Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant energy action,'' this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

In reviewing state submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a state submission, to use VCS in place of a state submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this action. In reviewing SIP submissions, EPA's role is to approve or disapprove state choices, based on the criteria of the CAA. Accordingly, this action merely disapproves certain state requirements for inclusion into the SIP under section 110 and subchapter I, part D of the CAA and will not in-and-of itself create any new requirements. Accordingly, it does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 26, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter.

Dated: August 14, 2015.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 52.745 is amended by revising paragraphs (c) and (e) to read as follows:

§ 52.745 Section 110(a)(2) infrastructure requirements.

* * * * *

(c) Approval and Disapproval—In an August 9, 2011, submittal, and supplemented on August 25, 2011, and June 27, 2012, Illinois certified that the State has satisfied the infrastructure SIP requirements of section 110(a)(2)(A) through (H), and (J) through (M) for the 2006 24-hour $PM_{2.5}$ NAAQS. EPA is approving Illinois' submission addressing the infrastructure SIP requirements of section 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(II) with respect to visibility protection, (D)(ii), (E) except for state board requirements, (F) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M). EPA is not taking action on (D)(i)(I). EPA is disapproving the state board requirements of (E)(ii). EPA is disapproving Illinois' submission addressing PSD in (C), (D)(i)(II), and the PSD portion of (J). Although EPA is disapproving portions of Illinois' submission addressing PSD, Illinois continues to implement the Federally promulgated rules for this purpose as they pertain to (C), (D)(i)(II), and the PSD portion of (J).

* * * * *

(e) Approval and Disapproval—In a December 31, 2012, submittal, Illinois certified that the State has satisfied the infrastructure SIP requirements of section 110(a)(2)(A) through (H), and (J) through (M) for the 2008 ozone NAAQS except for 110(a)(2)(D)(i)(I). EPA is approving Illinois' submission addressing the infrastructure SIP requirements of section 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(II) with respect to visibility protection, (D)(ii), (E) except for state board requirements, (F) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M). EPA is disapproving the state board requirements of (E)(ii). EPA is disapproving Illinois' submission addressing PSD in (C), (D)(i)(II), and the PSD portion of (J). Although EPA is disapproving portions of Illinois' submission addressing PSD, Illinois continues to implement the Federally promulgated rules for this purpose as they pertain to (C), (D)(i)(II), and the PSD portion of (J).

* * * * *

[FR Doc. 2015–21010 Filed 8–25–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0470; FRL–9929–61]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on artichoke, globe; ginseng; fruit, stone, group 12–12; and nut, tree, group 14–12. This regulation additionally removes existing tolerances in or on fruit, stone, group 12; nut, tree, group 14; and pistachio. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 26, 2015. Objections and requests for hearings must be received on or before October 26, 2015, 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–2014–0470, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., 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: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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://www.ecfr.gov/cgi-bin/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–2014–0470 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 October 26, 2015. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0470, 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 CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (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.html.*

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 September 5, 2014 (79 FR 53009) (FRL–9914–98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3),announcing the filing of a pesticide petition (PP 4E8274) by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 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 ginseng at 0.50 parts per million (ppm); artichoke, globe at 1.5 ppm; fruit, stone, group 12–12 at 2.5 ppm; and nut, tree, group 14–12 at 0.03 ppm. That document referenced a summary of the petition prepared on behalf of IR–4 by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance in or on ginseng. The reason for this change is 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 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 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.

Subchronic and chronic studies with difenoconazole in mice and rats showed decreased body weights, decreased body weight gains and effects on the liver (*e.g.* hepatocellular hypertrophy, liver necrosis, fatty changes in the liver). No systemic toxicity was observed at the limit dose in the most recently submitted rat dermal toxicity study.

The available toxicity studies indicated no increased susceptibility of rats or rabbits from *in utero* or postnatal exposure to difenoconazole. In prenatal developmental toxicity studies in rats and rabbits and in the 2-generation reproduction study in rats, fetal and offspring toxicity, when observed, occurred at equivalent or higher doses than in the maternal and parental animals.

In a rat developmental toxicity study, developmental effects were observed at doses higher than those which caused maternal toxicity. Developmental effects in the rat included increased incidence of ossification of the thoracic vertebrae and thyroid, decreased number of sternal centers of ossification, increased number of ribs and thoracic vertebrae, and decreased number of lumbar vertebrae. In the rabbit study, developmental effects (increases in post-implantation loss and resorptions and decreases in fetal body weight) were also seen at maternally toxic doses (decreased body weight gain and food consumption). In the 2-generation reproduction study in rats, toxicity to the fetuses and offspring, when observed, occurred at equivalent or higher doses than in the maternal and parental animals.

