

and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. This rule establishes a safety zone.

A final “Environmental Analysis Check List” and a final “Categorical Exclusion Determination” will be available in the docket where indicated under **ADDRESSES**.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–034 to read as follows:

##### § 165.T05–034 Safety zone; Fireworks Display, Potomac River, Oxon Hill, MD.

(a) *Location.* The following area is a safety zone: All waters of the Potomac River near Oxon Hill, Maryland, surface to bottom, within a radius of 150 yards around a fireworks barge which will be located at position latitude 38° 47′ 24.2″ N, longitude 077° 01′ 18.7″ W. All coordinates reference Datum NAD 1983.

(b) *Definition.* As used in this section the Captain of the Port Baltimore means the Commander, Coast Guard Sector Baltimore or any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(c) *Regulations.* The general regulations governing safety zones, found in § 165.23, apply to the safety zone described in paragraph (a) of this section.

(1) All vessels and persons are prohibited from entering this zone, except as authorized by the Captain of the Port, Baltimore, Maryland.

(2) Persons or vessels requiring entry into or passage within the zone must request authorization from the Captain of the Port or his designated representative by telephone at (410) 576–2693 or by marine band radio on VHF channel 16 (156.8 MHz).

(3) All Coast Guard vessels enforcing this safety zone can be contacted on marine band radio VHF channel 16 (156.8 MHz).

(4) The operator of any vessel within or in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign, and

(ii) Proceed as directed by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State and local agencies.

(e) *Enforcement period.* This section will be enforced from 8 p.m. to 10 p.m. on May 31, 2007.

Dated: April 2, 2007.

Jonathan C. Burton,

Commander, U.S. Coast Guard, Acting Captain of the Port, Baltimore, Maryland.

[FR Doc. E7–6784 Filed 4–10–07; 8:45 am]

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#### DEPARTMENT OF VETERANS AFFAIRS

##### 38 CFR Part 17

RIN 2900–AE87

##### Per Diem for Nursing Home Care of Veterans in State Homes; Correction

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Correcting amendment.

**SUMMARY:** This document contains a minor correction to the final regulation that the Department of Veterans Affairs (VA) published in 65 FR 23412 on January 6, 2000. The regulation relates to the payment of per diem to State homes that provide nursing home care to eligible veterans.

**DATES:** *Effective date:* April 11, 2007.

**FOR FURTHER INFORMATION CONTACT:** Candice Cornish, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420, (202) 273–9957.

**SUPPLEMENTARY INFORMATION:** The VA published a document in the **Federal Register** on January 6, 2000, 65 FR

23412, revising its medical regulations concerning payment of per diem to State homes that provide nursing home care to eligible veterans. In that document, we failed to properly punctuate the end of § 17.190(c). This document corrects that error by removing “, and” and adding, in its place, a period.

#### List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Robert C. McFetridge,

Assistant to the Secretary for Regulation Policy and Management.

■ For the reason set out in the preamble, VA is correcting 38 CFR part 17 as follows.

#### PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

**Authority:** 38 U.S.C. 501, 1721, and as stated in specific sections.

##### § 17.190 [Corrected]

■ 2. In § 17.190, paragraph (c) is amended by removing “, and” and adding, in its place, a period at the end of the paragraph.

[FR Doc. E7–6762 Filed 4–10–07; 8:45 am]

BILLING CODE 8320–01–P

#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 180

[EPA–HQ–OPP–2006–0576; FRL–8121–3]

##### Tetraconazole; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of tetraconazole in or on peanut, pecan, sugarbeet and soybean. Sipcam Agro USA, Inc. and Isagro S.p.A. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 11, 2007. Objections and requests for hearings must be received on or before June 11, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–

OPP-2006-0576. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Lisa Jones, Fungicide Branch, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9424; e-mail address: [jones.lisa@epa.gov](mailto:jones.lisa@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), 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 to provide a guide

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

###### B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot CFR site at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0576 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 11, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0576, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

##### II. Petition for Tolerance

In the **Federal Register** of July 26, 2006 (71 FR 42392) (FRL-8074-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F6971) by Isagro S.p.A., 430 Davis Dr., Suite 240, Morrisville, NC 27560. The petition requested that 40 CFR 180.557 be amended by establishing a tolerance for residues of the fungicide, tetraconazole, 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4-triazole] in or on soybean, seed at 0.1 parts per million (ppm), soybean, aspirated grain fractions/soybean, refined oil at 0.5 ppm, poultry, fat at 0.05 ppm, and poultry, egg/liver/meat/meat byproducts at 0.01 ppm. That notice referenced a summary of the petition prepared by Isagro S.p.A., the registrant, which is available to the public in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C. below.

