenicity.
870.5250	Gene mutation	There was no evidence of induced mutant colonies over background.
870.5300	Cytogenetics	There was no consistent evidence of chromosomal aberrations induced over background.
870.5375	Chromosome aberration	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any tested triticonazole dose at any harvest time.
870.5395	Micronucleus	There was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures [nuclear silver grain counts] was induced.
870.6200	Acute neurotoxicity screening battery-rat	NOAEL = 400 mg/kg/day LOAEL = 2,000 mg/kg/day (limit dose) based on dose-related increases in motor activity in both sexes...
870.6200	Subchronic neurotoxicity screening battery-rat	NOAEL = M: 695; F: 820 mg/kg/day LOAEL = Not established.
870.6300	Developmental neurotoxicity	Study is not available. Identified this as a data gap.
870.7485	Metabolism and pharmacokinetics-rat	Study is not available. Identified this as a data gap.
870.7600	Dermal penetration-rat	Dermal Absorption Factor [C ¹⁴]: 2 %.

B. 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 level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent

in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

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 Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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/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 1×10^{-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 ($MOE_{cancer} = \text{point of departure/exposures}$) is calculated. A summary of the toxicological endpoints for triticonazole used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRITICONAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 50 mg/kg/day UF = 100 Acute RfD = 0.5 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.5 mg/kg/day	Developmental study-rabbit Developmental LOAEL = 75 mg/kg/day based on cranial variations, abortions, and increased pre-and post-implantation losses.
Acute Dietary (General population including infants and children)	NOAEL = 400 mg/kg/day UF = 100 Acute RfD = 4 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 4 mg/kg/day	Acute Neurotoxicity study LOAEL = 2,000 mg/kg/day based on dose-related increases in motor activity in both sexes.
Chronic Dietary (All populations)	NOAEL = 17.4 mg/kg/day UF = 100 Chronic RfD = 0.17 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD ÷ FQPA SF = 0.17 mg/kg/day	Carcinogenicity study-mouse LOAEL = M: 202.2, F: 209.5 mg/kg/day based on decreased body weight gain and liver toxicity.
Incidental Oral Short-Term	NOAEL = 25 (Maternal toxicity)	LOC for MOE = 100 (Residential)	Developmental study-rabbit Maternal LOAEL = 50 mg/kg/day based on decreased body weight gain, reduced food consumption, and mortality.
Incidental Oral Intermediate-Term	NOAEL = 17.4	LOC for MOE = 100 (Residential)	Carcinogenicity study-mouse LOAEL = M: 202.2, F: 209.5 mg/kg/day based on decreased body weight gain and liver toxicity.
Short-Term Inhalation (1 to 7 days) (Residential)	Inhalation (or oral) study NOAEL = 25 mg/kg/day (inhalation absorption rate = 100%) (maternal toxicity)	LOC for MOE = 100 (Residential)	Developmental study-rabbit Maternal LOAEL = 50 mg/kg/day based on decreased body weight gain, reduced food consumption, and mortality.
Intermediate-Term Inhalation (1 week to several months) (Residential)	Inhalation (or oral) study NOAEL = 17.4 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Carcinogenicity study-mouse LOAEL = M: 202.2, F: 209.5 mg/kg/day based on decreased body weight gain and liver toxicity.
Long-Term Inhalation (Several months to lifetime) (Residential)	Inhalation (or oral) study NOAEL = 17.4 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Carcinogenicity study-mouse LOAEL = M: 202.2, F: 209.5 mg/kg/day based on decreased body weight gain and liver toxicity.
Cancer			This fungicide has not been classified. While the Agency has acceptable data to assess carcinogenicity in both sexes of mice and female rats, acceptable data are not available in male rats. Since the doses tested in male rats were too low to assess the carcinogenic potential for triticonazole, the cancer risk assessment was conducted using a potency factor (Q1*) of 8.56×10^{-3} based on data available at lower doses in the carcinogenicity study in male rats.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