In an acute neurotoxicity study in rats, reduced fore-limb grip strength was observed on day one in males at the lowest-observed-adverse-effect-level (LOAEL), and clinical signs of neurotoxicity were observed in females only at the highest dose tested. In a subchronic neurotoxicity study in rats, decreased hind limb strength was observed in males only at the mid- and high-doses. The effects observed in acute and subchronic neurotoxicity studies were considered transient. Although there is some evidence that difenoconazole affects antibody levels at doses that cause systemic 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 nonlinear reference dose (RfD) 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 carcinoma tumors were only induced at excessively-high doses. Adenomas (benign tumors) and liver necrosis only were seen at 300 ppm (46 and 58 milligram/kilogram/day (mg/kg/day) in males and females, respectively). Based on excessive toxicity observed at the two highest doses in the mouse carcinogenicity 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 no-observed-adverse-effect-level (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). EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to difenoconazole and a separate quantitative cancer exposure assessment is unnecessary since the chronic dietary risk estimate will be protective of potential cancer risk.

Specific information on the studies received and the nature of the adverse effects caused by difenoconazole as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Difenoconazole: Human Health Risk Assessment for Proposed New Foliar Uses on Globe Artichoke, Ginseng and Greenhouse Grown Cucumbers and Conversion of the Established Foliar Uses/Tolerances for Stone Fruit Group 12 and Tree Nut Crop Group 14 to Stone Fruit Group 12–12 and Tree Nut Group 14–12.'' at pp. 36–43 in docket ID number EPA–HQ–OPP–2014–0470.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological POD and levels of concern 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 the NOAEL and the LOAEL are identified. 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 an 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 April 2, 2015 (80 FR 17697) (FRL–9923–82).

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) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed

tolerance level residues and 100 percent crop treated (PCT) information.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA used USDA Pesticide Data Program (PDP) monitoring data, average field trial residues for some commodities, tolerance level residues for the remaining commodities, average PCT for some commodities, and 100 PCT for the remaining commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized.

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. Therefore, a separate quantitative cancer exposure assessment is unnecessary since the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide 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.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the chronic dietary exposure analysis, the Agency estimated the PCT for existing uses as follows:

Almond, 5%; cabbage, 2.5%; cucumber, 5%; garlic, 5%; grape, 5%; grapefruit, 2.5%; onion, 5%; orange, 2.5%; peach, 1%; pecan, 2.5%; pepper, 2.5%; pistachio, 2.5%; pumpkin, 2.5%; squash, 5%; strawberry, 2.5%; sugar beet, 15%; tangerine, 2.5%; tomato, 25%; walnut, 2.5%; watermelon, 5%; and wheat, 10%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which difenoconazole may be applied in a particular area.

2. *Dietary exposure from drinking water.* The drinking water assessment was performed using a total toxic residue method, which considers both parent difenoconazole and its major metabolite, CGA 205375, in surface and groundwater. Therefore, the Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for difenoconazole and its major metabolite in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of difenoconazole and CGA 205375. 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 Surface Water Concentration Calculator (SWCC), Screening Concentration in Ground Water (SCI–GROW), and Pesticide Root Zone Model Ground Water (PRZM GW) models, the combined estimated drinking water concentrations (EDWCs) of difenoconazole and CGA 205375 are estimated to be 20.0 parts per billion (ppb) for surface water and 1.77 ppb for ground water. For chronic exposure assessments, EDWCs are estimated to be 13.6 ppb for surface water; EDWCs were not detected for ground water for chronic assessments.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 20.0 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 13.6 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: Treatment of ornamental plants in commercial and residential landscapes and interior plantscapes. EPA assessed residential exposure using the following assumptions: For residential handlers, adult short-term dermal and inhalation exposure is expected from mixing, loading, and applying difenoconazole on ornamentals (gardens and trees). For residential post-application exposures, short-term dermal exposure is expected for both adults and children from post-application activities in treated residential landscapes.

