

Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

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

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

Dated: March 26, 2010.  
**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 180.414 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows:

**§180.414 Cyromazine; tolerances for residues**

(a)\* \* \* (1)\* \* \*

Commodity	Parts per million
* * *	* *
Bean, succulent ....	2.0
* * *	* *

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0162; FRL-8817-3]

**Difenoconazole Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of the fungicide difenoconazole in or on: Almond, hulls; brassica, head and stem, subgroup 5A; brassica, leafy green, subgroup 5B; citrus, dried pulp; citrus, oil; fruit, citrus, group 10; grape; grape, raisin; nut, tree, group 14; onion, bulb, subgroup 3-07A; onion, green, subgroup 3-07B; pistachio; and vegetable, cucurbit, group 9. EPA is also revising the difenoconazole crop and animal tolerance expressions; deleting all section 18 difenoconazole tolerances that are no longer needed as a result of this action; reinstating tolerances for wheat forage, wheat grain, and wheat straw, which were inadvertently removed when previous tolerances were established; correcting the existing tolerance for beet, sugar; and deleting the grape import superscript. Syngenta

Crop Protection, Inc. requested the new tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 28, 2010. Objections and requests for hearings must be received on or before June 28, 2010, 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-2009-0162. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Rosemary Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5611; e-mail address: [kearns.rosemary@epa.gov](mailto:kearns.rosemary@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be

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

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Test Guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods & Guidelines" on the left-side navigation menu.

#### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0162 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 28, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2009-0162, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One

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

#### **II. Petition for Tolerance**

In the **Federal Register** of April 8, 2009 (74 FR 15971) (FRL-8407-4), 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 8F7482) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. 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, in or on: Almond, hulls at 7 ppm; brassica, head and stem, subgroup 5A at 1.9 ppm; brassica, leafy green, subgroup 5B at 30 ppm; citrus, dried pulp at 2.5 ppm; citrus, oil at 28 ppm; fruit, citrus, group 10 at 0.6 ppm; grape at 4 ppm; grape, raisin at 14 ppm; nut, tree, group 14 at 0.03 ppm; onion, bulb, subgroup 3-07A at 6 ppm; onion, green, bulb, subgroup 3-07B at 0.15 ppm; pistachios at 0.03 ppm; vegetable, cucurbit, group 9 at 0.7 ppm. Although a tree nut group tolerance is being established, a separate pistachio tolerance is needed because pistachios are not currently part of the tree nut, group 14. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has increased the proposed tolerance for both brassica, leafy green, subgroup 5B; and onion, green, subgroup 3-07B. EPA has decreased the proposed tolerance for citrus, dried pulp; citrus, oil; grape, raisin; and onion, bulb, subgroup 3-07A. EPA is also revising the difenoconazole crop and animal tolerance expressions; deleting all difenoconazole section 18 tolerances that are no longer needed as a result of this action; reinstating tolerances for wheat forage, wheat grain, and wheat straw, which were inadvertently removed when previous tolerances were established; deleting the grape import superscript designation; and correcting the existing tolerance for

beet, sugar. The reasons for these changes are explained in Unit IV.D.

#### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for residues of difenoconazole in or on almond, hulls at 7.0 ppm; brassica, head and stem, subgroup 5A at 1.9 ppm; brassica, leafy greens, subgroup 5B at 35 ppm; citrus, dried pulp at 2.0 ppm; citrus, oil at 25 ppm; fruit, citrus, group 10 at 0.60 ppm; grape at 4.0 ppm; grape, raisin at 6.0 ppm; nut, tree, group 14 at 0.03 ppm; onion, bulb, subgroup 3-07A at 0.20 ppm; onion, green, subgroup 3-07B at 6.0 ppm; pistachio at 0.03 ppm; and vegetable, cucurbit, group 9 at 0.70 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

##### *A. Toxicological Profile*

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

Difenoconazole possesses low acute toxicity by the oral, dermal and

inhalation routes of exposure. It is not considered to be an eye or skin irritant and is not a sensitizer. Difenconazole exhibits some evidence of neurotoxicity in the database, but the effects are transient or occur at doses exceeding the limit dose. It is not mutagenic and it is not a developmental or reproductive toxicant. Chronic effects in rats and mice are seen as cumulative decreases in body weight gains.

