VIII. Other Considerations

A. Analytical Method

An analytical method is not required for enforcement purposes because the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Tolerances

There are no known international tolerances for residues of (S,S)–EDDS in food or animal feed.

IX. 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 final rule has been exempted from review under Executive Order 12866, this final 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 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) (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).

X. 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: October 31, 2008.

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. In § 180.920, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	*	*
(S,S)–Ethylenediaminedisuccinic acid (CAS Reg. No. 20846–91–7)		Sequestrant or chelating agent
* * *	*	*

[FR Doc. E8–26973 Filed 11–13–08; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1161; FRL–8386–7]

Tetraconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of tetraconazole in or on grape. Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 14, 2008. Objections and requests for hearings must be received on or before January 13, 2009, 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–2007–1161. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents 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 e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–1161 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 January 13, 2009.

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–2007–1161, 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. Petition for Tolerance

In the **Federal Register** of January 23, 2008 (73 FR 3964) (FRL–8345–7), 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 7E7273) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. 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]–1*H*–1,2,4–triazole, in or on grape at 0.15 parts per million (ppm). That notice referenced a summary of the petition prepared on behalf of IR–4 by Isagro, S.p.A, the registrant, which is available to the public in the docket, at *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance level for grape from 0.15 ppm to 0.20 ppm. The reason for this change is 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 the petitioned-for tolerance for residues of tetraconazole on grape at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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 not a dermal irritant or a dermal sensitizer. The liver and kidney are the primary target organs of tetraconazole. In the subchronic, chronic and reproduction rat studies, subchronic and carcinogenicity mouse studies, and the chronic dog study, increases in liver weight, increases in liver serum enzymes or gross and microscopic liver pathology were noted at various doses, providing evidence of liver toxicity. There is no evidence in the toxicity database that tetraconazole is an immuno- or neurotoxicant.

Tetraconazole is classified as ''likely to be carcinogenic to humans'' by the oral route of exposure, based on the occurrence of liver tumors in male and female mice. Cancer risk is assessed by EPA using the linear low dose extrapolation approach with a potency factor (Q_1*) of 2.3 x 10^{-2} milligrams/kilograms/day (mg/kg/day)$^{-1}$.

Oral rat and rabbit developmental toxicity studies showed no increased susceptibility of fetuses to tetraconazole. Maternal toxicity (decreased body weight gain and food consumption, increased water intake and increased liver and kidney weights) and developmental toxicity (increased incidence of small fetuses, supranumerary ribs and hydroureter and hydronephrosis) occurred at the same dose level in the rat study. No developmental toxicity was seen in the rabbit study, whereas maternal toxicity (decreased body weight gain) was noted at the highest dose tested. Similarly, there was no evidence of increased susceptibility of offspring in the 2–generation rat reproduction study. Parental toxicity (increased mortality in parental females) was observed at a lower dose (4.9 mg/kg/day) than the dose (35.5 mg/kg/day) resulting in pup effects (decreased litter weight and mean pup weight in litters of all generations before weaning and increased relative liver weight at weaning in both sexes of all litters).

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 lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Tetraconazole: Human-Health Risk Assessment for New Use on Grapes and a Label Amendment for Pecans*, page 34 in docket ID number EPA–HQ–OPP–2007–1161.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in the document *Tetraconazole: Human-Health Risk Assessment for New Use on Grapes and a Label Amendment for Pecans*, page 12 in docket ID number EPA–HQ–OPP–2007–1161.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tetraconazole, EPA considered exposure under the petitioned-for tolerance as well as all existing tetraconazole tolerances in 40 CFR 180.557. Additional metabolites of toxicological concern (M14360–alcohol (free and conjugated), M14360–acid, M14360–DFA, and M14360–hydroxydetriazolyl–O–malonyldiglucoside) that are not included in the tolerance expression were included in the dietary exposure assessments based on the ratio of metabolite to parent found in metabolism studies. 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. EPA identified such effects (increased incidence of small fetuses and supernumerary ribs) for the population subgroup, females 13 years and older; however, no such effects were identified for the general population, including infants and children.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues of tetraconazole and 100 percent crop treated (PCT) for all existing and new 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. The assessment was refined through the incorporation of empirical processing factors, average field trial residues, average residues from the feeding studies and projected percent crop treated (PPCT) estimates for the feed commodities. 100 PCT was assumed for all food commodities.

iii. *Cancer*. Tetraconazole is classified as ''likely to be carcinogenic to humans'' by the oral route of exposure. Cancer risk from tetraconazole exposure is assessed by EPA using the linear low dose extrapolation approach with a potency factor (Q_1*) of 2.3 x 10^{-2} (mg/kg/day)$^{-1}$. EPA used the same food residue estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of 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 require pursuant to section 408(f)(1) of FFDCA 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 section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used projected percent crop treated (PPCT) information as follows:

In the chronic and cancer dietary assessments, EPA used PPCT for the feed commodities derived from peanuts (77%), soybeans (27%) and sugar beets (70%). Since tetraconazole was registered for use on these crops recently (2007 and 2008), PCT estimates based on actual usage data are not sufficient indicators of potential usage on these crops.

