

§ 52.841 [Removed]

- 13. Section 52.841 is removed.

Subpart S—Kentucky**§ 52.940 [Removed]**

- 14. Section 52.940 is removed.

§ 52.941 [Removed]

- 15. Section 52.941 is removed.

Subpart T—Louisiana**§ 52.985 [Removed and reserved]**

- 16. Section 52.985 is removed and reserved.

Subpart W—Massachusetts**§ 52.1140 [Removed and reserved]**

- 17. Section 52.1140 is removed and reserved.

Subpart Z—Mississippi**§ 52.1284 [Removed]**

- 18. Section 52.1284 is removed.

§ 52.1285 [Removed]

- 19. Section 52.1285 is removed.

Subpart AA—Missouri**§ 52.1341 [Removed]**

- 20. Section 52.1341 is removed.

§ 52.1342 [Removed]

- 21. Section 52.1342 is removed.

Subpart HH—New York**§ 52.1684 [Removed]**

- 22. Section 52.1684 is removed.

§ 52.1685 [Removed]

- 23. Section 52.1685 is removed.

Subpart VV—Virginia**§ 52.2440 [Removed and reserved]**

- 24. Section 52.2440 is removed and reserved.

§ 52.2441 [Removed and reserved]

- 25. Section 52.2441 is removed and reserved.

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2006-0855; FRL-8360-5]

Metconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metconazole in or on wheat, barley, rye, oat, sugar beet, and soybeans. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also establishes tolerances for residues of metconazole in or on stone fruit, tree nuts, and peanuts. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 28, 2008. Objections and requests for hearings must be received on or before June 27, 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-2006-0855. 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](http://www.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 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: Tracy Keigwin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6605; e-mail address: keigwin.tracy@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-2006-0855 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 27, 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-2006-0855, 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 13, 2008 (73 FR 8307) (FRL-8351-5), 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 6F7094) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.617 be amended by establishing tolerances for residues of the fungicide metconazole, 5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, measured as the sum of *cis*- and *trans*-isomers in or on food commodities barley, grain at 2.0 parts per million (ppm); barley, hay at 7.0 ppm; barley straw at 7.0 ppm; beet, sugar, root at 0.1 ppm; beet, sugar, tops at 2.0 ppm; beet, sugar, pulp, dry at 1.9 ppm; beet, sugar, molasses at 0.2 ppm; beet, sugar, raw at 0.25 ppm; oat, grain at 1.0 ppm; oat, straw at 6.0 ppm; oat, hay at 17 ppm; rye, grain at 0.25 ppm; rye, straw at 14.0 ppm; soybean, forage at 3.0 ppm; soybean, hay at 6.0 ppm; soybean, seed at 0.10 ppm; soybean, aspirated grain fractions at 1.0 ppm; soybean, hulls at 0.2 ppm; triticale at 0.25 ppm; wheat, grain at 0.15 ppm; wheat, hay at 16.0 ppm; wheat, straw at 18.0 ppm; wheat, aspirated grain

fractions at 10.0 ppm; wheat, milled byproducts at 1.0 ppm. That notice referenced a summary of the petition prepared by BASF 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.

Additionally, in the **Federal Register** of February 13, 2008 (73 FR 8307) (FRL-8351-5), 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 6F7095) by Valent U.S.A. Company, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596-8025. The petition requested that 40 CFR 180.617 be amended by establishing tolerances for residues of the fungicide metconazole, 5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, measured as the sum of *cis*- and *trans*-isomers in or on food commodities fruits, stone (crop group 12) at 0.2 ppm; nuts, tree (crop group 14) including pistachio at 0.02 ppm; almond hulls at 5.0 ppm; and peanut at 0.02 ppm. That notice referenced a summary of the petition prepared by Valent U.S.A. 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 proposed tolerance levels as follows: Almond, hulls at 4.0 ppm; barley, grain at 2.5 ppm; beet, sugar, dried pulp at 0.70 ppm; beet, sugar, molasses at 0.08 ppm; beet, sugar, roots at 0.07 ppm; grain, aspirated grain fractions at 7.0 ppm; nut, tree, group 14 at 0.04 ppm; oat, grain at 1.0 ppm; peanut at 0.04 ppm; peanut, refined oil at 0.05 ppm; pistachio at 0.04 ppm; soybean, hulls at 0.08 ppm; soybean, seed at 0.05 ppm; wheat, milled byproducts at 0.20 ppm; and meat byproducts of cattle, goat, horse, and sheep at 0.04 ppm. Additionally, EPA is not establishing the tolerances requested for beet, sugar; sugar beet tops; and soybean meal. Finally, EPA has added tolerances for peanut, refined oil; for meat byproducts of cattle, goat, horse, and sheep. The reason for these changes is explained in Unit IV.D.

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 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 tolerances for residues of metconazole. 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.

Acute oral and dermal toxicities to metconazole are moderate, while acute inhalation toxicity is low. Metconazole is a moderate eye irritant and a mild skin irritant. It is not a skin sensitizer. The liver is the primary target organ in the mouse, rat and dog following oral exposure to metconazole via subchronic or chronic exposure durations. Developmental studies in rats and rabbits show some evidence of developmental effects, but only at dose levels that are maternally toxic. Metconazole did not demonstrate the potential for neurotoxicity in the four species (mouse, rat, dog and rabbit) tested. Metconazole is considered nongenotoxic and liver tumors seen in chronic mouse study appear to have been formed via a mitogenic mode of action and therefore, metconazole is classified as "not likely to be carcinogenic to humans" at levels that do not cause mitogenesis. The chronic

reference dose (RfD) would be protective of mitogenesis/carcinogenesis.

Specific information on the studies received and the nature of the adverse effects caused by metconazole 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> under docket ID number EPA-HQ-OPP-2005-0016.

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 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 metconazole used for human risk assessment is discussed in Unit III.B. of the final rule published in

the **Federal Register** of September 27, 2006 (71 FR 6383) (FRL-8085-2).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing metconazole tolerances in (40 CFR 180.617). EPA assessed dietary exposures from metconazole 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 United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

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 assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

iii. *Cancer.* Metconazole is classified as "not likely to be carcinogenic to humans" at levels that do not cause mitogenesis. The chronic RfD would be protective of mitogenesis/carcinogenesis and the chronic exposure assessment is appropriate for evaluating cancer risk.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for metconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of metconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of metconazole for acute exposures are estimated to be 45.48 parts per billion (ppb) for surface water and 0.384 ppb for ground water. The EECs for chronic exposures are estimated to be 31.25 ppb

for surface water and 0.384 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 45 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 31 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).

Metconazole is currently registered for the following residential non-dietary sites: Turf and ornamentals. Adult residential handlers may be exposed to metconazole as a result of applying metconazole to turf and ornamentals. Because dermal toxicity endpoints for the appropriate duration of exposure were not identified, only residential handler short-term inhalation exposures were assessed. Additionally, adults and adolescents may experience short-term and intermediate-term dermal post-application exposure from golfing and other activities on treated turf. Toddlers may experience short-term and intermediate-term dermal and incidental oral exposure from activities on treated turf. However, because dermal toxicity endpoints for the appropriate durations of exposure were not identified, and because inhalation exposure is considered to be insignificant for post-application exposures, only toddler incidental oral post-application exposures were assessed.

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."

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

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

Triazole-derived pesticides can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including metconazole, 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 as of September 1, 2005. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's September 1, 2005 risk assessment can be 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 Triazolylpyruvic Acid; Updated to Include New Uses of Fenbuconazole, Ipconazole, Metconazole, Tebuconazole, and Uniconazole* can be found at [http://](http://www.regulations.gov)

www.regulations.gov in docket ID EPA-HQ-OPP-2006-0855.

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.* Acceptable developmental toxicity studies are available in the rat and rabbit as well as a 2-generation reproductive toxicity study in the rat. There is no evidence of susceptibility following *in utero* exposure in the rabbit. In the rat there is qualitative evidence of susceptibility, however the concern is low since the developmental effects are characterized as variations (not malformations), occur in the presence of maternal toxicity, the NOAELs are well defined, and the dose/endpoint is used for acute dietary risk assessment for the sensitive population. There is no evidence of increased susceptibility in the offspring based on the result of the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for metconazole is complete.
- ii. There was no evidence of neurotoxicity observed in the toxicology database and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.
- iii. There is no evidence of susceptibility following *in utero* exposure in the rabbit or in young rats in the 2-generation reproduction study. In the rat there is qualitative evidence of susceptibility, however the concern is low since the developmental effects are characterized as variations (not malformations), occur in the presence of maternal toxicity, the NOAELs are well defined, and the dose/endpoint is used

for acute dietary risk assessment for the sensitive population.

