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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0395; FRL-9357-5]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil in or on multiple commodities which are identified and discussed later in this document, associated with pesticide petition (PP) 1E7853 and PP 1E7870. This regulation additionally revises several established tolerances, and removes several established permanent and time-limited tolerances. Interregional Research Project Number 4 (IR-4) and Syngenta Crop Protection, LLC, requested the tolerances associated with PP 1E7853 and PP 1E7870, respectively, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0395, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open

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

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: *nollen.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0395 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0395, by one of the following methods:

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0395 by one of the following methods:

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

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

● *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL-8880-1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition, PP 1E7853, by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.516 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 acerola at 5.0 parts per million (ppm); atemoya at 20 ppm; biriba at 20 ppm; cherimoya at 20 ppm; custard apple at 20 ppm; feijoa at 5.0 ppm; guava at 5.0 ppm; ilama at 20 ppm; jaboticaba at 5.0 ppm; passionfruit at 5.0 ppm; soursop at 20 ppm; starfruit at 5.0 ppm; sugar apple at 20 ppm;

wax jambu at 5.0 ppm; ginseng at 3.0 ppm; onion, bulb subgroup 3-07A at 0.2 ppm; onion, green subgroup 3-07B at 7.0 ppm; caneberry subgroup 13-07A at 5.0 ppm; bushberry subgroup 13-07B at 2.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1.0 ppm; berry, low growing, subgroup 13-07G, except cranberry at 2.0 ppm; vegetable, fruiting, group 8-10, except tomato at 0.7 ppm; fruit, citrus, group 10-10 at 10 ppm; fruit, pome, group 11-10 at 5.0 ppm; leafy greens subgroup 4A at 30 ppm; potato at 6.0 ppm; pineapple at 8.0 ppm; and dragon fruit at 1.0 ppm.

That notice additionally requested to amend established tolerances of fludioxonil in or on avocado from 0.45 ppm to 5.0 ppm; sapote, black from 0.45 ppm to 5.0 ppm; canistel from 0.45 ppm to 5.0 ppm; sapote, mamey from 0.45 ppm to 5.0 ppm; mango from 0.45 ppm to 5.0 ppm; papaya from 0.45 ppm to 5.0 ppm; sapodilla from 0.45 ppm to 5.0 ppm; star apple from 0.45 ppm to 5.0 ppm; longan from 1.0 ppm to 20 ppm; lychee from 1.0 ppm to 20 ppm; pulasan from 1.0 ppm to 20 ppm; rambutan from 1.0 ppm to 20 ppm; Spanish lime from 1.0 ppm to 20 ppm; and tomato from 0.50 ppm to 3.0 ppm. Upon approval of the aforementioned tolerances, the petition finally requested to amend 40 CFR 180.516 by removing the established tolerances for residues of fludioxonil in or on the following raw agricultural commodities: Onion, bulb at 0.2 ppm; onion, green at 7.0 ppm; caneberry subgroup 13A at 5.0 ppm; bushberry subgroup 13B at 2.0 ppm; Juneberry at 2.0 ppm; lingonberry at 2.0 ppm; salal at 2.0 ppm; grape at 1.0 ppm; strawberry at 2.0 ppm; vegetable, fruiting, group 8 at 0.01 ppm; tomatillo at 0.50 ppm; fruit, citrus, group 10 at 10 ppm; fruit, pome, group 11 at 5.0 ppm; and leafy greens subgroup 4A, except spinach at 30 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, LLC, the registrant, which is

available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of May 2, 2012 (77 FR 25954) (FRL-9346-1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7853) by IR-4, that requested that 40 CFR 180.516 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 commodities requested in the **Federal Register** of July 20, 2011, with one change. This petition requested to establish a tolerance for residues of fludioxonil in or on vegetable, tuberous and corm, subgroup 1C at 6.0 ppm. This request superseded the previous request to establish a tolerance in or on potato at 6.0 ppm, as potato is the representative commodity of crop subgroup 1C. The May 2, 2012 petition additionally requested that EPA remove the established tolerance in or on vegetable, tuberous and corm, subgroup 1D at 3.5 ppm, as the tolerance will be superseded by the vegetable, tuberous and corm, subgroup 1C tolerance. That notice referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received to this notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Additionally, in the **Federal Register** of April 4, 2012 (77 FR 20334) (FRL-9340-4), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346(d)(3), announcing the filing of PP 1E7870 by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27409. The petition requested that 40 CFR 180.516 be amended by establishing a tolerance for residues of the fungicide fludioxonil in or on leafy petioles

subgroup 04B at 14 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received to this notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has revised the proposed tolerance levels and/or has revised the commodity definitions for several commodities. Additionally, EPA has removed several established tolerances and has determined that tolerances should be established in or on several livestock commodities. Finally, the Agency has revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reasons 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 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.

