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: December 8, 2006.

Donald R. Stubbs,

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 180.589 is amended in the table to paragraph (a)(1) by removing the commodities ''celery'' and ''spinach'' and by adding alphabetically new commodities to read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a)* * *

(1)* * *

Commodity	Parts per million
* * * *	*
Leafy greens, subgroup 4A, except head and leaf lettuce	60
Leafy petioles, subgroup 4B	45
* * * *	*

* * * * *

[FR Doc. E6–21491 Filed 12–19–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0655; FRL–8095–4]

Metconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the fungicide metconazole, 5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazole-1-yl-methyl)cyclopentanol in or on aspirated grain fractions; egg; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep; milk; soybean, hulls; soybean, meal; soybean, refined oil; and soybean, seed. This action is associated with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of metconazole in these food commodities. These tolerances will expire and be revoked on December 31, 2010.

DATES: This regulation is effective December 20, 2006. Objections and requests for hearings must be received on or before February 20, 2007, 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–2006–0655. All documents in the docket are listed on the regulations.gov website. 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Room S-4400, One Potomac Yard (South Bldg.), 2777 South Crystal Dr. Arlington, VA 22202-3553. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax: (703) 308–8041; e-mail address: *rodia.carmen@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:

- 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 provides 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 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, as amended by the Food Quality Protection Act of 1996 (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2006–0655 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 on or before February 20, 2007.

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 your copies, identified by docket ID number EPA–HQ–OPP–2006–0655, 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, Room S–4400, One Potomac Yard (South Bldg.), 2777 South Crystal Dr., Arlington, VA 22202–3553. 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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing time-limited tolerances for residues of the fungicide metconazole in or on aspirated grain fractions at 1.00 parts per million (ppm); egg at 0.02 ppm; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep at 0.02 ppm; milk at 0.02 ppm; soybean, hulls at 1.20 ppm; soybean, meal at 0.25 ppm; soybean, refined oil at 1.20 ppm; and soybean, seed at 0.10 ppm. These tolerances will expire and be revoked on December 31, 2010. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR).

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of the section 408 safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Metconazole on Soybeans and FFDCA Tolerances

Australasian soybean rust (SBR) is a plant disease caused by two fungal species, *Phakopsora pachyrhizi* and *P. meibomiae*, and is spread primarily by windborne spores that can be transported over long distances. SBR models suggest that most of the soybean acreage in the United States could be compromised by an SBR epidemic. In accordance with the 2002 Agricultural Bioterrorism Protection Act, SBR was identified by the United States Department of Agriculture (USDA) as a select biological agent with the potential to pose a severe threat to the soybean industry and livestock production, in general. As such, USDA has invested in extensive readiness and outreach activities among soybean producers. The States of Minnesota and South Dakota petitioned EPA to allow under FIFRA section 18 the use of metconazole on soybeans for control of SBR in Minnesota and South Dakota. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of metconazole in or on aspirated grain fractions; egg; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep; milk; soybean, hulls; soybean, meal; soybean, refined oil; and soybean, seed. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance 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 tolerances will expire and be revoked on December 31, 2010, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on aspirated grain fractions; egg; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep; milk; soybean, hulls; soybean, meal; soybean, refined oil; and soybean, seed after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these 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 tolerances are being approved under emergency conditions, EPA has not made any decisions about whether metconazole meets EPA's registration requirements for use in soybeans or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of metconazole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for growers in any State other than those in which State lead agencies have obtained an exemption to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the

emergency exemption for metconazole, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of metconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for time-limited tolerances for residues of metconazole in or on aspirated grain fractions at 1.00 ppm; egg at 0.02 ppm; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep at 0.02 ppm; milk at 0.02 ppm; soybean, hulls at 1.20 ppm; soybean, meal at 0.25 ppm; soybean, refined oil at 1.20 ppm; and soybean, seed at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for intraspecies differences.

