

modified carrot, roots from 0.7 ppm to 0.45 ppm; celeriac, tops from 0.05 ppm to 0.20 ppm; cilantro, leaves from 4.0 ppm to 3.5 ppm; coriander, dried leaves from 15.0 ppm to 9.0 ppm; parsley, leaves from 0.7 ppm to 0.60 ppm. EPA revised these tolerance levels based on analysis of the residue field trial data using the Agency's tolerance spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data. EPA also revised the commodity term for cilantro dried to coriander, dried leaves, to be in compliance with correct commodity definition. Additionally, EPA determined that a tolerance is required for parsley, dried leaves at 1.5 ppm. Additionally, the tolerance for celery is removed since it is included in the leaf petioles subgroup 4B and the regional tolerance for parsley leaves is removed since it is superseded by the tolerance established in this action.

**V. Conclusion**

Therefore, tolerances are established for residues of prometryn, 2,4-bis(isopropylamino)-6-methylthio-s-triazine, in or on celeriac, roots at 0.05 ppm; celeriac, tops at 0.20 ppm; cilantro, leaves at 3.5 ppm; coriander, dried leaves at 9.0 ppm; leaf petioles subgroup 4B at 0.50 ppm; okra at 0.05 ppm; parsley, leaves at 0.60 ppm; parsley, dried leaves at 1.5 ppm and increases the tolerance level for carrot, root to 0.45 ppm. Additionally, the tolerance for celery is removed since it is included in the leafy petioles subgroup 4B and the regional tolerance for parsley leaves is removed since it is superseded by the tolerance established in this action.

**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) (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: December 8, 2009.

**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 § 180.222, in the table to paragraph (a) by revising the entry for "carrot, roots"; by removing footnote 1, and the entry for "celery," and by adding alphabetically entries for "celeriaceae, roots"; "celeriaceae, tops"; "cilantro, leaves"; "coriander, dried leaves"; "leaf petioles subgroup 4B"; "okra"; "parsley, leaves"; and "parsley, dried leaves" to read as follows, and in the table to paragraph (c) by removing the entry for "parsley, leaves."

**§ 180.222 Prometryn; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Carrot, roots .....	0.45
Celeriac, roots .....	0.05
Celeriac, tops .....	0.20
Cilantro, leaves .....	3.5
Coriander, dried leaves ..	9.0
* * *	* *
Leaf petioles subgroup 4B .....	0.50
Okra .....	0.05
Parsley, dried leaves .....	1.5
Parsley, leaves .....	0.60
* * *	* *

\* \* \* \* \*

[FR Doc. E9-30040 Filed 12-17-09; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2008-0704; FRL-8803-4]

**Fluoxastrobin; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of fluoxastrobin and its Z isomer in or on berry, low growing, subgroup 13-07G; corn, field, grain; corn, field, forage; corn, field, stover; soybean, forage; soybean, hay; soybean, hulls; soybean, seed; and aspirated grain fractions. Arysta LifeScience North America, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, 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-2008-0704. 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:** John Bazuin, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7381; e-mail address: [bazuin.john@epa.gov](mailto:bazuin.john@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 e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods & Guidelines" on the left-side navigation menu.

###### *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-2008-0704 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 February 16, 2010.

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-2008-0704, 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 December 3, 2008 (73 FR 73640) (FRL-8390-4), 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 8F7437) by Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, NC 27513. The petition requested that 40 CFR 180.609 be amended by establishing tolerances for combined residues of the fungicide fluoxastrobin, (1E)-[2-[[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime and its Z isomer, (1Z)-[2-[[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime, in or on corn, field, grain at 0.02 parts per million (ppm); corn, field, aspirated grain fractions at 0.50 ppm; corn, field, forage at 3.0 ppm; corn, field, fodder/stover at 4.5 ppm; soybean, seed at 0.05 ppm; soybean, aspirated grain fractions at 0.40 ppm; soybean, forage at 9.0 ppm; soybean, hay at 1.2 ppm; and soybean, hulls at 0.40 ppm.