Fludioxonil is of low acute toxicity and is not a dermal sensitizer. For subchronic and chronic toxicity, the primary effects in the mouse and rat were similar and included decreased body weight and food consumption associated with clinical pathological and histopathological effects in the liver and kidney. In the subchronic dog study, diarrhea was the most sensitive indicator of toxicity. In contrast, in the chronic toxicity study in dogs, decreased body-weight gain in females was the most sensitive indicator of toxicity. Liver toxicity was observed in both dog studies at higher doses.

Fludioxonil is not developmentally toxic in rabbits. In a rat developmental toxicity study at the highest dose tested (HDT), fludioxonil caused an increase in fetal incidence and litter incidence of dilated renal pelvis in the presence of maternal toxicity. There was no quantitative or qualitative evidence of increased susceptibility to rats and rabbits

following *in utero* exposure. There was also no quantitative or qualitative evidence of increased susceptibility to rats following postnatal exposure and there was no evidence of immunotoxicity when tested up to including the limit dose.

EPA determined that fludioxonil poses a negligible cancer risk. This conclusion was based on the fact that cancer studies with fludioxonil only showed marginal evidence of cancer in one sex of one species. There was no evidence of carcinogenicity in mice when tested up to the limited dose 7,000 ppm. There was no evidence of carcinogenicity in male rats, but there was a statistically significant increase, both trend and pairwise, of combined hepatocellular tumors in female rats. 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. Fludioxonil was not mutagenic in the tests for gene mutations. However, based on the induction of polyploidy in the *in vitro* Chinese hamster ovary cell cytogenetic assay and the suggestive evidence of micronuclei induction in rat hepatocytes *in vivo*, additional mutagenicity testing was performed in three studies specifically designed to address the concerns regarding aneuploidy. The results of these assays were negative for aneuploidy activity.

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. Tolerance Petitions for Residues in/on Ginseng, Leafy Petioles Crop Subgroup 4B, Pineapple (post-harvest treatment),

Tuberous and Corm Vegetable Subgroup 1C, Tropical Fruit (post-harvest treatment), Bulb Onion Subgroup 3-07A, Green Onion subgroup 3-07B, Caneberry Subgroup 13-07A, Bushberry Subgroup 13-07B, Small Fruit Vine Climbing Subgroup 13-07F (except fuzzy kiwifruit), Low-Growing Berry Subgroup 13-07G (except cranberry), Fruiting Vegetable Group 8-10 (except tomato), Citrus Fruit Group 10-10, Pome Fruit Group 11-10, Leafy Vegetable (except *Brassica*) Subgroup 04A, Dragon Fruit, and Tomato (post-harvest treatment). Human-Health Risk Assessment." pp. 40-42 in docket ID number EPA-HQ-OPP-2011-0395.

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 the Table of this unit.

Table —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 (Females 13-49 years of age)	NOAEL = 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1 mg/kg/day aPAD = 1 mg/kg/day	Prenatal developmental toxicity in rats LOAEL = 1,000 mg/kg/day based on the increased incidence of fetuses and litters with dilated renal pelvis and dilated ureter in rat developmental study.
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= 3.3 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.033 mg/kg/day cPAD = 0.033 mg/kg/day	Chronic toxicity in dogs LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs during weeks 1-52 of one-year dog feeding study.
Incidental oral short-term (1 to 30 days)	NOAEL= 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Rabbit developmental study LOAEL = 100 mg/kg/day based on decreased weight gain during dosing period.
Incidental oral intermediate-term (1 to 6 months)	NOAEL= 3.3 mg/kg/day UF_A= 10x UF_H= 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity in dogs LOAEL = 35.5 mg/kg/day based on decreased weight gain

			in female dogs during weeks 1-52 of one-year dog feeding study.
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 10x	LOC for MOE = 1000	Rabbit developmental study LOAEL = 100 mg/kg/day based on decreased weight gain during dosing period.
Cancer (Oral, dermal, inhalation)	Poses no greater than a negligible cancer risk.		