Due to the lack of adequate carcinogenicity data in male rats, the Agency is not currently able to classify triticonazole in terms of its carcinogenicity. To assess the potential cancer risk associated with triticonazole, the Agency analyzed the pituitary gland and skin tumors seen in the male rat carcinogenicity data along with tumor data for female rats (pituitary adenomas and carcinomas; mammary gland fibroadenomas) and male mice (pulmonary adenomas and carcinomas, and liver adenomas), and female mice (pulmonary adenomas and carcinomas). Structure-Activity data for other triazole fungicides indicate that some are carcinogenic while others are not. For these uses, the Agency developed a Q1* based upon the doses in the male rat carcinogenicity study and the apparent increase in tumor incidence to provide a "worst case" upper limit on cancer. It is unclear from the currently available data whether this apparent increase in tumor incidence in male rats is statistically significant. Therefore, by assuming that the increase in tumor incidence is statistically significant, the use of the Q1* approach is worst-case.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Triticonazole is a new chemical and currently there are no tolerances established in 40 CFR 180.583. Risk assessments were conducted by EPA to assess dietary exposures from triticonazole 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier I acute DEEM™ analysis was performed. This analysis assumed tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic Exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals

(CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues and 100% crop treated (CT) estimates were assumed.

iii. *Cancer.* The cancer dietary risk assessment was conducted using a potency factor (Q1*) of 8.56×10^{-3} , based on male CD rat pituitary combined adenomas and carcinoma tumor rates from the rat carcinogenicity study. Although the Agency determined that the doses tested in both sexes of mice and female rats were adequate to assess the carcinogenic potential of triticonazole, the doses tested in male rats were too low. A hypothetical Q1* value has been calculated as a worst-case, upper bound estimate of cancer risk until a partial carcinogenicity study in male rats, in which higher dose levels are evaluated, becomes available. The cancer risk estimate (food only) for the U.S. population (total) is 7.0×10^{-7} . This risk estimate is based upon a dietary exposure of 0.000082 mg/kg/day.

In conducting this chronic (cancer) dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic (cancer) exposure assessments: Tolerance level residues and 100% CT estimates were assumed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for triticonazole 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 triticonazole.

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 SCIGROW, which predicts pesticide concentrations in groundwater. 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 (DWLOCs) 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 triticonazole they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCIGROW models, the estimated environmental concentrations (EECs) of triticonazole for acute exposures are estimated to be 0.9 parts per billion (ppb) for surface water and 0.008 ppb for ground water. The EECs for chronic exposures are estimated to be 0.6 ppb for surface water and 0.008 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Triticonazole is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to 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."

EPA does not have, at this time, available data to determine whether triticonazole has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, triticonazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that triticonazole 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The Agency concluded that there is no concern for pre- and/or postnatal toxicity resulting from exposure to triticonazole. Developmental toxicity studies showed that triticonazole had limited maternal toxicity, with no significant evidence of increased sensitivity or susceptibility to offspring. In a developmental toxicity study on rats, there were no compound-related deaths, abortions, or clinical signs of toxicity throughout the study period. Based on reduction in mean body weight gain, the maternal toxicity LOAEL is 1,000 mg/kg/day and the NOAEL is 200 mg/kg/day. Treatment did not cause any statistically significant or treatment-related changes in gestational or cesarean section parameters at any treatment level. Based on a treatment-related increase in

unilateral and bilateral supernumerary ribs, the developmental toxicity LOAEL is 1,000 mg/kg/day and the developmental NOAEL is 200 mg/kg/day. In a developmental study on rabbits, there was maternal toxicity. Based on decreased body weight gain after dosing initiation, reduced food consumption, and mortality, the LOAEL for maternal toxicity is 50 mg/kg/day and the NOAEL is 25 mg/kg/day. No treatment-related increased incidences of external or visceral malformations/ variations were observed in any group as compared with the controls. In the high-dose group slight increases in the percent of fetuses with variations in midline cranial sutures were observed. Based on cranial variations, abortion, and pre- and post-implantation losses, the developmental LOAEL is 75 mg/kg/day and the NOAEL is 50 mg/kg/day. In a two-generation reproduction study with rats the systemic parental LOAEL is 250 mg/kg/day based on reduced body weights of F₀ females and F₁ males and females and microscopic lesions in the adrenal gland of F₀ and F₁ males and females. The reproductive NOAEL is 37.5 mg/kg/day and the LOAEL is 250 mg/kg/day based on F₀ maternal mortality, decreased fertility of the F₁ animals, reduced F₁ and F₂ pup survival and body weights.

