BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0496; FRL-9931-06]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil in or on carrots, the stone fruit group 12-12, and the rapeseed subgroup 20A, except flax seed. Interregional Research Project Number 4 (IR-4) requested the tolerances for carrots and the stone fruit group 12-12, and Syngenta Crop Protection requested the tolerance for the rapeseed subgroup 20A under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0496, 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-2014-0496 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (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-2014-0496, 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 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 (PP 4E8272) by IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide fludioxonil [4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile] in or on the raw agricultural commodity carrot at 7.0 ppm, and by changing the existing entry for ''fruit, stone, group 12 at 5.0 ppm'' to ''fruit, stone, group 12–12 at 5.0 ppm." That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov*.

In the **Federal Register** of October 24, 2014 (79 FR 63594) (FRL-9916-03), 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 4F8277) by Syngenta Crop Protection, LLC, 410 Swing Rd., Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide fludioxonil in or on the rapeseed subgroup 20A, except flax seed at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, 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.

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 fludioxonil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fludioxonil 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.

In all species tested, the effects in the fludioxonil database are indicative of toxicity to the liver and kidney. The hematopoietic system was also a target in dogs. There were also decreased body weights and clinical signs throughout the database. Fludioxonil was non-toxic through the dermal route, and there was no evidence of immunotoxicity when tested up to and including the limit dose. Fludioxonil was not mutagenic in the tests for gene mutations.

In a rat developmental toxicity study, fludioxonil caused an increase in fetal incidence and litter incidence of dilated renal pelvis at the limit dose (1,000 mg/kg/day). These effects are

known to occur spontaneously in the rat, in addition to being transient and reversible which is consistent with the fludioxonil hazard database (not seen in offspring in the 2-generation reproductive study). Under current policy, the agency considers classification of these effects as treatment-related but conservative and not indicative of increased fetal susceptibility. Maternal toxicity occurred at the same dose and manifested as body weight decrements. In the 2-generation reproduction study, parental and offspring effects occurred at the same dose and consisted of decreased body weights in parental and offspring animals, as well as increased clinical signs in parental animals.

There was no evidence of carcinogenicity in male or female CD-1 mice and male Sprague-Dawley rats following dietary administration at doses that were adequate for assessing the carcinogenic potential of fludioxonil. In female Sprague-Dawley rats, there was a statistically significant increase in tumor incidence only when hepatocellular adenomas and carcinomas were combined (not for individual tumor types). The pairwise increase for combined tumors was significant at p=0.03, which is not a strong indication of a positive effect. Further, statistical significance was only found when liver adenomas were combined with liver carcinomas. Finally, the increase in these tumors was within, but at the high-end, of the historical controls. Based on these findings and in accordance with the Agency's 1986 "Guidelines for Carcinogen Risk Assessment," fludioxonil was classified as a Group D carcinogen; therefore, there is no need for a quantitative cancer risk assessment.

Specific information on the studies received and the nature of the adverse effects caused by fludioxonil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in the document titled "Fludioxonil. Section 3 Registration for Use

on Carrots, Stone Fruit, Group 12-12, and Rapeseed, Subgroup 20A. Human Health Risk Assessment" at page 28 in docket ID number EPA-HQ-OPP-2014-0496.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (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 no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for fludioxonil used for human risk assessment is shown in Table 1 of this unit. Since the last assessment in 2012, (August 15, 2012) (77 FR 48907) (FRL-9357-5), the Agency has reevaluated the toxicological endpoints. Based upon current policy, it was determined that an acute dietary assessment was no longer necessary for fludioxonil. This decision was based upon the following weight of evidence: (1) after re-evaluation of the hazard database, it was determined that there were no effects that could be attributed to single dose and (2) the fetal effects in the developmental rat study occurred only

at the limit dose (1,000 mg/kg/day). Additionally, though the same study is being used to assess chronic dietary risk, the NOAEL and LOAEL have been reclassified. Further, the remaining endpoints for short-term incidental oral toxicity and short-term inhalation toxicity have changed as well.

