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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0300; FRL-9354-9]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on multiple commodities identified and discussed in this document and amends the established tolerances in or on vegetable, tuberous and corm, subgroup 1C and potato, processed waste. In addition, this regulation removes established tolerances for certain commodities/groups superseded by this action. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0300, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: *jackson.sidney@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 site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 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-2011-0300 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-

OPP-2011-0300, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL-8880-1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7852) by Interregional Research Project Number 4 (IR-4), IR-4 Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. 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]-1*H*-1,2,4,-triazole, including its metabolites and degradates in or on vegetable, fruiting, group 8–10 at 0.6 ppm; fruit, citrus, group 10–10 at 0.6 ppm; fruit, pome, group 11–10 at 1.0 ppm; and berry, low growing, subgroup 13–07G, except cranberry at 2.5 ppm; and by amending the established tolerance in or on

vegetable, tuberous and corm, subgroup 1C at 0.01 ppm to raise to 4.0 ppm. In addition, the petition proposes to remove established tolerances in or on the raw agricultural commodities: Potato, processed waste at 0.04 ppm; vegetables, fruiting, group 8 at 0.6 ppm; fruit, citrus, group 10 at 0.6 ppm; fruit, pome, group 11 at 1.0 ppm; and strawberry at 2.5 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available 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 this petition, EPA denied the Petitioner's request to remove the established tolerance on potato, processed waste at 0.04 ppm. Moreover, the Agency determined that the tolerance needs to be raised and the commodity terminology changed to potato, wet peel at 7.3 ppm. The Agency's rationale for these decisions is outlined in Unit IV.C.

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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** 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 difenoconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with difenoconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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 an eye or skin irritant and is not a sensitizer. Subchronic and chronic studies with difenoconazole in mice and rats showed decreased body weights, decreased body weight gains and effects on the liver. In an acute neurotoxicity study in rats, reduced fore-limb grip strength was observed on day 1 in males and clinical signs of neurotoxicity were observed in females at the limit dose of 2,000 milligrams/kilograms (mg/kg). In a subchronic neurotoxicity study in rats, decreased hind limb strength was observed in males only at the mid- and high-doses. However, the effects observed in acute and subchronic neurotoxicity studies are transient, and the dose-response is well

characterized with identified no-observed-adverse-effects-levels (NOAELs). No systemic toxicity was observed at the limit dose in the most recently submitted 28-day rat dermal toxicity study.

There is no concern for increased qualitative and/or quantitative susceptibility after exposure to difenoconazole in developmental toxicity studies in rats and rabbits, and a reproduction study in rats as fetal/offspring effects occurred in the presence of maternal toxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by difenoconazole.

EPA is using the non-linear (Reference Dose) approach to assess cancer risk. Difenoconazole is not mutagenic, and no evidence of carcinogenicity was seen in rats. Evidence for carcinogenicity was seen in mice (liver tumors), but statistically significant carcinomas tumors were only induced at excessively-high doses. Adenomas (benign tumors) and liver necrosis only were seen at 300 parts per million (ppm) (46 and 58 mg/kg/day in males and females, respectively). Based on excessive toxicity observed at the two highest doses in the study, the presence of only benign tumors and necrosis at the mid-dose, the absence of tumors at the study's lower doses, and the absence of genotoxic effects, EPA has concluded that the chronic point of departure (POD) from the chronic mouse study will be protective of any cancer effects. The POD from this study is the NOAEL of 30 ppm (4.7 and 5.6 mg/kg/day in males and females, respectively) which was chosen based upon only those biological endpoints which were relevant to tumor development (i.e., hepatocellular hypertrophy, liver necrosis, fatty changes in the liver and bile stasis).

Specific information on the studies received and the nature of the adverse 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 http://*www.regulations.gov* in document "Difenoconazole. Human Health Risk Assessment for Postharvest Use on Tuberous and Corm Vegetables Subgroup 1C.and Low growing Berry Subgroup 13-07G, Except Cranberry," dated May 30, 2012 at p. 34 in docket ID number EPA-HQ-OPP-2011-0300.

B. Toxicological POD/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological POD and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). 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 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 difenoconazole used for human risk assessment is discussed in Unit III. B. of the final rule published in the **Federal Register** of June 15, 2011 (76 FR 34877) (FRL-8876-4).

