

TABLE 5 OF § 165.801—SECTOR NEW ORLEANS ANNUAL AND RECURRING SAFETY ZONES—Continued

Date	Sponsor/name	Sector New Orleans location	Safety zone
5. July 4th .....	Independence Day Celebration, Main Street 4th of July (Fireworks Display).	Morgan City, LA .....	Morgan City Port Allen Route mile marker 0.0 to 1.0, Morgan City, LA.
6. July 4th .....	WBRZ—The Advocate 4th of July Fireworks Display.	Baton Rouge, LA .....	In the vicinity of the USS Kidd, the Lower Mississippi River from mile marker 228.8 to 230.0, Baton Rouge, LA.
7. The Saturday before July 4th or on July 4th if that day is a Saturday.	Independence Day Celebration/Bridge Side Marine.	Grand Isle, LA .....	500 Foot Radius from the Pier located at Bridge Side Marine, 2012 LA Highway 1, Grand Isle, LA (Lat: 29°12'14" N; Long: 090°02'28.47" W).
8. 1st Weekend of September	LA Shrimp and Petroleum Festival Fireworks Display, LA Shrimp and Petroleum Festival and Fair Association.	Morgan City, LA .....	Atchafalaya River at mile marker 118.5, Morgan City, LA.
9. 1st Weekend in December (Usually that Friday, subject to change due to weather).	Office of Mayor-President/Downtown Festival of Lights.	Baton Rouge, LA .....	Located on Left Descending Bank, Lower Mississippi River north of the USS Kidd, at mile marker 230, Baton Rouge, LA.
10. December 31st .....	Crescent City Countdown Club/New Year's Celebration.	Mississippi River, New Orleans, LA.	Mississippi River mile marker 93.5–96.5, New Orleans, LA.
11. December 31st .....	Boomtown Casino/New Year's Celebration.	Harvey Canal, Harvey, LA ...	Harvey Canal mile marker 4.0 to 5.0, Harvey, LA.
12. July 4th .....	USS Kidd Veterans Memorial/Fourth of July Star-Spangled Celebration.	Baton Rouge, LA .....	In the vicinity of the USS Kidd, the Lower Mississippi River from mile marker 228.8 to 230.0, Baton Rouge, LA.
13. Saturday before Labor Day.	Baton Rouge Paddle Club and Muddy Water Paddle Co./Big River Regional.	Baton Rouge, LA .....	Mississippi River from mile marker 215 to 230.4, Baton Rouge, LA.
14. July 4th .....	L'Auberge Casino Baton Rouge/July 4th Celebration.	Baton Rouge, LA .....	Mississippi River from mile marker 216.0 to 217.5, Baton Rouge, LA.
15. July 4th .....	Madisonville Old Fashioned 4th of July ...	Madisonville, LA .....	Tchefuncte River, at approximate position 30°24'11.63" N 090°09'17.39" W, in front of the Madisonville Town Hall.
16. Weekend before July 4th	Mandeville July 4th Celebration .....	Mandeville, LA .....	Approximately 600' off the shore of the Mandeville Lakefront 30°21'12.03" N 90°04' 28.95" W.

Dated: October 31, 2018.

**W.E. Watson,**

*Captain, U.S. Coast Guard, Acting Captain of the Port Sector New Orleans.*

[FR Doc. 2018–24230 Filed 11–5–18; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2017–0538; FRL–9982–75]

### Fludioxonil; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes revised tolerances for residues of fludioxonil in or on beet, sugar, roots at 4.0 parts per million. Syngenta Crop Protection, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective November 6, 2018. Objections and requests for hearings must be received on or before January 7, 2019, 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–2017–0538, 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:

Michael L. Goodis, 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: [RDPRNotices@epa.gov](mailto:RDPRNotices@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 11).
- 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](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-2017-0538 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 January 7, 2019. 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-2017-0538, 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 15, 2017 (82 FR 59604) (FRL-9970-50), 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 7F8592) by Syngenta Crop Protection, LLC, 410 Swing Road, Greensboro, NC 27409. The petition requested that the existing tolerance in 40 CFR 180.516 for residues of the fungicide fludioxonil, 4-(2, 2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile, in or on beet, sugar, roots be amended to 5.0 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, 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 determined that the tolerance be set at 4.0 ppm, which is less than the tolerance level of 5.0 ppm proposed by the petitioner. The reason for this change is explained 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, kidney, and hematopoietic system (dogs only). 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 the limit dose. Fludioxonil was not mutagenic in the tests for gene mutations. There was no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to rats and rabbits or following pre-/postnatal exposure to rats.

