appropriate circuit by October 28, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action 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, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 8, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart F—California

■ 2. Section 52.220, is amended by adding paragraph (c)(388)(i)(B) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(388) * * *

(i) * * *

(B) San Joaquin Valley Air Pollution Control District.

(*1*) Rule 4354, ''Glass Melting Furnaces,'' amended on September 16, 2010.

* * * * *

[FR Doc. 2011–21940 Filed 8–26–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0583; FRL–8885–1]

Tetraconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tetraconazole in or on multiple commodities which are identified and discussed later in this document. In addition, EPA is removing the existing grape tolerance because grape is now covered under the newly established tolerance for small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 29, 2011. Objections and requests for hearings must be received on or before October 28, 2011, 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–2010–0583. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Divison, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–7610; *e-mail address: jackson.sidney@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0583 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 28, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0583, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 8, 2010 (75 FR 54629) (FRL–8843–3) and December 15, 2010 (75 FR 78240) (FRL–8853–1), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP) 0E7735 by Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08450, and (PP) 0F7737 by Isagro S.p.A., 430 Davis Drive, Suite 240, Morrisville, NC 27560, respectively. The petitions requested that 40 CFR 180.557 be amended by establishing tolerances for residues of the fungicide tetraconazole, 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxyl)propyl]-1*H*-1,2,4-triazole, in or on small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.20 parts per million (ppm); and low growing berry, subgroup 13–07G at 0.25 ppm (0E7735), and corn, field, forage; corn field, grain; corn, field, stover; corn pop, grain; and corn, pop, stover at 1.0, 0.01, 1.5, 0.01 and 1.5 ppm, respectively (0F7737). Each notice referenced a summary of the petition prepared by Isagro, USA, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notices of filing. Based upon review of all available data supporting the petitions, EPA made the following modifications:

1. Revised the tolerance expression in § 180.557(a), and corrected commodities name.

2. Revised proposed tolerance levels for corn, field, forage; corn, field, stover; and corn, pop, stover.

3. EPA is also revising established tolerance levels for milk; milk, fat; poultry, meat by-products, and fat, liver, and meat by-products of cattle, goat, horse and sheep based on the proposed tolerances and revisions to existing feed commodity tolerances.

4. EPA is removing the existing grape tolerance because grape is covered under the newly established tolerance for small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F.

The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tetraconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tetraconazole 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.

Tetraconazole has low acute toxicity via the oral, dermal, and inhalation routes. It is a slight eye irritant, but is not a dermal irritant or a dermal sensitizer. The liver and kidney are the primary target organs of tetraconazole in mice, rats and dogs. Toxicity in these organs occurred following 28-day, 90-day, and 1- to 2-year oral exposures.

For chronic durations, the dog was the most sensitive species, followed by the mouse, and then the rat. Chronic toxicity in the dog included increased absolute and relative kidney weights and histopathological changes in the male kidney (cortical tubular hypertrophy) which were observed at the mid-dose. At the high dose, liver effects were observed in both sexes. In the mouse, effects included increased liver weights, hepatocellular vacuolization in both sexes, and increased kidney weights in males. In rats, several effects not related to liver and kidney toxicity were observed. These included histopathological changes of the bone, pale and thickened incisors, decreased absolute and relative adrenal and pituitary weights in males, and decreased body weight (at terminal sacrifice) in females. Centrilobular hepatocyte hypertrophy was observed in the high-dose groups for both sexes in this study.

Oral rat and rabbit prenatal developmental studies showed no increased quantitative susceptibility of the fetus to tetraconazole exposure *in utero.* In the developmental toxicity study in rats, the maternal toxicity was manifested as decreased body weight gain, food consumption, increased water intake, increased liver and kidney weights. There were developmental effects in rats which suggested qualitative susceptibility. They consisted of increased incidences of supernumerary ribs, and increased incidences of hydroureter and hydronephrosis, which exceeded the high end value of the historical control range. No developmental toxicity was seen in the rabbit study. The sole maternal effect in this rabbit study was decreased body weight gain which occurred at the highest dose tested.

A 2-generation rat reproduction study also revealed no increased quantitative susceptibility in offspring. Parental toxicity resulted in increased mortality in females of the P and F_1 generations at the mid dose. This increase in mortality had a higher incidence at the highest dose tested. Effects in parental animals that survived the duration of the study were consistent with other studies in the database including decreased body-weight gain and food consumption during pre-mating, increased relative liver and kidney weights, and hepatocellular hypertrophy in males and females at the lowest-observed adverse-effect levels (LOAELs).

