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 26, 2008.

Donald R. Stubbs,

Acting 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 180.448 is amended in paragraph (a), in the table by revising the entries for the following commodities to read as follows:

§180.448 Hexythiazox; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Apple, wet pomace	0.40
* * *	* *
Cattle, meat byproducts	0.02
Citrus, dried pulp	0.60
Citrus, oil	24
* * *	* *
Fruit, pome, group 11	0.25
* * *	* *
Goat, meat byproducts	0.02
* * *	* *
Horse, meat byproducts	0.02
* * *	* *
Sheep, meat byproducts	0.02
* * *	* *

[FR Doc. E8–20513 Filed 9–9–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0940; FRL–8379–9]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil in or on avocado; canistel; citrus, oil; mango; papaya; sapodilla; sapote, black; sapote, mamey; star apple; tomatillo; tomato; vegetable, cucurbit, crop group 9; vegetable, leaves of root and tuber, crop group 2; vegetable, root, except sugar beet, subgroup 1B; and vegetable, tuberous and corm, except potato, subgroup 1D. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) on behalf of the registrant, Syngenta Crop Protection, Greensboro, NC 27409.

DATES: This regulation is effective September 10, 2008. Objections and requests for hearings must be received on or before November 10, 2008, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0940. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305-7610; e-mail address: *jackson.sidney@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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007-0940 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before November 10, 2008.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007-0940, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of October 24, 2007 (72 FR 60369) (FRL–8150–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7234) by the Interregional Research Project Number 4 (IR-4), IR-4 Project Headquarters, 500 College Road East, Suite 201 W, 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)-1H-pyrrole-3-carbonitrile, in or on tomato at 0.4 parts per million (ppm); tomatillo at 0.4 ppm; tomato, paste at 1.0 ppm; avocado at 0.45 ppm; black sapote at 0.45 ppm; canistel at 0.45 ppm; mamey sapote at 0.45 ppm; mango at 0.45 ppm; papaya at 0.45 ppm; sapodilla at 0.45 ppm; star apple at 0.45 ppm; herb, subgroup 19A, fresh at 13 ppm; herb, subgroup19A, dried at 55 ppm; leaves of root and tuber vegetables at 40 ppm; root vegetables, except sugar beet, subgroup at 0.5 ppm; lemon at 0.25 ppm; lime at 0.25 ppm; cucurbits at 0.6 ppm; and tuberous and corm vegetables, except potato subgroup at 4.0 ppm. Additionally, IR-4 proposed that upon establishment of the above new tolerances, 40 CFR 180.516 be amended by removing the established tolerances for fludioxonil in or on the food commodities; herb, subgroup 19A, fresh at 10 ppm; herb, subgroup 19A, dried at 65 ppm; carrot at 0.75 ppm; and turnip, greens at 10 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Greensboro, NC 27409, the registrant, which is available to the public 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 made changes or modifications to some of the proposed tolerances and/or commodity listings as detailed in this document—Unit IV.C. Revisions to Petitioned-For Tolerances.

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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for residues of fludioxonil in or on tomato at 0.4 ppm; tomatillo at 0.4 ppm; tomato, paste at 1.0 ppm; avocado at 0.45 ppm; black sapote at 0.45 ppm; canistel at 0.45 ppm; mamey sapote at 0.45 ppm; mango at 0.45 ppm; papaya at 0.45 ppm; sapodilla at 0.45 ppm; star apple at 0.45 ppm; herb, subgroup 19A, fresh at 13 ppm; herb, subgroup19A, dried at 55 ppm; leaves of root and tuber vegetables at 40 ppm; root vegetables, except sugar beet subgroup at 0.5 ppm; lemon at 0.25 ppm; lime at 0.25 ppm; cucurbits at 0.6 ppm; and tuberous and corm vegetables, except potato subgroup at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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, decreased weight gain in females was the most sensitive indicator of toxicity in the chronic toxicity study in dogs. Liver toxicity was observed in both dog studies at higher doses. The available data did not indicate a need for acute or subchronic neurotoxicity studies. Fludioxonil was not teratogenic in rabbits. In a rat developmental toxicity study, it caused an increase in fetal incidence and litter incidence of dilated renal pelvis at the limit dose (1,000 mg/kg/day). There was no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to rats and rabbits or following pre-/post-natal exposure to rats.