The scenarios used in the aggregate assessment were those that resulted in the highest exposures. The highest exposures consist of the short-term dermal exposure to adults from post-application activities in treated gardens and short-term dermal exposure to children 6 to 11 years old from post-application activities in treated gardens. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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). This document may be found at EPA's Web site at *http://www.epa.gov/oppfead1/trac/science/cumulativeguidance.pdf.*

In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles 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 site at *http://www.epa.gov/pesticides/cumulative.*

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 Safety Factor (FQPA 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 complete risk assessment may be found in the propiconazole reregistration docket at *http://www.regulations.gov,* docket ID Number EPA–HQ–OPP–2005–0497. The Agency's latest complete risk assessment for the triazole-containing metabolites was finalized on April 9, 2015 and is entitled, ''Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address The New Section 3 Registrations For Use of Propiconazole on Tea, Dill, Mustard Greens, Radish, and Watercress; Use of Difenoconazole on Globe Artichoke, Ginseng and Greenhouse Grown Cucumbers and Conversion of the Established Foliar Uses/Tolerances for Stone Fruit and Tree Nut Crop Groups to Fruit, Stone, Group 12–12 and the Nut, Tree, Group 14–12.; and Use of Flutriafol on Hops.'' The assessment may be found in the propiconazole reregistration docket at *http://www.regulations.gov,* docket ID number EPA–HQ–OPP–2014–0470.

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 prenatal and postnatal toxicology database for difenoconazole includes rat and rabbit prenatal developmental toxicity studies and a 2-generation reproduction toxicity study in rats. The available Agency guideline studies indicated no increased qualitative or quantitative 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 a rat developmental toxicity study developmental effects were observed at doses higher than those which caused maternal toxicity. In the rabbit study, developmental effects (increases in post-implantation loss and resorptions and decreases in fetal body weight) were also seen at maternally toxic doses (decreased body weight gain and food consumption). In 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.

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 complete.

ii. There are no clear signs of neurotoxicity following acute, subchronic, or chronic exposure in multiple species in the difenoconazole

study database. The effects observed in acute and subchronic neurotoxicity studies are transient, and the dose-response is well characterized with identified NOAELs. Based on the toxicity profile, and lack of concern for neurotoxicity, there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that difenoconazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary risk assessment utilized tolerance level residues and 100 PCT for the acute assessment; the chronic assessment was refined by using USDA PDP monitoring data, average field trial residues for some commodities, tolerance level residues for remaining commodities, and average PCT for some commodities. These assumptions will not underestimate dietary exposure to difenoconazole. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to difenoconazole in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children. 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 49% of the aPAD for all infants less than 1 year 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 89% 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 170 for adults and 190 for children. 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.* Based on the data summarized in Unit III.A., the chronic dietary risk assessment is protective of any potential cancer effects. Based on the results of that assessment, EPA concludes that difenoconazole is not expected to pose a cancer risk to humans.

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 for the determination of residues of difenoconazole *per se* in or on plant commodities. Liquid chromatography 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.

The Codex has not established a MRL in or on artichoke, globe. Codex has established the following MRLs for difenoconazole: Ginseng at 0.08 ppm; dried and red ginseng at 0.2 ppm; ginseng extracts at 0.6 ppm; cherry and plum, including prune at 0.2 ppm; nectarine and peach at 0.5 ppm; and tree nut at 0.03 ppm. The MRL for tree nut at 0.03 ppm is the same as the tolerance being established for difenoconazole in the United States for nut, tree, group 14–12 at 0.03 ppm. Based on the data reviewed in conjunction with this action, harmonization with Codex MRLs is not possible for ginseng and stone fruit

commodities (including cherry, nectarine, peach, plum, and prune). The data supporting the EPA petition support the establishment of tolerance levels that are higher than the established Codex MRLs. The U.S. tolerances are being recommended by EPA are as follows: Ginseng at 1.0 ppm; and fruit, stone, group 12–12 at 2.5 ppm.

C. Response to Comments

Several comments were received in response to the notice of filing. All but one were concerned with potential environmental impacts, and were not specifically related to the difenoconazole action. EPA notes that these comments address potential environmental concerns; however, the safety standard for approving tolerances under section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

One additional comment was received that did not specifically address the difenoconazole action, but that raised concerns about the toxicity of pesticides and requested that no tolerance be established. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by Section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. EPA has found that there is a reasonable certainty of no harm to humans after considering the toxicological studies and the exposure levels of humans to difenoconazole.

D. Revisions to Petitioned-for Tolerances

Based on the data supporting the petition, EPA determined that the proposed tolerance in or on ginseng at 0.50 ppm should be established at 1.0 ppm. Residues of difenoconazole appeared to increase significantly with a pre-harvest interval (PHI) longer than the proposed 0-day PHI. Average per-trial residues increased by a factor of as much as 2.3x between the 0- and 21-day PHIs and based on this finding, EPA determined that average per-trial residues of difenoconazole for trials reflecting a 0-day PHI should be adjusted by a factor of 2.3x to account for the maximum demonstrated increase in difenoconazole residues resulting from PHIs longer than the proposed 0-day PHI. Therefore, the adjusted residues were used in the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures, resulting in the recommend tolerance in or on ginseng at 1.0 ppm.