In the **Federal Register** of December 20, 2006 (71 FR 76321) (FRL-8104-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 6F7084, 9F6023, 9F5066) by Sipcam Agro USA, Inc., Colonial Center Parkway, # 230, Roswell, GA 30076. Petition 6F7084 requested that 40 CFR 180.557 be amended by establishing tolerances for residues of the fungicide tetraconazole in or on pecan at 0.05 ppm. Petition 9F6023 requested that 40 CFR 180.557 be amended by establishing tolerances for residues of the fungicide tetraconazole in or on the food commodities peanut, nutmeat at 0.05 ppm, and peanut, refined oil at 0.15 ppm. Petition 9F5066 requested that 40 CFR 180.557 be amended by revising the existing tolerances for residues of the fungicide tetraconazole in or on sugarbeet roots 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. That notice referenced a summary of the petition prepared by Sipcam Agro USA, Inc., the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

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

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. . . ." These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of tetraconazole. 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. Specific information on the studies received and the nature of the adverse effects caused by as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of April 22, 2005 (70 FR 20821), (FRL-7702-4).

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for tetraconazole used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 22, 2005 (70 FR 20821) (FRL-7702-4).

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary

exposure to, EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances in (40 CFR 180.557). EPA assessed dietary exposures from tetraconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. An acute endpoint was not identified for the general population. In estimating acute dietary exposure for females aged 13 to 49, EPA used food consumption information from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that all food and feed commodities with established and proposed tolerances contain tolerance-level residues and that 100% of crops were treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 Nationwide CSFII. As to residue levels in food, EPA relied upon empirical processing factors, average field trial residues for all crops and average residues in meat and meat by-products derived from feeding studies. Percent crop treated information was not used.

iii. *Cancer.* In conducting the cancer dietary risk assessment, EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. The refined dietary cancer risk assessment used empirical processing factors, average field trial residues for all crops, average residues in meat and meat by-products derived from feeding studies and projected percent crop treated estimates for peanuts, soybean and sugarbeets.

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

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

a. The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue;

b. The exposure estimate does not underestimate exposure for any significant subpopulation group; and

c. Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

EPA estimates projected percent crop treated (PPCT) for a new pesticide use by initially assuming that the percent crop treated (PCT) during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one with the greatest PCT) on that site. EPA also examines all other available data to determine if this method of projecting percent crop treated produces a reliable estimate.

The Agency used PPCT information for the cancer dietary exposure assessment as follows: Peanuts - 77%; sugar beets - 70%; and soybeans - 27%.

The PPCT for peanuts was determined by averaging the PCTs of the leading fungicide, in this case, chlorothalonil, for the three most recent available years (1991, 1999 and 2004). These data show 77% PPCT based on average market leader values.

The PPCT for sugar beets was determined as the PCT of the leading fungicide, in this case, tetraconazole itself, for the year 2000, based on its use on sugar beets following registration under Section 18 of FIFRA for use in seven states (Colorado, Michigan, Minnesota, Montana, Nebraska, North Dakota, and Wyoming). Tetraconazole is the current market leader (55%) in those seven states where it is currently used. However, the acreage potentially treated by tetraconazole rises by 18% when four other sugarbeet growing states (California, Idaho, Oregon and Washington) are also considered. Treating all the planted acreage in these four additional states with tetraconazole could bring the PPCT up to 70%.

The PPCT for soybeans was determined using a modified approach. Due to the discovery of a new and important disease on soybeans (Asian

soybean rust), historical information was not considered useful for estimating PCT for soybeans. PCT estimates were obtained for future market leaders from soybean crop specialists. For a conservative estimate EPA utilized only the maximum projected values provided by each respondent, which ranged from 15 to 38%. These values translated into average and maximum PPCT values of 27 and 38%, respectively. EPA's evaluation of the basis for these estimates and other factors bearing on the potential use of tetraconazole show that it is unlikely that these estimates will be exceeded.

The Agency believes that the three conditions listed in the second paragraph of Unit III.C.1.iv have been met. With respect to Condition 1, the data relied upon is discussed above. Where EPA relies on PCT data on existing uses, EPA typically uses the United States Department of Agriculture, National Agricultural Statistical Service (USDA/NASS) as the primary source for PCT data. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data and calculates the PCT. Comparisons are only made among pesticides of the same pesticide types (i.e., the leading fungicide on the use site is selected for comparison with the new fungicide). The PCTs included in the average may be for the same pesticide, or for different pesticides, since the same, or different pesticides, may dominate for each year selected. 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 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 environmental fate characteristics of tetraconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentrations in Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) for acute exposures are estimated to be 20.01 parts per billion (ppb) for surface water. The EECs for chronic exposures are estimated to be a yearly average of 7.26 ppb for surface water and 1.79 ppb for ground water and a 30-year annual average of 4.97 for surface water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 20.01 ppb was used to access the contribution to drinking water. For chronic and cancer dietary risk assessment, the water concentration of value 4.97 ppb was used to access the contribution to drinking water.