There were signs of neurotoxicity in the acute neurotoxicity study. There is

no evidence of neurotoxicity in any of the other studies in the toxicity database for tetraconazole. In the absence of specific immunotoxicity studies, EPA has evaluated the available tetraconazole toxicity database to determine whether an additional database uncertainty factor (UF_{DB}) is needed to account for potential immunotoxicity. No evidence of immunotoxicity was found.

There were no systemic effects observed in the 21-day dermal toxicity study up to the highest dose used. In the 28-day inhalation study in rats, toxicity was observed at the lowest concentration/dose. At the highest concentration tested, there were treatment-related increases in absolute lung weights in both sexes. There were also treatment-related increases in absolute and relative liver weights in males. In the kidney, there were treatment-related increases in absolute and relative kidney and adrenal gland weights in females. In females there was a treatment-related statistically-significant increase in circulating globulins at the mid and high concentrations. Finally in the kidney, at the highest concentration tested, there was a 50% increase in the incidence of tubular hyaline droplets with features characteristic of α-2 microglobulin. This was observed only in males, and this effect is not considered relevant to humans.

Tetraconazole did not show evidence of mutagenicity in in vitro or in vivo studies. Carcinogenicity studies with tetraconazole resulted in an increased incidence of combined benign and malignant liver tumors in mice of both sexes. In contrast to mice, no tumors were noted in male or female rats after long-term dietary administration of tetraconazole. The Agency classified tetraconazole as ''likely to be carcinogenic to humans'' by the oral route based on the occurrence of liver tumors in male and female mice.

Specific information on the studies received and the nature of the adverse effects caused by tetraconazole as well as the no-observed-adverse-effect level (NOAEL) and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document ''Tetraconazole: Human-Health Risk Assessment for Proposed Uses of Small Fruit Vine Climbing Subgroup 13–07F, Low-Growing Berry Subgroup 13–07G, and Field Corn and Popcorn'' dated April 14, 2011 at pages 38–47 in docket ID number EPA–HQ–OPP–2010–0583–0004.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for tetraconazole used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TETRACONAZOLE FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	NOAEL = 22.5 milligrams/kilograms/day (mg/kg/day). UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.225 mg/kg/day ..... aPAD = 0.225 mg/kg/day	Developmental toxicity study in rats Developmental LOAEL = 100 mg/kg/day based on increased incidence of small fetuses, supernumerary ribs, and hydroureter and hydronephrosis.
Acute dietary (General population including infants and children).	NOAEL = 50 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day ..... aPAD = 0.5 mg/kg/day	Acute neurotoxicity (rat) LOAEL = 200 mg/kg/day based on decreased motor activity on day 0 in both sexes, and clinical signs in females including hunched posture, decreased defecation, and/or red or yellow material on various body surfaces.
Chronic dietary (All populations)	NOAEL= 0.73 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0073 mg/kg/day cPAD = 0.0073 mg/kg/day	Chronic oral toxicity (dog) Developmental LOAEL = 100 mg/kg/day based on absolute and relative kidney weights and histopathological changes in the male kidney.
Cancer (Oral, dermal, inhalation) ..	Classification: ''Likely to be Carcinogenic to Humans'' and report cancer slope factor (Q_1*) of 2.3 x 10^{-2} mg/kg/day derived from the male mouse liver benign and/or malignant combined tumor rates.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tetraconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing tetraconazole 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. Such effects were identified for tetraconazole. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all existing and proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, the chronic analysis (food and water) was refined through the incorporation of empirical processing factors, average field trial residues, average residues from the feeding studies, and PCT estimates for sugar beet, peanut, field corn and soybean.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determine a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that tetraconazole should be classified as ''Likely to be Carcinogenic to Humans'' and a linear approach has been used to quantify cancer risk. The cancer analysis (food and water) was refined through the incorporation of empirical processing factors, average field trial residues, average residues from the feeding studies, and projected PCT estimates for sugar beet, field corn, peanut, and soybean.

iv. *Percent crop treated (PCT) information.* 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:

- *Condition 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 the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT uses as follows: sugarbeet—70%; and peanut—77%.

In most cases, EPA uses available data from the United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency estimated the PCT for as follows: field corn—9% and soybean at 5%.