iv. Dietary exposure assessments were conducted using tolerance level residues and assumed 100% crop treated (CT). Therefore, the acute and chronic dietary, food only, exposure is considered an upper bound conservative estimate. Acute and chronic exposure estimates in this analysis are unlikely to underestimate actual exposure.

v. The drinking water component of the dietary assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

vi. While there is potential for post application residential exposure, the Agency used the current conservative approaches for residential assessment. The Agency believes that the calculated risks represent conservative estimates of exposure because maximum application rates are used to define residue levels upon which the calculations are based.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to metconazole will occupy 3% of the aPAD for the population group (females 13-49 years old) receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to metconazole from food and water will utilize 4% of the cPAD for the U.S. population and 9% of the cPAD for the most highly exposed population group (infants less than 1-year old).

3. *Short-term risk.* Short-term risk takes into account residential exposure plus chronic exposure to food and water (considered to a background exposure level). Metconazole is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for metconazole.

Metconazole is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for metconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that short-term aggregate MOEs from dietary exposure (food + drinking water) and non-occupational/residential handler exposure (inhalation) for adults are 2,700; the children's residential combined short-term MOE from treated turf is 810. The lowest MOE for residential handler short-term inhalation risks is 71,000. These MOEs are not of concern to the Agency, since they are greater than the level of concern MOE of 100.

4. *Intermediate-term risk.* Intermediate-term risk takes into account residential exposure plus chronic exposure to food and water (considered to a background exposure level). Metconazole is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for metconazole.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that intermediate-term aggregate MOEs from dietary exposure (food + drinking water) and non-occupational/residential handler exposure (inhalation) for adults are 2,700; the children's residential combined short-term risk from treated turf are 1,000. These MOEs are not of concern to the Agency, since they are greater than the level of concern MOE of 100.

5. *Aggregate cancer risk for U.S. population.* Metconazole is classified as "not likely to be carcinogenic to humans" at levels that do not cause mitogenesis. As explained in Unit III.E2, the cPAD is protective of mitogenesis and because the chronic risk assessment for metconazole shows exposure to be below the cPAD, there is no cancer concern.

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 metconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The following adequate enforcement methodologies are available to enforce the tolerance expression:

1. A liquid chromatography/mass spectrometry method (LC/MS) (method D0508) along with multi-residue methods serving as a confirmatory method are adequate to enforce tolerances for residues in small grain, soybean, and sugarbeet agricultural and processed commodities.

2. A gas chromatography/nitrogen-phosphorus detection method (GC/NPD) (method RM-41C-1-1) is adequate to enforce tolerances for residues in stone fruit, tree nuts, and peanut commodities.

3. A German multi-residue method (method DFG S19) is adequate for enforcing tolerances for residues in livestock commodities. 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.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican MRLs established for metconazole.

C. Response to Comments

There were no comments received in response to the notice of filing.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA determined that the proposed tolerances should be revised as follows: Almond, hulls decreased from 5.00 ppm to 4.0 ppm; barley, grain increased from 2.0 ppm to 2.5 ppm; beet, sugar, dried pulp reduced from 1.9 ppm to 0.70 ppm; beet, sugar, molasses reduced from 0.2 ppm to 0.08 ppm; beet, sugar, roots reduced from 0.1 ppm to 0.07 ppm; nut, tree, group 14 increased from 0.02 to 0.04 ppm; oat, grain increased from 0.1 ppm to 1.0 ppm; peanut increased from 0.02 ppm to 0.04 ppm; pistachio increased from 0.02 ppm to 0.04 ppm; soybean, hulls decreased from 0.2 ppm to 0.08 ppm; soybean, seed reduced from 0.1 ppm to 0.05 ppm; and wheat, milled byproducts reduced from 1.0 ppm to 0.20 ppm. The wheat, aspirated grain fraction and soybean, aspirated