No evidence of carcinogenicity was seen in rats. Evidence for carcinogenicity was seen in mice where liver tumors were induced at doses which were considered to be excessively high for carcinogenicity testing. Treatment-related non-neoplastic lesions were confined to the liver. Difenconazole is classified as a possible human carcinogen. Based on excessive toxicity observed at the doses at which tumors were seen, the absence of tumors at the lower doses, and the absence of genotoxic effects, EPA considers the cancer effects to be a threshold effect.

Specific information on the studies received and the nature of the adverse effects caused by difenconazole 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> in document "Difenconazole FQPA Human Health Risk Assessment for the Section 3 Registration of Difenconazole New Uses on Bulb Vegetables, Brassica Leafy Vegetables, Cucurbit Vegetables, Citrus Fruits, Grapes, Pistachios, and Tree Nuts" at pages 51–63 in docket ID number EPA–HQ–OPP–2009–0162.

#### B. Toxicological Endpoints

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

and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for difenconazole used for human risk assessment can be found at <http://www.regulations.gov> in document "Difenconazole FQPA Human Health Risk Assessment for the Section 3 Registration of Difenconazole New Uses on Bulb Vegetables, Brassica Leafy Vegetables, Cucurbit Vegetables, Citrus Fruits, Grapes, Pistachios, and Tree Nuts" at pages 16–18 in docket ID number EPA–HQ–OPP–2009–0162.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to difenconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing difenconazole tolerances in 40 CFR 180.475. EPA assessed dietary exposures from difenconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues, 100% crop treated for all the registered and proposed crops, and default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues for some commodities, field trial residues for the majority of commodities, and 100% crop treated. EPA used experimental processing factors for some crops and default processing factors for the remainder.

iii. *Cancer.* A quantitative exposure assessment to evaluate cancer risk is unnecessary. The cancer NOAEL for difenconazole is higher than the NOAEL used as a Point of Departure in calculating the chronic RfD. Therefore, chronic exposure would be equal to or greater than the exposure value used in assessing cancer risk, and the chronic dietary risk estimate is protective of any cancer effects.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use PCT information in the dietary assessment for difenconazole. EPA did use anticipated residues in the chronic dietary assessment for difenconazole; field trial residues and experimental processing factors were used for some commodities.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for difenconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of difenconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on using PRZM/EXAMS and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations

(EDWCs) of difenoconazole for acute exposures are estimated to be 15.8 parts per billion (ppb) for surface water and 0.0123 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 10.4 ppb for surface water and 0.0123 ppb for ground water.

EDWCs for chronic exposures for cancer assessments are estimated to be 7.62 ppb for surface water and 0.0123 ppb for ground water. These EDWCs are the same or lower than the EDWC for chronic non-cancer exposure.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 15.8 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 10.4 ppb was used to assess the contribution to drinking water.

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

Difenoconazole is currently registered for the following uses that could result in residential exposures: ornamentals. EPA assessed residential exposure using the following assumptions: No new residential uses are being requested at this time. However, adults and adolescents may be exposed to difenoconazole from its currently registered use on ornamentals.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Difenoconazole is a member of the triazole-containing class of pesticides, often referred to as the conazoles. EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. The conazole pesticides, as a whole, tend to exhibit carcinogenic, developmental, reproductive, and/or neurological effects in mammals. Additionally, all the members of this class of compounds are capable of forming, via environmental and metabolic activities, 1,2,4-triazole, triazolylalanine and/or triazolylacetic acid. These metabolites have also been shown to cause

developmental, reproductive, and/or neurological effects. Structural similarities and sharing a common effect does 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. Hence, the underlying basis of toxicity is the same, or essentially the same for each chemical. A number of potential events could contribute to the toxicity of conazoles (e.g., altered cholesterol levels, stress responses, altered DNA methylation). At this time, there is not sufficient evidence to determine whether conazoles share common mechanisms of toxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding for the diverse range of effects found. Investigations into the conazoles are currently being undertaken by EPA's Office of Research and Development. When the results of this research are available, the Agency will make a determination of whether there is a common mechanism of toxicity and, therefore, a basis for assessing cumulative risk. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

Triazole-derived pesticides can form the common metabolite 1,2,4-triazole and three triazole conjugates (triazole alanine, triazole acetic acid, and triazolylpyruvic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including prothioconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide as of September 1, 2005. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment included evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's September 1, 2005 risk assessment can be found in the propiconazole reregistration docket at [http://](http://www.regulations.gov)

[www.regulations.gov](http://www.regulations.gov) (docket ID EPA-HQ-OPP-2005-0497).

