Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 24, 2011.

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 the table to § 180.910 add alphabetically a new inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * *	*	* *
Isobutane (CAS Reg. No. 75–28–5)	None	Propellant.
* * * * *	*	* *

■ 3. In the table to § 180.930, add alphabetically a new inert ingredient to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * *	*	* *
Isobutane (CAS Reg. No. 75–28–5)	None	Propellant.
* * * * *	*	* *

[FR Doc. 2011–2265 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0385; FRL–8860–3]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends tolerances for residues of cyprodinil in or on fruit, pome, group 11 and apple wet pomace. This regulation also establishes tolerances for meat byproducts of cattle, goats, horses and sheep. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, 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–2010–0385. 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: Lisa Jones, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9424; e-mail address: *jones.lisa@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://www.gpoaccess.gov/ecfr.*

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–2010–0385 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 4, 2011. 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–2010–0385, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 8, 2010 (75 FR 32466) (FRL–8827–5), 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 0F7696) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27409. The petition requested that 40 CFR 180.532 be amended by raising tolerances for residues of the fungicide cyprodinil, in or on fruit, pome, group 11 from 0.1 parts per million (ppm) to 1.7 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has increased the tolerance for apple, wet pomace from 0.15 ppm to 4.6 ppm. EPA has also established tolerances for meat byproducts of cattle, goats, horses, and sheep at 0.02 ppm. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

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

Cyprodinil has low acute toxicity via the oral, dermal, and inhalation routes. Cyprodinil is mildly irritating to the eyes and negligibly irritating to the skin. It is a dermal sensitizer. The major target organs of cyprodinil are the liver in both rats and mice and the kidney in rats. Liver effects observed consistently in subchronic and chronic studies in rats and mice include increased liver weights, increases in serum clinical chemistry parameters associated with adverse effects on liver function, hepatocyte hypertrophy, and hepatocellular necrosis. Adverse kidney effects include tubular lesions and inflammation following subchronic exposure of male rats. The hematopoietic system also appeared to be a target of cyprodinil, causing mild anemia in rats exposed subchronically. Chronic effects in dogs were limited to decreased body-weight gain, decreased food consumption and decreased food efficiency. There was no evidence of increased susceptibility in the developmental rat or rabbit study following *in utero* exposure or in the 2-generation reproduction study following prenatal or postnatal exposure. There was no evidence of neuropathological or other neurological effects in the available subchronic neurotoxicity study. The results of a preliminary immunotoxicity study provided no evidence for immunotoxicity. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies.

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 (LOC) 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 cyprodinil used for human risk assessment is discussed in Unit III.A of the final rule published in the **Federal Register** of April 28, 2010 (75 FR 22242) (FRL–8818–8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyprodinil, EPA considered exposure under the petitioned-for tolerances as well as all existing cyprodinil tolerances in 40 CFR 180.532. EPA assessed dietary exposures from cyprodinil 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 cyprodinil. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model–Food Consumption Intake Database (DEEM–FCID™, Version 2.03), which uses food consumption data from the U. S. Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994–1996 and 1998. As to residue levels in food, EPA performed a screening level acute dietary exposure analysis for the population subgroup females 13 to 49 only. No acute endpoint was identified for the remaining population subgroups. Tolerance level residues and 100 percent crop treated (PCT) assumptions were used. DEEM default and empirical processing factors were used to modify the tolerance values.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the DEEM–FCID™, Version 2.03, which uses food consumption data from the USDA 1994–1996 and 1998 CSFII. A moderately refined chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. Average field trial residues for pome fruit, tolerance level residues for the remaining commodities, and 100 PCT assumptions were used. DEEM default and empirical processing factors were used.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determine a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Data summarized in Table 2 of the document "Human Health Risk—Cyprodinil Increased Pome Fruit Tolerance", pp. 24 through 29, in docket ID number EPA–HQ–OPP–2010–0385 at *http://www.regulations.gov,* showed no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies. EPA therefore concluded that cyprodinil does not pose a cancer risk to humans. Therefore a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) 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 cyprodinil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyprodinil. 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 cyprodinil for acute exposures are 34.79 parts per billion (ppb) for surface water and 0.0861 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 24.65 ppb for surface water and 0.0861 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 34.79 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 24.65 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). Cyprodinil is not registered for any specific use patterns that would result in residential 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 cyprodinil to share a common mechanism of toxicity with any other substances, and cyprodinil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyprodinil 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 Web site 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 database is considered adequate for selection of study endpoints and determination of a dose/response to characterize the potential prenatal or postnatal toxicity of cyprodinil to infants and children. No increase in susceptibility was seen in developmental toxicity studies in rat and rabbit or reproductive toxicity studies in the rat. Toxicity to offspring was observed at dose levels the same or greater than those causing maternal or parental toxicity. Based on the results of developmental and reproductive toxicity studies, there is not a concern for increased qualitative and/or quantitative susceptibility following *in utero* exposure to cyprodinil.

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 toxicology database for cyprodinil is largely complete, missing only the recently-required acute neurotoxicity study and the functional immunotoxicity study. EPA has determined that an additional uncertainty factor is not needed to account for the lack of these studies for the following reasons:

The functional immunotoxicity study for cyprodinil is not expected to alter the RfD. A preliminary immunotoxicity study was submitted. The study did not meet all requirements, but is considered Upgradeable/Guideline. The registrant must either submit a required Natural Killer cell activity assay or provide justification that it is not needed. Otherwise, the results of the preliminary study provided no evidence of immunotoxicity. Specifically, there were no treatment-related effects on absolute, adjusted, or relative spleen or thymus weights; no effects on specific activity or total activity of splenic IgM antibody-forming cells to the T cell-dependent antigen sRBC. There is no evidence in the other existing studies that cyprodinil targets the immune system. No other immunotoxicity studies have been submitted.

The acute neurotoxicity study is not expected to alter the RfD for cyprodinil because the available data show no evidence of neurotoxic potential for cyprodinil. The NOAEL from an acute study is unlikely to be appreciably lower than the NOAEL of 600 mg/kg/day from the subchronic neurotoxicity study. Neurotoxicity was not observed in subchronic neurotoxicity study or the prenatal developmental toxicity studies in rats and rabbits.

ii. A developmental neurotoxicity study is not required. As noted, the available data show no evidence of neurotoxic potential for cyprodinil.

iii. There is no evidence that cyprodinil 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 acute dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The chronic dietary food exposure assessments were performed based on average field trial residues for pome fruit, tolerance level residues for the remaining commodities, and 100 PCT assumptions. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyprodinil in drinking water. These assessments will not underestimate the exposure and risks posed by cyprodinil.

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 population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyprodinil will occupy 4% 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 cyprodinil from food and water will utilize 86% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure.

3. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyprodinil is not expected to pose a cancer risk to humans.

4. *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 cyprodinil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate High Performance Liquid Chromatography, using ultra-violet detection (HPLC/UV) methods with column switching (Syngenta Methods AG–631 and AG–631B) are available for enforcing tolerances of cyprodinil on plant commodities. The level of quantitation (LOQs) for these methods range from 0.01 to 0.05 ppm depending on the plant commodities. Method AG–631B also contains procedures for confirmatory analysis by gas chromatography with nitrogen phosphorus detection (GC/NPD).

An adequate HPLC/mass spectrometry method (GRM010.01A) is also available for enforcing tolerances in livestock commodities. This method determines residues of both parent and the metabolite CGA–304075 (free and conjugated), expressed as parent. The LOQ is 0.01 ppm for each analyte for a combined LOQ of 0.02 ppm.

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

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 U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for residues of cyprodinil in/on apple (0.05 mg/kg, the LOQ) and pear (1 mg/kg). There is also a currently established Canadian MRL for residues of cyprodinil in/on pome fruit (0.1 ppm); but none is established in Mexico. It is not possible to harmonize with Codex and Canadian MRLs for residues of cyprodinil in/on pome fruit commodities because the proposed use in the United States results in residue levels greater than the Codex and Canadian MRLs due to the shorter preharvest interval in the United States.

C. Revisions to Petitioned-For Tolerances

Based on the submitted apple field trial and available apple processing data, the currently established tolerance for residues of cyprodinil in apple wet pomace will need to be increased from 0.15 ppm to 4.6 ppm to cover the proposed amended uses of cyprodinil on pome fruit. Additionally, the Agency has determined the currently established 0.02 ppm tolerance level for meat byproducts of cattle, goats, horses, and sheep are adequate but the currently established tolerance expression for livestock commodities should be changed to reflect measurements of both parent and metabolite CGA–304075.

V. Conclusion

Therefore, tolerances are established for residues of cyprodinil, in or on pome fruit at 1.7 ppm and in apple wet pomace at 4.6 ppm. Tolerances are also established for cyprodinil and (free and conjugated) CGA–304075, expressed in parent equivalents on meat byproducts of cattle, goats, horses, and sheep at 0.02 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, 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 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) (Pub. L. 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: January 24, 2011.

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 180.532 is amended by revising paragraph (a) to read:

§ 180.532 Cyprodinil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide cyprodinil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only cyprodinil 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine.

Commodity	Parts per million
Almond	0.02
Almond, hulls	8.0
Apple, wet pomace	4.6
Avocado	1.2
Bean, dry	0.6
Bean, succulent	0.6
Brassica, head and stem, subgroup 5A	1.0
Brassica, leafy greens, subgroup 5B	10.0

Commodity	Parts per million
Bushberry subgroup 13B	3.0
Caneberry subgroup 13A	10
Canistel	1.2
Canola, seed [1]	0.03
Citrus, dried pulp	8.0
Citrus, oil	340
Fruit, pome	1.7
Fruit, stone	2.0
Grape	2.0
Grape, raisin	3.0
Herb subgroup 19A, dried, except parsley	15.0
Herb subgroup 19A, fresh, except parsley	3.0
Juneberry	3.0
Kiwifruit	1.8
Leafy greens subgroup 4A, except spinach 35	30
Lemon	0.60
Lime	0.60
Lingonberry	3.0
Longan	2.0
Lychee	2.0
Mango	1.2
Onion, bulb	0.60
Onion, green	4.0
Papaya	1.2
Parsley, dried leaves	170
Parsley, leaves	35
Pistachio	0.10
Pulasan	2.0
Rambutan	2.0
Salal	3.0
Sapodilla	1.2
Sapote, black	1.2
Sapote, mamey	1.2
Spanish lime	2.0
Star apple	1.2
Strawberry	5.0
Tomatillo	0.45
Tomato	0.45
Tomato, paste	1.0
Turnip, greens	10.0
Vegetable, cucurbit, group 9	0.70
Vegetable, leaves of root and tuber, group 2	10
Vegetable, root, except sugarbeet, subgroup 1B 41	0.75
Watercress	20

[1] Import only.

(2) Tolerances are established for residues of the fungicide cyprodinil, including its metabolites and degradates, in the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of cyprodinil 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine and free and conjugated CGA–304075 4-(4-cyclopropyl-6-methyl-pyrimidin-2-ylamino)-phenol, calculated as the stoichiometric equivalent of cyprodinil.

Commodity	Parts per million
Cattle, meat byproducts	0.02
Goat, meat byproducts	0.02
Horse, meat byproducts	0.02
Sheep, meat byproducts	0.02

* * * * *

[FR Doc. 2011–2157 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0980; FRL–8861–1]

Fluazifop-P-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazifop-P-butyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, 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–2009–0980. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0980 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