EPA estimates of the PCT for proposed new uses of tetraconazole represent the upper bound of use expected during the pesticide's initial 5 years of registration. Because soybean has not been registered for 5 years, the Agency has treated it as a new use for analyzing PCT. The PCT for new uses for use in the chronic dietary assessment is calculated as the average PCT of the market leader or leaders (*i.e.,* the pesticides with the greatest PCT) on that site over the three most recent years of available data. Comparisons are only made among pesticides of the same pesticide type (*e.g.,* the market leader for fungicides on the use site is selected for comparison with a new fungicide). The market leader included in the estimation may not be the same for each year since different pesticides may dominate at different times.

To evaluate whether the PCT estimate for tetraconazole could be exceeded, EPA considered whether there may be unusually high pest pressure, as indicated in emergency exemption requests for tetraconazole; the pest spectrum of the new pesticide in comparison with the market leaders and whether the market leaders are well established for that use; and whether pest resistance issues with past market leaders provide tetraconazole with significant market potential. Given currently available information, EPA concludes that it is unlikely that actual PCT for tetraconazole will exceed the estimated PCT for new uses during the next 5 years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 reliable 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 used screening level water exposure models in the dietary exposure analysis and risk assessment for tetraconazole in drinking water.

These simulation models take into account data on the physical, chemical, and fate/transport 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 (PRZM ver. 3.12.2) and Exposure Analysis Modeling System (EXAMS ver. 2.98.04.06) and Screening Concentration in Ground Water (SCI–GROW) models, ver. 2.3, the estimated drinking water concentrations (EDWCs) of tetraconazole for acute exposures are estimated to be 10.45 parts per billion (ppb) for surface water and 0.40 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 4.68 ppb for surface water and 0.40 ppb for ground water. Chronic exposures for cancer assessments are estimated to be 3.29 ppb for surface water and 0.40 ppb for ground 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 10.45 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 4.68 ppb was used to assess the contribution to drinking water. For cancer dietary risk assessment, the water concentration of value 3.29 ppb was used to assess the contribution to drinking water.

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

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

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 Web site at *http://www.epa.gov/pesticides/cumulative.*

Triazole-derived pesticides can form the common metabolite T and two triazole conjugates (TA and TAA). 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 T, TA, and TAA resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (*e.g.,* use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (*i.e.,* high-end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA SF 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, and an update to assess the addition of the commodities included in this action may be found in docket ID EPA–HQ–OPP–2010–0583 in the document titled ''Common Triazole Metabolites, Updated Aggregate Human-Health Risk Assessment to address tolerance petitions for Tetraconazole''.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There are no residual uncertainties for pre- and post-natal toxicity. There is no evidence of increased quantitative susceptibility of rat or rabbit fetuses to *in utero* exposure to tetraconazole. There is evidence of increased qualitative susceptibility to fetuses in the rat prenatal developmental toxicity (increased incidences of supernumary ribs, and hydroureter and hydronephrosis). The level of concern is low however because:

i. The fetal effects were seen at the same dose as the maternal effects.

ii. A clear NOAEL was established.

iii. The developmental NOAEL from the study in rats is being used as the POD for the acute dietary endpoint (females 13–49 years of age).

iv. There were no developmental effects in the rabbit study. There is also no evidence of increased quantitative or qualitative susceptibility to offspring in the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings: The toxicity database for tetraconazole is complete. The EPA has recently received an immunotoxicity study for tetraconazole. Preliminary review of the study shows no evidence of immunotoxicity and does not impact the selection of endpoints. EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the FQPA, and an additional safety factor does not need to be applied.

i. There were effects indicative of neurotoxicity (motor activity effects) in the acute neurotoxicity study in rats. However, the level of concern is low for the following reasons:

• A clear NOAEL was established which is being used in endpoint selection.

• Comparison of the LOAELs from the acute neurotoxicity and chronic dog studies reveal a ~70-fold difference between the effects from the two studies, with the chronic effects being the more sensitive of the two.

• Neither of the more severe endpoints indicative of neurotoxicity (changes in brain weight or histopathological changes in the brain or nerve processes) were observed in the acute neurotoxicity study. Additionally, the EPA has recently received a subchronic neurotoxicity study for tetraconazole. A preliminary review of this study shows no signs of neurotoxicity. Furthermore, neurotoxicity was not seen in any other study in the toxicity database for tetraconazole. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

ii. There is no evidence that tetraconazole results in increased quantitative susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. There is evidence of increased qualitative susceptibility to fetuses in the rat prenatal developmental toxicity (increased incidences of supernumary ribs, and hydroureter and hydronephrosis). The level of concern is low however because:

• The fetal effects were seen at the same dose as the maternal effects.