EPA estimates PPCT for a new pesticide use by assuming that the 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. Typically, EPA uses USDA/National Agriculture Statistic Service (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. This PPCT, based on the average PCT of the market leader, is appropriate for use in chronic dietary risk assessment. The method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. The predominant factors that bear on whether the estimated PPCT could be exceeded are whether a new pesticide use or new pesticide is more efficacious or controls a broader spectrum of pests than the dominant pesticide; and/or whether there are concerns with pest pressures as indicated in emergency exemption requests or other readily available information; and/or other factors based on analysis of additional information, such as the total crop acreage and the geographical distribution of the crops and pests. All information currently available for the predominant factors mentioned above or relevant to the case in question have been considered for this chemical, and EPA has determined that it is unlikely that actual PCT for tetraconazole will exceed the PPCT 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's 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 Concentration in Ground Water (SCI–GROW) models, 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. For chronic exposures for non-cancer assessments, EDWCs are estimated to be 4.68 ppb for surface water and 0.40 ppb for ground water. For chronic exposures for cancer assessments, EDWCs 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 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 necessarily 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 efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Tetraconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite, 1,2,4–triazole (T), and several triazole conjugates, including triazole alanine (TA) and triazole acetic acid (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 was 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 included 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 ID EPA–HQ–OPP–2005–0497). In March of 2008, EPA updated the triazole risk assessment to include new uses of fenbuconazole, ipconazole, metconazole, tebuconazole and uniconazole. The updated risk assessment can be found at *http://www.regulations.gov* in the document *Dietary Exposure Assessments for the Common Triazole Metabolites 1,2,4–Triazole, Triazolylalanine, Triazolylacetic Acid, and Triazolylypyruvic Acid; Updated to Include New Uses of Fenbuconazole, Ipconazole, Metconazole, Tebuconazole, and Uniconazole; and a Change in Plant-back Restriction for Tetraconazole* in docket ID number EPA–HQ–OPP–2007–1199. When EPA updated the triazole risk assessment, it considered triazole residues on grapes, because other triazole fungicides are already registered for this use site. Triazole residues on grapes from the use of tetraconazole are not expected to exceed those from the use of other triazole fungicides on grapes; therefore, establishing this tolerance for tetraconazole on grape will not increase aggregate exposure to the triazole metabolites, and an updated triazole risk assessment is unnecessary.

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*. The pre- and postnatal toxicology database for tetraconazole includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. As discussed in section III.A, Toxicological Profile, there was no evidence of increased susceptability to tetraconazole of *in utero* rats or rabbits or offspring in these studies. In the rat developmental toxicity study, maternal and developmental toxicity occurred at the same dose, and in the rabbit study, no developmental toxicity was seen at doses that resulted in maternal toxicity. In the rat reproduction study, parental toxicity was observed at a lower dose than that which resulted in pup effects.

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:

i. The toxicity database for tetraconazole is complete, except for immunotoxicity testing. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect well after the tolerance petition was submitted, these studies are not yet available for tetraconazole. In the absence of specific immunotoxicity studies, EPA has evaluated the available tetraconazole toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There was no evidence of adverse effects on the organs of the immune system at the LOAEL in any study with tetraconazole. In addition, tetraconazole does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on these considerations, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a point of departure less than the NOAEL of 0.73 mg/kg/day used in calculating the cPAD for tetraconazole; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. There is no indication that tetraconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs 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 acute dietary food exposure assessment assumed tolerance-level residues and 100 PCT. The chronic and cancer dietary food exposure assessments were refined using reliable PPCT information and anticipated residue values calculated from valid field trial results. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tetraconazole in drinking water. Residential exposure to tetraconazole is not expected. These assessments will not underestimate the

exposure and risks posed by tetraconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs 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% of the aPAD for females, 13 to 49 years old, the only population group for which an acute toxicity endpoint of concern was identified.

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 7.7% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for tetraconazole.

3. *Short-/intermediate-term risk*. Short- and intermediate term aggregate exposures take into account short- and intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Tetraconazole is not registered for any use patterns that would result in residential exposure. Therefore, the short- and intermediate-term aggregate risk is the sum of the risk from exposure to tetraconazole through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Using the exposure assumptions described in this unit for the cancer risk assessment, EPA has concluded that exposure to tetraconazole from food and water will result in a lifetime cancer risk of 3 x 10^{-6} for the U.S. population. 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 3.16 x 10^{-7} and 3.16 x 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, 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 x 10^{-6}. Since the calculated cancer risk for tetraconazole falls within this range, estimated cancer risk is considered to be negligible.

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

B. International Residue Limits

There are no CODEX, Canadian or Mexican maximum residues levels established for tetraconazole.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA has revised the tolerance level for grape from 0.15 ppm to 0.20 ppm. EPA revised the tolerance level based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. The recommended value differs from the value proposed by IR–4, because only data from field plots harvested at the proposed pre-harvest interval (PHI) were used in calculating the tolerance level.

V. Conclusion

Therefore, a tolerance is established for residues of tetraconazole, 1–[2–(2,4–dichlorophenyl)–3–(1,1,2,2–tetrafluoroethoxy)propyl]–1*H*–1,2,4–triazole, in or on grape at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 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) (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: October 31, 2008.

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 alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.557 Tetraconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Grape	0.20
* * *	* *

* * * * *

[FR Doc. E8–26946 Filed 11–13–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4138–IFC2]

RIN 0938–AP52

Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs: Clarification of Compensation Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) revises the regulations governing the Medicare Advantage (MA) program (Part C), and prescription drug benefit program (Part D). This IFC sets forth new requirements governing the marketing of Part C and Part D plans which by statute must be in place at a date specified by the Secretary, but no later than November 15, 2008. The new marketing requirements, which set forth new limits on the compensation that can be paid to agents or brokers with respect to Part C and Part D plans, are based on authority under provisions in the Medicare Improvements for Patients and Providers Act (MIPPA) that became law on July 15, 2008.

DATES: *Effective date:* These regulations are effective on November 10, 2008.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 15, 2008.

ADDRESSES: In commenting, please refer to file code CMS–4138–IFC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4138–IFC2, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4138–IFC2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201;

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Camille Brown, 410–786–0274, or Chevell Thomas, 410–786–1387.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the