

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 180.474 is amended in paragraph (a)(1) in the table by alphabetically adding the commodities Almond, hulls and Nut, tree, group 14 and by revising the following commodities to read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	6.0
* * *	*
Barley, grain	0.15
Barley, hay	7.0
Barley, straw	3.5
* * *	*
Nut, tree, group 14	0.05
* * *	*
Wheat, forage	3.0
Wheat, grain	0.05
Wheat, hay	7.0
Wheat, straw	1.5

* * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0149; [FRL-8362-9]

Cyproconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the free and conjugated residues of cyproconazole, α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol in or on aspired grain fractions; field corn, forage, grain and stover; soybean, seed, forage, hay and oil; wheat, forage, hay, straw, grain, grain, milled by products; fat of cattle, goat, horse and sheep; and meat byproducts (except liver) of cattle, goat, horse and sheep. Additionally, this regulation establishes tolerances for cyproconazole and its metabolite, δ -(4-chlorophenyl)- β , δ -dihydroxy- γ -methyl-1H-1,2,4-triazole-1-hexenoic acid in or on milk and for cyproconazole and its metabolite, 2-(4-chlorophenyl)-3-cyclopropyl-1-[1,2,4]triazol-1-yl-butane-2,3-diol in or on liver of cattle, goat,

hog, horse, and sheep. Syngenta Crop Protection, Inc., requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 14, 2008. Objections and requests for hearings must be received on or before July 14, 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-2008-0149. 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:

Mary L. Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are

not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot 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-2008-0149 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 July 14, 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-2008-0149, 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 November 22, 2006 (71 FR 67575) (FRL-8089-9), 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 6F7072) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.485 be amended by establishing tolerances for residues of the fungicide cyproconazole, in or on the following commodities: Soybean, seed at 0.05 parts per million (ppm); soybean, forage at 1.0 ppm; soybean, hay at 2.5 ppm; corn, field, grain at 0.02 ppm; corn, field, forage at 0.6 ppm; corn, field, stover at 1.5 ppm; wheat, straw at 1.0 ppm; wheat, grain at 0.05 ppm; wheat, forage at 1.0 ppm; wheat, hay at 1.5 ppm; aspirated grain fractions at 0.6 ppm; cattle, fat at 0.01 ppm; cattle, liver at 0.3 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts (except liver) at 0.01 ppm; milk at 0.01 ppm; goat, fat at 0.01 ppm; goat, liver at 0.3 ppm; goat, meat at 0.01 ppm; goat, meat byproducts (except liver) at 0.01 ppm; hog, fat at 0.01 ppm; hog, liver at 0.3 ppm; hog, meat at 0.01 ppm; hog, meat byproducts (except liver) at 0.01 ppm; horse, liver at 0.3 ppm; horse, meat at 0.01 ppm; horse, meat byproducts (except liver) at

0.01 ppm; sheep, fat at 0.01 ppm; sheep, kidney at 0.3 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts (except liver) at 0.01 ppm. This notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA concluded that the preferred chemical name for cyproconazole is " α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol." 40 CFR 180.485 is being revised to use this terminology. Also, EPA determined that the time-limited tolerance established for soybean seed under 40 CFR 180.485(b) can be deleted given that a tolerance for soybean seed without time limitation is being established in section (a).

Additionally, EPA has determined that, as a result of the tolerances sought in this petition, a tolerance is needed for the combined free and conjugated residues of cyproconazole α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol and its metabolite [δ -(4-chlorophenyl)- β , δ -dihydroxy- γ -methyl-1H-1,2,4-triazole-1-hexenoic acid in or on the commodity: Milk at 0.02 ppm and that tolerances are needed for the combined free and conjugated residues of cyproconazole [α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol and its metabolite [2-(4-chlorophenyl)-3-cyclopropyl-1-[1,2,4]triazol-1-yl-butane-2,3-diol in or on the commodities: Liver of cattle, goat, horse, and sheep at 0.50 ppm and hog liver at 0.01 ppm.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for-tolerance. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

