Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 21, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not 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, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: April 14, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

■ 40 CFR part 52 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 SS—Texas

■ 2. In § 52.2270, the table in paragraph (e) entitled ''EPA approved nonregulatory provisions and quasi-regulatory measures'' is amended by adding one new entry to the end of the table to read as follows:

§ 52.2270 Identification of plan.

* * * * *

(e)* * *

EPA APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE TEXAS SIP

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/effective date	EPA approval date	Comments
* *	* *	*	*	*
Memorandum of Agreement between Texas Council on Environmental Quality and the North Central Texas Council of Governments Providing Emissions Offsets to Dallas Fort Worth International Airport.	Dallas-Fort Worth	01/14/04	04/22/05 [Insert FR page number where document begins].	

[FR Doc. 05–8121 Filed 4–21–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0388; FRL–7702–4]

Tetraconazole; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of tetraconazole, 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1*H*-1,2,4-triazole in or on sugarbeet roots at 0.05 parts per million (ppm), sugarbeet top at 3.0 ppm, sugarbeet dried pulp at 0.15 ppm, sugarbeet molasses at 0.15 ppm, meat of cattle, goat, horse, and sheep at 0.05 ppm, liver of cattle, goat, horse, and sheep at 4.0 ppm, fat of cattle, goat, horse, and sheep at 0.30 ppm, meat byproducts except liver of cattle, goat, horse and sheep at 0.10 ppm and milk at 0.05 ppm. Sipcam Agro USA, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Registrations will be limited to the following States: Colorado, Minnesota, Michigan, Montana, North Dakota, Nebraska, and Wyoming where use has previously occurred under section 18 of FIFRA. The tolerances will expire on November 30, 2012.

DATES: This regulation is effective April 22, 2005. Objections and requests for hearings must be received on or before June 21, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2004–0388. 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: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311),, e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be

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

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**FederalRegister**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/.*

II. Background and Statutory Findings

In the **Federal Register** of October 14, 1999 (64 FR 55714) (FRL–6382–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of three pesticide petitions (9F5066, 9F6023 and 7E4830) by Sipcam Agro, USA, Inc., 300 Colonial Center Parkway, Roswell, GA 30076, formerly of 70 Mansell Court, Suite 230, Rosewell, GA 30076. The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide tetraconazole, in or on the following raw agricultural commodities: beets, sugar at 0.01 ppm, beets, sugar, roots at 0.1 ppm, beets, sugar, tops at 7.0 ppm, beets, sugar, pulp, dried at 0.3 ppm, and beets, sugar, molasses at 0.3 ppm, cattle, meat at 0.01 ppm, cattle meat byproducts at 2.0 ppm, cattle fat at 0.1 ppm, and milk at 0.02 ppm (9F5066); peanuts meat (hulls removed) at 0.03 ppm, peanuts meal at 0.03 ppm, and peanuts oil at 0.1 ppm (9F6023); and imported bananas at 0.2 ppm (7E4830). Petition 7E4830 was later withdrawn. Petition 9F6023 was placed in abeyance by the petitioner. There were no comments received in response to the notice of filing. The tolerances will expire on February 28, 2009.

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 of November 26, 1997 (62 FR 62961) (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 tolerances for residues of tetraconazole 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1*H*-1,2,4-triazole in or on sugarbeet roots at 0.05 ppm; sugarbeet tops at 3.0 ppm; sugarbeet dried pulp at 0.15 ppm; sugarbeet molasses at 0.15 ppm; meat of cattle, goat, horse, and sheep at 0.05 ppm; liver of cattle, goat, horse, and sheep at 4.0 ppm; fat of cattle, goat, horse, and sheep at 0.30 ppm; meat byproducts except liver of cattle, goat, horse and sheep at 0.10 ppm; and milk 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 tetraconazole are discussed below. Table 1 of this unit presents the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

1. *Acute toxicity*. Acute toxicity data were as follows: Acute oral lethal dose $(LD)_{50}$ = 1,031 milligrams/kilogram (mg/kg) (toxicity category III); acute dermal LD_{50} < 2,000 mg/kg (toxicity category III); acute inhalation lethal concentration $(LC)_{50}$ = 3.66 mg/liter (L) (toxicity category IV); primary eye irritation - clear by 72 hours (toxicity category III); primary skin irritation - slight irritation (toxicity category IV); and dermal sensitization - negative.