In October and December of 2008, EPA updated the dietary and aggregate risk assessments for exposure to 1,2,4-triazole, triazole alanine, triazole acetic acid, and triazolylpyruvic acid resulting from the use of all current and pending uses of any triazole-derived fungicide to support existing tolerances and to establish new tolerances for new uses of metconazole (canola, corn, cotton, and sugarcane; PP 7F7221, 7F7292, 08FL03), propiconazole (beets, parsley, and pineapple; PP 7F7300), prothioconazole (wheat and barley; PP 7F7279), and tetraconazole (grapes; PP 7E7273). These updated dietary and aggregate assessments are below the Agency's level of concern. These updated triazole risk assessments can be found in the rule's docket (EPA-HQ-OPP-2008-0327) and the following associated dockets at <http://www.regulations.gov>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The Agency determined that the available studies indicate no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to difenoconazole. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals. The developmental toxicity was manifested as alterations in fetal ossifications at 171 mg/kg/day; the developmental NOAEL was 85 mg/kg/day. In a developmental toxicity study in rabbits, maternal and developmental toxicity were seen at the same dose level (75 mg/kg/day). Maternal toxicity in rabbits were manifested as decreased in body weight gain and decreased in food consumption, while developmental toxicity was manifested as decreased

fetal weight. In a 2-generation reproduction study in rats, there were decreases in maternal body weight gain and decreases in body weights of F1 males at the LOAEL of 12.5 mg/kg/day; the parental systemic and off spring toxicity NOAEL was 1.25 mg/kg/day.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for difenoconazole is adequate for conducting this risk assessment. In accordance with 40 CFR part 158 toxicology data requirements, an immunotoxicity study (OPPTS Harmonized Guideline 870.7800) is required for difenoconazole. In the absence of specific immunotoxicity studies, EPA has evaluated the available difenoconazole toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by difenoconazole, and difenoconazole does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Therefore, EPA does not believe that conducting immunotoxicity testing will result in a point of departure lower than those already selected for difenoconazole risk assessment, and an additional database uncertainty factor is not needed to account for the lack of this study.

ii. Difenoconazole exhibits some evidence of neurotoxicity in the database, but the effects are transient or occur at doses exceeding the limit dose. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no indication of increased susceptibility of rats or rabbits fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data.

iv. Although some storage stability data are still required, tolerances and field trial data used in the risk assessment are sufficiently high, that even if residues degrade in frozen storage prior to analysis, the risk assessment will be protective. Although a confined rotational crop study is still required, the plant back interval is sufficiently long that no detectable residues are expected in rotated commodities. Furthermore, conservative (protective) acute dietary food exposure

assessments were performed based on 100% crop treated and tolerance-level residues. Chronic dietary exposure assessments were based on tolerance-level residues for some commodities, field trial residues for the majority of commodities, and experimental processing factor for some crops, and 100% crop treated. The field trial data and experimental processing factors from processing studies are based on reliable data from the maximum use rate, and are unlikely to understate the residues. EPA also made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to difenoconazole in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by difenoconazole.

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

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to difenoconazole from food and water will utilize 16% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

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 44% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of difenoconazole are not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus

chronic exposure to food and water (considered to be a background exposure level).

Difenoconazole is currently registered for ornamentals that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to difenoconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of at least 180. Values higher than 100 are not of concern. The proposed residential scenarios result in exposure only to adults. Therefore, short-term aggregate assessments were not conducted for infants and children.