EPA determined that fludioxonil was not classifiable as to human carcinogenicity but nonetheless 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 the 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. Human Health Risk Assessment for Section 3 Tolerances on Avocado.....and Brassica Vegetables, dated July 10, 2008 at page 20 in docket ID number EPA–HQ–OPP–2007–0940-003.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in document Fludioxonil. Human Health Risk Assessment for Section 3 Tolerances on Avocado.....and Brassica Vegetables, dated July 10, at page 20 in docket ID number EPA–HQ–OPP–2007–0940-0003.

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.

In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, acute dietary exposure analysis is based on tolerance-level residues. EPA assumed that 100% of the crops with fludioxonil tolerances are treated. The only population subgroup that is relevant for this acute assessment is females of child-bearing age (i.e., females 13 to 49 years old).

ii. *Chronic exposure.* In conducting the chronic dietary (food + water) exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide CSFII. As to residue levels in food, the chronic dietary exposure analyses assumed tolerance-level residues for most commodities with existing and proposed tolerances. Anticipated residues (AR) values were determined for apple, grapefruit, lemon, lime, pear, orange and orange juices using average residues from field trials and processing factors from processing studies. Processing factors were set to 1X for all relevant processed commodities. DEEM-FCID default processing factors were used for all other processed commodities. The population subgroup of highest exposure is children 1to 2 years old. The Agency assumed 100% of crops with fludioxonil tolerances are treated.

iii. *Cancer.* As explained above, EPA determined that fludioxonil was not classifiable as to human carcinogenicity. Therefore, no assessment of exposure for the purpose of estimating cancer risk is necessary.

iv. *Anticipated residue.* 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.

Anticipated residue data were used in the chronic (non-cancer) dietary risk analyses but not in the acute dietary risk analysis. For certain proposed tolerance crops, the anticipated residues values were determined from the field trial studies. Additionally, results of processed commodities studies show that fludioxinil residues do not concentrate to the extent that the existing crop tolerance would be exceeded.

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*.

The maximum application rates for the new uses are less than the application rate for turfgrass. Therefore, the values for turfgrass (worst case) were used in the human health risk assessment. Tier 1 drinking water assessment for fludioxonil on turfgrass is based on the label application rate for turfgrass, which is used in this current assessment, and is three applications of 0.67 lb active ingredient/Acre (ai/A) applied using 14-day intervals, for a total application rate of 2 lb ai/A/year.

Based on the First Index Reservoir Screening Tool (FIRST and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fludioxonil for acute and chronic (non-cancer) exposures. EDWCs were modeled based on the use site with the highest application rate; i.e., spray/foliar applications to turfgrass of 2.0 lbs ai/A/yr. For acute exposure, EDWCs are estimated to be 81.3 parts per billion (ppb) for surface water and 0.20 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 37.4 ppb for surface water and 0.20 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 81.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 37.4 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: turfgrass and ornamentals. EPA assessed residential exposure using the following assumptions: The current petition for fludioxonil results in no residential/non-occupational exposures. Since the product registered for residential uses, Medallion® (EPA Reg. No. 100–769), is restricted for residential uses to commercial applicators-only, and since the Agency did not identify short- or intermediate-term dermal endpoints, only a toddler post-application assessment for incidental ingestion exposures to treated lawns was included.

The combined short-term oral exposure risk estimate, which includes hand-to-mouth, object-to-mouth and soil ingestion pathways, was previously determined to be 0.013 milligrams/kilogram of bodyweight/day (mg/kg bw/day), while the intermediate-term was determined to be 0.0074 mg/kg bw/day. It should be noted that each of the incidental oral assessments (i.e., hand-to-mouth, object-to-mouth and soil ingestion) are considered conservative. Therefore, combining all the assessments is expected to provide a highly conservative assessment of children's incidental oral exposure.