2. *Developmental toxicity in rats*. A developmental toxicity study was conducted using rats gavaged with doses of 0, 5, 22.5, 100 mg/kg/day from days 2 through 15 of gestation. The maternal toxicity LOAEL is 100 mg/kg/day based on decreased body weight gain, and food consumption and increased liver and kidney weights. The maternal toxicity NOAEL is 22.5 mg/kg/day. Developmental toxicity was noted at 100 mg/kg/day and consisted of an increased incidence of small fetuses, and supernumerary ribs. The LOAEL and NOAEL for developmental toxicity were 100 and 22.5 mg/kg/day, respectively.

3. *Development toxicity study in rabbits*. A developmental toxicity study was conducted using rabbits gavaged with doses of 0, 7.5, 15, and 30 mg/kg/day from days 6 through 18 of gestation. Compound-related maternal toxicity was limited to depressed body weight gain during the dosing period. No treatment-related effects occurred in maternal mortality, clinical signs, food consumption, or cesarean parameters. The maternal LOAEL is 30 mg/kg/day based on decreased body weight gain. The maternal NOAEL is 15 mg/kg/day. No treatment-related effects in developmental parameters were noted. The developmental LOAEL is greater than 30 mg/kg/day. The developmental NOAEL is 30 mg/kg/day, the highest dose tested (HDT).

4. *Two-generation reproduction study*. A two-generation reproduction study was conducted using rats fed diets with dose levels of 0, 10, 70, or 490 ppm (0, 0.7, 4.9, and 35.5 mg/kg/day for males or 0, 0.8, 5.9, and 40.6 mg/kg/day for females). The LOAEL for parental toxicity was 70 ppm (4.9 mg/kg/day in males and 5.9 mg/kg/day in females) based on increased mortality in P generation females. The NOAEL was 10 ppm (0.7 mg/kg/day in males and 0.8 mg/kg/day in females). The LOAEL for offspring toxicity was 490 ppm (40.6

mg/kg/day from the P generation female intake) based on decreased litter weight and mean pup weight in litters of all generations before weaning and increased relative liver weights at weaning in both sexes of all litters. The NOAEL was 70 ppm (5.9 mg/kg/day). The LOAEL for reproductive toxicity was 70 ppm (4.9 mg/kg/day for males and 5.9 mg/kg/day for females) based on increased mean gestation duration in P generation parental females and related evidence of compound toxicity in the parturition process. The NOAEL was 10 ppm (0.7 mg/kg/day for males and 0.8 for females).

5. *Chronic toxicity.* A chronic toxicity study was conducted using dogs fed diets containing 0, 22.5, 90, or 360 ppm for 52 weeks. Treatment-related effects at the high dose included slight but nonsignificant body weight reductions in both sexes from study week 3 to termination; significantly increased alkaline phosphatase, gamma-glutamyltransferase, alanine aminotransferase and ornithine carbamoyl transferase in both sexes from study week 13 to 52, increased absolute and relative liver and kidney weights for both sexes, and histopathological changes in both organs. In the mid-dose group, effects were manifested as increased absolute and relative kidney weights for males correlated with histopathological findings in the males (apparent hypertrophy in cortical tubules of the kidneys in one male). No adverse effects were seen at the low dose. The NOAEL is 22.5 ppm (equivalent to achieved intakes of 0.73 mg/kg/day for males or 0.82 mg/kg/day for females) and the LOAEL is 90 ppm (equivalent to achieved intakes of 2.95 mg/kg/day for males or 3.33 mg/kg/day for females) based on increased absolute and relative kidney weights and histopathological changes in the male kidney.

