distributive impacts; and equity). The Executive Order classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined and it has been determined to be a significant regulatory action under the Executive Order because it is likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are 64.109, Veterans Compensation for Service-Connected Disability, and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Veterans, Vietnam.

Approved: April 3, 2009.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

■ For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

■ 1. The authority citation for part 3, subpart A, continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

§ 3.309 [Amended]

■ 2. In § 3.309(e), the listing of diseases is amended by adding ''AL amyloidosis'' immediately preceding ''Chloracne or other acneform disease consistent with chloracne.''

[FR Doc. E9–10627 Filed 5–6–09; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0514; FRL–8408–6]

Metconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the residues of metconazole, including its metabolites and degradates, in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover; cotton, undelinted seed; and cotton, gin byproducts. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also establishes tolerances for residues of metconazole, including its metabolites and degradates, in or on canola seed, and eggs. Valent U.S.A. Corporation requested the tolerance for canola seed under the FFDCA. EPA required an additional tolerance for eggs based on findings in the studies submitted by the registrant.

In addition, this action establishes time-limited tolerances for the residues of metconazole, including its metabolites and degradates, in or on sugarcane, cane at 1.6 ppm and sugarcane, molasses at 3.2 ppm, in response to the approval of crisis exemptions declared by the states of Florida and Louisiana under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the quarantine use of the fungicide on sugarcane to control the fungal pathogen, *Puccinia kuehnii*. This regulation establishes a maximum permissible level of residues in this food commodity. The time-limited tolerances expire and are revoked on December 31, 2011.

DATES: This regulation is effective May 7, 2009. Objections and requests for hearings must be received on or before July 6, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for these actions under docket identification (ID) number EPA–HQ–OPP–2007–0514 (for BASF Corporation requested tolerances) and EPA–HQ–OPP–2008–0718 (for Valent U.S.A. Corporation requested tolerances). All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: For further information regarding the tolerances requested by BASF Corporation or Valent U.S.A. Corporation, please 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*. For further information regarding the time-limited tolerance for the use of metconazole on sugarcane, please contact Libby Pemberton, Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: *pemberton.libby@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0514 (for BASF Corporation requested tolerances) and EPA–HQ–OPP–2008–0718 (for Valent U.S.A. Corporation requested tolerances) 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 6, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0514 (for BASF Corporation requested tolerances) and EPA–HQ–OPP–2008–0718 (for Valent U.S.A. Corporation requested tolerances), by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of November 5, 2008 (73 FR 65849) (FRL–8385–1), 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 7F7221) by BASF Corporation, 26 Davis Drive, 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 the food commodities corn, field, aspirated grain fractions at 0.05 parts per million (ppm); corn, field, forage at 3.5 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 4.5 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 4.5 ppm; corn, sweet, forage at 3.5 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 4.5 ppm; cotton, undelinted seed at 0.25 ppm; and cotton, gin byproducts at 8.0 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*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Additionally, in the **Federal Register** of November 5, 2008 (73 FR 65849), 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 7F7292) 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 a tolerance 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 the food commodity canola seed at 0.04 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*. 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 has modified the proposed tolerance levels as follows: Corn, field, forage and corn, sweet, forage decreased to 3.0 ppm. Additionally, no specific tolerance for corn, field, aspirated grain fractions is needed since residues from this commodity are covered under the 7.0 ppm tolerance for ''grain, aspirated grain fractions'' already established under § 180.617. Finally, a tolerance is required for metconazole residues in egg at 0.04 ppm. EPA has also modified the tolerance expression to clarify the scope of the tolerance and how compliance with the tolerance levels is to be determined.

The reason for these changes is explained in Unit IV.D.

At this time, EPA is also establishing time-limited tolerances for the residues of metconazole, including its

metabolites and degradates, in or on sugarcane, cane at 1.6 ppm and sugarcane, molasses at 3.2 ppm. These tolerances expire and are revoked on December 31, 2011. The Agency is establishing these time-limited tolerances in response to a crisis exemption request under FIFRA section 18 on behalf of the Florida Department of Agriculture & Consumer Services and the Louisiana Department of Agriculture & Forestry for emergency use of metconazole as a quarantine use on sugarcane to control fungal growth of *Puccinia kuehnii*.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of metconazole in or on sugarcane, cane and sugarcane, molasses. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although these time-limited tolerances expire and are revoked on December 31, 2011, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sugarcane, cane and sugarcane, molasses after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether metconazole meets FIFRA's registration requirements for use in or on sugarcane, cane and sugarcane, molasses or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerances serve as a basis for registration of metconazole by a State for Special Local Needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than Florida and Louisiana to use this pesticide on these crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for metconazole, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

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 residues of metconazole, including its metabolites and degradates, in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover; cotton, undelinted seed; cotton, gin byproducts; canola seed, and eggs. Additionally, EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of the additional emergency exemption request and the time-limited tolerances for the residues of metconazole including its metabolites and degradates, in or on sugarcane, cane at 1.6 ppm and sugarcane, molasses at 3.2 ppm. EPA's assessment of exposures and risks associated with establishing the permanent and time-limited tolerances follows.