Table 1.--Summary of Toxicological Doses and Endpoints for Fludioxonil for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	There were no appropriate toxicological effects attributable to a single exposure (dose) observed in available oral toxicity studies, including maternal toxicity in the developmental toxicity studies. Therefore, a dose and endpoint were not identified for this risk assessment.		
Chronic dietary (All populations)	NOAEL= 33.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.33 mg/kg/day cPAD = 0.33 mg/kg/day	Chronic toxicity in dogs- LOAEL = 297.8 mg/kg/day based upon decreased absolute body weights, increased platelets and fibrin in both sexes, cholesterol in males, and increased alkaline phosphatase release in both sexes. Enlarged livers in two females were observed along with biliary epithelial cell proliferation in one female.

Incidental oral short-term (1 to 30 days)	NOAEL= 50 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic toxicity in dogs- LOAEL = 250 mg/kg/day based upon decreased absolute body weights in both sexes, diarrhea, hematological alterations (increased platelets and fibrin, decreased red cells, hemoglobin, and packed cell volume), clinical chemistry alterations (increased alpha-1 and alpha-2 globulin in females), increased liver weights in both sexes, increased testes and ovary weights, and an increased severity (but not incidence) of bile duct proliferation.
Inhalation short-term (1 to 30 days)	Oral study NOAEL= 50 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic toxicity in dogs- LOAEL = 250 mg/kg/day based upon decreased absolute body weights in both sexes, diarrhea, hematological alterations (increased platelets and fibrin, decreased red cells, hemoglobin, and packed cell volume), clinical chemistry alterations (increased alpha-1 and alpha-2 globulin in females), increased liver weights in both sexes, increased testes and ovary weights, and an increased severity (but not incidence) of bile duct proliferation.
Cancer (Oral, dermal, inhalation)	Classified as a Group D carcinogen; not cancer assessment is necessary.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from

animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to fludioxonil, EPA considered exposure under the petitioned-for tolerances as well as all existing fludioxonil tolerances in 40 CFR 180.516. EPA assessed dietary exposures from fludioxonil 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.

No such effects were identified in the toxicological studies for fludioxonil; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, an unrefined chronic dietary exposure and risk assessment was performed assuming tolerance-level residues, 100 percent crop treated (PCT) estimates, and DEEM (ver. 7.81) default processing factors.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has classified fludioxonil as a group D carcinogen. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for fludioxonil. Tolerance-level residues and 100 PCT were assumed for all food commodities.

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

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fludioxonil for chronic exposures are estimated to be 38.5 parts per billion (ppb) for surface water and 0.2 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 38.5 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).

Fludioxonil is currently registered for the following uses that could result in residential exposures: parks, golf courses, athletic fields, residential lawns, ornamentals, and greenhouses. To assess residential handler exposure, the Agency used the short-term inhalation exposure to adults from mixing/loading/applying a wettable powder in water-soluble packaging with hose end sprayer (both for turf and gardens). To assess post-application exposure, the Agency used short-term incidental oral exposures (hand-to-mouth) to children 1<2 years old from exposure to outdoor treated 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."

EPA has not found fludioxonil to share a common mechanism of toxicity with any other substances, and fludioxonil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fludioxonil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

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 Safety Factor (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*. There was no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to rats and rabbits or following pre-/postnatal exposure. In a rat developmental toxicity study, fludioxonil caused an increase in

fetal incidence and litter incidence of dilated renal pelvis at the limit dose (1,000 mg/kg/day). Maternal toxicity occurred at the same dose and manifested as body weight decrements. Fludioxonil was not developmentally toxic in rabbits. In the 2-generation reproduction study, parental and offspring effects occurred at the same dose and consisted of decreased body weights in parental and offspring animals, as well as increased clinical signs in 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 fludioxonil is complete.

ii. The only potential indicator of neurotoxicity for fludioxonil was convulsions in mice following handling in the mouse carcinogenicity study at the mid- and high-doses. The concern is low however since there was no supportive neuropathology, the effect was not seen at similar doses in a second mouse carcinogenicity study, there were no other signs of potential neurotoxicity observed in the database, and selected endpoints are protective of the effect seen in mice. Therefore, there is no residual uncertainty concerning neurotoxicity and no need to retain the FQPA 10X safety factor.

iii. There is no evidence that fludioxonil 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 food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fludioxonil in drinking water. EPA used similarly conservative assumptions

to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fludioxonil.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fludioxonil is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fludioxonil from food and water will utilize 71% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fludioxonil 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).