For dietary risk assessment (other than cancer), the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10x to account for interspecies differences and 10x for intraspecies differences), the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for metconazole used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METCONAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (U.S. general population including infants and children)	Not applicable	None	An endpoint of concern (effect) attributable to a single exposure (dose) for the U.S. general population was not identified in the oral toxicity studies reviewed.
Acute Dietary (Females 13-49 years of age)	NOAEL = 12.0 milligram/kilogram/day (mg/kg/day) UF = 100x Acute RfD = 0.12 mg/kg/day	FQPA SF = 1x aPAD = acute RfD ÷ FQPA SF = 0.12 mg/kg/day	Developmental toxicity—rat; LOAEL = 30.0 mg/kg/day based on increases in skeletal variations.
Chronic Dietary (All populations)	NOAEL= 4.3 mg/kg/day UF = 100x Chronic RfD = 0.04 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD ÷ FQPA SF = 0.04 mg/kg/day	Chronic oral toxicity - rat; LOAEL = 13.1 mg/kg/day based on increased liver weights and associated hepatocellular lipid vacuolation and centrilobular hypertrophy observed in males. Similar effects were observed in females at 54 mg/kg/day, plus increased spleen weight.
Short-Term Incidental Oral (1 to 30 days)	NOAEL = 9.1 mg/kg/day UF = 100x	LOC for MOE = 100	28-day oral toxicity - rat; LOAEL = 90.5 mg/kg/day based on decreased body weight gain in males, increased liver and kidney weight and hepatocellular hypertrophy and vacuolation in both sexes.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METCONAZOLE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Incidental Oral(1 to 6 months)	NOAEL = 6.4 mg/kg/day UF =100 x	LOC for MOE = 100	90-day oral toxicity—rat; LOAEL = 19.2 mg/kg/day based on hepatic vacuolation in males and increased spleen weight in females.
Short-Term Dermal (1 to 30 days)	NOAEL = 9.1 mg/kg/day UF = 100x (dermal absorption rate = 5%)	LOC for MOE = 100	28-day oral toxicity—rat; LOAEL = 90.5 mg/kg/day based on decreased body weight gain in males, increased liver and kidney weight and hepatocellular hypertrophy and vacuolation in both sexes.
Intermediate-Term Dermal(1 to 6 months)	NOAEL = 6.4 mg/kg/day UF = 100x (dermal absorption rate = 5%)	LOC for MOE = 100	90-day oral toxicity—rat; LOAEL = 19.2 mg/kg/day based on hepatic vacuolation in males and increased spleen weight in females.
Long-Term Dermal (>6 months)	NOAEL= 4.3 mg/kg/day UF = 100x (dermal absorption rate = 5%)	LOC for MOE = 100	Chronic oral toxicity—rat; LOAEL = 13.1 mg/kg/day based on increased liver weights and associated hepatocellular lipid vacuolation and centrilobular hypertrophy observed in males. Similar effects were observed in females at 54 mg/kg/day, plus increased spleen weight.
Short-Term Inhalation (1 to 30 days)	NOAEL= 9.1 mg/kg/day UF = 100x (inhalation-absorption rate = 100% oral equivalent)	LOC for MOE = 100	28-day oral toxicity—rat; LOAEL = 90.5 mg/kg/day based on decreased body weight gain in males, increased liver and kidney weight and hepatocellular hypertrophy and vacuolation in both sexes.
Intermediate-Term Inhalation (1 to 6 months)	NOAEL= 6.4 mg/kg/day UF = 100x (inhalation-absorption rate = 100% oral equivalent)	LOC for MOE = 100	90-day oral toxicity—rat; LOAEL = 19.2 mg/kg/day based on hepatic vacuolation in males and increased spleen weight in females.
Long-Term Inhalation (>6 months)	NOAEL= 4.3 mg/kg/day UF = 100x (inhalation-absorption rate = 100% oral equivalent)	LOC for MOE = 100	Chronic oral toxicity—rat; LOAEL = 13.1 mg/kg/day based on increased liver weights and associated hepatocellular lipid vacuolation and centrilobular hypertrophy observed in males. Similar effects were observed in females at 54 mg/kg/day, plus increased spleen weight.
Cancer (oral, dermal, inhalation)	Metconazole has been classified as ''not likely to be carcinogenic in humans.'' As a result, a quantified carcinogenic assessment (Q* approach) is not required for metconazole.		

B. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Metconazole is not currently registered for any use in the United States. An import tolerance has been established for metconazole on bananas. Risk assessments were conducted by EPA to assess dietary exposures from metconazole in food as follows:

i. *Acute exposure*. Acute dietary 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 one day or single exposure. The Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

The acute dietary exposure analysis for metconazole was conducted for the proposed food use and drinking water. Except for drinking water, the acute analysis is based on Tier 1 assumptions of the proposed/recommended tolerance-level residues and 100% crop treated (CT). A Tier 2 drinking water assessment for the proposed use in soybeans was performed using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model with index reservoir (IR) scenarios and percent cropped area (PCA) adjustment factors. Estimated concentrations of metconazole in drinking water (from use in soybeans) were incorporated directly into the acute dietary risk assessment.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment, the DEEM-FCID™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994-1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity.

The chronic dietary exposure analysis for metconazole was conducted for the proposed food use and drinking water. Except for drinking water, the chronic analysis is based on Tier 1 assumptions of the proposed/recommended tolerance-level residues and 100% CT. A Tier 2 drinking water assessment for the proposed use in soybeans was performed using PRZM/EXAMS model with IR scenarios and PCA adjustment

factors. As with the acute analysis, estimated concentrations of metconazole in drinking water (from use in soybeans) were incorporated directly into the chronic dietary risk assessment.