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

Tetraconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same,

or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

Triazole-derived pesticides can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including tetraconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide as of September 1, 2005. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at <http://www.regulations.gov>, Docket Identification (ID) Number EPA-HQ-OPP-2005-0497.

For tetraconazole, the new use on pecans was not received by the Agency prior to September 1, 2005, and therefore, was not included in the human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine and triazolylacetic acid. The Agency has evaluated the

additional dietary risk from 1,2,4-triazole and the two conjugates resulting from the use of tetraconazole on pecans in the Agency's human health risk assessment for tetraconazole. The Agency has determined that dietary exposure to 1,2,4-triazole, triazolylalanine and triazolylacetic acid does not exceed the Agency's level of concern.

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

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional (10X) 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 based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional uncertainty/safety 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 highest dose tested. In the 2-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.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- i. The toxicity database for tetraconazole is complete.
- ii. There is no indication that tetraconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or

additional uncertainty factors to account for neurotoxicity.

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

iv. There are no residual uncertainties identified in the exposure databases. The assumptions and estimates used to model ground and surface water concentrations are discussed in Unit III.C.2 and the assumptions and estimations underlying the dietary food exposure assessments are discussed in Unit III.C.1. These assessments will not underestimate the exposure and risks posed by tetraconazole.

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

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tetraconazole will occupy <1.0% of the aPAD for the population group (females 13-49 years old) receiving the greatest exposure. No acute toxicity endpoint was identified for the remaining population subgroups.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tetraconazole from food and water will utilize ≤10.1% of the cPAD for the population group all infants <1 year old. There are no residential uses for tetraconazole that result in chronic residential exposure to tetraconazole. Based on the use pattern, chronic residential exposure to residues of tetraconazole is not expected.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure take 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.

4. *Aggregate cancer risk for U.S. population.* The estimated cancer risk for the proposed use of tetraconazole on sugarbeets, peanuts, pecans and soybeans is  $3 \times 10^{-6}$ . EPA considers risk estimates as high as  $3 \times 10^{-6}$  to be within the negligible risk range of  $1 \times 10^{-6}$ . This aggregate risk is the sum of the risk from food and water.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to tetraconazole residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

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

##### B. International Residue Limits

There are no established Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) established for tetraconazole in or on the relevant crops and commodities.

##### C. Response to Comments

One comment was received from a private citizen objecting to the establishment of tolerances for tetraconazole. The Agency has received similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), 69 FR 63096-63098 (October 29, 2004) for the Agency's response to these objections. In addition, the commenter noted several adverse effects seen in animal toxicology studies with tetraconazole and claims because of these effects no tolerance should be approved. However, EPA found in its tetraconazole risk assessment that there is a reasonable certainty of no harm to humans after considering the toxicological studies (and the adverse effects seen therein) and the exposure levels of humans to tetraconazole. The commenter did not provide any information that questioned EPA's risk assessment.

#### V. Conclusion

Upon completing the review of the current tetraconazole database, the Agency concluded that tolerances for hog meat commodities are necessary as a result of concern for secondary residues, and a sugar beet top tolerance is unnecessary since it is not a human food commodity and is being eliminated as a feed commodity from OPPTS 860.1000. The Agency concluded that the appropriate tolerance levels and preferred commodity terms for tetraconazole residues in or on pending crops and livestock commodities should be established as follows:

Tolerances are established for residues of tetraconazole in or on beet, sugar, root at 0.05 ppm; beet, sugar, dried pulp at 0.15 ppm; beet, sugar, molasses at 0.15 ppm; peanut at 0.03 ppm; peanut, oil at 0.10 ppm; pecan at 0.04 ppm; soybean, seed at 0.15 ppm; soybean, refined oil at 0.80 ppm; aspirated grain fractions at 1.0 ppm; poultry, meat at 0.01 ppm; poultry, fat at 0.05 ppm; poultry, meat byproducts at 0.01 ppm; eggs at 0.02 ppm; cattle, meat at 0.01 ppm; cattle, liver at 0.20 ppm; cattle, fat at 0.02 ppm; cattle, meat byproducts (except liver) at 0.01 ppm; milk at 0.01 ppm; milk, fat at 0.25 ppm; goat, meat at 0.01 ppm; goat, liver at 0.20 ppm; goat, fat at 0.02 ppm; goat, meat, byproducts (except liver) at 0.01 ppm; hog, meat at 0.01 ppm; hog, liver at 0.05 ppm; hog, fat at 0.01 ppm; hog, meat byproducts (except liver) at 0.01 ppm; horse, meat at 0.01 ppm; horse, liver at 0.20 ppm; horse, fat at 0.02 ppm; horse, meat, byproducts (except liver) at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, liver at 0.20 ppm; sheep, fat at 0.02 ppm; sheep, meat, byproducts (except liver) at 0.01 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any

information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller

General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

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

Dated: April 2, 2007.

**Lois Rossi,**

Director, Registration Division, Office of Pesticide Programs.

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

#### PART 180—[AMENDED]

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

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

■ 2. Section 180.557 is amended by revising paragraph (a), and removing and reserving paragraphs (b) and (c) to read as follows.

#### § 180.557 Tetraconazole; tolerances for residues.

(a) *General.* 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
Aspirated grain fractions	1.0
Beet sugar, dried pulp ....	0.15
Beet sugar, molasses ....	0.15
Beet sugar, root .....	0.05
Cattle, fat .....	0.02
Cattle, liver .....	0.20
Cattle, meat .....	0.01
Cattle, meat byproducts (except liver) .....	0.01
Eggs .....	0.02
Goat, fat .....	0.02
Goat, liver .....	0.20
Goat, meat .....	0.01
Goat, meat byproducts (except liver) .....	0.01
Hog, fat .....	0.01
Hog, liver .....	0.05
Hog, meat .....	0.01
Hog, meat byproducts (except liver) .....	0.01
Horse, fat .....	0.02
Horse, liver .....	0.20
Horse, meat .....	0.01
Horse, meat byproducts (except liver) .....	0.01
Milk .....	0.01
Milk, fat .....	0.25
Peanut .....	0.03
Peanut, oil .....	0.10
Pecan .....	0.04
Poultry, fat .....	0.05

Commodity	Parts per million
Poultry, meat .....	0.01
Poultry meat byproducts .....	0.01
Sheep, fat .....	0.02
Sheep, liver .....	0.20
Sheep, meat .....	0.01
Sheep, meat byproducts (except liver) .....	0.01
Soybean, refined oil .....	0.80
Soybean, seed .....	0.15

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

(c) *Tolerances with regional registrations.* [Reserved].

\* \* \* \* \*

[FR Doc. E7-6837 Filed 4-10-07; 8:45 am]

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#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

#### 50 CFR Part 622

[Docket No. 001005281-0369-02; I.D. 040407C]

#### Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS closes the commercial hook-and-line fishery for king mackerel in the exclusive economic zone (EEZ) in the southern Florida west coast subzone. This closure is necessary to protect the Gulf king mackerel resource.

**DATES:** The closure is effective 12:01 a.m., local time, April 10, 2007, until 12:01 a.m., July 1, 2007.

**FOR FURTHER INFORMATION CONTACT:** Steve Branstetter, telephone: 727-824-5305, fax: 727-824-5308, e-mail: [Steve.Branstetter@noaa.gov](mailto:Steve.Branstetter@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, and, in the Gulf of Mexico only, dolphin and bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the

Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, on April 30, 2001 (66 FR 17368, March 30, 2001), NMFS implemented a commercial quota of 2.25 million lb (1.02 million kg) for the eastern zone (Florida) of the Gulf migratory group of king mackerel. That quota is further divided into separate quotas for the Florida east coast and west coast subzones. The Florida west coast subzone is that part of the eastern zone south and west of 25°20.4' N. lat. (a line directly east from the Miami-Dade/Monroe County, FL, boundary) along the west coast of Florida to 87°31.1' W. long. (a line directly south from the Alabama/Florida boundary). The Florida west coast subzone is further divided into a northern and southern subzone. The southern subzone is that part of the Florida west coast subzone, which from November 1 through March 31 extends south and west from the Miami-Dade/Monroe County boundary to 25°20.4' N. lat. to 26°19.8' N. lat. (a line directly west from the Lee/Collier County, FL, boundary), i.e., the area off Collier and Monroe Counties. From April 1 through October 31, the southern subzone is that part of the Florida west coast subzone which is between 26°19.8' N. lat. and 25°48' N. lat. (a line directly west from the Monroe/Collier County, FL, boundary), i.e., the area off Collier County. The quota implemented for the southern Florida west coast subzone is 1,040,625 lb (472,020 kg). That quota is further divided into two equal quotas of 520,312 lb (236,010 kg) for vessels in each of two groups fishing with run-around gillnets and hook-and-line gear (50 CFR 622.42(c)(1)(i)(A)(2)(i)).

Under 50 CFR 622.43(a)(3), NMFS is required to close any segment of the king mackerel commercial fishery when its quota has been reached, or is projected to be reached, by filing a notification at the Office of the **Federal Register**. NMFS has determined that the commercial quota of 520,312 lb (236,010 kg) for Gulf group king mackerel for vessels using hook-and-line gear in the southern Florida west coast subzone has been met. Accordingly, the commercial fishery for king mackerel for such vessels in the southern Florida west coast subzone is closed at 12:01 a.m., local time, April 10, 2007, through 12:01 a.m., July 1, 2007, the beginning of the next (2007 - 2008) fishing season.