

“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

#### XI. 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 31, 2006.

**James Jones,**

*Director, Office of Pesticides 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 180.1271 is added to subpart D to read as follows:

#### § 180.1271 Eucalyptus oil; exemption from the requirement of a tolerance.

An exemption from the requirement of tolerance is established for residues

of eucalyptus oil in or on honey, honeycomb, and honeycomb with honey when used at 2g or less eucalyptus oil per hive, where the eucalyptus oil contains 80% or more eucalyptol.

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2006-0024; FRL- 8085-1]

#### Difenoconazole; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of difenoconazole, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole), when used as a seed treatment in or on barley, hay; barley, straw; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover; cotton, gin byproducts; cotton, undelinted seed; and as a foliar treatment on fruit, pome, group 11 (import); and on grape (import). Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This rule also revises 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 the following, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole). EPA is also deleting certain difenoconazole tolerances that are no longer needed as result of this action.

**DATES:** This regulation is effective September 13, 2006. Objections and requests for hearings must be received on or before November 13, 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-2006-0024. 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:

Tony Kish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9443; e-mail address: [kish.tony@epa.gov](mailto:kish.tony@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>.

### 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-2006-0024 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-2006-0024, 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 12, 2006 (71 FR 18748) (FRL-7765-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 0F6155, 6F4748, 8F4953, and 9E5076) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.475 be amended by establishing tolerances for residues of the fungicide difenoconazole, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole), when used as a seed treatment, in or on barley, hay at 0.05 parts per million (ppm) (PP 6F4748); barley, straw at 0.05 ppm (PP 6F4748); corn, sweet, forage at 0.01 ppm (PP 0F6155); corn, sweet, kernel plus cob with husks removed at 0.01 ppm (PP 0F6155); corn, sweet, stover at 0.01 ppm (PP 0F6155); cotton, gin byproducts at 0.05 ppm (PP 8F4953); cotton, undelinted seed at 0.05 ppm (PP 8F4953); and as a foliar treatment on fruit, pome, group 11 at 0.10 ppm (PP 9E5076); and on grape at 0.1 ppm (9E5076). That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

Syngenta requested a tolerance of 0.05 ppm on barley, forage. However, a tolerance is not being established for barley forage because: It is an insignificant animal feed item; it is not included in Table 1 of the Residue Chemistry Test Guidelines, OPPTS 860.1000; and it is not an accepted name in the Food and Feed Commodity Vocabulary (<http://www.epa.gov/pesticides/foodfeed/>); for these reasons, a tolerance is not required.

EPA is also deleting several established tolerances in § 180.475(b) that are no longer needed, as a result of this action. The tolerance deletions under § 180.475(b) are time-limited tolerances established under section 18 emergency exemptions that are superseded by the establishment of permanent tolerances for difenoconazole § 180.475(a). The revisions to § 180.475 are as follows:

1. Delete the time-limited tolerance (expires 12/31/08) for corn, sweet, kernel plus cob with husks removed at 0.1 ppm under § 180.475(b), because a permanent tolerance for corn, sweet, kernel plus cob with husks removed at

0.01 ppm is being established by this action under § 180.475(a).

2. Delete the time-limited tolerance (expires 12/31/08) for corn, sweet, forage at 0.1 ppm under § 180.475(b), because a permanent tolerance for corn, sweet, forage at 0.01 ppm is being established by this action under § 180.475(a).

3. Delete the time-limited tolerance (expires 12/31/08) for corn, sweet, stover at 0.1 ppm under § 180.475(b) because a permanent tolerance for corn, sweet, stover at 0.01 ppm is being established by this action under § 180.475(a).

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 difenoconazole, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole), when used as a seed treatment in or on barley, hay at 0.05 ppm; barley, straw at 0.05 ppm; corn, sweet, forage at 0.01 ppm; corn, sweet, kernel plus cob with

husks removed at 0.01 ppm; corn, sweet, stover at 0.01 ppm; cotton, gin byproducts at 0.05 ppm; cotton, undelinted seed at 0.05 ppm; and as a foliar treatment on fruit, pome, group 11 at 0.10 ppm; and on grape at 0.10 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 difenoconazole 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 the following website: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/September/Day-15/p23773.htm>.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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 level of concern (LOC). 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.

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/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for difenoconazole used for human risk assessment is discussed in Unit III.B. of the final rule published in

the **Federal Register** of September 15, 2000 (65 FR 55911) (FRL-6589-3).

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.475) for the residues of difenoconazole, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from difenoconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The only population subgroup for which an acute dietary exposure analysis was performed was females 13–49 years old. No endpoint of concern for the general population that was attributable to a single exposure (dose) from the oral toxicity studies was identified. The Dietary Exposure Evaluation Model with Food Commodity Intake Database (DEEM-FCID™, version 2.03) 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 following assumptions were made for the acute exposure assessments: Tolerance-level residues; 100% percent of each crop treated; and DEEM™, version 7.76, processing factors for all proposed and registered commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 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 for barley, rye, and all proposed commodities; anticipated residues for all previously registered commodities, except barley and rye; 100% of each crop treated; and DEEM™, version 7.76, default processing factors for all commodities.

iii. *Cancer.* The Agency determined that a reference dose (RfD) approach is appropriate to evaluate potential cancer risk to difenoconazole because the chronic RfD is lower than the cancer RfD. No separate exposure assessment was conducted for evaluating cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the 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 pursuant to section 408(f)(1) 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. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for difenoconazole in 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 difenoconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppfead1/trac/science>.

Based on the First Index Reservoir Screening Tool (FIRST) and screening concentration in groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of difenoconazole for acute exposures are estimated to be 0.60 parts per billion (ppb) for surface water and 0.00084 ppb for ground water. The EECs for chronic exposures are estimated to be 0.14 ppb for surface water and 0.00084 ppb for ground water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Difenoconazole 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."

Difenoconazole 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 propiconazole reregistration docket at [www.regulations.gov](http://www.regulations.gov) in 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.* The evidence shows that difenoconazole is neither a developmental nor a reproductive toxicant, and that there are no residual uncertainties in the toxicology database for difenoconazole. Therefore, infants and children are not expected to exhibit increased sensitivity and the Agency's LOC for prenatal and postnatal toxicity is not exceeded.

3. *Conclusion.* The Agency has concluded that the default 10x FQPA Safety Factor should be reduced to 1x in assessments of both acute and chronic dietary exposures, for the following reasons: There is a complete toxicological database for difenoconazole; there was no evidence of increased pre-natal or post-natal susceptibility to difenoconazole; difenoconazole is neither a developmental nor a reproductive toxicant; exposure data are complete, or are estimated, based on data that reasonably account for potential exposures; and there is high overall confidence in the risk assessment.

#### 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 and water to difenoconazole will occupy <1.0% of the acute population adjusted dose (aPAD) for females 13–49 years old. An endpoint of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies (including the rat and rabbit developmental toxicity studies) for the general U.S. population, or for the infants and children subgroups, therefore acute risk analyses were not performed for these groups.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to difenoconazole from food and water will utilize 2.4% of the chronic population adjusted dose (cPAD) for the U.S. population; 10% of the cPAD for all infants (<1 year old); and 16% of the cPAD for children 1–2 years old. There are no residential uses for difenoconazole that result in chronic residential exposure to difenoconazole.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure in addition to chronic exposure to food and water (which are considered to be the background exposure level).

Difenoconazole is not registered for use on any site(s) that would result in residential exposure, so the aggregate short-term risk is solely the sum of the risk from food and water. These risks do not exceed the Agency's LOC.

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).

Difenoconazole is not registered for use on any site(s) that would result in residential exposure, so the aggregate short-term risk is solely the sum of the risk from food and water. These risks do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* The Agency determined that an RfD approach is appropriate to evaluate potential cancer risks to difenoconazole. The chronic risk assessment adequately protects against cancer risk because the chronic RfD is lower than the cancer RfD.

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 difenoconazole residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology is available for tolerance enforcement. Method AG-575B, the current enforcement method for plant commodities, quantitates levels of difenoconazole by gas chromatography (GC) with nitrogen/phosphorous (N/P) detection. Its limit of quantitation (LOQ) is 0.01 ppm for difenoconazole residues. Method AG-544, the current enforcement method for livestock commodities, also quantitates levels of difenoconazole by GC with N/P detection. The LOQs for difenoconazole residues using this method are 0.01 ppm in meat and eggs and 0.01 ppm in milk. Additionally a GC/mass-spectrometry detection (MSD) method for the confirmation of difenoconazole residues in/on canola seed has recently undergone petition method validation (PMV) at EPA's Analytical Chemistry Lab (ACL). The confirmatory method has been determined to be suitable for tolerance enforcement once the

revisions recommended by ACL are incorporated into it.

#### B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for difenoconazole. Therefore, no conflict exists between any of the existing and proposed U.S. difenoconazole tolerances and any difenoconazole MRL.

#### C. Response to Comments

A notice of filing was published in the **Federal Register**, of April 12, 2006 (71 FR 18748, FRL-7765-7, EPA-HQ-OPP-2006-0024). No public comments were received regarding the notice.

#### V. Conclusion

Tolerances are established for residues of difenoconazole, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole), when used as a seed treatment, in or on barley, hay at 0.05 ppm; barley, straw at 0.05 ppm; corn, sweet, forage at 0.01 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.01 ppm; cotton, gin byproducts at 0.05 ppm; cotton, undelinted seed at 0.05 ppm; and as a foliar treatment on fruit, pome, group 11 at 0.10 ppm; and on grape at 0.10 ppm.

This rule also changes 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 the following, (1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole). The change in the chemical name of the active ingredient is necessary to conform to the nomenclature of the Chemical Abstracts Service, the body which the Office of Pesticide Programs regards as authoritative for issues of chemical nomenclature. This name change makes no substantive change to either the chemical identity of difenoconazole or to the effect of the tolerances.

EPA is not establishing the requested tolerance of 0.05 ppm on barley, forage, because as stated previously, a tolerance is no longer required for this commodity. EPA is also deleting several established tolerances in Sec. 180.475 (b) that are no longer needed, as a result of this action: 0.1 ppm on corn, sweet, kernel plus cob with husks removed with a 12/31/08 expiration date; 0.1 ppm on corn, sweet, forage with a 12/31/08 expiration date; and 0.1 ppm on corn, sweet, stover with a 12/31/08 expiration date.

#### 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 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]

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**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.