Also in the **Federal Register** of December 3, 2008 (73 FR 73644) (FRL-8386-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of another pesticide petition (PP 8F7406) by Arysta LifeScience North America, LLC. The petition requested that 40 CFR 180.609 be amended by establishing

tolerances for the combined residues of the fungicide fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime, in or on low growing berries (crop subgroup 13-07G) at 1.9 ppm. Each notice referenced a summary of the appropriate petition which had been prepared by Arysta LifeScience North America, LLC, the registrant, and 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 corrected the commodity and subgroup names, and replaced “corn, field, aspirated grain fractions” and “soybeans, aspirated grain fractions” with “aspirated grain fractions.” EPA has also substantially increased the tolerance for aspirated grain fractions and decreased the tolerance for soybean, hulls. The reasons for these changes are 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 upper 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 the combined residues of fluoxastrobin and its Z isomer in or on aspirated grain fractions at 20 ppm; berry, low growing, subgroup 13-07G at 1.9 ppm; corn, field, forage at 3.0 ppm; corn, field grain at 0.02 ppm; corn, field, stover at 4.5 ppm; soybean, forage at 9.0 ppm; soybean, hay at 1.2 ppm; soybean, hulls at 0.20 ppm; soybean, seed at 0.05 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 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. Fluoxastrobin shows low acute toxicity via the oral, dermal, and inhalation routes of exposure; is a moderate eye irritant; and is neither a dermal irritant nor a sensitizer. Following repeated administration, fluoxastrobin has mild or low toxicity in all tested species other than the dog which displayed adverse liver toxicity at considerably lower doses than those noted for other testing species. The most common finding across all testing species is decreased body weight. In the available toxicity studies on fluoxastrobin, there is no estrogen, androgen, and/or thyroid mediated toxicity. Fluoxastrobin does not produce developmental toxicity in rats or rabbits. In the rat and rabbit developmental toxicity studies and the two-generation reproduction rat study, there is no increased susceptibility to prenatal or postnatal exposure to fluoxastrobin and no effects on reproduction. Fluoxastrobin is not neurotoxic following acute or repeated dosing in the rat. Fluoxastrobin is not genotoxic, and it is also not carcinogenic in rats or mice. Specific information on the studies received and the nature of the adverse effects caused by fluoxastrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of September 16, 2005 (70 FR 54640) (FRL-7719-9).

#### 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 fluoxastrobin used for human risk assessment can be found at <http://www.regulations.gov> in the document “Fluoxastrobin. Human Health Risk Assessment for Proposed Uses on Field Corn, Soybean, and the Low-Growing Berry Subgroup 13-07G,” at page 20 in docket ID number EPA-HQ-OPP-2008-0704.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluoxastrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing fluoxastrobin tolerances in 40 CFR 180.609. EPA assessed dietary exposures from fluoxastrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if

a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for fluoxastrobin; therefore, a quantitative acute dietary exposure assessment was not performed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture 1994–1996 and 1998 CSFII. As to residue levels in food, EPA performed an unrefined dietary (food and drinking water) exposure assessment. The assumptions of this dietary assessment included tolerance level residues and 100% crop treated. Experimentally derived processing factors were applied for tomato puree, potato chips, dry potato granules/flakes, and potato flour. For all other processed commodities, DEEM version 7.81 default processing factors were assumed.

iii. *Cancer.* The Agency has concluded that fluoxastrobin is not likely to be carcinogenic to humans. Therefore cancer risk is not of concern for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or less than 100% crop treated information in the dietary assessment for fluoxastrobin. Tolerance level residues and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluoxastrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluoxastrobin. 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 FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fluoxastrobin for chronic exposures for non-cancer assessments are estimated to be 28 parts per billion (ppb) for surface water and less than 1 ppb for ground water. The modeled estimate of surface drinking water concentration was directly entered into the dietary exposure model. For chronic dietary risk assessment, a water concentration value of 28 ppb was used to assess the contribution of 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, termite control, and flea and tick control on pets).

Fluoxastrobin is currently registered for the following uses that could result in postapplication residential exposures: Turf, including lawns and golf courses. No residential handler exposure uses have been registered because all applications to residential turf must be made by a certified pest control operator. EPA assessed residential exposure using the following assumptions: Maximum application rates, no dissipation of residues after the day of application, and no dissipation of residues because of periodic growth and recutting of the grass. The Agency believes that the calculated risks represent screening level estimates. Principal potential routes of exposure include dermal and incidental oral ingestion. The Agency has assumed that most residential use will result in short-term exposures but that intermediate-term exposures are also possible. It should be noted that the new fluoxastrobin uses assessed for this final rule do not include any residential uses.