6. *Carcinogenicity study*—i. *Rats.* A 2-year carcinogenicity study was conducted using rats fed diets containing 0, 10, 80, 640 and 1,280 ppm for males and 0, 10, 80, and 640 ppm for females. The LOAEL is 640 ppm (27.7/39.4 mg/kg/day in male/female) based on histopathology of the bone (osseous hypertrophy of the cranium/parietal bone), pale and thickened incisors, and decreased absolute and relative adrenal and pituitary weights in males; decreased body weight (at terminal sacrifice) in females. The NOAEL is 80 ppm (3.4/4.4 mg/kg/day in male/female). Under the conditions of this study, there was no evidence of a treatment-related increase in tumor incidence when compared to controls. Therefore, tetraconazole is not a carcinogen in this study.

ii. *Mice.* An 80-week carcinogenicity study was conducted using mice fed diets containing 0, 10, 90, 800, or 1,250 ppm (0, 1.4, 12, 118, or 217 mg/kg/day for males; 0, 1.6, 14.8, 140, or 224 mg/kg/day for females). The systemic toxicity LOAEL is 90 ppm (12 and 14.8 mg/kg/day for males and females, respectively), based on increased liver weight and hepatocyte vacuolation in both sexes and increased kidney weights in males. The NOAEL is 10 ppm (1.4 and 1.6 mg/kg/day for males and females, respectively). There was evidence of increased incidence of combined benign and malignant liver tumors in mice of both sexes treated with 95.05% tetraconazole at 800 ppm (48% for males and 22% for females) and 1,250 ppm (84% for males and 64% for females) compared to the control (20% for males and 0% for females). The doses were found to be adequate to test the carcinogenic potential based on the reduction of body weight gain and increased mortality at the highest dose.

7. *Mutagenicity studies.* A battery of mutagenicity studies yielded negative results in *Salmonella typhimurium*, cultured Chinese hamster ovary (CHO) cells, and mouse lymphoma cells. There was no evidence of clastogenicity *in vitro* or *in vivo* and tetraconazole did not induce unscheduled DNA synthesis in human HeLa cells.

B. Toxicological Endpoints

The dose at which 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 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 intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) 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 (SF).

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} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for tetraconazole used for human risk assessment is shown in the following Table 1.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TETRACONAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment UF	FQPA SF* and Special Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary general population (Infants and Children)	Not established	None	An end-point of concern attributable to a single dose was not identified An acute RfD was not established
Acute dietary, females (13– 50 years of age)	NOAEL = 22.5 mg/kg/day UF = 100 Acute RfD = 0.225 mg/kg	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.225 mg/kg	Oral developmental toxicity study - rat Developmental NOAEL = 22.5 mg/kg/day, based on increased incidence of small fetuses, and supernumerary ribs
Chronic dietary, all populations	NOAEL = 0.73 mg/kg/day UF = 100 Chronic RfD = 0.0073 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.0073 mg/kg/day	Chronic oral toxicity - dog Systemic toxicity LOAEL = 2.95/3.33 (M/F) mg/kg/day, based on absolute and relative kidney weights and histopathological changes in the male kidney
Cancer (oral, dermal, inhalation)	"likely to be carcinogenic to humans"		Q_1 * = 2.30 x 10^{-2}, based on male mouse liver benign and/or malignant combined tumor rates

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Section 18 tolerances have been established (40 CFR 180.557) for the residues of tetraconazole, in or on the following raw agricultural commodities: Sugarbeet roots, tops, molasses and dried pulp and cattle meat, meat byproducts and milk. The tolerances proposed in this assessment are numerically different from the current section 18 tolerance levels which were based on higher use rates. Additionally, tolerances are being proposed for goat, horse, and sheep commodities in addition to cattle. Since section 18 registrations have been authorized for the use of tetraconazole on soybeans to control soybean rust, this dietary assessment for use of tetraconazole on sugarbeets assumes residues on soybean products as well as poultry and swine commodities. Risk assessments were conducted by EPA to assess dietary exposures from tetraconazole 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™-FCID™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (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: Tolerance level residues were used for all commodities and it was assumed that 100% of all crops were treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™-FCID™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 Nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues were assumed for all soybean commodities, poultry liver, poultry meat byproducts, and eggs. Anticipated residues were assumed for poultry fat, poultry meat, milk, and all sugarbeet, goat, horse, sheep, cattle, and swine commodities. It was assumed that 100% of all crops were treated.