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_{DB} = to account for the absence of data or other data deficiency. 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. Such effects were identified for fludioxonil for females 13-49 years old (i.e., females of child-bearing age). 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 assumed tolerance-level residues, 100 percent crop treated (PCT) estimates, and

DEEM™ ver. 7.81 default processing factors. There were no appropriate toxicological effects attributable to a single exposure for the general population; therefore, these population subgroups were not included in this assessment.

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 assumed tolerance-level residues for most commodities, with the exception of the following commodities for which anticipated residues were used: Celery, pineapple, potato, spinach, apple, grapefruit, lemon, lime, orange, pear, tomato, head lettuce, leaf lettuce, fresh parsley, brassica leafy vegetables group 5, grape, cherry, peach, and plum. The anticipated residues were estimated from field trial and processing study data for the chronic analysis. The chronic dietary exposure assessment also incorporated 100 PCT estimates and DEEM™ ver. 7.81 default processing factors, with the exception of citrus fruit juice (1X), apple juice (1X), grape juice (0.42X), raisin (1.65X), potato commodities (1X), and tomato commodities (1X), except dried tomato (14.3X). These processing factors are based upon crop-specific processing study data.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that fludioxonil poses a negligible cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section

408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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 surface water are expected to be 83.8 parts per billion (ppb) for acute exposures and 38.5 ppb for chronic exposures. The EDWCs of fludioxonil for ground water are expected to be 0.2 ppb for acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 83.8 ppb was used to assess the contribution to drinking water. For 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. In addition to the conventional uses of fludioxonil in residential areas, there are also antimicrobial uses. However, residential turf uses of fludioxonil are expected to result in the highest potential exposure of all registered residential uses of fludioxonil and, therefore, were assessed.

EPA assessed residential exposure using the following assumptions: Short-term inhalation for residential handler exposure scenarios, including mixing/loading/applying fludioxonil. Residential handler exposures were considered to be short-term only due to the infrequent use patterns associated with homeowner products. Additionally, EPA assessed potential short- and intermediate-term postapplication exposures to toddlers (children 1-2 years old) resulting from physical activities on turf. These included incidental oral exposures from hand-to-mouth, object-to-mouth, and incidental soil ingestion. 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*. The fludioxonil toxicity database includes developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats. In the rat developmental study, there was an increase in the number of fetuses and litters with dilated renal pelvis and dilated ureter at the limit dose (1,000 mg/kg/day); maternal toxicity occurred at the same dose and was manifested as a reduction in corrected body-weight gain, indicating that there is no quantitative susceptibility for these

fetal effects. In the rabbit developmental study, no developmental toxicity was seen up to the HDT. Maternal toxicity was demonstrated at that dose. In the 2-generation rat reproduction study, offspring toxicity was seen at the same dose that produced parental toxicity. The parental toxicity was manifested as increased clinical signs, decreased body weight, body weight gain and food consumption. Offspring toxicity was manifested as decreased weight gain in pups. Parental and offspring toxicity were comparable; therefore, it was concluded that there is no increased susceptibility in the 2-generation reproduction study.

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 for risks other than those related to inhalation exposure. EPA is retaining the 10X FQPA safety factor for risks from inhalation exposure. That decision is based on the following findings:

i. The toxicity database for fludioxonil is complete except for a 90-day inhalation study. The point of departure for assessing risk from inhalation exposure is being extrapolated from an oral study. The uncertainty associated with this extrapolation requires the retention of the 10X FQPA SF for these exposures.

ii. The only potential indicator of neurotoxicity in the fludioxonil toxicity database was convulsions noted in mice following handling at high doses. The convulsions were considered to be agonal in nature. Therefore, EPA has determined that there is no need for a developmental neurotoxicity study or an additional safety factor to account for neurotoxicity.

iii. There is no evidence that fludioxonil results in increased susceptibility in *in utero* rabbits in the prenatal developmental study or in young rats in the 2-generation reproduction study. In the rat developmental toxicity study, fetal effects were noted at the limit dose in the presence of maternal toxicity. However, EPA determined that the degree of concern is low for the noted fetal effects because the effects were observed at the same doses as maternal effects, and there is a clear NOAEL established which was used in endpoint selection.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary assessment for females 13-49 years old was unrefined, assuming 100 PCT and tolerance-level residues, and the chronic dietary exposure assessment assumed 100 PCT and used tolerance-level residues or made use of average residues derived from crop field trial studies. The chronic assessment also assumed DEEM default or other processing factors based on reliable processing data. 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 short- and intermediate-term postapplication exposure resulting from 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. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fludioxonil will occupy 16% of the aPAD for females 13-49 years old, the population group identified as having a potential acute exposure to fludioxonil.