3. *Conclusion.* There is a complete toxicity data base for triticonazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposure. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed for the following reasons:

- The toxicological data base is complete for FQPA assessment.
- There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.
- The requirement of a developmental neurotoxicity study is not based on criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a DNT study - and a safety factor (e.g., neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) - and, therefore, does not warrant an FQPA safety factor.
- The dietary (food and drinking water) and residential exposure assessments will contain all identified metabolites and/or degradates of concern and will not underestimate the potential exposures for infants and children.

The Agency has identified the need for a developmental neurotoxicity study for this compound based upon the following considerations:

- Clinical signs indicative of neurotoxicity in the rat and mice, acute oral and inhalation toxicity studies; micronucleus assay; and chronic toxicity study in the dog.
- Concern for structure-activity relationship. Triticonazole is structurally related to triadimenol, biteranol, uniconazole, propiconazole, etaconazole, azaconazole, hexaconazole, and cyproconazole. All of these compounds, except etaconazole and hexaconazole, have shown a developmental toxicity LOAEL below the maternal toxicity LOAEL in rats and/or rabbits.

Although EPA has required submission of a developmental neurotoxicity study (DNT) for triticonazole, EPA believes it has sufficient reliable toxicity data to make a safety finding for infants and children without use of the additional 10X safety factor. The DNT study will help to complete the overall picture of triticonazole's neurotoxicity profile; however, the toxicity data currently available to the Agency indicate that the DNT is unlikely to affect the manner in which triticonazole is regulated. Three considerations are of importance here. First, the requirement for the DNT for triticonazole was based only on the presence of clinical signs indicative of neurotoxicity in adult animals and the concern for Structure-Activity Relationship (similar chemicals demonstrating neurotoxicity in adult animals). Generally, a DNT is not requested unless the underlying data reveal some special concern for the developing fetuses or young (e.g., neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring). No such evidence was seen in triticonazole studies. Second, although the request for the DNT indicates some uncertainty regarding neurotoxic effects, existing triticonazole toxicity data demonstrate that neurotoxic effects are unlikely to be a regulatory endpoint other than with regard to acute effects for the general population and that even here the overall conservativeness of the EPA assessment indicates that it is unlikely that the DNT results will cause any regulatory change. The available data show that the neurotoxic effects resulting from triticonazole exposure all occurred at dose levels far exceeding the levels chosen for making risk evaluations and regulatory

determinations. In other words, a large margin of safety already exists to protect the young against any potential neurotoxic effects that might be seen in the DNT. Clinical signs of neurotoxicity (the reason for requiring a DNT) were seen only at a very high dose (2,000 mg/kg/day; twice the Limit Dose) in the acute neurotoxicity study. In the subchronic neurotoxicity, no evidence of neurotoxicity or neuropathology was seen at the highest dose tested that approached the Limit Dose. The NOAEL was 695 mg/kg/day in males and 820 mg/kg/day in females; a LOAEL was not established in the subchronic neurotoxicity study.

In contrast, the NOAEL of 50 mg/kg/day used for acute dietary risk assessment for Females 13–50 years of age (i.e. pre-natal children) is 8X lower than the NOAEL of 400 mg/kg/day established following a single dose in the acute neurotoxicity study and the LOAELs from these two studies differ by approximately 27X. Similarly, the NOAEL of 17.4 mg/kg/day used for chronic dietary risk assessment is 40X lower than the NOAEL of 700 mg/kg/day established following repeated dosing in the subchronic neurotoxicity study. Additionally, although the NOAEL of 400 mg/kg/day from the acute neurotoxicity study was used for acute dietary risk assessment for the General Population including infants and children the choice of this NOAEL was itself very conservative. The NOAEL is believed to be conservative since the NOAEL could be an artifact of the dose selection (0, 80, 400 or 2,000 mg/kg/day). Because of this wide gap in the doses tested, the “true” NOAEL could have been higher (i.e., somewhere between 400 and 2,000 mg/kg/day) than the one established. Additionally, the

NOAEL of 400 mg/kg/day used for acute dietary risk assessment for the General Population is 5X lower than the dose (2,000 mg/kg/day) that caused neurotoxic effects in that study. Third, in addition to the DNT being requested due to effects seen in adult animals (and not due to neurological findings in the young) and the large margin of safety between these effects and regulatory endpoints, it is worth reiterating that there is no evidence (quantitative or qualitative) of increased susceptibility in the pre-natal developmental or two generation reproduction toxicity studies.

