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.

V. 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: September 20, 2006.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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.

§ 180.143 [Removed]

■ 2. Section 180.143 is removed.

■ 3. Section 180.301 is amended by revising paragraph (a) to read as follows:

§ 180.301 Carboxin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide carboxin (5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide) and its metabolites determined as aniline and expressed as parent compound, in or on food commodities as follows:

Commodity	Parts per million
Barley, grain	0.2
Barley, straw	0.2
Bean, dry, seed	0.2
Bean, succulent	0.2
Canola, seed	0.03
Cattle, fat	0.05
Cattle, meat byproducts	0.1
Cattle, meat	0.05
Corn, field, forage	0.2
Corn, field, grain	0.2
Corn, field, stover	0.2
Corn, pop, grain	0.2
Corn, pop, stover	0.2
Corn, sweet, forage	0.2
Corn, sweet, kernel plus cob with husks removed	0.2
Corn, sweet, stover	0.2
Cotton, undelinted seed	0.2
Egg	0.05
Goat, fat	0.05
Goat, meat byproducts	0.1
Goat, meat	0.05
Hog, fat	0.05
Hog, meat byproducts	0.1
Hog, meat	0.05
Horse, fat	0.05
Horse, meat byproducts	0.1
Horse, meat	0.05
Milk	0.05
Oat, forage	0.5
Oat, grain	0.2
Oat, straw	0.2
Onion, bulb	0.2
Peanut	0.2
Peanut, hay	0.2
Poultry, fat	0.1
Poultry, meat byproducts	0.1
Poultry, meat	0.1
Rice, grain	0.2
Rice, straw	0.2
Safflower, seed	0.2
Sheep, fat	0.05
Sheep, meat byproducts	0.1
Sheep, meat	0.05
Soybean, seed	0.2
Wheat, forage	0.5
Wheat, grain	0.2
Wheat, straw	0.2

* * * * *

■ 4. Section 180.355 is amended by revising the table in paragraph (a)(1) to read as follows:

§ 180.355 Bentazon; tolerances for residues.

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

Commodity	Parts per million
Bean, dry, seed	0.05
Bean, succulent	0.5
Corn, field, forage	3.0
Corn, field, grain	0.05
Corn, field, stover	3.0
Corn, pop, grain	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Cowpea, forage	10.0
Cowpea, hay	3.0
Flax, seed	1.0
Pea, dry, seed	1.0
Pea, field, hay	8.0
Pea, field, vines	3.0
Pea, succulent	3.0
Peanut	0.05
Peanut, hay	3.0
Pepper, nonbell	0.05
Peppermint, tops	1.0
Rice, grain	0.05
Rice, hulls	0.25
Rice, straw	3.0
Sorghum, forage	0.20
Sorghum, grain	0.05
Sorghum, grain, stover	0.05
Soybean, forage	8.0
Soybean, hay	8.0
Soybean, seed	0.05
Spearmint, tops	1.0

* * * * *

§§ 180.1238 and 180.1239 [Removed]

■ 5. Section 180.1238 and 180.1239 are removed.

[FR Doc. 06–8255 Filed 9–26–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0016; FRL–8085–2]

Metconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of metconazole in or on bananas. BASF Agricultural Products requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 27, 2006. Objections and requests for hearings must be received on or before November 27, 2006, 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–2005–0016. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open 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: Mary L. Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather 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*. 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 the FFDCA, as amended by the 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–2005–0016 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 November 27, 2006.

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–2005–0016, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of April 8, 2005, (67 FR 18008) (FRL–7703–7), 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 9E5052) by BASF Agricultural Products, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528 agent for Kureha Corporation, 3–3–2 Nihonbashi-Hamacho, Chuo-ku, Tokyo 103–8552, Japan. The petition requested that 40 CFR 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, in or on bananas at 0.05 parts per million (ppm). That notice included a summary of the petition prepared by BASF Agricultural Products, the agent for the petitioner. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV,C. below.

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. . . .''

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 the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of metconazole on banana at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic 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 the docket ID number EPA–HQ–OPP–2005–0016.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL of concern are identified 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/oppfead1/trac/science/*, and *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

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, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-49 years of age)	NOAEL = 12 mg/kg/day UF = 100 Acute RfD = 0.12 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.12 mg/kg/day	Developmental toxicity - rats LOAEL = 30 mg/kg/day based on increases in skeletal variations
Chronic Dietary (All populations)	NOAEL = 4.3 mg/kg/day UF = 100 Chronic RfD = 0.04 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.04 mg/kg/day	Chronic oral toxicity - rats LOAEL = 13.1 mg/kg/day based on increased liver (M) weights and associated hepatocellular lipid vacuolation (M) and centrilobular hypertrophy (M). Same effects seen (F) at 54 mg/kg/day, plus increased speen weight
Cancer (oral, dermal, inhalation)	Classification: ''Not Likely to be Carcinogenic to Humans''		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. There are currently no tolerances established (40 CFR 180) for the residues of metconazole. Use of metconazole on soybeans has been authorized under Section 18 of FIFRA. Risk assessments were conducted by EPA to assess dietary exposures from metconazole in/on imported bananas and soybeans 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 conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, version 2.03), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessment: Tolerance level residues and 100% crop treated were assumed for bananas and soybeans.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the software with the (DEEM-FCID™, version 2.03), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues and 100% crop treated were assumed for bananas and soybeans.

iii. *Cancer*. Metconazole is classified as ''Not Likely to be Carcinogenic to 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. An exposure assessment is not necessary.