A. Toxicological Profile

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

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 a 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.

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–2006–0855.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the

human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-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 April 28, 2008 (73 FR 22823) (FRL–8360–5).

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 and its metabolites, 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). An acute dietary (food and drinking water) analysis for metconazole was conducted using tolerance level residues (for parent compound) and 100 percent crop treated (%CT) for all existing and proposed uses. For commodities that include metabolites as residues of concern in the risk assessment (i.e., cereal grains and livestock commodities), maximum residue values for the metabolites from field trials were added to the metconazole tolerance levels. Default concentration factors were used for processed commodities that do not have tolerances.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the same assumptions as stated in Unit C.1.i. for acute exposure.

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

iv. *Anticipated residue information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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 parts per billion (ppb) for surface water and 0.38 ppb for ground water. The EECs for chronic exposures for non-cancer assessments are estimated to be 31 ppb for surface water and 0.38 ppb for ground water. The EECs for chronic exposures for cancer assessments are estimated to be 22 ppb for surface water and 0.38 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 value of 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 inhalation short-term 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 three triazole conjugates (triazole alanine, triazole acetic acid, and triazolylpyruvic 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 (SF) for the protection of infants and children. The assessment included evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's September 1, 2005 risk assessment can be found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket Identification Number EPA–HQ–OPP–2005–0497. In October and December of 2008, EPA updated the dietary and aggregate risk assessments for exposure to 1,2,4-triazole, triazole alanine, triazole acetic acid, and triazolylpyruvic acid resulting from the use of all current and pending uses of any triazole-derived fungicide to support existing tolerances and to establish new tolerances for new uses of metconazole (canola, corn, cotton, and sugarcane; PP#s 7F7221, 7F7292, 08FL03), propiconazole (beets, parsley, and pineapple; PP# 7F7300), prothioconazole (wheat and barley; PP# 7F7279), and tetraconazole (grapes; PP# 7E7273). These updated dietary and aggregate assessments are below the Agency's LOC. These updated triazole risk assessments can be found in the dockets associated with this Rule at *http://www.regulations.gov* (Docket IDs EPA–HQ–OPP–2007–0514 and EPA–HQ–OPP–2008–0718).

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 SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF 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. *Immunotoxicity*. An immunotoxicity study is one of the new 40 CFR Part 158 toxicological data requirements. The Agency has evaluated the available metconazole toxicity database and has determined there is no evidence of immunotoxicity. Splenic effects were observed in the subchronic and chronic rat (19.2 and 56.2 milligrams/kilogram/day (mg/kg/day), respectively), subchronic and cancer mouse (50.5 and 56.2 mg/kg/day, respectively) and subchronic and chronic dog (22.5 and 114 mg/kg/day, respectively). However, the observed splenic effects including increased spleen weight and spleen congestion are likely a secondary effect of increased erythropoiesis due to a reduction in erythroctyes. The Agency does not believe that conducting an immunotoxicity study (OPPTS 870.7800) will result in a NOAEL lower than 4.3 mg/kg/day, which is presently used as the chronic Reference dose (cRfD) point of departure. An additional uncertainty factor for database uncertainties (UFDB) does not need to be applied.

4. *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 except for immunotoxicity testing. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect after the tolerance petition was submitted, these studies are not yet available for metconazole. The Agency has evaluated the available metconazole toxicity database and has determined there is no evidence of immunotoxicity. Due to the lack of evidence of immunotoxicity for metconazole, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the NOAEL of 4.3 mg/kg/day, which is already established as the cRfD point of departure for metconazole. An additional factor (UF_{DB}) for database uncertainties is not needed to account for potential immunotoxicity.

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. There are no residual uncertainties identified in the exposure databases. Dietary exposure assessments were conducted using tolerance level residues and assumed 100% crop treated for all crops. 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. 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. 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 the residues of metconazole, including its metabolites and degradates, will occupy 3.7% 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 the residues of metconazole, including its metabolites and degradates, from food and water will utilize 5.6% of the cPAD for the U.S. population and 12% of the cPAD for the most highly exposed population group (children 1–2 years old).

3. *Short-term risk*. Short-term risk takes into account residential exposure plus chronic exposure to food and water (considered to be 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, water, and short-term exposures for the residues of metconazole, including its metabolites and degradates.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that short-term aggregate MOE from dietary exposure (food + drinking water) and non-occupational/residential handler exposure (inhalation) for adults is 1,900. The short-term aggregate MOE from dietary exposure (food + drinking water) and non-occupational/residential exposure (incidental oral) for children 1–2 years old is 430. These MOEs are not of concern to the Agency since they are greater than the LOC of 100.