Fludioxonil 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 fludioxonil.

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 81,000 for adults and 4,800 for children 1-2 years old. Because EPA's level of concern for fludioxonil 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**,** fludioxonil 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 fludioxonil**.**

5. *Aggregate cancer risk for U.S. population*. Based on the discussion contained in Unit III.A., fludioxonil 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 fludioxonil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate high-performance liquid chromatography/ultraviolet (HPLC/UV) methods (Methods AG-597 and AG-597B) are available for enforcing tolerances for fludioxonil on plant

commodities. An adequate liquid chromatography, tandem mass spectrometry (LC–MS/MS) method (Analytical Method GRM025.03A) is available for enforcing tolerances for residues of fludioxonil in or on livestock commodities.

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 established MRLs for fludioxonil in or on multiple stone fruit commodities (peaches, apricots, etc.) at 5.0 ppm. These MRLs are the same as the tolerances established for fludioxonil in the United States.

The Codex has established an MRL for fludioxonil in or on carrot roots at 0.7 ppm. This MRL is different than the tolerance established for fludioxonil in the United States because it is based on a foliar use, whereas the U.S. use is based on a post-harvest use. Harmonization with

the Codex MRL is likely to result in tolerance exceedances when fludioxonil is applied to carrots in accordance with the label.

The Codex has established an MRL for fludioxonil in or on rape seed at 0.02 ppm. This MRL is different than the 0.01 ppm tolerance established for fludioxonil on the rapeseed subgroup 20A in the U.S., which is aligned with the existing Canadian MRL on rapeseed. In their petition, Syngenta requested to remain aligned with Canada at 0.01 ppm for rapeseed in order to prevent NAFTA trade barriers.

C. Response to Comments

Several comments were received in response to the Notice of Filing regarding adverse impacts to bees but did not reference any specific active ingredient. The commenters by and large stated this action should be denied due to toxicity to bees and that all use of chemicals should be stopped. The comments primarily appear directed to the registration of the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). One comment referenced the establishment of a tolerance for an unnamed Syngenta pesticide, so to the extent that comment is directed at the present tolerance action, the Agency understands the commenters' 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 Federal Food, Drug and Cosmetic Act (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. The comment appears to be directed at the underlying statute and not EPA's implementation of it; no contentions have been made that EPA has acted in violation of the statutory framework. As to bees the EPA considers impacts to the environment and non-target species under the authority of the (FIFRA).

V. Conclusion

Therefore, tolerances are established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1 *H*-pyrrole-3-carbonitrile), in or on carrots at 7.0 ppm; fruit, stone, group 12-12 at 5.0 ppm; and the rapeseed subgroup 20A, except flax seed at 0.01 ppm. In addition, upon establishment of these tolerances, the existing tolerance for rapeseed, seed is removed as unnecessary since it is part of the rapeseed subgroup 20A.

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 tolerances 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 6, 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 § 180.516:

a. Remove the entry in the table in paragraph (a) for “Rapeseed, seed”.

b. Add alphabetically the entries for “Carrots” and “Rapeseed subgroup 20A, except flax seed” to the table in paragraph (a).

c. Revise the entry for “Fruit, stone, group 12” to read “Fruit, stone, group 12-12” in the table in paragraph (a).

The additions and revisions read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Carrots	7.0
* * * * *	
Fruit, stone, group 12-12	5.0
* * * * *	
Rapeseed subgroup 20A, except flax seed	0.01
* * * * *	

* * * * *

[FR Doc. 2015-20019 Filed: 8/13/2015 08:45 am; Publication Date: 8/14/2015]