iii. *Cancer.* In conducting the cancer dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™-FCID™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the cancer exposure assessments: Tolerance level residues were assumed for poultry liver, poultry meat byproducts, and eggs. Anticipated residues were assumed for poultry fat, poultry meat, milk, and all soybean, sugarbeet, cattle, goat, sheep, horse and swine commodities. For sugarbeets, 52 percent crop treated (PCT) was assumed and 67 PCT was assumed for soybeans. Additionally, water was included as a dietary commodity with a tetraconazole concentration of 0.00446 ppm, equal to the 30–year average surface water concentration.

iv. *Anticipated residue and 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 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. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues 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 under section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

The cancer dietary exposure analysis used 52 PCT for sugarbeets and 67 PCT for soybeans. The sugarbeet 52 PCT was based on information from the United States Department of Agriculture (USDA) and from a propietary source used by the Agency. The soybean 67 PCT was taken from the maximum acreage per state allowed on Section 18 applications for tetraconizole on soybeans; the maximum acreages for the 28 States with these Section 18 applications were added together and divided by an estimate of the total number of acres where soybeans would be grown in the United States.

The Agency believes that the three conditions listed in Unit C.1.iv. 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.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 tetraconazole 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 tetraconazole 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 tetraconazole.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW (screenimg concentration in ground water) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC 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 tetraconazole they are further discussed in the aggregate risk sections in Unit III. E.

Based on the PRZM 3.12/ EXAMS 2.7.97 model, the estimated EECs of tetraconazole for acute exposures are estimated to be 8.38 parts per billion (ppb) for surface water, representing the 1 in 10 year annual peak concentrations. The surface water EECs are estimated to be 5.58 ppb for chronic non-cancer exposures (the 1 in 10 year annual average concentration) and 4.46 ppb for chronic cancer exposures (the 30 year annual average concentration).

Based on the SCI-GROW model the ground water EECs for all exposures are estimated to be 0.5 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). Tetraconazole is not registered for use on any sites that would result in residential exposure.

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

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 tetraconazole and any other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tetraconazole 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 its level of concern. 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 databases.

i. *Toxicology*. The toxicological database for 1,2,4-triazole is incomplete. Preliminary summary data presented by the USTTF to EPA indicate that the most conservative endpoint currently available for use in a risk assessment for 1,2,4-triazole is a LOAEL of 15 mg/kg/day, based on body weight decreases in male rats in the reproductive toxicity study (currently underway). This endpoint, with an uncertainty factor of 1,000 was used for both acute and chronic dietary risk, resulting in an RfD of 0.015 mg/kg/day. The uncertainty factor of 1,000 includes an additional 10X safety factor for the protection of infants and children. The resulting PAD is 0.015 mg/kg/day.

ii. *Dietary exposure*. The USTTF conducted an acute dietary exposure assessment based on the highest triazole-derivative fungicide tolerance level combined with worst-case molecular weight and plant/livestock metabolic conversion factors. This approach provides a conservative estimate of all sources for 1,2,4-triazole except the *in vivo* conversion of parent compounds to free-triazole following dietary exposure. The degree of animal *in vivo* conversion is dependent on the identity of the parent fungicide. In rats, this conversion ranges from 0 to 77%—the *in vivo* conversion for tetraconazole is 77%. For purposes of this interim assessment, EPA used the dietary exposure estimates provided by the USTTF adjusted based on the highest rate of conversion observed for any of the parent triazole-derivative fungicides to account for this metabolic conversion. The assessment includes residue estimates for all food commodities with either existing or pending triazole-derivative fungicide registrations. The resulting acute dietary exposure estimates are extremely conservative and range from 0.0032 mg/kg/day for males 20+ years old to 0.014 mg/kg/day for children 1 to 6 years old. Estimated risks range from 22 to 93% of the PAD. In order to estimate chronic exposures via food, EPA used the 70th percentile of exposures from the acute assessment. The 70th percentile is a common statistic used to estimate central tendency from a distribution and its use to estimate chronic exposures is appropriate. Estimated risks range from 10 to 47% of the PAD. The dietary assessment does not include potential exposure via residues in water. It is emphasized that the use of both highest-tolerance-level residues and the highest *in vivo* conversion factor results in dietary risk estimates that far exceed the likely actual risk.