4. *Intermediate-term risk*. Intermediate-term risk takes into account residential exposure plus chronic exposure to food and water (considered to be 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, water, and intermediate-term exposures for the residues of metconazole, including its metabolites and degradates.

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 is 1,400. The intermediate-term aggregate MOE from dietary exposure (food + drinking water) and non-occupational/residential exposure (incidental oral) for children 1–2 years old is 480. These MOEs are not of concern to the Agency since they are greater than the LOC 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 above, 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

Adequate enforcement methodology (gas chromatography/nitrogen-phosphorus detection (GC/NPD) and liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) Method) is available to enforce the tolerance expression. 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

EPA received a total of three comments with regard to either EPA–HQ–OPP–2007–0514 or EPA–HQ–OPP–2008–0718. One of the comments appeared to have been filed in error as it discussed the security requirements for aircraft exceeding 12,500 lbs. The remaining two comments expressed concern regarding the potential for residues of metconazole to remain in the human body and the potential for adverse effects from pesticide application. EPA responds that before a chemical is registered for a particular use pattern a registrant is required to submit extensive data regarding the nature of the chemical and the potential for adverse effects on either the human or ecological population. This data is evaluated using the most conservative and stringent methods of safety, including the addition of extra SFs established for the protection of infants and children in order to ensure the well-being of the general U.S. population and various population subgroups.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition for tolerance for corn commodities, EPA has modified the proposed tolerance levels for corn commodites as follows: Corn, field, forage decreased from 3.5 ppm to 3.0 ppm and corn, sweet, forage decreased from 3.5 ppm to 3.0 ppm. EPA revised these 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). Additionally, no specific tolerance for corn, field, aspirated grain fractions is required

since residues from this commodity are covered under the established 7.0 ppm tolerance for ''grain, aspirated grain fractions.'' EPA is establishing a tolerance for metconazole residues in egg at 0.04 ppm because quantifiable residues of cis-metconazole were found in eggs in the animal feed study involving hens. Finally, EPA is modifying the tolerance expression for metconazole, as it applies to the newly-established tolerances, to clarify the scope of the tolerance and how compliance with the tolerance levels is to be determined. The revised tolerance expression makes clear that the tolerance covers metconazole, including all of its metabolites and degradates, although compliance with the residue levels specified in the tolerance is to be determined by measuring only metconazole (5-[4(-chlorophenyl)-methyl]-2, 2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) as the sum of its cis- and trans-isomers. The new tolerances will be included in a new paragraph with the revised tolerance expression. This revised expression is meant to capture more precisely EPA's intent with regard to the tolerance expression for the exisiting tolerances. EPA plans to update the tolerance expression for the existing tolerances in its next metconazole tolerance action.

V. Conclusion

Therefore, tolerances are established for the residues of metconazole, 5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, including its metabolites and degradates, in or on canola seed at 0.04 ppm; corn, field, forage at 3.0 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 4.5 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 4.5 ppm; corn, sweet, forage at 3.0 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 4.5 ppm; cotton, undelinted seed at 0.25 ppm; cotton, gin byproducts at 8.0 ppm; egg at 0.04 ppm; and time-limited tolerances for sugarcane, cane at 1.6 ppm and sugarcane, molasses at 3.2 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 24, 2009.

Daniel J. Rosenblatt,

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:

i. Redesignating paragraph (a) as paragraph (a)(1);

ii. Adding paragraph (a)(2); and

iii. Revising paragraph (b) to read as follows:

§ 180.617 Metconazole; tolerances for residues.

(a) *General.* (1) * * *.

(2). Tolerances are established for the residues of the fungicide metconazole, including its metabolites and degradates, in or on commodities in the following table. Compliance with the tolerance levels specified in the table is to be determined by measuring only metconazole, 5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) as the sum of its cis- and trans- isomers in or on the following commodities:

Commodity	Parts per million
Canola seed	0.04
Corn, field, forage	3.0
Corn, field, grain	0.02
Corn, field, stover	4.5
Corn, pop, grain	0.02
Corn, pop, stover	4.5

Commodity	Parts per million
Corn, sweet, forage	3.0
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	4.5
Cotton, undelinted seed	0.25
Cotton, gin byproducts	8.0
Egg	0.04

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the fungicide metconazole, including its metabolites and degradates, in or on the commodities listed in the following table in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances expire and are revoked on the dates specified in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only metconazole (5-[(4-chlorophenyl)-methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) as the sum of its cis- and trans-isomers in or on the following commodities:

Commodity	Parts per million	Expiration/revocation date
Sugarcane, cane	1.6	12/31/11
Sugarcane, molasses	3.2	12/31/11

* * * * *

[FR Doc. E9–10500 Filed 5–6–09; 8:45 am]
BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2008–0020; Internal Agency Docket No. FEMA–8073]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.;* unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.