As a result, all acute and chronic dietary risk estimates were less than the Agency's LOC for the U.S. general population and all population subgroups (i.e., they are all less than 100% of the aPAD and cPAD).

iii. *Cancer*. Metconazole has been classified as ''not likely to be carcinogenic in humans'' based on convincing evidence that carcinogenic effects are not likely below a defined dose range. As a result, a quantified carcinogenic assessment (Q* approach) is not required for metconazole.

2. *Dietary exposure from drinking water*. The Agency used the PRZM/EXAMS to calculate estimated drinking water concentrations (EDWCs) for the use of metconazole in soybeans, using the IR scenarios and PCA adjustment factors. Thus, the estimated exposure concentrations for water are based on the proposed highest use rate. Ground water concentrations were estimated with the Screening Concentration in Ground Water (SCI-GROW) model.

A Tier 2 drinking water assessment was conducted for the proposed use of metconazole in soybeans using the proposed maximum application rate of 0.07 lbs. a.i./acre with 2 applications per year and a 10- to 21-day RTI. The preharvest interval (PHI) will be 30 days. Based on PRZM/EXAMS, the EDWCs for metconazole in surface water are 1.57 parts per billion (ppb) and 0.48 ppb for acute and chronic (non-cancer) exposures, respectively. For chronic/cancer assessments, the 30-year annual average from PRZM/EXAMS is 0.34 ppb. The EDWC for both acute and chronic exposures is estimated as 0.04 ppb for ground water using the SCI-GROW model.

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

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

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 (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation). It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's 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*.

Metconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including 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 triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with the common metabolites (e.g., use of 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 population subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket ID number EPA–HQ–OPP–2005–0497–0013.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and/or post-natal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies*. Developmental studies in rats and rabbits show some evidence of developmental effects (skeletal variations, post-implantation loss, reduction in fetal body weight), but only at dose levels that are maternally toxic. In the developmental toxicity study in rats, skeletal variations (predominantly lumbar ribs) occurred in the presence of maternal toxicity (decreased body weight gains). In the pre-natal developmental toxicity study in rabbits, developmental effects (increased post-implantation loss and reduced fetal body weights) were observed at the same dose that caused maternal toxicity (decreased body weight gains, reduced food consumption and alterations in hematology parameters). In the 2-generation reproduction study in rats with cis metconazole, offspring toxicity (reduced fetal body weights in F_1 and F_2 offspring) were observed only at the highest tested dose which also resulted in evidence of parental toxicity (reduced parental body weight gains and increased ovarian weight). The chemical is non-genotoxic and not likely to be carcinogenic below a defined dose range based on bioassays in the rat and the mouse combined with a lack of *in vitro* or *in vivo* mutagenicity. Metconazole did not demonstrate the potential for neurotoxicity in the four species (mouse, rat, dog and rabbit) tested. NOAELs/LOAELs are well characterized and are used as endpoints for appropriate risk assessments.

There are adequate data in the metconazole toxicology database to characterize the potential for pre- and/or post-natal risks to infants and children: a 2-generation reproduction study in rats (cis-only isomer; one with

the cis/trans mixture has been completed and will be submitted in the near future); a developmental study in rats; and several developmental studies with rabbits. The effects seen in these studies do not suggest that pups are more susceptible: pup effects were only seen in the presence of maternal toxicity and, in general, were of comparable or less severity to the effects observed in adults. Thus, there are no residual uncertainties for pre- and/or post-natal exposure to metconazole and the Agency has determined that the special FQPA safety factor can be reduced to 1x.

3. *Reproductive toxicity study*. In the submitted 2-generation reproduction study in rats with cis metconazole, offspring toxicity (reduced fetal body weights in F1 and F2 offspring) was observed only at the highest tested dose, which also resulted in evidence of parental toxicity (reduced parental body weight gains and increased ovarian weight). As discussed in Unit IV.C.2., there are no residual uncertainties for pre- and/or post-natal exposure to metconazole.

4. *Pre-natal and post-natal sensitivity*. Please refer to the explanation provided in Unit IV.C.2. for a detailed discussion regarding ''pre- and/or post-natal sensitivity.''

5. *Conclusion*. The Agency evaluated the quality of the hazard and exposure database for metconazole to characterize its potential for pre- and/or post-natal risks to infants and children. The effects observed in the developmental and reproductive studies do not suggest that pups are more susceptible; pup effects were only seen in the presence of maternal toxicity and, in general, were of comparable or less severity to the effects observed in adults. Thus, based on the hazard and exposure data, the special FQPA SF is reduced to 1x as there are low concerns and no residual uncertainties with regard to pre- and/or post-natal toxicity.

D. Aggregate Risks and Determination of Safety

EPA conducted human health risk assessments for acute, chronic and cancer dietary exposures (food + drinking water only) for the proposed use. Because there are no uses of metconazole that are expected to result in residential exposures, this aggregate risk assessment takes into consideration dietary (food + drinking water) exposure only; therefore, the acute and chronic aggregate estimates would be the same as the dietary exposure results.