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 68% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 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 an aggregate MOE of 310 for children 1-2 years old. Because EPA's level of concern for fludioxonil is a MOE of 100 or below, this MOE is not of concern.

Because the short-term oral and inhalation risks were estimated using the same oral POD, these routes of exposure could be combined for the adult short-term exposure assessment. However, because the level of concern for oral and inhalation routes of exposure are not the same (an MOE of <100 defines the level of concern for incidental oral risk while inhalation risk is defined by an MOE of <1,000) an aggregate risk index (ARI) was required to estimate aggregate risk for adults. Only adults are assumed to be exposed to a combination of oral and inhalation exposures because inhalation exposures for fludioxonil may occur only as to those who apply the pesticide. EPA identifies ARIs at or below one as a risk estimate of concern. The short-term aggregate ARI exposure estimates to fludioxonil residues for adults are 9.5 for the general population and 11 for adults 50 years and older.

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). Fludioxonil is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to fludioxonil.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 105 for children 1-2 years old. Because EPA's level of concern for fludioxonil is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the data summarized in Unit III.A., EPA has concluded that fludioxonil poses a negligible cancer risk to humans. Therefore, 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 light detector (HPLC/UV) methods (Syngenta Methods AG-597 and AG-597B) are available for enforcing tolerances for residues of fludioxonil in or 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.

There are no Codex MRLs established for the following tolerances associated with these petitions: Ginseng; tropical fruit commodities; onion, green, subgroup 3-07B; leaf petioles crop subgroup 4B; and fat of cattle, goat, horse, and sheep. The following United States tolerances being established by this action are harmonized with comparable Codex MRLs: Caneberry subgroup 13-07A at 5.0 ppm; bushberry subgroup 13-07B at 2.0 ppm; and fruit, pome, group 11-10 at 5.0 ppm; onion, bulb, subgroup 3-07A at 0.50 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; and berry, low growing, subgroup 13-07G, except cranberry at 3.0 ppm.

The following United States tolerances being established by this action cannot be harmonized with the comparable Codex MRL: Tomato; leafy greens subgroup 4A; vegetable, tuberous and corm, subgroup 1C; fruit, citrus, group 10-10; and fruit, pome, group 11-10. The residue data and use patterns in the United States for these commodities support a higher tolerance value than what is established by Codex. The Codex has proposed, though has not yet approved, MRLs on citrus fruits at 10 ppm and pome fruits at 5.0 ppm that would result in harmonization with the United States for these commodities.

Finally, EPA is establishing a tolerance on vegetable, fruiting, group 8-10, except tomato that is not harmonized with Codex MRLs on eggplant at 0.3 ppm or sweet peppers at 1 ppm, which are members of the fruiting vegetable crop group. The United States tolerance was established as the result of a joint review of residue field trial data with Canada's Pest Management Regulatory Agency (PMRA). Based on the EPA and PMRA review of the data supporting the petition, the resulting tolerance for vegetable, fruiting, group 8-10, except tomato is 0.5 ppm. This tolerance cannot be harmonized with the Codex MRLs on eggplant at 0.3 ppm and sweet peppers at 1 ppm since the MRLs are established for two individual members of the fruiting vegetable crop group at different levels.

C. Response to Comments

EPA received one comment to the notice of filing for PP 1E7870, which requested additional information about the nature of the residue and the adverse effects noted from exposure to fludioxonil. A summary of information about the nature of the residue and the adverse effects from fludioxonil was available to the commenter in the docket at the time of the notice of filing. That information, as well as specific information on the nature of the residue, including physical and chemical characteristics, and the adverse effects caused by fludioxonil from the toxicity studies can be found in the supporting and related material at http://*www.regulations.gov* in docket ID number EPA-HQ-OPP-2011-0395.

