

**List of Subjects in 40 CFR Part 180**

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

Dated: August 25, 2006.

**Lois Rossi,**

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 180.475 is amended as follows:
  - i. In paragraph (a) by revising the chemical name of the active ingredient, difenoconazole, from “(2S,4R)/(2R/4S) [[2R/4R]]/(2S,4S) 1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl]-1H-1,2,4-triazole” to “(1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole)”; by alphabetically adding commodities to the table; and
  - ii. Paragraph (b) is removed and reserved.
- The amendments read as follows:

**§ 180.475 Difenoconazole; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Barley, hay .....	0.05
Barley, straw .....	0.05
* * *	* *
Corn, sweet, forage .....	0.01
Corn, sweet, kernel plus cob with husks removed .....	0.01
Corn, sweet, stover .....	0.01
Cotton, gin byproducts ...	0.05
Cotton, undelinted seed	0.05
* * *	* *
Fruit, pome, group 11 <sup>3</sup> ...	0.10
* * *	* *
Grape <sup>3</sup> .....	0.10
* * *	* *

<sup>3</sup> There are no U.S. Registrations on fruit, pome, group 11 or on grapes, as of September 13, 2006.

(b) Section 18 emergency exemptions. [Reserved]

\* \* \* \* \*

[FR Doc. E6-15090 Filed 9-12-06; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2005-0071; FRL-8080-9]

**Epoxiconazole; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of epoxiconazole in or on bananas and coffee. BASF Corporation, Agricultural Products requested these tolerances 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 13, 2006. Objections and requests for hearings must be received on or before November 13, 2006.

**ADDRESSES:** EPA has established a docket for this action under docket Identification (ID) number EPA-HQ-2005-0071. 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&ndash;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 telephone number for the Docket Facility 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](mailto: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 affectedP 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>.

*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-2005-0071 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 13, 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-2005-0071, 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 telephone number for the Docket Facility is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of September 22, 2000, (65 FR 57338) (FRL-6737-8), and February 15, 2006, (71 FR 7952) (FRL-7759-5), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 7E4885 and 0E6128) by BASF Corporation, Agricultural Products, P.O. Box 13528; Research Triangle Park, NC 27709-3528. These petitions requested that 40 CFR 180 be amended by establishing tolerances for residues of the fungicide epoxiconazole, (2RS, 3SR)-3-(2-chlorophenyl)-2-(4-fluorophenyl)-2(1H-1,2,4-triazol-1-yl)methyl oxirane, in or on bananas at 0.5 parts per million (ppm) (PP 7E4885) and coffee, bean at 0.05 ppm (PP 0E6128). These notices included a summary of the petition prepared by BASF, the registrant. Comments were received on the notices

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 tolerances for residues of epoxiconazole in or on bananas at 0.5 parts per million (ppm) and coffee, bean at 0.05 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 epoxiconazole 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-2005-0071-0005.

### 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 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 and 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>.

Summaries of the toxicological endpoints for epoxiconazole used for the human risk assessment are shown in the following Table 1.

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

Exposure/Scenario	Dose used in risk assessment, inter-species 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 = 5 mg/kg/day UF = 100 Acute RfD = 0.05 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/ Special FQPA SF = 0.05 mg/kg/day	Developmental toxicity - rat LOAEL = 15 mg/kg/day based on increased incidence of skeletal variations
Chronic dietary (all populations)	NOAEL = 2 mg/kg/day UF = 100 Chronic RfD = 0.02 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/ Special FQPA SF = 0.02 mg/kg/day	2-Year rat carcinogenicity LOAEL = 7 mg/kg/day based on increased incidences of ovarian cysts and adrenal histopathological findings in females
Cancer (oral, dermal, inhalation)	Classification: Likely human carcinogen with a $Q_1^*(\text{mg/kg/day})^{-1}$ of $3.04 \times 10^{-2}$ by oral route based on the occurrence of liver tumors in male and female mice		

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* This final rule establishes the first tolerances for residues of epoxiconazole in or on imported bananas and coffee. There are no registered uses in the United States, therefore the only expected exposure to epoxiconazole is from imported bananas and coffee. Risk assessments were conducted by EPA to assess dietary exposures from epoxiconazole 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 one-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™), 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 assessments: The acute analysis was based on the highly conservative assumption of tolerance-level residues and 100% crop treated (CT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™, 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: The chronic analysis was based on the highly conservative assumption of tolerance-level residues and 100% CT.

iii. *Cancer.* The Agency classified epoxiconazole as “likely to be carcinogenic to humans” by the oral route based on the occurrence of liver tumors in male and female mice. The cancer dietary exposure estimate for the general U.S. population is  $3 \times 10^{-5}$  mg/kg/day. The cancer dietary exposure assessment was performed for the general U.S. population using anticipated residues, and 100% CT. Anticipated residues were calculated for coffee and banana using the average field trial values from the crop field trial data.

iv. *Anticipated residue and percent crop treated (PCT) 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 chemicals that have been measured in food. If EPA relies on such information, EPA must require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* There is no expectation that epoxiconazole residues would occur in surface water or ground water sources of drinking water. Epoxiconazole is

proposed for use only on imported coffee and banana commodities, the sole anticipated exposure route for the U.S. population is via dietary (food) exposure. There are no registered uses of epoxiconazole 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).

Epoxiconazole is not registered for use on any sites that would result in residential exposure and a non-dietary risk assessment is not required.

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.”

Epoxiconazole 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 (EPA, 2002). 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>. The Agency's risk assessment for the common metabolites is available in the prothioconazole reregistration docket at <http://www.regulations.gov>, docket 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 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 special FQPA safety factors, as appropriate.

#### 2. Prenatal and postnatal sensitivity.—

a. There is no evidence of susceptibility following *in utero* exposure in the rabbit developmental toxicity and both *in utero* and postnatal exposure in the 2-generation rat reproduction study.

b. There is low concern for the susceptibility seen in the rat developmental toxicity study because the effects observed were relatively mild for both the pregnant dams (decrease in body weight gain/food consumption) and the rat pups (increased incidence of minor skeletal variations - rudimentary cervical ribs and accessory 14<sup>th</sup> rib).

c. There does not appear to be any enhanced susceptibility in the young to endocrine effects based on the results of the two-generation study (parental male reduced adrenal weights were not observed in offspring).

d. Although there is some uncertainty associated with the acute and subchronic neurotoxicity data, it is unlikely that the information requested to upgrade these studies will alter the NOAELs used for the dietary endpoints. This is because the positive findings in the acute neurotoxicity study were mild and at high doses (1,000 mg/kg in males and 2,000 mg/kg in females). Also, the piloerection observed in the females in the acute neurotoxicity study would likely have been noted or recorded during the subchronic and chronic rodent studies as part of the daily cageside observations for clinical signs. Clinical observations were made, but no signs were noted in any of the studies. This suggests that chronic exposure up to 80 mg/kg/day in rats (rat carcinogenicity study) does not lead to readily observable clinical signs such as piloerection.

e. The non-cancer dietary food exposure assessment utilizes proposed tolerance level residues and 100% CT information for all commodities. By using these screening-level assessments, acute and chronic exposures/risks will not be underestimated.

f. Drinking water and residential exposure are not expected.

3. *Conclusion.* There is a complete toxicity data base for epoxiconazole 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 rabbit developmental toxicity and in the 2-generation rat reproduction study. There is low concern for the susceptibility seen in the rat developmental toxicity study and no residual uncertainty for prenatal and/or postnatal toxicity. There is no evidence of significant neurotoxicity, as indicated by both the acute and subchronic neurotoxicity studies. Acute and chronic dietary food exposure estimates are based on conservative (Tier 1) assumptions, and will not underestimate exposure/risk. There is no potential for drinking water or residential exposure. Based on these data and conclusions, there are no FQPA UFs and the FQPA Safety Factor can be reduced to 1x.

#### E. Aggregate Risks and Determination of Safety

1. *Acute risk.* Using the exposure assumptions discussed in this unit for

acute exposure, the acute dietary exposure from food to epoxiconazole will occupy 2% of the aPAD for females 13-49 years, the only population subgroup of concern. There are no proposed or existing residential uses for epoxiconazole. The proposed uses are limited to imported bananas and coffee. Since there are no registered uses associated with epoxiconazole in the U.S., the only route of exposure is dietary (food only). Aggregate risk is limited to dietary exposure (food only) and does not exceed 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 epoxiconazole from food will utilize 1.0% of the cPAD for the U.S. population, 3.7% of the cPAD for all infants <1 year, and 4.6% of the cPAD for children 1-2 years, the most highly exposed population subgroup. There are no residential uses for epoxiconazole that result in chronic residential exposure to epoxiconazole, and no exposure is expected from drinking water. Therefore, aggregate risk does not exceed 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).