• A clear NOAEL was established.

• The developmental NOAEL from the study in rats is being used as the POD for the acute dietary endpoint (females 13–49 years of age).

• There were no developmental effects in the rabbit study. There is also no evidence of increased quantitative or qualitative susceptibility to offspring in the 2-generation reproduction study.

iii. There are no residual uncertainties identified for pre- and post-natal toxicity in the exposure databases. Tolerance-level residues, 100% crop treated, and modeled water estimates were incorporated into the acute dietary exposure analysis. Therefore, the acute analysis is highly conservative. The chronic and cancer dietary exposure analyses utilized empirical processing factors, average field trial residues, average residues from the feeding studies, percent crop treated estimates, and modeled drinking water estimates. A critical commodity analysis for the chronic/cancer runs indicated that more than half of the exposure was derived from water. The models upon which the water estimates were based incorporate conservative (protective) assumptions with actual concentrations likely to be significantly lower. As a result, it can be concluded that the chronic/cancer risk estimates provided in this document do not underestimate the risks posed by tetraconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 1.8% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tetraconazole from food and water will utilize 5% of the cPAD for all infants < 1 year old, the population group receiving the greatest exposure. There are no residential uses for tetraconazole.

3. *Short-term risk and intermediate-term risks.* Short-term and intermediate-term aggregate risk takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term and intermediate-term adverse effect was identified; however, tetraconazole is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Short-term and intermediate-term risk is assessed based on short-term and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-term and intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term and intermediate-term risk), no further assessment of short-term and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risk for tetraconazole.

4. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in Unit III.C.1.iii., EPA has concluded the cancer risk from food and water for all existing and proposed tetraconazole uses will result in a lifetime cancer risk of 3×10^{-6}. A critical commodity analysis for the cancer/chronic risk assessment indicated that water was the major contributor to the estimated cancer risk (63% of total exposure). The drinking water estimate incorporated into the cancer dietary assessment was based on models which make conservative (protective) assumptions to derive a concentration in ground and surface water. Actual concentrations are likely to be significantly lower. EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above in this unit, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment.

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 is available to enforce the tolerance expression currently established for tetraconazole plant and livestock tolerances. As part of the corn petition, Isagro submitted adequate method validation and independent laboratory validation (ILV) data which indicate that the QuEChERS multi-residue method L 00.00–115 is capable of quantifying tetraconazole residues in or on a variety of fruit, cereal grain, root, oilseed, and livestock commodities (note that mean recoveries in or on wheat straw were 50–70%). Based on these data and since the extraction

solvent employed in the QuEChERS method is similar to the extraction solvent employed in the radiovalidated enforcement methods, the Agency concludes that the QuEChERS method is adequate for enforcement of established tolerances.

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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Canadian or Codex maximum residue limits (MRLs) established for tetraconazole.

C. Revisions to Petitioned-For Tolerances

After completing review of the current tetraconazole database and utilizing the Agency's tolerance spreadsheet (*see Guidance for Setting Tolerances Based on Field Trial Data* SOP (August 2009 version)), EPA revised, added or deleted tolerances, or otherwise modified the tolerance levels proposed in the notices of filing. EPA is removing the existing grape tolerance because grape is covered under the newly established tolerance for small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F. The Agency corrected listings of certain commodity names and replaced them with the preferred commodity terms. In addition, the Agency revised existing tolerance levels for tetraconazole residues in or on certain livestock commodities and established the following tolerances: Cattle, fat at 0.15 ppm; cattle, liver at 1.5 ppm; cattle, meat by-products, except liver at 0.15 ppm; goat, fat at 0.15 ppm; goat, liver at 1.50 ppm; goat, meat by-product, except liver at 0.15 ppm; horse, fat at 0.15 ppm; horse, liver at 1.50 ppm; horse, meat by-products, except liver at 0.15 ppm; milk at 0.03 ppm; milk, fat at 0.75 ppm; poultry, meat by-products at 0.05 ppm; sheep, fat at 0.15 ppm; sheep, liver at 1.50 ppm; and sheep, meat by-products, except liver at 0.15 ppm. Using resources defined above in this section, the Agency revised tolerance levels for livestock commodities because of increased livestock dietary exposure as a result of newly established corn tolerances and to take into account all tetraconazole residues in animal feed commodities.

