Commodity	Parts per million	Expiration/ revocation date
Corn, sweet, kernel plus cob with husks removed	0.01	12/31/11
Corn, sweet, stover	6.0	12/31/11
Milk	0.03	12/31/11
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[FR Doc. E8–20520 Filed 9–5–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1199; FRL–8376–6]

Uniconazole-P; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of uniconazole-P, its *R*-enantiomer and its *Z*-isomer in or on vegetable, fruiting, group 8. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 5, 2008. Objections and requests for hearings must be received on or before November 4, 2008, 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–2007–1199. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket 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 an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–1199 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 November 4, 2008.

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–2007–1199, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of February 6, 2008 (73 FR 6964) (FRL–8350–9), 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 7E7268) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by adding a section for the fungicide uniconazole-P and

establishing a tolerance therein for residues of uniconazole-P *per se* in or on vegetable, fruiting, group 8 at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Valent USA Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the tolerance expression to include uniconazole-P, its *R*-enantiomer and its *Z*-isomer. 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 combined residues of uniconazole-*P*, its *R*-enantiomer and its *Z*-isomer on vegetable, fruiting, group 8 at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing this tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Uniconazole-*P* (hereafter referred to as uniconazole) is rapidly absorbed after oral ingestion and extensively metabolized by the liver. There is no accumulation in the tissues, and the metabolites are rapidly excreted in the feces and urine. Uniconazole has moderate acute oral toxicity and low acute dermal and inhalation toxicity. It is a slight eye irritant but not a skin irritant or skin sensitizer. In mouse, rat and dog repeated-dose studies, oral ingestion of high doses caused an increase in the size and weight of the liver. Fat accumulation in the liver was also consistently observed at high doses. Although observed less consistently, increases in the activity of some enzymes indicated altered liver function as a response to uniconazole exposure. There was no evidence of carcinogenicity in the combined chronic toxicity/carcinogenicity study in the rat; however, in the mouse study an increase in liver neoplasms was noted. Mutagenicity studies were generally negative except for the *in vitro* mammalian chromosome aberration test (CHO), which was positive with metabolic activation. Based on the limited evidence of carcinogenicity in the mouse, EPA classified uniconazole as a Group C (Possible Human) carcinogen but concluded that quantification of cancer risk using a low dose extrapolation model was not appropriate. The point of Departure (POD) selected for deriving the chronic reference dose will adequately account for all chronic effects determined to result from exposure to uniconazole in chronic animal studies, including potential cancer effects. Uniconazole had no effects on reproductive performance of rats in the 2-generation reproduction toxicity study and no effect on fetal development in the rabbit developmental toxicity study. In the developmental toxicity study in rats, developmental toxicity (increased incidence of 14th ribs) was noted, but only at doses that were also maternally toxic. There was no evidence of neurotoxicity in the submitted uniconazole toxicity studies or in the open literature.

Specific information on the studies received and the nature of the adverse effects caused by uniconazole, 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 *Uniconazole-P Human Health Risk Assessment for Proposed Uses on Fruiting Vegetables (Except Cucurbits), Crop Group 8* pages 52–75 in docket ID number EPA–HQ–OPP–2007–1199.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological 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-term, intermediate-term, 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 uniconazole used for human risk assessment can be found at *http://www.regulations.gov* in the document *Uniconazole-P Human Health Risk Assessment for Proposed Uses on Fruiting Vegetables (Except Cucurbits), Crop Group 8* pages 26–27 in docket ID number EPA–HQ–OPP–2007–1199.

C. Exposure Assessment

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

exposure to uniconazole, EPA considered exposure under the petitioned-for tolerance on fruiting vegetables, the first food use of uniconazole. EPA assessed dietary exposures from uniconazole 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 an effect relevant to the population group females, 13 years of age and older (increased incidence of 14th rib following *in utero* exposure to uniconazole in the rat developmental toxicity study). No acute 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 that all foods covered by the fruiting vegetable tolerance contain tolerance-level residues and that 100% of fruiting vegetables are treated with uniconazole.

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, EPA again assumed that all foods covered by the fruiting vegetable tolerance contain tolerance-level residues and that 100% of fruiting vegetables are treated with uniconazole.

iii. *Cancer*. Based upon statistically significant increases in hepatocellular neoplasms in high-dose male mice, EPA classified uniconazole as a Group C (Possible Human) carcinogen but concluded that quantification of cancer risk using a low dose extrapolation model was not appropriate. This determination was based on the fact that the tumor induced is primarily of a benign nature, occurred at the highest dose tested in one sex of one species only with no acceleration in the rate of tumor formation and did not exhibit any uncommon biological behavior. The POD selected for deriving the chronic reference dose (cRfD) will adequately account for all chronic effects determined to result from exposure to uniconazole in chronic animal studies, including potential cancer effects.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for uniconazole. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for uniconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of uniconazole. 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of uniconazole for acute exposures are estimated to be 3.1 parts per billion (ppb) for surface water and 0.076 ppb for ground water; and for chronic exposures for non-cancer assessments are estimated to be 1.5 ppb for surface water and 0.076 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 3.1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1.5 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). Uniconazole 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.''