Specific information on the studies received and the nature of the adverse effects caused by cyproconazole 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 in the docket established by this action, which is described under **ADDRESSES**, and is identified as "Cyproconazole: Human-Health Risk Assessment for Proposed Uses" in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute

and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

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

A summary of the toxicological endpoints for cyproconazole used for human risk assessment can be found at <http://www.regulations.gov> in document "Cyproconazole Human Health Risk Assessment for Proposed Uses on Corn, Soybean and Wheat" in docket ID number EPA-HQ-OPP-2008-0149.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyproconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing cyproconazole tolerances in 40 CFR 180.485. EPA assessed dietary exposures from cyproconazole 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.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. 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 all foods for which there are tolerances were treated and contain tolerance-level residues.

ii. *Chronic exposure.* In conducting this chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996, or 1998 CSFII. As to residue levels in food, EPA assumed all foods for

which there are tolerances were treated and contain tolerance-level residues.

iii. *Cancer.* Cyproconazole has been classified by the Agency as "Not Likely to be Carcinogenic to Humans". The decision was based on the weight of evidence that supports a non-genotoxic mitogenic mode of action for cyproconazole. Therefore, a cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for cyproconazole in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of cyproconazole. 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 FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of cyproconazole for acute exposures are estimated to be 1.14 parts per billion (ppb) for surface water and 0.05 ppb for ground water. The EECs for chronic exposures are estimated to be 0.11 ppb for surface water and 0.05 ppb for ground 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).

Cyproconazole is not registered for use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for cyproconazole and any other substance. Other than as discussed below for the cyproconazole metabolite 1,2,4-triazole

for the purposes of this tolerance action, therefore, EPA has assumed that cyproconazole does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

Cyproconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including cyproconazole, 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. 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). An addendum to the risk assessment, "Dietary Exposure Assessments for the Common Triazole Metabolites 1,2,4-triazole, Triazolylalanine, Triazolylacetic Acid and Triazolyl Pyruvic Acid; Updated to Include New Uses of Fenbuconazole, Ipconazole, Metconazole, Tebuconazole, and Uniconazole" can be found at <http://www.regulations.gov> in docket ID EPA-HQ-OPP-2008-0149.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the

completeness of the 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility in the developmental study in rats or in the 2-generation reproduction study in rat. There is no concern for the increased susceptibility in the New Zealand white (NZW) rabbit study since clear NOAELs/LOAELs were established for maternal and developmental toxicities and malformations were observed at doses higher than the dose that produced marginal maternal toxicity. The concern is low for the increased susceptibility in the Chinchilla rabbit study since the incidences of hydrocephaly were low, there was no dose response, high concentration of the vehicle (CMC) used, and the hydrocephaly was not seen at the same doses in the NZW strain of rabbit. Therefore, there is no residual uncertainty for prenatal and/or postnatal toxicity.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- i. The toxicity database for cyproconazole is complete.
- ii. There is no indication that cyproconazole 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 studies in rats and rabbits, EPA did not identify any residual uncertainties after establishing toxicity endpoints and selecting traditional UFs to be used in the risk assessment of cyproconazole.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level residues. Conservative ground water and surface water modeling estimates were used. There are no residential uses of cyproconazole.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable 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 cyproconazole will occupy 3% of the aPAD for the population group (females 13–49 years old).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyproconazole from food and water will utilize 13% of the cPAD for the population group (children 1 – 2 years old). There are no residential uses for cyproconazole that result in chronic residential exposure to cyproconazole.

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

Cyproconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyproconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Cancer risk is expected to be negligible because EPA concluded that cyproconazole is not likely to be a human carcinogen.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Method AM-0842-0790-0 for determining cyproconazole in plant commodities is an improved version of the current enforcement, which allows for use of either Nitrogen-Phosphorous Detection (NPD) or Mass-Selective Detection (MSD). As this method is superior to the current enforcement method, it will be forwarded to FDA to either replace or supplement the existing tolerance enforcement method for plant commodities. The liquid chromatography with tandem mass spectrometry (LC-MS/MS) method (Syngenta Method RAM 499/01) for determining cyproconazole in livestock commodities has undergone a successful Independent Laboratory Validation (ILV) trial and radiovalidation trial. Therefore, a copy of the method will be forwarded to the Analytical Chemistry Branch for evaluation as an enforcement method. The methods 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.