2. *Dietary exposure from drinking water*. There is no expectation that

residues from metconazole use on imported banana would occur in surface or ground water sources of drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical 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/models4.htm*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Groundwater (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of metconazole, resulting from use on soybeans for acute exposures are estimated to be 1.57 parts per billion (ppb) for surface water and 0.04 ppb for ground water. The EDWCs for chronic exposures are estimated to be 0.48 ppb for surface water and 0.04 ppb for ground water. Use on imported bananas will not contribute to residues in water in the United States.

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 the 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 this 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. A variable pattern of toxicological responses are found for conazoles. 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 have 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 the 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, U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at http://www.regulations.gov, Docket Identification (ID) Number EPA–HQ–OPP–2005–0497.

D. 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data 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 Margin of Exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The database for metconazole is adequate for FQPA consideration. The two-generation reproduction study was performed with *cis*-only metconazole (not *cis/trans* metconazole). However, the database contains a sufficient number of subchronic and developmental toxicity studies with *cis/trans* metconazole to adequately assess *cis/trans* metconazole toxicity and to bridge the data gap. In addition, acceptable development toxicity studies are available in both rats and rabbits. The effect seen in these studies do not indicate 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. Metconazole did not exhibit neurotoxicity in any of the submitted data.

3. *Conclusion.* There is a complete toxicity data base for metconazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. There is no evidence of susceptibility following *in utero* and/or postnatal exposure in the developmental toxicity studies in rats or rabbits, and in the 2-generation rat reproduction study. There are no residual uncertainties concerning prenatal and postnatal toxicity and no neurotoxicity concerns. The acute and chronic dietary (food + drinking water) exposure assessments are conservative assessments that are based on reliable data and will not underestimate exposure/risk. There is no potential for drinking water exposure from the proposed use on imported bananas. Additionally, there is no potential for residential exposure. Based on these data and conclusions, the FQPA Safety Factor is reduced to 1X.

E. Aggregate Risks and Determination of Safety

To assess aggregate risk, drinking water estimates were incorporated directly into the dietary analysis, rather than using back-calculated drinking water levels of comparison (DWLOCs).

To better evaluate aggregate risk associated with exposure through food and drinking water, EPA is no longer comparing Estimated Drinking Water Concentrations (EDWCs) generated by water quality models with DWLOC. Instead, EPA is now directly incorporating the actual water quality model output concentrations into the risk assessment. This method of incorporating water concentration into our aggregate assessments relies on actual CSFII reported drinking water consumptions and more appropriately reflects the full distribution of drinking water concentrations.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to metconazole will occupy < 1% of the aPAD for females 13 years and older, the only population subgroup of concern. EPA does not expect the aggregate exposure to exceed 100% of the aPAD, and therefore is below the Agency's level of concern.

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. population, 5% of the cPAD for children 1-2 years old, the most highly exposed population subgroup. There are no residential uses for metconazole that result in chronic residential exposure to metconazole. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, and therefore is below the Agency's level of concern.

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

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

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

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

5. *Aggregate cancer risk for U.S. population*. The Agency has classified metconazole as ''Not Likely to be Carcinogenic to Humans'' based on convincing evidence that carcinogenic effects are not likely below a defined dose range and that carcinogenic effects were seen in animals only at higher doses. A non-genotoxic mode of action for mouse liver tumors was established. Given that metconazole's cancer effects are a threshold effect and that the threshold is well above other chronic effects, the chronic RfD is protective against any cancer risk.

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 and 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) method (American Cyanamid Method M 2722)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no Canadian, Mexican or Codex MRL or tolerances for metconazole.

C. Response to Comments

A private citizen responded to PP 9E5052. Comments were received on April 17, 2005 objecting to the use and sale of this product, animal testing, profiteering and lack of satisfactory combined and long-term testing. The Agency response is as follows: The Agency has a toxicity data base and it is considered sufficient to adequately assess metconazole, which includes several long-term or chronic studies. The commenter submitted no scientific information or data to support their claims. EPA has responded to such generalized comments on numerous previous occasions, for example, on January 7, 2005 (70 FR 1354) (FRL–7681–9) and on October 29, 2004 (69 FR 63083) (FRL–7691–4).

V. Conclusion

Therefore, a tolerance is established for residues of metconazole, 5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on banana at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 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–). 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 104–13, section 12(d) (15 U.S.C. 272 note). 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. 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.

VII. 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: September 18, 2006.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.617 is added to read as follows:

§ 180.617 Metconazole; tolerances for residues.

(a) *General.* Tolerances are established for the residue of the fungicide metconazole (5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) in or on the following commodity:

Commodity	Parts per million
Banana[1]	0.1

[1] No U.S. registration as of August 30, 2006.

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

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

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

[FR Doc. 06–8256 Filed 9–26–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0058; FRL–8091–5]

Ethaboxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of ethaboxam in or on grape at 6.0 parts per million (ppm), with no U.S. registration. Landis International, Inc., agent for LG Life Sciences, Ltd. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 27, 2006. Objections and requests for hearings must be received on or before November 27, 2006, 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–2005–0058. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open 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: Bryant Crowe, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0025; e-mail address: *crowe.bryant@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide