TABLE 1 TO SUBPART DDDDDD OF PART 63—EMISSION LIMITS AND STANDARDS FOR EXISTING AFFECTED SOURCES—Continued

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
Stripped resin	Vinyl chloride	Bulk resin	7.1 parts per million by weight (ppmw).
		Dispersion resin	1,500 ppmw.
		Suspension resin	36 ppmw.
		Suspension blending resin	140 ppmw.
		Copolymer resin	790 ppmw.
	Total non-vinyl chloride organic HAP.	Bulk resin	170 ppmw.
		Dispersion resin	320 ppmw.
		Suspension resin	36 ppmw.
		Suspension blending resin	500 ppmw.
		Copolymer resin	1,900 ppmw.
Process Wastewater	Vinyl chloride	All resin types	2.1 ppmw.

[a] Emission limits at 3-percent oxygen, dry basis.
[b] Affected sources have the option to comply with either the total hydrocarbon limit or the total organic HAP limit.

■ 3. Table 2 to Subpart DDDDDD of Part 63 is revised to read as follows:

TABLE 2—TO SUBPART DDDDDD OF PART 63—EMISSION LIMITS AND STANDARDS FOR NEW AFFECTED SOURCES

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
PVC-only process vents[a]	Vinyl chloride	All resin types	5.3 parts per million by volume (ppmv).
	Total hydrocarbons	All resin types	46 ppmv measured as propane.
	Total organic HAP[b]	All resin types	140 ppmv.
	Dioxins/furans (toxic equivalency basis).	All resin types	0.13 nanograms per dry standard cubic meter (ng/dscm).
PVC-combined process vents[a]	Vinyl chloride	All resin types	0.56 ppmv.
	Total hydrocarbons	All resin types	2.3 ppmv measured as propane.
	Total organic HAP[b]	All resin types	29 ppmv.
	Dioxins/furans (toxic equivalency basis).	All resin types	0.076 ng/dscm.
Stripped resin	Vinyl chloride	Bulk resin	7.1 parts per million by weight (ppmw).
		Dispersion resin	1,500 ppmw.
		Suspension resin	36 ppmw.
		Suspension blending resin	140 ppmw.
		Copolymer resin	790 ppmw.
	Total non-vinyl chloride organic HAP.	Bulk resin	170 ppmw.
		Dispersion resin	320 ppmw.
		Suspension resin	36 ppmw.
		Suspension blending resin	500 ppmw.
		Copolymer resin	1,900 ppmw.
Process Wastewater	Vinyl chloride	All resin types	2.1 ppmw.

[a] Emission limits at 3 percent oxygen, dry basis.
[b] Affected sources have the option to comply with either the total hydrocarbon limit or the total organic HAP limit.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0151; FRL–9920–98]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on rapeseed subgroup 20A, and dragon fruit. Syngenta Crop Protection requested the rapeseed subgroup 20A tolerance, and Dragonberry/YW International Produce requested the dragonfruit tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 4, 2015. Objections and requests for hearings must be received on or before April 6, 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–2013–0151, 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; 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.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2013–0151 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 April 6, 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–2013–0151, 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 June 5, 2013 (78 FR 33785) (FRL–9386–2), 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 2F8134) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.475 be amended by establishing a tolerance 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 rapeseed subgroup 20A at 0.1 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which was inadvertently missing from the docket in *http://www.regulations.gov.* Because the summary of the petition was missing from the docket, the announcement was republished in the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL–9918–90), with a new comment period. There were no comments received in response to the original notice of filing, but one comment was received on the republished notice of filing. EPA's response to this comment is discussed in Unit IV.C.

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL–9918–90), 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 (4E8296) by Dragonberry/YW International Produce, Inc., 386 S. Sequoia Parkway, Canby, Oregon 97013. The petition requested that 40 CFR 180.475 be amended by establishing tolerances for residues of the fungicide difenoconazole, [1-[2-[2-chloro-4(4-chlorophenoxy) phenyl]-4 methyl-1,3-dioxolan-2-ylmethyl]1H-1,2,4-triazole, in or on dragon fruit at 1.5 ppm. That document referenced a summary of the petition prepared by Dragonberry/YW International Produce, 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 the petition, EPA has changed the requested rapeseed subgroup 20A tolerance from 0.1 ppm to 0.10 ppm, and is also removing the current tolerance for canola, seed. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

aggregate exposure to the pesticide chemical residue. . . .''