grain fraction proposals at 10.0 ppm and 1.0 ppm, respectively, should be expressed as grain, aspirated grain fractions and revised to 7.0 ppm. EPA revised the tolerance levels 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 Standard Operating Procedure (SOP)*. No tolerances are needed for beet sugar and soybean meal since metconazole does not increase in these commodities on processing. The tolerance on sugar beet root covers sugar. No tolerance is needed for sugar beet tops since this commodity is no longer a significant feed item. Separate tolerances are being established for meat byproducts of cattle, goat, horse, and sheep at 0.04 ppm based on a cattle feeding study in which dairy cattle were fed metconazole at levels corresponding to 1.3x, 3.9x, and 12x, respectively, the dietary burden for beef cattle and 0.54x, 1.7x, and 5.2x, respectively, the dietary burden for dairy cattle. In liver, residues of *cis* and *trans*-metconazole were <0.02-0.021 ppm and <0.02 ppm, respectively, in samples from the high-dose group and below the LOQ (both isomers) in samples from the low-dose and mid-dose groups. Maximum total metconazole residues (sum of *cis* and *trans* isomers) in liver were 0.041 ppm from the high-dose group. Because quantifiable residues of *cis*-metconazole were observed in liver (0.021 ppm) at the highest dosing level, tolerances are needed for meat byproducts at the limit of quantitation of the enforcement method (0.04 ppm).

V. Conclusion

Therefore, the tolerances are established for residues of metconazole, 5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on almond, hulls at 4.0 ppm; barley, grain at 2.5 ppm; barley, hay at 7.0 ppm; barley, straw at 7.0 ppm; beet, sugar, dried pulp at 0.70 ppm; beet, sugar, molasses at 0.08 ppm; beet, sugar, roots at 0.07 ppm; cattle, meat byproducts at 0.04 ppm; fruit, stone, group 12 at 0.20 ppm; goat, meat byproducts at 0.04 ppm; grain, aspirated grain fractions at 7.0 ppm; horse, meat byproducts at 0.04 ppm; nut, tree, group 14 at 0.04 ppm; oat, grain at 1.0 ppm; oat, hay at 17 ppm; oat, straw at 6.0 ppm; peanut at 0.04 ppm; peanut, refined oil at 0.05 ppm; pistachio at 0.04 ppm; rye, grain at 0.25 ppm; rye, straw at 14 ppm; sheep, meat byproducts at 0.04 ppm; soybean, forage at 3.0 ppm; soybean, hay at 6.0 ppm; soybean, hulls at 0.08

ppm; soybean, seed at 0.05 ppm; wheat, grain at 0.15 ppm; wheat, hay at 16 ppm; wheat, milled byproducts at 0.20 ppm; wheat, straw at 18 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 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 9, 2000) do not apply

to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 15, 2008.

Daniel Kenny,
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 180.617 is amended by alphabetically adding the following commodities to the table in paragraph (a) and by removing and reserving paragraph (b) with heading to read as follows:

180.617 Metconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	4.0
Barley, grain	2.5
Barley, hay	7.0

Commodity	Parts per million
Barley, straw	7.0
Beet, sugar, dried pulp ...	0.70
Beet, sugar, molasses	0.08
Beet, sugar, roots	0.07
Cattle, meat byproducts	0.04
Fruit, stone, group 12	0.20
Goat, meat byproducts ...	0.04
Grain, aspirated grain fractions	7.0
Horse, meat byproducts	0.04
Nut, tree, group 14	0.04
Oat, grain	1.0
Oat, hay	17
Oat, straw	6.0
Peanut	0.04
Peanut, refined oil	0.05
Pistachio	0.04
Rye, grain	0.25
Rye, straw	14
Sheep, meat byproducts	0.04
Soybean, forage	3.0
Soybean, hay	6.0
Soybean, hulls	0.08
Soybean, seed	0.05
Wheat, grain	0.15
Wheat, hay	16
Wheat, milled byproducts	0.20
Wheat, straw	18

(b) *Section 18 emergency exemption.*

[Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA-HQ-SFUND-1990-0011; FRL-8558-5]

National Oil and Hazardous Substances Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of partial deletion of the Seneca Army Depot Activity Superfund Site from the National Priorities List.

SUMMARY: The United States Environmental Protection Agency (EPA) Region 2 announces the deletion from the National Priorities List (NPL) of the following two specific parcels of real property located at the Seneca Army Depot Activity (SEDA) Superfund Site (Site), Romulus, New York: Real Estate Parcel 1, except for a portion of this parcel known as SEAD-24; and the entirety of Real Estate Parcel 2. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is found at Appendix B of 40 CFR part 300, which is an appendix to the National