#### *4. Intermediate-term risk.*

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

Difenoconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to difenoconazole through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* As discussed above the chronic dietary risk assessment is protective of any cancer effects.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to difenoconazole residues.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate analytical methodology is available to enforce the tolerances listed under 40 CFR 180.475. Method AG-575B (gas chromatography/nitrogen-phosphorus detection) is available for enforcement in crops, and Method AG-676 (gas chromatography/mass selective detection) is available for confirmation. Method AG-676A is available for enforcement and confirmation in canola and barley. Method REM 147.07b (liquid chromatography/mass spectrometry/mass spectrometry) is available for enforcement in livestock and methods AG-544A (gas chromatography/nitrogen-phosphorus

detection) and REM 147.06 (high performance liquid chromatography/UV detection), which determine difenoconazole and CGA 205375, respectively, are available for confirmation. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (401) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

#### B. International Residue Limits

Codex Maximum Residue Limits (MRLs) for residues of difenoconazole *per se* have been established at 0.3 ppm for leek, 0.5 ppm for broccoli, 0.2 ppm for Brussels sprouts, 0.2 ppm for cabbage, 0.2 ppm for cauliflower, and 0.1 ppm for grape. Canadian and Mexican MRLs have been established for difenoconazole; however, no MRLs have been established for the requested crops. Based on the submitted field trial data for brassica vegetables, green onions, and grapes, harmonization with established Codex MRLs is not possible because the MRLs for brassica vegetables, leek, and grape are lower than residue values seen in U.S. field trials. This is a result of differences in agricultural practices.

#### C. Response to Comments

There were no public comments received.

#### D. Revisions to Petitioned-For Tolerances

1. The existing time-limited section 18 tolerances in/on almond and almond hulls are 0.05 ppm, and 5.0 ppm, respectively. This rule establishes new tolerances in/on the nut, tree, group 14 (which includes almonds); and on almond, hulls, at 0.03 ppm and 7.0 ppm, respectively. As explained below, keeping the currently established higher section 18 tolerance in/on almond (0.05 ppm) is not needed and is being revoked, and because a new higher tolerance for almond, hulls is being established at 7.0 ppm, the currently established lower section 18 tolerances in/on almond, hulls (5.0 ppm) is also being revoked.

The section 18 tolerances were based on the same almond field trial study used to establish the new section 3 nut, tree, group 14 tolerance, and to revise the almond, hulls tolerance. The original data were submitted by Interregional Research Project Number 4 (IR-4) in support of the section 18 and then samples were transferred to Syngenta where they were re-analyzed and the new re-analysis data were submitted in support of this section 3

petition. The differences in the analyses/re-analyses data of the same almond and almond hulls samples is the reason for the differences in section 18 and section 3 tolerance determinations. It should be noted that in the original data submitted by IR-4, residues in/on all nutmeat samples were determined to be <0.05 ppm and so the section 18 tolerance in/on almonds was set at 0.05 ppm.

2. The existing time-limited section 18 tolerances for cantaloupe, cucumber, and watermelon are all 1.0 ppm. This rule establishes a new tolerance for vegetable, cucurbit group 9 (which includes all three crops) at a lower tolerance of 0.70 ppm. The section 18 tolerances are based on translation from available fruiting vegetable data using a 1-day PHI. For this petition, Syngenta has provided actual cucurbit vegetable data reflecting the section 18 use rate and a more conservative 0-day PHI, which resulted in a lower tolerance. Therefore, separate higher tolerances at 1.0 ppm are not needed for cantaloupe, cucumber, and watermelon, and the section 18 tolerances in/on these crops are being revoked.

3. Based upon review of the residue data supporting the petition, EPA has increased the proposed tolerance for brassica, leafy green, subgroup 5B from 30 ppm to 35 ppm.

4. The registrant requested a tolerance for bulb onions, subgroup 3-07A at 6.0 ppm, and for green onions, subgroup 3-07B at 0.15 ppm. These proposed tolerances appear to have been transposed by the petitioner. Based on the submitted residue data, EPA is establishing tolerances at 0.20 ppm for onions, bulb, subgroup 3-07A and at 6.0 ppm for onions, green, subgroup 3-07B.

5. EPA has decreased the proposed tolerances for citrus, dried pulp (2.5 ppm); citrus, oil (28 ppm); and grape, raisin (14 ppm). The processing data indicate the proposed tolerances for processed commodities are too high and that tolerances of 2.0 ppm for citrus, dried pulp; 25 ppm for citrus, oil; and 6.0 ppm for grape, raisin are appropriate.