E. 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 + residential 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: 2L/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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in 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 triticonazole will occupy < 1% of the aPAD for all population subgroup. In addition, there is potential for acute dietary exposure to triticonazole in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRITICONAZOLE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	4	< 1.0	0.9	0.008	1.4 x 10 ⁵
All infants	4	< 1.0	0.9	0.008	4.0 x 10 ⁴
Females (13–50 years)	0.5	< 1.0	0.9	0.008	1.5 x 10 ⁴
Children (1–6 years)	4	< 1.0	0.9	0.008	4.0 x 10 ⁴
Males (13–19 years)	4	< 1.0	0.9	0.008	1.4 x 10 ⁵

The EECs for assessing acute aggregate dietary risk are 0.008 µg/L (for groundwater, based on SCI GROW) and 0.9 µg/L (in surface water, based on PRZM/EXAMS). The back-calculated

DWLOCs (Table 3) for assessing acute aggregate dietary risk range from 15,000 µg/L for the population subgroup females (13 to 50 years old) to 140,000

µg/L for the U.S. population and males (13 to 19 years old).

The SCI GROW and PRZM/EXAMS acute EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for

triconazole residues in drinking water as a contribution to acute aggregate exposure. EPA thus concludes with reasonable certainty that residues of triconazole in drinking water will not contribute significantly to the aggregate acute human health risk and that the acute aggregate exposure from triconazole residues in food and drinking water will not exceed the Agency's level of concern (100% of the Acute PAD) for acute dietary aggregate exposure by any population subgroup.

EPA generally has no concern for exposures below 100% of the Acute PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, very conservative, and very protective of human health.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to triconazole from food

will utilize < 1% of the cPAD for all population subgroups. There are no residential uses for triconazole that result in chronic residential exposure to triconazole. In addition, there is potential for chronic dietary exposure to triconazole in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRITICONAZOLE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.17	< 1.0	0.6	0.008	5.9 x 10 ³
All infants	0.17	< 1.0	0.6	0.008	1.7 x 10 ³
Children (1–6 years)	0.17	< 1.0	0.6	0.008	1.7 x 10 ³
Females (13–50 years)	0.17	< 1.0	0.6	0.008	5.1 x 10 ³
Males (55 years +)	0.17	< 1.0	0.6	0.008	5.9 x 10 ³

The EECs for assessing chronic aggregate dietary risk are 0.008 µg/L (for groundwater) and 0.6 µg/L (for surface water). The back-calculated DWLOCs (Table 4) for assessing chronic aggregate dietary risk range from 1,700 µg/L for the population subgroups. All infants and children (1 to 6 years old) to 5,900 µg/L for the U.S. population and males (55 years +).

The SCI GROW and PRZM/EXAMS chronic EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for triconazole residues in drinking water as a contribution to chronic aggregate exposure. EPA thus concludes with reasonable certainty that residues of triconazole in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from triconazole residues in food and drinking water will not exceed the Agency's level of concern (100% of the Chronic PAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the Chronic PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, very conservative, and very protective of human health.

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). Triconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Triconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* As summarized previously, the cancer risk estimate (food only) for the U.S. population (total) is 7.01 x 10⁻⁷. This risk estimate is based upon an exposure of 0.000082 mg/kg/day. The results of this dietary exposure analysis should be viewed as very conservative (health protective). Refinements such as use of PCT information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

The EECs for assessing chronic (cancer) aggregate dietary risk are 0.008

µg/L (for ground water) and 0.4 µg/L (for surface water). The back-calculated DWLOC) for assessing chronic (cancer) aggregate dietary risk is 1.2 µg/L.

The SCI-GROW and PRZM/EXAMS chronic (cancer) EECs are less than the Agency's level of comparison for triconazole residues in drinking water as a contribution to chronic (cancer) aggregate exposure. The Agency thus concludes with reasonable certainty that residues of triconazole in drinking water will not contribute significantly to the aggregate chronic (cancer) human health risk and that the chronic (cancer) aggregate exposure from triconazole residues in food and drinking water will not exceed the Agency's level of concern (i.e. cancer risk estimate in the range of 1 x 10⁻⁶) for chronic (cancer) dietary aggregate exposure by the U.S. population. EPA generally has no concern for exposures which result in a cancer risk estimate in the range of or below 1 x 10⁻⁶, because it is a level at which daily aggregate dietary exposure over a lifetime will pose no greater than negligible risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, very conservative, and very protective of human health.

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 triticonazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed liquid chromatography/mass spectrometer (LC/MS) and liquid chromatography/mass spectrometer/mass spectrometer (LC/MS/MS) methods (Aventis Method MS 148.02) for determining residues and enforcing tolerances for uses of triticonazole. The methods determine residues of triticonazole and two of its dihydroxy metabolites (RPA 404886 and RPA 406341). Each residue is measured individually in/on wheat and barley RACs and processed commodities. The Agency has determined that the residues of concern in plants for the proposed seed treatment uses are triticonazole *per se*. The LC/MS/MS method was used in the submitted crop field trials and processing studies. The validated level of quantitation (LOQ) based on the field trial and processing data for the LC/MS/MS method is 0.005 ppm for residues in forage, straw and grain. The petitioner submitted adequate concurrent method recovery data for the LC/MS/MS method in conjunction with the crop field trials and processing studies on wheat and barley. A successful independent laboratory validation (ILV) (MRID 44904518) was conducted for the LC/MS and LC/MS/MS methods on wheat forage. The Agency is conducting a petition method validation (PMV) for Analytical Method MS 148.02, Revision 2 for both LC/MS and LC/MS/MS detection methods for use with wheat grain, forage, and straw. Pending a successful EPA petition method validation of Aventis Method 148.02, the method is adequate for enforcement of the proposed tolerances on wheat and barley resulting from the proposed seed treatment uses. The petitioner will be required to make any modifications or revisions to the proposed method resulting from EPA's validation.

The Agency currently has adequate fortification recovery data for triticonazole from wheat and barley commodities. The method was adequately validated by an independent laboratory for use with a representative commodity (wheat forage).

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of triticonazole in/on wheat and barley commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances.

V. Conclusion

Therefore, the tolerance is established for residues of triticonazole, (1RS)-(E)-5-[4-chlorophenyl)methylene]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw at 0.05 ppm.

VI. 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 of 1996, 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 FFDCA sections 408 and 409. 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-2002-0199 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 November 26, 2002.

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 issues(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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP-2002-0199, 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. In person or by courier, bring a copy to the location of

the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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: September 19, 2002.

James Jones,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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), 346(a) and 371.

2. Section 180.583 is added to subpart C to read as follows:

§ 180.583 Triticonazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol, from the treatment of seed prior to planting in or on raw agricultural commodities as follows:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.05
Barley, straw	0.05
Wheat, forage	0.05
Wheat, grain	0.05
Wheat, hay	0.05
Wheat, straw	0.05

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertent residues. [Reserved]

[FR Doc. 02-24650 Filed 9-26-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0233; FRL-7198-8]

Pseudozyma flocculosa strain PF-A22 UL; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities. Plant Products Co. Ltd., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Pseudozyma flocculosa* strain PF-A22 UL.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0233, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0233 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sharlene R. Matten, c/o Product

Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605-0514; e-mail address: matten.sharlene@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgrstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta

site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0233. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of August 30, 2000 (65 FR 52749) (FRL-6739-8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 0F6136) by Plant Products Co. Ltd., f314 Orenda Rd., Brampton, Ontario, Canada L6T 1G1. This notice included a summary of the petition prepared by the petitioner Plant Products Co. Ltd. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the