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 fluoxastrobin to share a common mechanism of toxicity with any other substances, and fluoxastrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluoxastrobin 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 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 toxicity database for fluoxastrobin, including acceptable developmental toxicity studies in rats and rabbits, as well as a two-generation reproduction toxicity study, provides no indication of prenatal and/or postnatal sensitivity.

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 fluoxastrobin is considered adequate to support endpoint selection for risk assessment and FQPA evaluation. The submitted studies are of good quality and provide sufficient information to determine whether fluoxastrobin poses a human health hazard. The only data deficiency that exists is the requirement for additional information concerning the mouse subchronic immunotoxicity study, for potential upgrade of the study. To address the immunotoxicity data requirement as presented in 40 CFR part 158 the Agency has examined the entire toxicity database for fluoxastrobin and drawn the following conclusion: There is no evidence of biologically relevant effects on the immune system that are related to fluoxastrobin and the overall weight of the evidence indicates that this chemical does not directly target the immune system.

ii. There is no indication that fluoxastrobin 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 indication of increased quantitative or qualitative susceptibility in rats or rabbits following *in utero* and/or postnatal exposure to fluoxastrobin.

iv. There are no residual uncertainties identified in the exposure database. The chronic dietary food exposure assessment utilizes proposed tolerance-level residues and 100% crop treated information for all commodities. Use of these screening-level assessment values helps ensure that chronic exposures and risks will not be underestimated. EPA additionally made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluoxastrobin in

drinking water. EPA used similarly conservative assumptions to assess residential post-application exposure of children as well as incidental oral exposure of toddlers to fluoxastrobin. These assessments will not underestimate the exposure and risks posed by fluoxastrobin.

#### *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. Therefore, fluoxastrobin is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluoxastrobin from food and water will utilize 38% 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 fluoxastrobin is not expected.

3. *Short- and intermediate-term risk.* Fluoxastrobin is currently registered for uses that could result in both short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to fluoxastrobin. Short- and intermediate-term aggregate exposure assessments take into account short- and intermediate-term residential exposure, respectively, plus chronic exposure to food and water (considered to be a background exposure level). Because all short- and intermediate-term quantitative hazard estimates (via the dermal and incidental oral routes) for

fluoxastrobin are based on the same endpoint, a screening-level, conservative aggregate risk assessment was conducted that combined the short-term incidental oral and intermediate-term exposure estimates (i.e., the highest exposure estimates). The Agency believes that most residential exposure will be short-term, based on the use pattern.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short- and intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of 750 for adult males, 840 for adult females, and 160 for children 1 to 2 years old. For adult males and adult females, residential exposure is via the oral (background) and dermal (primary) routes. For children 1 to 2 years old, residential exposure is via the oral (background) and incidental oral and dermal (primary) routes.

4. *Aggregate cancer risk for the U.S. population.* The Agency has concluded that fluoxastrobin is not likely to be carcinogenic to humans. Therefore cancer risk is not of concern for this chemical.

5. *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 fluoxastrobin residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry method) is available to enforce the tolerance expression. Method No. 00604 is available for plant commodities and Method No. 00691, Modification 001, is available for animal 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; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

There are currently no established Codex, Canadian, or Mexican Maximum Residue Levels (MRLs) for fluoxastrobin for the low-growing berry subgroup 13-07G, soybean, or field corn commodities.