C. Exposure Assessment

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

Such effects were identified for difenoconazole. 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 used an unrefined acute analysis for food and water that assumed tolerance-level residues, 100 percent crop treated (PCT), and the available empirical or dietary exposure evaluation model (DEEM^{TM} version 7.81) 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, a refined chronic analysis for food and water assumed tolerance-level residues for some commodities, average field trial residues for the majority of

commodities, the available empirical or DEEM™ version 7.81 default processing factors, and 100 PCT.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to difenoconazole. A separate quantitative cancer exposure assessment is unnecessary since the NOAEL (4.7 and 5.6 mg/kg/day in males and females, respectively) to assess cancer risk is higher than the NOAEL (0.96 and 1.27 mg/kg/day in males and females, respectively) to assess chronic risks and exposure for the purpose of assessing cancer risk would be no higher than chronic exposure. Therefore, the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residue and PCT information*. EPA did not use PCT information in the dietary assessment for difenoconazole and assumed 100 PCT. EPA used anticipated residues in the form of average field trial residues for the majority of commodities in the chronic dietary exposure assessment.

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 difenoconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of difenoconazole. 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 the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) for registered and proposed new uses and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of difenoconazole for acute exposures are estimated to be 17.4 parts per billion (ppb) for surface water and 0.0128 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 11.8 ppb for surface water and 0.0128 ppb for ground water.

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

For acute dietary risk assessment, the water concentration value of 17.4 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 11.8 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/golf course turf. EPA assessed residential exposure using the following assumptions: Adults may be exposed to difenoconazole from its currently registered use on ornamentals. Residential pesticide handlers may be exposed to short-term duration (1-30 days) only. The dermal and inhalation (short-term) residential exposure was assessed for homeowners mixer/loader/applicator wearing short pants and short-sleeved shirts as well as shoes plus socks using garden hose-end sprayer, pump-up compressed air sprayer, and backpack sprayer.

Residential post-application exposure may occur from use of difenoconozole on golf course turf. Short-term dermal exposure was assessed for post-application exposure to golf course turf. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the

same, or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some events are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's Web sites at: *http://www.epa.gov/pesticides/cumulative* and *http://www.epa.gov/fedrgstr/EPA_PEST/2002/January/Day_16/.*

Difenoconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including difenoconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the

additional 10x Food Quality Protection Act (FQPA) safety factor (SF) for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket Identification (ID) Number EPA-HQ-OPP-2005-0497. The requested amended uses of difenoconazole resulted in an increase in dietary exposure estimates for free triazole or conjugated triazoles. Therefore, updated dietary exposure analyses were conducted. The most recent update for triazoles may be found in docket ID number EPA-HQ-OPP-2011-0300.

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 SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. EPA determined that the available data indicated 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 2-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental

animals. In the prenatal developmental toxicity study in rats, maternal toxicity was manifested as decreased body weight gain and food consumption at the LOAEL of 85 mg/kg/day; the NOAEL was 16 mg/kg/day. Developmental toxicity in this study 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 was manifested as decreased body weight gain and decreased 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 F_1 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 is complete except for results of a recently submitted immunotoxicity study required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration. However, the existing toxicology database for difenoconazole does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. Accordingly, the Agency does not believe that findings from the ongoing review of the immunotoxicity study will result in a lower POD than that currently in use for overall risk assessment, and therefore, a database uncertainty factor is not needed to account for lack of this study.

ii. The acute and subchronic neurotoxicity studies in rats are available. These data show that difenoconazole exhibits some evidence of neurotoxicity, but the effects are transient or occur at the limit dose. EPA concluded that difenoconazole is not a neurotoxic compound. Based on the toxicity profile, and lack of neurotoxicity, a developmental neurotoxicity study in rats is not required.

iii. There is no evidence that difenoconazole results in increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data.

iv. There are no residual uncertainties identified in the exposure databases. A conservative dietary food exposure assessment was conducted. Acute dietary food exposure assessments were performed based on tolerance-level residues, 100 PCT, and the available empirical or (DEEM^{TM} version 7.81) default processing factors.

Chronic dietary exposure assessments were based on tolerance-level residues for some commodities, average field trial residues for the majority of commodities, the available empirical or (DEEM^{TM} version 7.81) default processing factors, and 100 PCT. These are conservative approaches and are unlikely to understate the residues in food commodities.

EPA also made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to difenoconazole in drinking water. Post-application residential exposure of children is not expected. 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer 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 appropriate PODs to ensure that an adequate MOE exists.

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 27% of the aPAD for children 1 to 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 utilize75% of the cPAD for children 1 to 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 is 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 uses 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 result in aggregate MOEs of 200 or greater. Because EPA's level of concern for difenoconazole is a MOE of 100 or below, these MOEs are not of concern.

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).

An intermediate-term adverse effect was identified; however**,** difenoconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for difenoconazole**.**

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., the chronic dietary risk assessment is protective of any potential 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 enforcement methodology, gas chromatography with nitrogen/phosphorus detection (GC/NPD) method AG-575B, is available to enforce the tolerance expression for residues of difenoconazole in/on plant commodities. An adequate enforcement method, liquid chromatography coupled with tandem mass spectrometry (LC/MS/MS) method REM 147.07b, is available for the determination of residues of difenoconazole and CGA-205375 in livestock commodities. Adequate confirmatory methods are also available.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex maximum residue levels (MRLs) for residues of difenoconazole *per se* have been established at 0.5 ppm for tomato; 0.5 ppm for pome fruits; and 0.02 ppm for

potato. Based on the available magnitude of the residue data, harmonization with these established Codex MRLs is not possible because, the Codex MRLs are too low to adequately cover residues resulting from the proposed use rates in the United States. Canadian MRLs for residues of difenoconazole have been established at 0.6 ppm for a number of fruiting vegetables and 1.0 ppm for a number of pome fruit, and are in agreement with proposed U.S. tolerances. The data for vegetable, tuberous and corm, subgroup 1C at 4.0 ppm was a joint review between EPA and the Health Canada Pest Management Regulatory Agency (PMRA). The two agencies are in agreement regarding tolerance level for subgroup 1C.

C. Revisions to Petitioned-For Tolerances

The Petitioner proposed removal of the established tolerance in or on potato, processed waste at 0.04 ppm. However, the Agency has determined that this tolerance needs to be retained and raised to 7.3 ppm. Further, the commodity definition should be changed to potato, wet peel. The potato processing data indicate that residues of difenoconazole do not concentrate in flakes and chips but do concentrate in wet peel. Based on the highest-average-field-trial value for residues in/on potatoes (2.34 ppm) and the average processing factor (3.1x), expected residues could be as high as 7.3 ppm in potato, wet peel. Because this value is higher than the recommended 4.0 ppm tolerance for vegetable, tuberous and corm, subgroup 1C, a separate tolerance is needed in potato, wet peel at 7.3 ppm.

The Petitioner's proposed commodity terminology for berry, low growing, subgroup 13-07G, except cranberry was corrected to comply with current crop terminology policy.

V. Conclusion

Therefore, tolerances are established for residues of difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4,-triazole, including its metabolites and degradates, in or on Berry, low growing, subgroup 13-07G, except cranberry at 2.5 ppm, Fruit, citrus, group 10-10 at 0.60 ppm, Fruit, pome, group 11-10 at 1.0 ppm, and Vegetable, fruiting, group 8-10 at 0.60 ppm; and by revising the established tolerance in or on Vegetable, tuberous and corm, subgroup 1C at 0.01 ppm by increasing the residue level to 4.0 ppm. The difenoconazole tolerances are further amended by correcting the commodity terminology for Potato, processed waste to read Potato, wet peel and increasing the tolerance level from 0.04 ppm to 7.3 ppm. In addition, this regulation removes established tolerances in or on Vegetables, fruiting, group 8, Fruit, citrus, group 10, Fruit, pome, group 11 and Strawberry, as these commodities are included in new crop groups or subgroups for which tolerances are established by this action.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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: July 11, 2012

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, the table to paragraph (a)(1) is amended as follows:

i. Remove the entries for "Fruit, citrus, group 10," "Fruit, pome, group 11," "Potato, processed waste," "Strawberry," and "Vegetables, fruiting, group 8."

ii. Add alphabetically new entries for Berry, low growing, subgroup 13-07G, except cranberry; Fruit, citrus, group 10-10; Fruit, pome, group 11-10; Potato, wet peel; and Vegetable, fruiting, group 8-10, as shown below.

iii. Revise the entry in the table to paragraph (a)(1) for "Vegetable, tuberous and corm, subgroup 1C".

The added and revised text read as follows:

§ 180.475 Difenconazole, tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Berry, low growing, subgroup 13-07G, except cranberry	2.5

* * * * *	
Fruit, citrus, group 10-10	0.60
Fruit, pome, group 11-10	1.0
* * * * *	
Potato, wet peel	7.3
* * * * *	
Vegetable, fruiting, group 8-10	0.60
Vegetable, tuberous and corm, subgroup 1C	4.0

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