Additionally, the Agency received one comment to the May 2, 2012 notice of filing for PP 1E7853. The commenter raised concerns about the proposal to increase an existing tolerance for fludioxonil 5-10 times the current level and further stated that EPA

would need to amend the protocol and develop a completely new method. In response to these concerns, EPA notes that the appropriate residue field trial data to support the amended use pattern for a post-harvest use was submitted to the Agency. From the risk assessment for the action, which included review of the field trial data supporting petitioned-for tolerance amendments, EPA has determined that the tolerance levels to be established by the Agency are appropriate and safe.

D. Revisions to Petitioned-For Tolerances

Based on the data supporting the petitions, EPA revised the proposed tolerances on several commodities, as follows: Ginseng from 3.0 ppm to 4.0 ppm; vegetable, fruiting, group 8-10, except tomato from 0.7 ppm to 0.50 ppm; tomato from 3.0 ppm to 5.0 ppm; pineapple from 8.0 ppm to 20 ppm; and leaf petioles crop subgroup 4B from 14 ppm to 15 ppm. Upon review of the data supporting the petitions, EPA also determined that several tolerances should be established on livestock commodities, as follows: Milk at 0.01 ppm; cattle, goat, horse, and sheep meat at 0.01 ppm; meat byproducts of cattle, goat, horse, and sheep at 0.05 ppm; and fat of cattle, goat, horse, and sheep at 0.05 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures.

Additionally, EPA revised the onion, bulb, subgroup 3-07A from 0.20 ppm to 0.50 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F from 1.0 ppm to 2.0 ppm; and berry, low growing, subgroup 13-07G, except cranberry from 2.0 ppm to 3.0 ppm, in order to align with the Codex MRLs associated with these tolerances.

EPA also removed the established tolerance in or on vegetable, leafy, except brassica, group 4 at 0.01 ppm, as it will be superseded by tolerances on leafy greens subgroup 4A at 30 ppm and leaf petioles subgroup 4B at 15 ppm. Similarly, EPA removed the established tolerance on vegetable, bulb, group 3 at 0.02 ppm, as the tolerance will be superseded by tolerances on bulb onion subgroup 3-07A at 0.50 ppm and green onion subgroup 3-07B at 7.0 ppm. In order to clarify the established vegetable, root and tuber, group 1 tolerance at 0.02 ppm, the Agency revised the entry to beet, sugar at 0.02 ppm. This change has been made because all other commodity members currently in crop group 1 will be superseded by tolerances in or on vegetable, root, except sugar beet, subgroup 1B at 0.75 ppm and vegetable, tuberous and corm, subgroup 1C at 6.0 ppm. EPA also revised the proposed commodity definitions to reflect the correct designation for fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F and dragon fruit.

Finally, the Agency has revised the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of fludioxonil not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

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 guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 5.0 ppm; sugar apple, atemoya, custard apple, cherimoya, ilama, soursop and biriba at 20 ppm; ginseng at 4.0 ppm; onion, bulb,

subgroup 3-07A at 0.50 ppm; onion, green, subgroup 3-07B at 7.0 ppm; caneberry subgroup 13-07A at 5.0 ppm; bushberry subgroup 13-07B at 2.0 ppm; fruit, small, vine climbing, subgroup 13-07F, except fuzzy kiwifruit at 2.0 ppm; berry, low growing, subgroup 13-07G, except cranberry at 3.0 ppm; vegetable, fruiting, group 8-10, except tomato at 0.50 ppm; fruit, citrus, group 10-10 at 10 ppm; fruit, pome, group 11-10 at 5.0 ppm; leafy greens subgroup 4A at 30 ppm; vegetable, tuberous and corm, subgroup 1C at 6.0 ppm; pineapple at 20; dragon fruit at 1.0 ppm; and leaf petioles subgroup 4B at 15 ppm. This regulation additionally amends established tolerances of fludioxonil in or on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla and star apple from 0.45 ppm to 5.0 ppm; longan, lychee, pulasan, rambutan, and Spanish lime from 1.0 ppm to 20 ppm; and tomato from 0.50 ppm to 5.0 ppm.

Tolerances are established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1-*H*-pyrrole-3-carbonitrile), and its metabolites converted to 2,2-difluoro-l,3-benzodioxole-4-carboxylic acid, calculated as the stoichiometric equivalent of fludioxonil, in or on milk at 0.01 ppm; cattle, meat byproducts at 0.05 ppm; cattle, meat at 0.01 ppm; cattle, fat at 0.05 ppm; goat, meat byproducts at 0.05 ppm; goat, meat at 0.01 ppm; goat, fat at 0.05 ppm; horse, meat byproducts at 0.05 ppm; horse, meat at 0.01 ppm; horse, fat at 0.05 ppm; sheep, meat byproducts at 0.05 ppm; sheep, meat at 0.01 ppm; and sheep, fat at 0.05 ppm.