1. *Acute risk*. Using the exposure assumptions discussed in this unit, the acute dietary exposure from food and water to metconazole will occupy 1% of the aPAD for females 13–49 years old, the population subgroup of concern. Given the proposed use, the Agency has no risk concern for exposure to metconazole through food and/or drinking water. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

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 2% of the cPAD for the U.S. general population and 5% of the cPAD for children 1-2 years old. There are no residential uses for metconazole that will result in chronic residential exposure to metconazole. Given the proposed use, the Agency has no risk concern for exposure to metconazole through food and/or drinking water. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short- and intermediate-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and drinking water (considered to be a background exposure level). Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and drinking water (considered to be a background exposure level). Since metconazole is not registered for use on any sites that would result in residential exposure, short- and intermediate-term aggregate risk assessments are not needed.

4. *Aggregate cancer risk for U.S. population*. Metconazole is ''not likely to be carcinogenic in humans'' based on convincing evidence that carcinogenic effects are not likely below a defined dose range. A non-genotoxic mode of action for mouse liver tumors was established. No quantification is required.

5. *Determination of safety*. Based on all these considerations, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. general population and to infants and children from aggregate exposure to metconazole residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No CODEX, Canadian or Mexican maximum residue limits (MRLs) or tolerances have been established for metconazole in or on soybeans. Further, no provisional MRL has been established in Japan for imported soybeans. Therefore, international harmonization is not an issue at this time.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of metconazole in or on aspirated grain fractions at 1.00 ppm; egg at 0.02 ppm; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep at 0.02 ppm; milk at 0.02 ppm; soybean, hulls at 1.20 ppm; soybean, meal at 0.25 ppm; soybean, refined oil at 1.20 ppm; and soybean, seed at 0.10 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of FFDCA. 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175 requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: December 5, 2006.

Donald R. Stubbs,

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 adding text and table to paragraph (b) to read as follows:

§ 180.617 Metconazole; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide metconazole, 5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazole-1-yl-methyl)cyclopentanol in or on aspirated grain fractions; egg; meat, fat and meat by-products of cattle, goat, hog, horse, poultry and sheep; milk; soybean, hulls; soybean, meal; soybean, refined oil; and soybean, seed in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and be revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Aspirated grain fractions	1.00	12/31/10
Cattle, fat	0.02	12/31/10
Cattle, meat	0.02	12/31/10
Cattle, meat byproducts	0.02	12/31/10
Egg	0.02	12/31/10
Goat, fat	0.02	12/31/10
Goat, meat	0.02	12/31/10
Goat, meat byproducts	0.02	12/31/10
Hog, fat	0.02	12/31/10
Hog, meat	0.02	12/31/10
Hog, meat byproducts	0.02	12/31/10
Horse, fat	0.02	12/31/10
Horse, meat	0.02	12/31/10
Horse, meat byproducts	0.02	12/31/10
Milk	0.02	12/31/10
Poultry, fat	0.02	12/31/10
Poultry, meat	0.02	12/31/10
Poulty, meat byproducts	0.02	12/31/10
Sheep, fat	0.02	12/31/10
Sheep, meat	0.02	12/31/10
Sheep, meat byproducts	0.02	12/31/10

Commodity	Parts per million	Expiration/revocation date
Soybean, hulls	1.20	12/31/10
Soybean, meal	0.25	12/31/10
Soybean, refined oil	1.20	12/31/10
Soybean, seed	0.10	12/31/10

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0942; FRL–8105–4]

Extension of Tolerances for Emergency Exemptions (Multiple Chemicals)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in this document. These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

DATES: This regulation is effective December 20, 2006. Objections and requests for hearings must be received on or before February 20, 2007, 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–2006–0942. All documents in the docket are listed on the regulations.gov website. 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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: See the table in this unit for the name of a specific contact person. The following information applies to all contact persons: Emergency Response Team, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

Pesticide/CFR section	Contact person
Acibenzolar-*S*-methyl, 180.561 Mancozeb, 180.176	Libby Pemberton *pemberton.libby@epa.gov* (703) 308–9364
Bifenthrin, 180.442 Thiophanate-methyl, 180.371	Andrea Conrath *conrath.andrea@epa.gov* (703) 308–9356
Flufenacet, 180.527 Propyzamide, 180.317	Andrew Ertman *ertman.andrew@epa.gov* (703) 308–9367
Zoxamide, 180.567	Stacey Groce *groce.stacey@epa.gov* (703) 305–2505

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:

- 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 provides 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 one of the persons listed in the table 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 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, as amended by the Food Quality Protection Act of 1996 (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2006–0942 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 on or before February 20, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please