Finally, the Agency is modifying the tolerance expression for tetraconazole to clarify that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of tetraconazole not specifically mentioned; and that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of tetraconazole, including its metabolites and degradates, in or on the commodities listed in the Table below under § 180.557. Compliance with the following tolerance levels is to be determined by measuring only tetraconazole (1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1*H*-1,2,4-triazole).

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 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: August 18, 2011.

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:

■ i. Revising the introductory text in paragraph (a);

■ ii. Removing the commodity ''Grape'' from the table in paragraph (a);

■ iii. Revising the tolerance level for these commodities: ''Cattle, fat'' ''Cattle, liver'' ''Cattle, meat byproducts, except liver'' ''Goat, fat'' ''Goat, liver'' ''Goat, meat byproducts, except liver'' ''Horse, fat'' ''Horse, liver'' ''Horse, meat byproducts, except liver'' ''Milk'' ''Milk, fat'' ''Poultry, meat byproducts'' ''Sheep, fat'' ''Sheep, liver'' and ''Sheep, meat byproducts, except liver'' in the table in paragraph (a); and

■ iv. Alphabetically adding the following commodities: ''Corn, field, forage'' ''Corn, field, grain'' ''Corn, field, stover'' ''Corn, pop, grain'' ''Corn, pop stover'' ''Low growing berry subgroup 13–07G, except cranberry;'' and ''Small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F'' to the table in paragraph (a) to read as follows:

§ 180.557 Tetraconazole; Tolerances for residues.

(a) *General.* Tolerances are established for residues of tetraconazole, including its metabolites and degradates, in or on the commodities listed below. Compliance with the following tolerance levels is to be determined by measuring only tetraconazole (1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4-triazole), in or on the following commodities.

Commodity	Parts per million
* * * * *	
Cattle, fat	0.15
Cattle, liver	1.50
Cattle, meat byproducts, except liver	0.15
Corn, field, forage	1.1
Corn, field, grain	0.01
Corn, field, stover	1.7
Corn, pop, grain	0.01
Corn, pop, stover	1.7
Goat, fat	0.15
Goat, liver	1.50
* * * * *	
Goat, meat byproducts, except liver	0.15
Horse, fat	0.15
Horse, liver	1.50
* * * * *	
Horse, meat byproducts, except liver	0.15
Low growing berry subgroup 13–07G, except cranberry	0.25
Milk	0.03
Milk, fat	0.75
* * * * *	
Poultry, meat byproducts	0.05
* * * * *	
Sheep, fat	0.15
Sheep, liver	1.50
* * * * *	
Sheep, meat byproducts, except liver	0.15
Small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.20
* * * * *	

* * * * *

[FR Doc. 2011–21947 Filed 8–26–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2008–0149]

RIN 2127–AK25

Federal Motor Vehicle Safety Standards: Occupant Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends the Federal motor vehicle safety standard (FMVSS) on occupant crash protection to remove the sunset of a requirement that a vehicle's lap belt must be lockable, without the use of special tools, to tightly secure a child restraint system (CRS). We refer to this as the ''lockability'' requirement. Under the current standard, the lockability requirement ceases to apply to seating positions that are equipped with a child restraint anchorage system (commonly referred to as a ''LATCH'' system) on vehicles manufactured on or after September 1, 2012. Because data indicate that motorists are still using lockable belts to install CRSs even in seating positions with LATCH, there is a continuing need for the lockability requirement even in seating positions with LATCH. Thus, this final rule ensures that the lockability requirement continues in effect for all seating positions past September 1, 2012.

DATES: *Effective date:* The final rule is effective December 27, 2011. Petitions for reconsideration of the final rule must be received not later than October 13, 2011.

ADDRESSES: Any petitions for reconsideration should refer to the docket number of this document and be submitted to: Administrator, National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For non-legal issues, you may call Ms. Carla Rush, Office of Crashworthiness Standards, Light Duty Vehicle Division (Phone: 202–366–4583; fax: 202–493–2739). For legal issues, you may call Mr. Thomas Healy, Office of the Chief Counsel (Phone: 202–366–2992; fax: 202–366–3820). You may send mail to these officials at: National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: This final rule amends FMVSS No. 208 to retain the lockability requirement, which is slated to sunset September 1, 2012. The agency is issuing this final rule because data indicate that motorists are still using vehicle belts to a large degree to attach CRSs to the vehicle seats. The NPRM preceding this final rule was published September 12, 2008 (73 FR 52939, Docket No. NHTSA–2008–0149).

I. Background

On October 13, 1993, NHTSA amended FMVSS No. 208, *Occupant Crash Protection,* to require all passenger cars, trucks, buses, and