6. EPA is revising the existing difenoconazole tolerance expressions in paragraphs (a)(1) and (a)(2) to clarify what needs to be analyzed for tolerance compliance.

7. Tolerances are being reinstated at 0.1 ppm for wheat forage; wheat grain; and wheat straw. These tolerances were inadvertently removed from 40 CFR 180.475(a) as a result of a rulemaking that added new difenoconazole tolerances but used inaccurate terminology as to how the CFR was to

be amended. (73 FR 1503, January 9, 2008) (FRL-8343-5).

8. The petitioner previously requested beet, sugar at 0.3 ppm via petition 6F7115 which published August 22, 2007. (72 FR 47010) (FRL-8142-5). The associated rule for that petition published January 9, 2008, and erroneously established this tolerance at 0.01 ppm even though the preamble to that rule noted that the petition sought a tolerance level 0.3 ppm. (73 FR 1503, January 9, 2008). Therefore, the existing beet sugar tolerance is being revised from 0.01 to 0.3 ppm to correct this inadvertent error.

9. Revising the existing grape tolerance and deleting the import superscript designation which is no longer needed.

#### V. Conclusion

Therefore, tolerances are established for residues of the fungicide, difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, in or on almond, hulls at 7.0 ppm; brassica, head and stem, subgroup 5A at 1.9 ppm; brassica, leafy greens, subgroup 5B at 35 ppm; citrus, dried pulp at 2.0 ppm; citrus, oil at 25 ppm; fruit, citrus, group 10 at 0.60 ppm; grape at 4.0 ppm; grape, raisin at 6.0 ppm; nut, tree, group 14 at 0.03 ppm; onion, bulb, subgroup 3-07A at 0.20 ppm; onion, green, subgroup 3-07B at 6.0 ppm; pistachio at 0.03 ppm; and vegetable, cucurbit, group 9 at 0.70 ppm. This rule also revises the crop and animal difenoconazole tolerance expressions; deletes all section 18 difenoconazole tolerances that are no longer needed as a result of this action; reinstates 0.1 ppm tolerances for wheat forage, wheat grain, and wheat straw; corrects the existing tolerance for beet, sugar to 0.3 ppm; and deletes the grape import superscript designation.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from*

*Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

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

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

Dated: April 19, 2010.

**G. Jeffrey Herndon,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.475 is amended by revising paragraph (a)(1); revising (a)(2) introductory text; and removing and reserving paragraph (b).

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

(a) General. (1) Tolerances are established for residues of difenoconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls .....	7.0
Apple, wet pomace .....	4.5
Banana <sup>1</sup> .....	0.2
Barley, grain .....	0.1
Barley, hay .....	0.05
Barley, straw .....	0.05
Beet, sugar .....	0.3
Beet, sugar, dried pulp .....	1.9
Brassica, head and stem, subgroup 5A .....	1.9
Brassica, leafy green, subgroup 5B .....	35
Canola, seed .....	0.01
Citrus, dried pulp .....	2.0
Citrus, oil .....	25
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, citrus, group 10 .....	0.60
Fruit, pome group 11 .....	1.0
Grape .....	4.0
Grape, raisin .....	6.0
Nut, tree, group 14 .....	0.03
Onion, bulb, subgroup 3-07A .....	0.20
Onion, green, subgroup 3-07B .....	6.0
Papaya <sup>1</sup> .....	0.30
Pistachio .....	0.03
Potato, processed waste .....	0.04
Rye, grain <sup>1</sup> .....	0.1
Vegetable, cucurbit, group 9 .....	0.70

Commodity	Parts per million
Vegetable, fruiting, group 8 .....	0.60
Vegetable, tuberous and corn, subgroup 1C .....	0.01
Wheat, forage .....	0.1
Wheat, grain .....	0.1
Wheat, straw .....	0.1

<sup>1</sup>There are no U.S. registrations.