As metabolites in liver and in milk need to be included in the tolerance expression, enforcement methods will be required for these residues. Methods have been sent to the Analytical Chemistry Branch for evaluation.

B. International Residue Limits

There are no established or proposed Canadian or Codex maximum residue limits (MRLs) for cyproconazole on food or feed crops. Mexico has established tolerances for cyproconazole at 0.05 ppm in barley and wheat grain, which is equivalent to the recommended U.S. tolerance for wheat grain. Therefore, there are generally no questions about the compatibility of the proposed tolerances with international tolerances. However, EPA notes that Japan has established numerous tolerances for cyproconazole, including MRLs on wheat (0.2 ppm), corn (0.1 ppm), and soybeans (0.05 ppm).

C. Response to Comment

Comments were received on the notice of filing. EPA has responded to similar comments from the commenter on previous occasions. Refer to **Federal Register** cites: 70 FR 37686 (June 30, 2005); 70 FR 1354 (January 7, 2005); and 69 FR 63083 (October 29, 2004).

V. Conclusion

Therefore, the tolerance is established for free and conjugated residues of

cyproconazole, α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol in or on the following commodities at the indicated tolerance levels in parts per million.

Aspirated grain fractions . . .	2.5
Corn, field, forage, . . .	0.60
Corn, field, grain . . .	0.01
Corn, field, stover . . .	1.2
Fat of cattle, goat, horse and sheep . . .	0.01
Meat byproducts (except liver) of cattle, goat, horse and sheep . . .	0.01
Soybean, seed . . .	0.05
Soybean, forage . . .	1.0
Soybean hay . . .	3.0
Soybean, oil . . .	0.10
Wheat, forage . . .	0.80
Wheat, hay . . .	1.3
Wheat, straw . . .	0.90
Wheat, grain . . .	0.05
Wheat, grain, milled byproducts . . .	0.10

A tolerance is also established for the combined free and conjugated residues of cyproconazole [α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol] and its metabolite [δ -(4-chlorophenyl)- β , δ -dihydroxy- γ -methyl-1H-1,2,4-triazole-1-hexenoic acid in or on the following commodity:

Milk . . . 0.02

Also, tolerances are established for the combined free and conjugated residues of cyproconazole α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol and its metabolite [2-(4-chlorophenyl)-3-cyclopropyl-1-[1,2,4]triazol-1-yl-butane-2,3-diol in or on the following commodities:

Liver of cattle, goat, horse, and sheep . . .	0.50
Hog liver . . .	0.01

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork

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

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

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

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

VII. Congressional Review Act

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

Federal Register. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 6, 2008.

Deborah McCall,

Acting 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 180.485 is amended by revising paragraph (a) and removing the text from paragraph (b) and reserving to read as follows:

§ 180.485 Cyproconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for the free and conjugated residues of the fungicide cyproconazole, α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol, in or on the following food commodities:

Commodity	Parts per million
Aspirated grain fractions	2.5
Cattle, fat	0.01
Cattle, meat byproducts (except liver)	0.01
Coffee bean, green (Imported) ¹	0.1
Corn, field, forage	0.60
Corn, field, grain	0.01
Corn, field, stover	1.2
Goat, fat	0.01
Goat, meat byproducts (except liver)	0.01
Horse, fat	0.01
Horse, meat byproducts (except liver)	0.01
Sheep, fat	0.01
Sheep, meat byproducts (except liver)	0.01
Soybean, forage	1.0
Soybean, hay	3.0
Soybean, oil	0.10
Soybean, seed	0.05
Wheat, forage	0.80
Wheat, grain	0.05
Wheat, grain, milled by-products	0.10
Wheat, hay	1.3
Wheat, straw	0.90

¹There are no U.S. registrations as of February 15, 2008 for use on coffee bean.

(2) A tolerance is established for the combined free and conjugated residues

of cyproconazole α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1*H*-1,2,4-triazole-1-ethanol] and its metabolite [δ -(4-chlorophenyl)- β , δ -dihydroxy- γ -methyl-1*H*-1,2,4-triazole-1-hexenoic acid in or on the following commodity:

Commodity	Parts per million
Milk	0.02

(3) Tolerances are established for the combined free and conjugated residues of cyproconazole α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1*H*-1,2,4-triazole-1-ethanol and its metabolite 2-(4-chlorophenyl)-3-cyclopropyl-1-[1,2,4]triazol-1-yl-butane-2,3-diol in or on the following commodities:

Commodity	Parts per million
Cattle, liver	0.50
Goat, liver	0.50
Hog, liver	0.01
Horse, liver	0.50
Sheep, liver	0.50

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 268

[EPA-HQ-RCRA-2007-0936; FRL-8565-9]

Land Disposal Restrictions: Site-Specific Treatment Variance for P- and U-Listed Hazardous Mixed Wastes Treated by Vacuum Thermal Desorption at the Energy Solutions' Facility in Clive, UT

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is promulgating a final rule granting a site-specific treatment variance to EnergySolutions LLC (EnergySolutions) in Clive, Utah for the treatment of certain P- and U-listed hazardous waste containing radioactive contamination ("mixed waste") using vacuum thermal desorption (VTD). This variance is an alternative treatment standard to treatment by combustion (CMBST) required for these wastes under EPA's rules in implementing the land disposal restriction (LDR) provisions of the Resource Conservation and Recovery Act (RCRA). The Agency has determined that combustion of the solid

treatment residue generated from the VTD unit is technically inappropriate due to the effective performance of the VTD unit. Thus, once the P- and U-listed mixed waste are treated using the VTD unit, the solid treatment residue can be land disposed without further treatment. This variance is conditioned upon EnergySolutions complying with a Waste Family Demonstration Testing (WFDT) plan specifically addressing the treatment of these P- and U-listed wastes, which is to be implemented through a RCRA Part B permit modification for the VTD unit.

DATES: This final rule will be effective June 13, 2008.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-RCRA-2007-0936. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information may not be publicly available, because for example, it may be Confidential Business Information (CBI) or other information, the disclosure of which is restricted by statute. Certain material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the RCRA Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the RCRA Docket is (202) 566-0270. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: For more information on this rulemaking, contact Elaine Eby, Hazardous Waste Minimization and Management Division, Office of Solid Waste (MC 5302 P), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone (703) 308-8449; fax (703) 308-8443; or eby.elaine@epa.gov.

SUPPLEMENTARY INFORMATION:

A. Does This Action Apply to Me?

This action applies only to EnergySolutions located in Clive, Utah.

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I. Summary of This Action

EPA is promulgating, as proposed, a site-specific treatment variance to EnergySolutions in Clive, Utah for the treatment of certain P- and U-listed mixed waste using an alternative treatment standard of VTD.¹ The current treatment standard for these wastes is combustion (CMBST). See 40 CFR 268.40 and 268.42.

EnergySolutions' VTD unit currently operates pursuant to a Part B RCRA permit issued by the State of Utah which (among other things) authorizes the treatment of mixed waste containing both semi-volatile organic compounds (SVOC) and volatile organic compounds (VOC). In 2006, EnergySolutions submitted a petition to EPA for a site-specific treatment variance from the LDR treatment standard of CMBST for various P- and U-listed mixed waste. The petitioner is seeking an alternative treatment standard of VTD.

¹ Mixed waste is defined as radioactive waste that contains hazardous waste that either: (1) Is listed as a hazardous waste in Subpart D of 40 CFR Part 261; or (2) causes the waste to exhibit any of the hazardous waste characteristics identified in Subpart C of 40 CFR Part 261. Mixed waste is regulated under multiple authorities: RCRA (for the non-radioactive component), as implemented by EPA or authorized States; and the Atomic Energy Act (AEA) (for the source, special nuclear, or by-product material component), as implemented by the Nuclear Regulatory Commission (NRC), NRC agreement States (for commercially-generated mixed wastes), or the Department of Energy (DOE) (for defense-related mixed waste generated by DOE activities). The variance is limited to the RCRA requirements for treatment of the hazardous waste portion of the mixed waste and does not affect the regulations under AEA authority.