This regulation additionally removes established tolerances in or on onion, bulb; onion, green; caneberry subgroup 13A; bushberry subgroup 13B; Juneberry; lingonberry; salal; grape; strawberry; vegetable, fruiting group 8; tomatillo; fruit, citrus, group 10; fruit, pome, group 11; leafy green subgroup 4A, except spinach; vegetable, tuberous and

corm, except potato, subgroup 1D; vegetable, leafy, except brassica, group 4; and vegetable, bulb, group 3. This regulation also removes the time-limited tolerances in or on starfruit and pineapple. Finally, this regulation revises the established tolerance on vegetable, root and tuber, group 1 at 0.02 ppm to beet, sugar at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S.

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 3, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.516 is amended by revising paragraphs (a) and (b) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide fludioxonil, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1-*H*-pyrrole-3-carbonitrile).

Commodity	Parts per million
Acerola	5.0
Animal feed, nongrass, group 18	0.01
Atemoya	20
Avocado	5.0
Bean, dry	0.4
Bean, succulent	0.4
Beet, sugar, roots	0.02
Berry, low growing, subgroup 13-07G, except cranberry	3.0
Biriba	20
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	10
Bushberry subgroup 13-07B	2.0
Caneberry subgroup 13-07A	5.0
Canistel	5.0
Cherimoya	20
Citrus, oil	500

Cotton, gin byproducts	0.05
Cotton, undelinted seed	0.05
Custard apple	20
Dragon fruit	1.0
Feijoa	5.0
Flax, seed	0.05
Fruit, citrus, group 10-10	10
Fruit, pome, group 11-10	5.0
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.0
Fruit, stone, group 12	5.0
Ginseng	4.0
Grain, cereal, group 15	0.02
Grain, cereal, forage, fodder, and straw, group 16	0.01
Grass, forage, fodder and hay, group 17	0.01
Guava	5.0
Herb subgroup 19A, dried leaves	65
Herb subgroup 19A, fresh leaves	10
Ilama	20
Jaboticaba	5.0
Kiwifruit, fuzzy	20
Leaf petioles subgroup 4B	15
Leafy greens subgroup 4A	30
Longan	20
Lychee	20
Mango	5.0
Melon subgroup 9A	0.03
Onion, bulb, subgroup 3-07A	0.50
Onion, green, subgroup 3-07B	7.0
Papaya	5.0
Passionfruit	5.0
Peanut	0.01
Peanut, hay	0.01
Pineapple	20
Pistachio	0.10
Pomegranate	5.0
Pulasan	20
Rambutan	20
Rapeseed, forage	0.01
Rapeseed, seed	0.01
Safflower, seed	0.01
Sapodilla	5.0
Sapote, black	5.0

Sapote, mamey	5.0
Soursop	20
Spanish lime	20
Spice subgroup 19B	0.02
Star apple	5.0
Starfruit	5.0
Sugar apple	20
Sunflower, seed	0.01
Tomato	5.0
Turnip, greens	10
Vegetable, cucurbit, group 9	0.45
Vegetable, foliage of legume, group 7	0.01
Vegetable, fruiting, group 8-10, except tomato	0.50
Vegetable, leaves of root and tuber, group 2	30
Vegetable, legume, group 6	0.01
Vegetable, root, except sugar beet, subgroup 1B	0.75
Vegetable, tuberous and corm, subgroup 1C	6.0
Watercress	7.0
Wax jambu	5.0
Yam, true, tuber	8.0

(2) Tolerances are established for residues of the fungicide fludioxonil, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1-*H*-pyrrole-3-carbonitrile), and its metabolites converted to 2,2-difluoro-l,3-benzodioxole-4-carboxylic acid, calculated as the stoichiometric equivalent of fludioxonil.

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.01
Cattle, meat byproducts	0.05
Goat, fat	0.05

Goat, meat	0.01
Goat, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.01
Horse, meat byproducts	0.05
Milk	0.01
Sheep, fat	0.05
Sheep, meat	0.01
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

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