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]-1H–1,2,4-triazole, in or on artichoke, globe at 1.5 ppm; ginseng at 1.0 ppm; fruit, stone, group 12–12 at 2.5 ppm; and nut, tree, group 14–12 at 0.03 ppm. Additionally, this regulation removes the established tolerances for residues of difenoconazole in or on fruits, stone group 12 at 2.5 ppm; nut, tree, group 14 at 0.03 ppm; and pistachio at 0.03 ppm.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 13, 2015.

Susan Lewis,

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. In § 180.475:

■ a. Remove the entries ''Fruits, stone, group 12''; ''Nut, tree, group 14''; and ''Pistachio'' from the table in paragraph (a)(1).
■ b. Add alphabetically the following commodities to the table in paragraph (a)(1).

The amendments read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* * * * *	
Artichoke, globe	1.5
* * * * *	
Fruit, stone, group 12–12	2.5
Ginseng	1.0
* * * * *	
Nut, tree, group 14–12	0.03
* * * * *	

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[FR Doc. 2015–21078 Filed 8–25–15; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202, 204, 212, 239, and 252

[Docket No. DARS–2015–0039]

RIN 0750–AI61

Defense Federal Acquisition Regulation Supplement: Network Penetration Reporting and Contracting for Cloud Services (DFARS Case 2013–D018)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule.

SUMMARY: DoD is issuing an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2013 and a section of the National Defense Authorization Act for Fiscal Year 2015, both of which require contractor reporting on network penetrations. Additionally, this rule implements DoD policy on the purchase of cloud computing services.

DATES: Effective August 26, 2015.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before October 26, 2015 to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2013–D018, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2013–D018'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2013–D018.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2013–D018'' on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2013–D018 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Mr. Dustin Pitsch, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Dustin Pitsch, OUSD(AT&L)DPAP/DARS, telephone 571–372–6090.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule requires contractors and subcontractors to report cyber incidents that result in an actual or potentially adverse effect on a covered contractor information system or covered defense information residing therein, or on a contractor's ability to provide operationally critical support. DoD is working to establish a single reporting mechanism for DoD contractor reporting of cyber incidents on unclassified information systems. This rule is intended to streamline the reporting process for DoD contractors and minimize duplicative reporting processes. Cyber incidents involving classified information on classified contractor systems will continue to be reported in accordance with the National Industrial Security Program Operating Manual (see DoD–M 5220.22 available at *http://www.dtic.mil/whs/directives/corres/pdf/522022m.pdf*).

The rule revises the DFARS to implement section 941 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112–239) and section 1632 of the NDAA for FY 2015. Section 941 of the NDAA for FY 2013 requires cleared defense contractors to report penetrations of networks and information systems and allows DoD personnel access to equipment and information to assess the impact of reported penetrations. Section 1632 of the NDAA for FY 2015 requires that a contractor designated as operationally critical must report each time a cyber incident occurs on that contractor's network or information systems.

In addition, this rule also implements DoD policies and procedures for use when contracting for cloud computing services. The DoD Chief Information Officer (CIO) issued a memo on December 15, 2014, entitled ''Updated Guidance on the Acquisition and Use of Commercial Cloud Computing Services'' to clarify DoD guidance when acquiring commercial cloud services (See memo here: *http://iase.disa.mil/cloud_security/Pages/docs.aspx*). The DoD CIO also released a Cloud Computing Security Requirements Guide (SRG) Version 1, Release 1 on January 13, 2015, for cloud service providers to comply with when providing the DoD with cloud services (See SRG here: *http://iase.disa.mil/cloud_security/Pages/index.aspx*). This rule implements these new policies developed within the DoD CIO memo and the SRG in the DFARS to ensure uniform application when contracting for cloud services across the DoD. The combination of the two statutes as well as the cloud computing policy will serve to increase the cyber security requirements placed on DoD information in contractor systems and will help the DoD to mitigate the risks related to compromised information as well as gather information for future improvements in cyber security policy.

II. Discussion and Analysis

To implement section 941 of the NDAA for FY 2013 and section 1632 of the NDAA for FY 2015, an existing DFARS subpart and clause have been utilized and expanded upon, and a new provision and clause added. A new subpart, provision, and clause are added for the implementation of cloud contracting policies.

(1) DFARS subpart 204.73 is modified to expand safeguarding and reporting policy to require protection of covered defense information, which includes controlled technical information, export controlled information, critical