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 prenatal/postnatal exposure to rats. In the rat developmental study, there was an increase in the number of fetuses and litters with dilated renal pelvis and dilated ureter. This finding was considered to be related to maternal toxicity rather than an indication of increased susceptibility. Therefore, it is concluded that there is no evidence of increased susceptibility in the developmental toxicity study in the rat. In the rabbit developmental study, no developmental toxicity was seen up to the highest dose tested. Materal toxicity was demonstrated at that dose. In the 2-generation rat reproduction study, offspring toxicity was seen at the 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. Since parental and offspring toxicity were comparable, 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. That decision is based on the following findings:

i. The toxicity database for fludioxonil is complete.

ii. There is no indication that fludioxonil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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% CT and tolerance-level residues or residues from crop field trials. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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 for the general population including infants and children. Therefore, fludioxonil is not expected to pose an acute risk.

Using the exposure assumptions discussed in this unit for acute exposure for females 13 to 49 years old, the acute dietary exposure from food and water to fludioxonil will occupy 14% of the aPAD for (females 13 to 49 years old) the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fludioxonil from food and water will utilize 89% of the cPAD for (children 1 to 2 years old) the population group receiving the greatest exposure.

Based on the discussions above regarding residential use patterns, chronic residential exposure to residues of fludioxonil is not expected. The chronic aggregate risk does not exceed the Agency's level of concern.

3. *Short-term risk*. In aggregating short-term risk, EPA considers background chronic dietary exposure (food + water) and short-term, residential non-dietary oral and dermal exposures. Fludioxonil is restricted to commercial handlers. Therefore, the only non-occupational exposure expected to result from the residential uses of fludioxonil is post-application exposure. For adults, post-application exposures may result from dermal contact with treated turf. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. However, the Agency did not identify short-term dermal endpoints for fludioxonil. Therefore, the short-term aggregate risk for fludioxonil considers food, water, and residential non-dietary oral exposures (for toddlers).

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 250 for children (1 to 2 years old) and 280 for children (3 to 5 years old) for short-term scenario. These values are well above the Agency's level of concern of an aggregate MOE level of below 100.

4. *Intermediate-term risk*. In aggregating intermediate-term risk, the Agency considers background chronic dietary exposure (food + water) and intermediate-term, residential non-dietary oral and dermal exposures. Based on the residential use pattern, there is a possibility, although unlikely, that a toddler may experience intermediate-term exposures to fludioxonil residues on treated lawns. As with the short-term aggregate assessment, only non-dietary exposures are included. Therefore, the intermediate-term aggregate risk for fludioxonil considers food, water, and residential non-dietary oral exposures (for toddlers).

All intermediate-term aggregate risk estimates result in MOEs greater than 100, with the exception that the MOE for children 1 to 2 years old is 98, just below 100. Due to the conservative nature of the dietary exposure assessment (assumes 100% of crops with tolerances are treated and most crops have residues at the tolerance-level and the fact that dietary exposure is 78 percent of the aggregate exposure), EPA does not have any concern for the purposes of this action. Intermediate-term aggregate exposure to fludioxonil, as a result of all registered and proposed uses, is below EPA's level of concern.

5. *Aggregate cancer risk for U.S. population*. Fludioxonil poses a negligible cancer risk. 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.

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 is available to enforce the tolerance expression. 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; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Canadian or Mexican Maximum Residue Limits (MRLs) for residues of fludioxonil. There are Codex limits on tomato (higher than the U.S. limit; 0.5 ppm vs 0.40 ppm, proposed), herbs (equal to or lower than the U.S. limit), cucurbits (lower than the U.S. limit), and carrot (lower than the U.S. limit). Except for tomato, the Codex MRLs are not a restriction on items for which there is a significant import trade. Since having the U.S. tolerance lower than the Codex MRL would cause a barrier to tomato imports, the tomato and tomatillo tolerances were raised from 0.40 ppm to 0.50 ppm.