Epoxiconazole is not registered for use on any sites that would result in residential exposure and there is no expectation that epoxiconazole residues would occur via drinking water consumption. Therefore, the aggregate risk is the sum of the risk from food, which does 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).

Epoxiconazole is not registered for use on any sites that would result in residential exposure and there is no expectation that epoxiconazole residues would occur via drinking water consumption. Therefore, the aggregate risk is the sum of the risk from food, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency classified epoxiconazole as "likely to be carcinogenic to humans" by the oral route based on the occurrence of liver tumors in male and female mice. The estimated unit risk,  $Q_1^*$  is  $3.04 \times 10^{-2}$ . The cancer dietary exposure estimate for the general U.S. population is 9.03 x

10<sup>-7</sup> which is below the Agency's level of concern (generally in the range of 1x 10<sup>-6</sup>).

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 epoxiconazole residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/electron capture detector (GC/ECD) method - BASF method 309/1) 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 0755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

Codex Alimentarius and Canada have not established or proposed any MRLs for epoxiconazole. As there are no established or proposed MRLs for either banana or coffee, harmonization with international tolerances is not an issue for the current petitions.

##### C. Response to Comments

A private citizen responded to PP 0E6128. Comments were received on February 15, 2006 objecting to the use, manufacturing and sale of this product. The comments further stated that not enough tests have been completed (long term or combined tests), that there is little indication of safety and questioned the validity of animal testing.

The Agency response is as follows: The Agency has a complete toxicity database on epoxiconazole, including several long-term or chronic studies. The commenter submitted no scientific information or data to support their claims. For additional in-depth response, refer to docket EPA-HQ-OPP-2004-0325, 69 FR 63083 at <http://www.regulations.gov>.

#### V. Conclusion

Therefore, tolerances are established for residues of epoxiconazole, [*rel*-1-[(2R,3S)-3-(2-chlorophenyl)-2-(4-fluorophenyl)oxiranyl]methyl]-1*H*-1,2,4-triazole], in or on bananas at 0.5 ppm and coffee at 0.05 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 104-4). 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 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: August 28, 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 180.619 is added to read as follows:

**§ 180.619 Epoxiconazole; tolerances for residues.**

(a) *General.* Tolerances are established for the residues of the fungicide epoxiconazole [(*rel*-1-[[[2R,3S]-3-(2-chlorophenyl)-2-(4-fluorophenyl)oxiranyl]methyl]-1*H*-1,2,4-triazole)] in or on the following commodities:

Commodity	Parts per million
Banana*	0.5
Coffee*	0.05

\*No U.S. Registration as of August 4, 2006

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

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

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

[FR Doc. E6-14994 Filed 9-12-06; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 271**

[EPA-R04-RCRA-2006-0575; FRL-8219-5]

**Alabama: Final Authorization of State Hazardous Waste Management Program Revision**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Immediate final rule.

**SUMMARY:** Alabama has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant final authorization to Alabama. In the "Rules and Regulations" section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect

comments that oppose it. We have explained the reasons for this authorization in the preamble of the immediate final rule. Unless we get written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we receive comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment.

**DATES:** Final authorization will become effective on November 13, 2006 unless EPA receives adverse written comment on or before October 13, 2006. If EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04-RCRA-2006-0575 by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail:* [middlebrooks.gail@epa.gov](mailto:middlebrooks.gail@epa.gov).
- *Fax:* (404) 562-8439 (prior to faxing, please notify the EPA contact listed below).
- *Mail:* Send written comments to Gail Middlebrooks, RCRA Services Section, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960.
- *Hand Delivery:* Gail Middlebrooks, RCRA Services Section, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-R04-RCRA-2006-0575. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov> including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. (For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>).

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov>, or in hard copy. You may view and copy Alabama's application at the EPA Region 4 Library, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. The Library is open from 8 a.m. to 4:30 p.m. Monday through Friday, excluding legal holidays. The Library telephone number is (404) 562-8190.

You may also view and copy Alabama's application from 8 a.m. to 4:30 p.m. at The Alabama Department of Environmental Management, 1400 Coliseum Blvd., Montgomery, Alabama 36110-2059.

**FOR FURTHER INFORMATION CONTACT:** Gail Middlebrooks, RCRA Services Section, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960; (404) 562-8494; fax number: (404)