iii. *Non-dietary exposure*. Triazole-derivative fungicides are registered for use on turf, resulting in the potential for residues of free triazole in grass and/or soil. Thus, dermal and incidental oral exposures to children may occur. It is believed that residues of free triazole occur within the plant matrices and are not available as surface residues. Therefore, direct dermal exposure to 1,2,4-triazole due to contact with plants is not likely to occur. However, dermal exposure to parent fungicide and subsequent *in vivo* conversion to 1,2,4-triazole may occur. In order to account for this indirect exposure to free triazole, EPA used a conversion factor of 10%, which is the highest rate of *in-vivo* conversion observed in rats for any of the triazole-derivative fungicides with registrations on turf. Incidental oral exposure may occur by direct and indirect routes. To assess direct exposure, EPA used a conversion factor of 17%, which is the highest rate of conversion to free triazole observed in any of the plant metabolism studies. As with indirect dermal exposure, EPA used a conversion factor of 10% in its assessment of indirect oral exposure.

Based on residential exposure values estimated for propiconazole (0.0005 mg/kg/day via the dermal route and 0.03 mg/kg/day via the oral route) and the conversion factors described above, combined direct and indirect dermal exposures are estimated to be less than 0.0001 mg/kg/day and combined oral exposures are estimated to be less than 0.0019 mg/kg/day. The overall residential exposure is likely to be less than 0.0020 mg/kg/day. Relative to the 15 mg/kg/day point of departure, this gives an MOE of approximately 7,500 for children. Based on the current set of uncertainty factors, the target MOE is 1,000, indicating that the risk associated with residential exposure to 1,2,4-triazole for children is below EPA's level of concern. The adult dermal exposure estimate is slightly less than that of children. Incidental oral exposure is not expected to occur with adults.

iv. *Drinking water*. Modeled estimates of 1,2,4-triazole residues in surface and ground water, as reported by the USTTF, and the DWLOC approach were used to address exposure to free triazole in drinking water. Estimated environmental concentrations (EECs) of free triazole in ground water were obtained from the SCI-GROW model and range from 0.0 to 0.026 ppb, with the higher concentrations associated with uses on turf. Surface water EECs were obtained using the FIRST model. Acute surface water EECs ranged from 0.29 to 4.64 ppb for agricultural uses and up to 32.1 ppb from use on golf course turf. EPA notes that ground water monitoring studies in New Jersey and California showed maximum residues of 16.7 and 0.46 ppb, respectively, which exceed the SCI-GROW estimates significantly. Contrarily, preliminary monitoring data from USDA's Pesticide Data Program for 2004 show no detectable residues of 1,2,4-triazole in any drinking water samples, either treated or untreated (maximum limit of detection (LOD) = 0.73 ppb, n=40 each).

v. *Aggregate exposure*. In estimating aggregate exposure, EPA combined potential dietary and non-dietary sources of 1,2,4-triazole. To account for the drinking water component of dietary exposure, EPA used the DWLOC approach, as noted above. The DWLOC represents a maximum concentration of a chemical in drinking water at or below which aggregate exposure will not exceed EPA's level of concern. In considering non-dietary exposure, EPA used the residential exposure estimate for children and applied it to all population subgroups. As previously noted, this estimate is considered to be highly conservative for children. Since adults are not expected to have non-dietary oral exposure to 1,2,4-triazole and that pathway makes up the majority of the residential exposure estimate for children, application of that exposure estimate to adults is considered to be extremely conservative. Residential exposure is expected to occur for short-term and/or intermediate-term durations, and therefore, is not a component in the acute or chronic aggregate exposure assessment. In order to assess aggregate short-term and intermediate-term exposure, EPA combined the residential exposure estimate and the background level of exposure to free triazole via food. Less than 1% of lawns in the United States are expected to be treated with triazole fungicides, so the likelihood of co-occurring dietary and residential exposures is very low.

With the exception of the acute DWLOCs for infants and children 1 to

6 years old, all DWLOCs are greater than the largest EEC (surface water estimate from use on turf). The EEC's for these two population groups exceed the DWLOC's by 1.1 to 3.2-fold, a result typically interpreted to mean that aggregate exposure exceeds EPA's level of concern. Although comparing the EEC's and the acute DWLOCs for infants and children 1 to 6 years old indicate that aggregate exposure may exceed the aPAD of 0.015 mg/kg/day, EPA does not believe this to be the case due to the extremely conservative nature of the overall assessment (highest-tolerance level residues, 100% crop treated (CT), 77% *in vivo* conversion factor). Furthermore, the drinking water monitoring data from the Pesticide Data Program found no detectable residues of either free triazole or parent triazole - derivative fungicide in its preliminary 2004 dataset, indicating that neither parent compounds nor 1,2,4-triazole are likely to occur in drinking water. For all exposure durations and population subgroups, EPA does not expect aggregate exposures to 1,2,4-triazole to exceed its level of concern.

The Agency is planning to conduct a more sophisticated human health assessment in 2005 following submission and review of the ongoing toxicology and residue chemistry studies for 1,2,4-triazole.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to tetraconazole. In the developmental toxicity study in rats, developmental effects were seen at the same dose that induced maternal toxicity. In the developmental toxicity study in rabbits, no developmental toxicity was seen at the HDT. In the two-generation reproduction study, offspring toxicity occurred at doses higher than the dose that induced parental/systemic toxicity. There are no concerns or residual uncertainties for prenatal and/or postnatal toxicity. Additionally, there is no concern for neurotoxicity resulting from exposure to tetraconazole since there was no evidence of neurotoxicity in short-term studies in rats, mice and dogs; and a long-term toxicity study in dogs.

3. *Conclusion*. Based on the following, EPA concluded that the additional safety factor for the protections of infants and children could be removed:

- There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies.
- There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study.
- There are no residual uncertainties for prenatal/postnatal toxicity.
- The toxicological database is complete for FQPA assessment.
- The chronic non-cancer dietary food exposure assessment utilizes anticipated residue data and assumed 100% CT.
- The chronic assessment will not underestimate exposure or risk since the refinement is based on reliable data derived from studies designed to produce worst-case residues.
- At this time, only agricultural uses have been proposed for tetraconazole. There are no uses that would result in residential or recreational exposures.

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 U.S. EPA 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 the pesticide 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 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 tetraconazole will occupy 0.5% of the aPAD for females 13 to 49 years old, the only population subgroup for which an acute toxicity endpoint was determined. In addition, there is potential for acute dietary exposure to tetraconazole in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2.

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

Population Subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–49 years old)	0.225	0.5	8.38	0.51	6,720

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tetraconazole from food will utilize 3.9% of the cPAD for the U.S. population, 11.1% of the cPAD for non-nursing infants and 8.9% of the cPAD for all infants < 1 year old. There are no residential uses for tetraconazole that result in chronic residential exposure to tetraconazole. In addition, there is potential for chronic dietary exposure to tetraconazole in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in following Table 3.

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0073	3.9	5.58	0.51	246
All infants (< 1 year old)	0.0073	8.9	5.58	0.51	67
Non-nursing infants	0.0073	11.1	5.58	0.51	65
Children (1–2 years old)	0.0073	8.4	5.58	0.51	67
Children (3–5 years old)	0.0073	8.5	5.58	0.51	67
Children (6–12 years old)	0.0073	6.1	5.58	0.51	69
Youth (13–19 years old)	0.0073	4.0	5.58	0.51	210
Adults (20–49)	0.0073	3.1	5.58	0.51	248
Adults (50+ years old)	0.0073	2.5	5.58	0.51	249
Females (13–49 years old)	0.0073	3.0	5.58	0.51	210

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). Tetraconazole 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. The risk does 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).

Tetraconazole 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. The risk does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. The estimated cancer risk for the proposed use on sugarbeets and existing section 18 exemptions for soybeans is 2.5×10^{-6}, a value that falls within the Agency's risk standard for cancer in the range of 1×10^{-6}.