C. Revisions to Petitioned-For Tolerances

The Agency modified/amended certain tolerances as proposed by the registrant and/or indicated by available supporting data, as follows:

i. Proposed new tolerances for herb subgroup 19A, fresh at 13 ppm and herb subgroup 19A, dried at 55 ppm were rejected by EPA and existing tolerances at 10 ppm and 60 ppm, respectively, were retained. The petitioner requested that the existing data for fresh and dry basil and chive be combined with the submitted parsley data and used in support of the requested tolerances on the herb subgroup 19A, fresh and dried at 13 ppm and 55 ppm, respectively. There are adequate residue field trials to support a tolerance on parsley, fresh and dried. The analytical results show

that fludioxonil residues were 3.87 ppm in fresh parsley and 22.29 ppm in dried parsley. It is EPA policy to analyze each crop in a group separately and establish the group tolerance using the highest of the individual analyses. Since there are existing tolerances for herb subgroup 19A, fresh and dried at 10 ppm and 65 ppm, respectively, and the data from the parsley residue field trials do not exceed those established tolerances using the same treatment pattern, no change in the group tolerance is required.

ii. Proposed tolerances for lime at 0.25 ppm; and lemon at 0.25 ppm were determined to be unnecessary due to the existing tolerance on fruit, citrus, group 10 at 10 ppm and the citrus, oil tolerance at 500 ppm established by this regulation.

iii. Proposed tolerances for tomato at 0.40 and tomatillo at 0.40 were both raised to 0.50 ppm to address international harmonization issues. Proposed tolerances for tomato paste at 1.0 ppm is not needed. Results of processed commodities studies show that fludioxonil residues do not appreciably concentrate, and

iv. Certain commodity definitions in the petition were corrected or revised to comply with EPA's Pesticide Tolerance Crop Grouping Program outlined in the **Federal Register** of December 7, 2007, 72 FR 69150

V. Conclusion

Therefore, tolerances are established for residues of the fungicide fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile, in or on avocado at 0.45 ppm, canistel at 0.45 ppm, citrus, oil at 500 ppm, mango at 0.45 ppm, papaya at 0.45 ppm, sapodilla at 0.45 ppm, sapote, black at 0.45 ppm, sapote, mamey at 0.45 ppm, star apple at 0.45 ppm, tomatillo at 0.50 ppm, tomato at 0.50 ppm, vegetable, cucurbit, crop group 9 at 0.45 ppm, vegetable, leaves of root and tuber, crop group 2 at 30 ppm, vegetable, root, except sugar beet, subgroup 1B at 0.75 ppm, and vegetable, tuberous and corm, except potato, subgroup 1D at 3.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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, *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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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 25, 2008.

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. In § 180.516 the table to paragraph (a) is amended by removing the entries for ''carrot;'' ''grapefruit oil'' and ''leaves and roots of tuber vegetables,'' and by alphabetically adding the following commodities, except for ''vegetable, cucurbit, group 9,'' which is revised. The added and revised entries read as follows:

§ 180.516 Fludioxonil; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * * *	*
Avocado	0.45
* * * *	*
Canistel	0.45
* * * *	*
Citrus, oil	500
* * * *	*
Mango	0.45
* * * *	*
Papaya	0.45
* * * *	*
Sapodilla	0.45
Sapote, black	0.45
Sapote, mamey	0.45
* * * *	*
Star apple	0.45
* * * *	*
Tomatillo	0.50
Tomato	0.50
* * * *	*
Vegetable, cucurbit, crop group 9	0.45

Commodity	Parts per million
* * * *	*
Vegetable, leaves of root and tuber, crop group 2	30
Vegetable, root, except sugar beet, subgroup 1B	0.75
* * * *	*
Vegetable, tuberous and corn, except potato, subgroup 1D	3.5
* * * *	*

* * * * *

[FR Doc. E8–20547 Filed 9–9–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0262; FRL–8379–8]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises the tolerances for combined residues of spiromesifen and its enol metabolite in or on corn. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 10, 2008. Objections and requests for hearings must be received on or before November 10, 2008, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0262. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Amer Al-Mudallal, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0566; e-mail address: *al-mudallal.amer@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 Access Electronic Copies of This Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0262 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before November 10, 2008.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0262, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of May 16, 2008 (73 FR 28461) (FRL–8361–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7274) by Bayer CropScience, P. O. Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.607 be amended by increasing tolerances for combined residues of the insecticide/miticide spiromesifen in or on corn, field, forage from 3.0 ppm to 6.0 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public 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 revised