Uniconazole is a member of the triazole-containing class of pesticides, sometimes referred to as conazoles. 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 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. 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*.

Uniconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and several triazole conjugates (including triazole alanine, triazole acetic acid, triazole pyruvic acid and triazole lactic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including uniconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. Triazole pyruvic acid and triazole lactic acid were not included in the risk assessment due to their low occurrence in metabolism studies. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (*e.g.*, use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov* (Docket ID EPA–

HQ–OPP–2005–0497). Additional information regarding the uses proposed for uniconazole in this action can also be found at *http://www.regulations.gov* in the documents *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 and Uniconazole-P: Acute, Chronic and Cancer Aggregate Dietary (Food and Drinking Water) Exposure Analyses for the Section 3 Registration Action* in docket ID number EPA–HQ–OPP–2007–1199.

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 prenatal and postnatal toxicology database for uniconazole includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. There was no evidence of increased qualitative or quantitative susceptibility of rabbit fetuses following *in utero* exposure to uniconazole and no evidence of increased susceptibility of offspring in the 2-generation reproduction study in rats. There was evidence of increased qualitatative susceptibility of fetuses in the rat developmental study. In this study, an increased incidence of 14th rib in the fetuses was observed in the presence of minimal maternal toxicity (decreased body weight). The degree of concern for the qualitative susceptibility seen in the rat developmental study is low because:

- The additional rib was the only skeletal variation noted
- The fetal effect occurred only in the presence of maternal toxicity
- In the reproduction study in rats, higher doses resulted in minimal pup toxicity (slightly reduced body weights); and:
- The NOAEL for the fetal effect is used for assessing acute risk of females 13 years and older and is, therefore, protective of potential developmental 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 uniconazole database is adequate to assess prenatal and postnatal toxicity.

ii. There is no indication that uniconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is qualitative evidence of increased susceptibility in the prenatal developmental study in rats, EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of uniconazole. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to uniconazole in drinking water. Residential exposure to uniconazole is not expected. These assessments will not underestimate the exposure and risks posed by uniconazole.

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-term, intermediate-term, 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*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to uniconazole will occupy <1% of the aPAD for females 13 to 49 years old, the only population group for which an acute 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 uniconazole from food and water will utilize <1% of the cPAD for the general population and all population subgroups, including infants and children. There are no residential uses for uniconazole.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Uniconazole 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 uniconazole through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. The Agency has determined that the chronic risk assessment based on the established cPAD is protective of potential cancer effects. Based on the results of the chronic risk assessment discussed above in Unit E.2, EPA concludes that uniconazole is not expected to pose a cancer risk.

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 uniconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas Chromatography/Nitrogen Phosphorus Detector (GC/NPD); Valent Method RM-25-1b) 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

No Codex, Canadian, or Mexican MRLs have been established for uniconazole.

C. Revisions to Petitioned-For Tolerance

The petitioner proposed a tolerance for residues of uniconazole-*P per se* in or on vegetable, fruiting, group 8. However, based on the results of plant metabolism studies, EPA has determined that the residues of concern to be included in the tolerance expression for fruiting vegetables are uniconazole-*P*, its *R*-enantiomer and its *Z*-isomer. Therefore, EPA has modified the tolerance expression to include all three compounds.

V. Conclusion

Therefore, the tolerance is established for combined residues of uniconazole-*P*, (E)-(S)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1*H*-1,2,4-triazol-1-yl)pent-1-en-3-ol, its *R*-enantiomer and its *Z*-isomer in or on vegetable, fruiting, group 8 at 0.01 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, *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: August 26, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.643 is added to read as follows:

§ 180.643 Uniconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide/plant growth regulator uniconazole-P, (E)-(S)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pent-1-en-3-ol, its *R*-enantiomer and its *Z*-isomer in or on the following raw agricultural commodities:

Commodity	Parts per million
Vegetable, fruiting, group 8	0.01

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

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

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

[FR Doc. E8–20548 Filed 9–4–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0097; FRL–8376–7]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; final order.

SUMMARY: This order amends the pesticide tolerance regulation for tebuconazole by establishing a tolerance for pistachios. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA). This order resolves an objection filed by Bayer CropScience in response to a final rule on tebuconazole tolerances published on May 14, 2008.

DATES: This regulation is effective September 5, 2008.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0097. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the