In a rat developmental toxicity study, fludioxonil caused an increase in fetal incidence and litter incidence of both dilated renal pelvis and ureter at the limit dose (1000 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 two-generation reproductive study). Maternal toxicity occurred at the same dose and manifested as body-weight decrements. Fludioxonil was not developmentally toxic in rabbits. In the two-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.

Fludioxonil was classified as a Group D carcinogen (not classifiable as to human carcinogenicity); 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 document Fludioxonil. "Human Health Risk Assessment for the Proposed New Post

Harvest Use on Sugar Beets.” at pg. 11 in docket ID number EPA–HQ–OPP–2017–0538.

### 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 discussed in Unit III.B. of the final rule published in the **Federal Register** of April 14, 2015 (80 FR 48743) (FRL–9931–06).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fludioxonil, EPA considered exposure under the petitioned-for tolerance 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 United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA an unrefined chronic dietary exposure and risk assessment was conducted assuming 100% percent crop treated (PCT) and tolerance-level residues for all food commodities. The Processing Factor Focus (PFFG) default processing factors were used.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has classified fludioxonil as a group D carcinogen, *i.e.*, not classifiable as to human carcinogenicity. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.*

EPA did not use anticipated residue and/or PCT information in the dietary assessment for fludioxonil. Tolerance level residues and/or 100% CT 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM) and the Variable Volume Water Model (VWWM) along with the Pesticide Root Zone Model Ground Water (PRZM GW) were used, the estimated drinking water concentrations (EDWCs) of fludioxonil for chronic exposures for non-cancer assessments are estimated to be 17.7 parts per billion (ppb) for surface water and 48.34 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 48.34 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. EPA assessed residential exposure based on the following: The residential exposure for use in the adult aggregate assessment reflects inhalation exposures from handler exposure to applying paints with airless sprayers. The residential exposure for use in the children 1 to <2 years old aggregate assessment reflects incidental oral exposures (hand-to-mouth) from post-application 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/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

### 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 Food Quality Protection Act Safety Factor (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.* 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. There is low concern that fludioxonil is a neurotoxic chemical. 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. 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 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 postapplication 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 51% 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 15,000 for adults and 4,600 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).

Intermediate- and long-term aggregate risk assessments were not performed because there are no registered or proposed uses of fludioxonil that result in intermediate- or long-term residential exposures.

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 enforcement methodology 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 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](mailto: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.

There is no Codex MRL for sugar beet roots for fludioxonil.

*C. Revisions to Petitioned-For Tolerances*

All tolerance levels are based upon the Organization for Economic Co-operation and Development's (OECD) tolerance calculation procedures. Based on the residue chemistry data and the OECD tolerance-calculation procedure, the tolerance level established in this notice for fludioxonil on beet, sugar, roots is lower (4.0 ppm) than that requested by the petitioner (5.0 ppm).

**V. Conclusion**

Therefore, the tolerance is amended for residues of fludioxonil: [4-(2, 2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile], in or on beet, sugar, roots from 0.02 ppm to 4.0 ppm.

**VI. Statutory and Executive Order Reviews**

This action amends a tolerance 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) nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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: October 16, 2018.

**Michael Goodis,**

*Director, Registration Division, Office of Pesticide Program.*

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, revise the tolerance for "Beet, sugar, roots" in the table of paragraph (a)(1), to read as follows:

**§ 180.516 Fludioxonil; tolerance for residues.**

(a) *General.* (1) \* \* \*

Commodity	Parts per million
* * * * *	*
Beet, sugar, roots .....	4.0
* * * * *	*

\* \* \* \* \*  
[FR Doc. 2018-24265 Filed 11-5-18; 8:45 am]

**BILLING CODE 6560-50-P**