(2) Tolerances are established for residues of difenoconazole, including its metabolites and degradates, in the commodities in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, and its metabolite, CGA-205375, 1-[2-chloro-4-(4-chlorophenoxy)phenyl]-2-[1,2,4]triazol-1-yl-ethanol, in the following commodities:

\* \* \* \* \*

(b) Section 18 emergency exemptions.

[Reserved]

\* \* \* \* \*

[FR Doc. 2010-9759 Filed 4-27-10; 8:45 am]

BILLING CODE 6560-50-S

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### 44 CFR Part 64

[Docket ID FEMA-2010-0003; Internal Agency Docket No. FEMA-8115]

#### Suspension of Community Eligibility

##### Correction

In rule document 2010-2487 beginning on page 5890 in the issue of February 5, 2010 make the following corrections:

##### **§64.6 [Corrected]**

1. On page 5891, in §64.6, in the table, under the "Current effective map date" heading, in the first entry, "Apr. 17, 2010" should read "Feb. 17, 2010".

2. On the same page, in the same section, in the same table, under the "Date certain federal assistance no longer available in SFHAs" heading, in the first entry, "Apr. 17, 2010" should read "Feb. 17, 2010".

[FR Doc. C1-2010-2487 Filed 4-27-10; 8:45 am]

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 20

[WT Docket No. 05-265; FCC 10-59]

#### Reexamination of Roaming Obligations of Commercial Mobile Radio Service Providers

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In the Order on Reconsideration, the Commission modifies the automatic roaming obligation that the Commission adopted for voice and related services in 2007 by eliminating the home roaming exclusion.

**DATES:** Effective May 28, 2010.

**FOR FURTHER INFORMATION CONTACT:** For further information concerning this proceeding, please contact Peter Trachtenberg, Spectrum and Competition Policy Division at 202-418-7369, Christina Clearwater, Spectrum and Competition Policy Division at 202-418-1893 or Nese Guendelsberger, Spectrum and Competition Policy Division at 202-418-0634.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's rules noted in the Order on Reconsideration and Second Further Notice of Proposed Rulemaking in WT Docket No. 05-265; FCC 10-59, adopted April 21, 2010, and released on April 21, 2010. This summary should be read with its companion document, the Second Further Notice of Proposed Rulemaking (Second FNPRM) summary published elsewhere in this issue of the **Federal Register**. The full text of the Order on Reconsideration and Second Further Notice of Proposed Rulemaking is available for public inspection and copying during business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY-A257, Washington, DC 20554. It also may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street SW., Room CY-B402, Washington, DC 20554; the contractor's Web site, <http://www.fcc.gov>;

[www.bcpiweb.com](http://www.bcpiweb.com); or by calling (800) 378-3160, facsimile (202) 488-5563, or e-mail [FCC@BCPIWEB.com](mailto:FCC@BCPIWEB.com). Copies of the public notice also may be obtained via the Commission's Electronic Comment Filing System (ECFS) by entering the docket number, WT Docket No. 05-265. Additionally, the complete item is available on the Federal Communications Commission's Web site at <http://www.fcc.gov>.

#### Synopsis of the Order on Reconsideration Section of the Order on Reconsideration and Second Further Notice of Proposed Rulemaking

##### I. Introduction

1. In this order, the Commission takes action to increase consumers' access to seamless nationwide mobile services, wherever and whenever they choose, and to promote investment, innovation, and competition in mobile wireless services. In the Order on Reconsideration, the Commission creates a framework for voice roaming that will encourage carriers of all sizes to reach reasonable commercial roaming agreements, while also encouraging these carriers to continue investing in the coverage and capacity of their networks. The Commission will adjudicate any disputes that may arise between carriers through a tailored, fact-based process. In the Second FNPRM, consistent with the recommendation of the National Broadband Plan, the Commission opens an examination of the critical issue of data roaming, by seeking comment on the rules that should apply to roaming for mobile data services such as mobile broadband service.

2. First, in the Order on Reconsideration, the Commission modifies the automatic roaming obligation that the Commission adopted for voice and related services in 2007 by eliminating the home roaming exclusion. With this decision, the Commission continues to strive to adopt policies that balance competing interests, including—promoting competition among multiple carriers; ensuring that consumers have access to seamless coverage nationwide; and providing incentives for all carriers to invest and innovate by using available