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 tetraconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromotography with electron capture detector (GC/ECD)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no established Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) established for tetraconazole.

C. Conditions

The following conditions will be applied to the registration of tetraconazole for use on sugarbeets:

1. Registration and tolerances will be time-limited to allow review of triazole data and completion of the triazole risk assessment.

2. Registrations will be limited to the following States: Colorado, Minnesota, Michigan, Montana, North Dakota, Nebraska, and Wyoming where use has previously occurred under section 18 of FIFRA.

3. The registrant will be required to provide one additional side-by-side sugarbeet field trial comparing two and six applications of Eminent 125SL at 0.10 lb ai/acre/application.

4. The registrant will be required to provide a 28 day inhalation study.

5. Well documented estimates of how many pounds of tetraconazole will be placed on the market to treat sugarbeets.

6. Tetraconazole use reporting on sugarbeets. This information should be reported as how many pounds of tetraconazole will be applied per acre on sugarbeets.

V. Conclusion

Therefore, the tolerances are established for residues of tetraconazole, 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1*H*-1,2,4-triazole in or on sugarbeet root at 0.05 ppm, sugarbeet top at 3.0 ppm, sugarbeet dried pulp at 0.15 ppm, sugarbeet molasses at 0.15 ppm, meat of cattle, goat, horse, and sheep at 0.05 ppm, liver of cattle, goat, horse, and sheep at 4.0 ppm, fat of cattle, goat, horse, and sheep at 0.30 ppm, meat byproducts except liver of cattle, goat, horse and sheep at 0.10 ppm and milk 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. 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), 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–2004–0388 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 June 21, 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 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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0388, 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*. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of 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.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 14, 2005.

James Jones,

Director, 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 180.557 is revised to read as follows:

§ 180.557 Tetraconazole; tolerances for residues.

(a) General. [Reserved]

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

(c) *Tolerances with regional registrations.* Tolerances are established for residues of the fungicide, tetraconazole 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1*H*-1,2,4-triazole in or on the following commodities:

Commodity	Parts per million	Expiration/revocation date
Beet, sugar, dried pulp	0.15	11/30/12
Beet, sugar, molasses	0.15	11/30/12
Beet, sugar, roots	0.05	11/30/12
Beet, sugar, tops	3.0	11/30/12
Cattle, fat	0.30	11/30/12
Cattle, liver	4.0	11/30/12
Cattle, meat	0.05	11/30/12
Cattle, meat byproducts, except liver	0.10	11/30/12
Goat, fat	0.30	11/30/12
Goat, liver	4.0	11/30/12
Goat, meat	0.05	11/30/12
Goat, meat byproducts, except liver	0.10	11/30/12
Horse, fat	0.30	11/30/12
Horse, liver	4.0	11/30/12
Horse, meat	0.05	11/30/12
Horse, meat byproducts, except liver	0.10	11/30/12
Milk	0.05	11/30/12
Sheep, fat	0.30	11/30/12
Sheep, liver	4.0	11/30/12
Sheep, meat	0.05	11/30/12
Sheep, meat byproducts, except liver	0.10	11/30/12

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 05–8123 Filed 4–21–05; 8:45 am]
BILLING CODE 6560–50–S

DEPARTMENT OF DEFENSE

48 CFR Parts 202, 204, 211, 212, 243, and 252

[DFARS Case 2003–D081]

Defense Federal Acquisition Regulation Supplement; Unique Item Identification and Valuation

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has issued a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to establish policy for unique identification and valuation of items delivered under DoD contracts.

DATES: Effective April 22, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Michele Peterson, Defense Acquisition Regulations Directorate, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–0311; facsimile (703) 602–0350. Please cite DFARS Case 2003–D081.

SUPPLEMENTARY INFORMATION:

A. Background

DoD published an interim rule at 68 FR 75196 on December 30, 2003, containing policy that requires contractors to provide unique item identification (UID) and the Government's unit acquisition cost for items delivered under DoD contracts. Thirteen sources submitted comments on the interim rule. The following is a discussion of the comments and the changes made to the rule as a result of those comments:

1. *Comment:* A respondent stated that the implementation date of January 1, 2004, was too aggressive. The respondent recommended a later implementation date that would allow time in which to alert both Federal agencies and Federal contractors about the specifics of the new rule.

DoD Response: DoD agrees that the implementation schedule was aggressive. However, the rule is considered to be a strategic imperative. The implementation schedule could not be slipped.

2. *Comment:* We have been instructed to identify ''to be determined'' in the clause fill-in. We have also been instructed to contact our requirements (logistics) counterparts for their determination if this clause applies. According to our counterparts, they don't have the technical training or knowledge to make that determination. Also, there is currently no training or knowledge in the contracting world on a realistic cost for this information.

DoD Response: The clause must go into all contracts that require the delivery of ''items'' as defined in the clause, unless an exception applies. Items valued at or above $5,000 must be marked with UID. The fill-ins are for items that meet other specified conditions, as well as embedded items that meet specified conditions. The implementing guidance in section 211.274 has been reworded for clarity to specify that the requiring activity determines what embedded items, subassemblies, or components require UID. There is less technical training or knowledge required than the interim rule implied; however, additional information is available at *http://www.acq.osd.mil/dpap/uid.*

3. *Comment:* DoD should give special consideration to communicating, aiding, and making available, training to all suppliers that will need to comply with this requirement—whether as prime contractors, or as subcontractors at any tier.

DoD Response: Concur. DoD is engaged in a large communication effort through its UID Program Office. The UID Web site at *http://www.acq.osd.mil/dpap/uid* should be consulted for information and resources that are available.

4. *Comment:* Both government buying offices and prime contractors should be encouraged to make special efforts to assist small and small disadvantaged, minority- or women-owned firms and make accommodations as needed to help them achieve the goals of this new requirement.

DoD Response: Concur. Small businesses will find that there are a number of vendors, many of which are small businesses themselves, that can provide UID marking assistance. Additionally, the final rule permits exceptions to marking requirements for items acquired from small business concerns when it is more cost effective for the Government requiring activity to assign, mark, and register the UID after delivery.

5. *Comment:* Not all requirements are generated from DoD. How does this requirement apply when a foreign government is the customer? A related comment was whether UID is applicable to Foreign Military Sales (FMS) contracts and whether our FMS customers were consulted about UID applicability and advised of potential cost impacts.

DoD Response: Items valued at or above $5,000, or items delivered to DoD that meet other specified conditions, must be marked with UID. There is no exception for FMS contracts. This rule has been developed with assistance from our allies and in consideration of international standards.

6. *Comment:* Does UID apply to items that we lease but of which we never take ownership?

DoD Response: Yes. Items valued at or above $5,000, or items delivered to DoD that meet other specified conditions, must be marked with UID.

7. *Comment:* Two respondents asked whether UID and valuation apply to classified or COMSEC contracts. One respondent suggested that the final rule include instructions to require that all such issues be directed to the contracting officer for resolution.

DoD Response: Yes, the UID and valuation apply to classified contracts, unless there is an exemption cited in program directives.

8. *Comment:* Does UID apply to furniture that has an acquisition cost of $5,000 and above?

DoD Response: Yes, all items over $5,000 in value require unique identification.

9. *Comment:* The clause should include a statement that the contractor must comply with the most current version of MIL–STD–130.

DoD Response: Concur. After much consideration, it was considered best to refer to the version of MIL–STD–130 that is cited in the contract Schedule. This allows for updating, if necessary, at the time of award.

10. *Comment:* Is UID really appropriate when, in all likelihood, it probably will not survive the manufacturing process?

DoD Response: If an item is valued at or above $5,000, and it is delivered to DoD, it must be marked with UID. One of the purposes of UID is to be able to track items that may be warehoused for a period of time prior to being incorporated into a manufactured end item. The property record that was created when the item was delivered should be annotated with the item's disposition when it is incorporated into a manufactured item.

11. *Comment:* One respondent believes that, in an effort to save taxpayer dollars, items required for their own base operations, that are never used/received by the warfighter (*i.e.*, is not a spare part), should be excluded.

DoD Response: Do not concur. Items valued at or above $5,000, or items meeting other specified conditions that