Consistent with 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.

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. 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 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 ppm (46 and 58 milligrams/kilograms/day (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 mid-dose, the absence of tumors at the study's lower dose, 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 NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are found in the document, ''Difenoconazole: Human Health Risk Assessment for New Foliar Use and Tolerance in/on Rapeseed subgroup 20A and New Foliar Use on Imported Dragonfruit'' in docket ID number EPA–HQ–OPP–2013–0151.

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

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food EPA used tolerance-level residues for some commodities, average field trial residues for the majority of commodities, and the available empirical or Dietary Exposure Evaluation Model (DEEM) (ver. 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. 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 percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT

information in the dietary assessment for difenoconazole. EPA used average field trial residues for some commodities, tolerance level residues for the other commodities, and 100 PCT.

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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) for registered and proposed new uses as well as Pesticide Root Zone Model for Groundwater (PRZM–GW) and Screening Concentration In Ground Water (SCI–GROW) models the maximum estimated drinking water concentrations (EDWCs) of difenoconazole for acute exposures are estimated to be 20.0 parts per billion (ppb) for surface water and 2.24 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 13.6 ppb for surface water and 0.82 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 20.0 ppb was used to assess the contribution to drinking water. For chronic dietary risk assess the water concentration 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: Ornamentals and 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 homeowner's 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 difenoconazole 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 procedure s 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/Day16/.*

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 pesticide, including difenoconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylanine, 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 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 most recent update for the triazoles is found in the docket for this rapeseed action at *http://www.regulations.gov,* Docket ID Number EPA–HQ–OPP–2013–0151.

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 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 the 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 decreased 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 dosing in multiple species in the difenoconazole 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 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. 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 as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by difenoconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic 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 29% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to difenoconazole from food and water will utilize 78% of the cPAD for children 1–2 years old the population group receiving the greatest exposure.

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 160. Because EPA's level of concern (LOC) for difenoconazole is 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).

Because no intermediate-term adverse effect was identified, difenoconazole is not expected to pose an intermediate-term risk.

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. 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

An adequate enforcement method, Gas chromatography/Nitrogen-Phosphorus Detector (GC/NPD) method AG–575B, is available for the determination of residues of difenoconazole *per se* in/on plant commodities. An adequate enforcement method, Liquid chromatography/Mass Spectrometry/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 method 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.

A Codex MRL is established for residues of difenoconazole in or/on rapeseed at 0.05 mg/kg based on data reflecting foliar use of difenoconazole, but with a significantly longer pre-harvest intervals than currently proposed in the U.S. The Codex MRL

would not be adequate to cover residues expected from the proposed use in the U.S., therefore, harmonization with Codex is not possible at this time.

There is no Codex MRLs for difenoconazole in/on dragonfruit.

C. Response to Comments

EPA received one comment to the republished Notice of Filing for the petition requesting that EPA establish a rapeseed subgroup 20A tolerance that stated, in part, that no residue should be allowed for difenoconazole. 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 the Agency determines 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.

D. Revisions to Petitioned-For Tolerances

EPA has changed the requested rapeseed subgroup 20A tolerance from 0.1 to 0.10 ppm to be consistent with the tolerance setting procedures which involve using two significant numbers after the decimal point. EPA is also removing the current tolerance for canola, seed at 0.01 ppm because canola is included in the Rapeseed subgroup 20A crops and the tolerance being established for this group at 0.10 ppm will supersede the lower tolerance for canola seed treatment.

V. Conclusion

Therefore, tolerances are established for residues of difenoconazole, [1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-4methyll-[1,3]dioxolan-2-ylmethyl]-1H-[1,2,4]triazole, in or on rapeseed subgroup 20A at 0.10 ppm, and dragonfruit which is imported, at 1.5 ppm. Also, the current tolerance for canola, seed is being removed.

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: January 28, 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 Section 180.475:

■ a. Remove the entry for ''Canola, seed''.

■ b. Add alphabetically the following commodities to the table to paragraph (a)(1).

§ 180.475 Difenoconazole; Tolerance for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Dragonfruit [1]	1.5
* * * * *	
Rapeseed subgroup 20A	0.10
* * * * *	

[1] There are no U.S. registrations.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0482; FRL–9922–06]

Flutriafol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).