##### *C. Revisions to Petitioned-For Tolerances*

EPA converted “corn, field, fodder/stover” to “corn, field, stover” to

conform to the terminology in the current pesticide commodity vocabulary. The Agency also replaced “corn, field, aspirated grain fractions” and “soybean, aspirated grain fractions” with “aspirated grain fractions” to conform to the terminology in the current pesticide commodity vocabulary. The proposed tolerances of 0.50 ppm in or on corn, field, aspirated grain fractions and 0.40 ppm in or on soybean, aspirated grain fractions were changed to a tolerance of 20 ppm in or on aspirated grain fractions based on current guidance, which recommends that the established tolerance be based on the aspirated grain fraction that has the highest residues. In this case it is soybean. The soybean highest available field trial (HAFT) residue of 0.031 ppm multiplied by the expected processing factor for aspirated grain fractions of 611x produces calculated expected residues in aspirated grain fractions of 18.9 ppm. The fluoxastrobin tolerance in/on aspirated grain fractions was therefore set at 20 ppm. The proposed tolerance of 0.40 ppm in/on soybean hulls was reduced to 0.20 ppm because the HAFT residue for soybean of 0.031 ppm is expected to concentrate 4x in soybean hulls. This produces a calculated residue of 0.124 ppm and a decision that a tolerance of 0.20 ppm is appropriate. In addition, the establishment of tolerances on field corn commodities requires that the tolerance for indirect and inadvertent residues for fluoxastrobin and its Z isomer in/on grain, cereal, forage, fodder, and straw, group 16, be modified to apply to grain, cereal, forage, fodder, and straw, group 16, except corn instead. The tolerance expressions in 40 CFR 180.609 are also being modified to conform to new Agency guidance on the language tolerance expressions should conform to, but this change does not have any other effect on the existing fluoxastrobin tolerances.

#### **V. Conclusion**

Therefore, tolerances are established for the combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime, in or on aspirated grain fractions at 20 ppm; berry, low growing, subgroup 13-07G at 1.9 ppm; corn, field, forage at 3.0 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 4.5 ppm; soybean, forage at 9.0 ppm; soybean,

hay at 1.2 ppm; soybean, hulls at 0.20 ppm; and soybean, seed at 0.05 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) (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: December 8, 2009.

**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 180.609 is revised to read as follows:

**§ 180.609 Fluoxastrobin; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of fluoxastrobin, 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 fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone

O-methyloxime, calculated as the stoichiometric equivalent of fluoxastrobin.

Commodity	Parts per million
Aspirated grain fractions .....	20
Berry, low growing, subgroup 13-07G .....	1.9
Corn, field, forage .....	3.0
Corn, field, grain .....	0.02
Corn, field, stover .....	4.5
Leaf petioles subgroup 4B ...	4.0
Peanut .....	0.010
Peanut, hay .....	20.0
Peanut, refined oil .....	0.030
Soybean, forage .....	9.0
Soybean, hay .....	1.2
Soybean, hulls .....	0.20
Soybean, seed .....	0.05
Tomato, paste .....	1.5
Vegetable, fruiting, group 8 ..	1.0
Vegetable, tuberous and corm, subgroup 1C .....	0.010

(2) Tolerances are established for residues of fluoxastrobin, 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 fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its phenoxy-hydroxy pyrimidine, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, calculated as the stoichiometric equivalent of fluoxastrobin.

Commodity	Parts per million
Cattle, fat .....	0.10
Cattle, meat .....	0.05
Cattle, meat byproducts .....	0.10
Goat, fat .....	0.10
Goat, meat .....	0.05
Goat, meat byproducts .....	0.10
Horse, fat .....	0.10
Horse, meat .....	0.05
Horse, meat, byproducts .....	0.10
Milk .....	0.02
Milk, fat .....	0.50
Sheep, fat .....	0.10
Sheep, meat .....	0.05
Sheep, meat byproducts .....	0.10

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of

fluoxastrobin, including its metabolites and degradates, in or on the commodities in the table below, when present therein as a result of the application of fluoxastrobin to the growing crops listed in paragraph (a)(1) of this section. Compliance with the tolerance levels specified below is to be determined by measuring only fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, calculated as the stoichiometric equivalent of fluoxastrobin.

Commodity	Parts per million
Alfalfa, forage .....	0.050
Alfalfa, hay .....	0.10
Cotton, gin byproducts .....	0.020
Grain, cereal, forage, fodder, and straw, group 16, except corn .....	0.10
Grass, forage .....	0.10
Grass, hay .....	0.50
Vegetable, foliage of legume, group 7 .....	0.050

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2008-0276; FRL-8800-8]

**Prosulfuron; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of prosulfuron and its metabolites and degradates in or on cereal grain commodities. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, 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-2008-0276. 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](mailto: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 cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods & Guidelines" on the left-side navigation menu.

*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-2008-0276 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 February 16, 2010.

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-2008-0276, 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 August 13, 2008 (73 FR 47186) (FRL-8375-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a