List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 18, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(354)(i)(A)(*5*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(354) * * *

(i) * * *

(A) * * *

(*5*) Rule 1113, ''Architectural Coatings,'' amended on July 13, 2007.

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[FR Doc. 2011–20842 Filed 8–16–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0725; FRL–8884–4]

Fluoxastrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fluoxastrobin in or on squash/cucumber subgroup 9B. Arysta LifeScience North America, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 17, 2011. Objections and requests for hearings must be received on or before October 17, 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–2010–0725. 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: Heather Garvie, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0034; e-mail address: *garvie.heather@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

B. How can I get electronic access to other related information?

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0725 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 October 17, 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–2010–0725, 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 September 23, 2010 (75 FR 57942) (FRL–8845–4), 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 0F7726) by Arysta LifeScience North America, LLC, 15401 Weston Pkwy., Suite 150, Cary, NC 27513. The petition requested that 40 CFR 180.609 be amended by establishing a tolerance for residues of the fungicide, fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]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-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on raw agricultural commodities listed under crop squash/cucumber subgroup 9B at 0.50 parts per million (ppm). That notice referenced a summary of the petition prepared by Arysta LifeScience, North America, LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has made the following changes to the proposed fluoxastrobin tolerance. A minor change has been made to the commodity name to conform to the Agency's Food and Feed Commodity Vocabulary.

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 fluoxastrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluoxastrobin 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 has a low order of acute toxicity via the oral, dermal and inhalation routes of exposure. Fluoxastrobin is a moderate eye irritant but is neither a dermal irritant nor a skin sensitizer.

Fluoxastrobin appears to have mild or low toxicity following repeated administration in all tested species other than the dog. In both the 90-day and 1-year oral feeding dog studies, there was liver toxicity in the form of cholestasis as evidenced by hepatocytomegaly and cytoplasmic granular changes associated with increased liver weight and increased serum liver alkaline phosphatase (ALP). In addition, several phase I and phase II liver drug metabolizing enzymes were induced.

In the rat and rabbit developmental toxicity studies and the 2-generation reproduction rat study, there was no increased susceptibility to prenatal or postnatal exposure to fluoxastrobin and no effects on reproduction.

Fluoxastrobin is not acutely neurotoxic in rats up to a single high dose of 2,000 milligrams/kilogram/day (mg/kg/day) or by repeated dietary feeding in the rat subchronic neurotoxicity screening study where the top dose was nearly half the limit dose of 1,000 mg/kg/day. Other studies in rats including the subchronic, chronic toxicity/carcinogenicity, 2-generation reproduction, and developmental toxicity were tested to or above the limit dose with no indication of clinical signs, histopathology or other signs of toxicity that could be attributed to neurotoxicity. Also, in both the 90-day and 1-year dog studies, neurologic examinations, including mental status/behavior, gait characteristics, postural status and reactions, and spinal/cranial reflexes, were carried out and were found to be within normal limits.

Fluoxastrobin is not immunotoxic based on repeated dosing studies in rats and mice. In the 90-day oral toxicity rat study, there was no difference between the controls and treated animals in spleen cell count, macrophage activities after phorbol myristate acetate (PMA) stimulation and plaque-forming cell assay after challenge with sheep erythrocytes. Slight decreases were noted in immunoglobulin G concentration in the high dose males but not females. An unacceptable subchronic immunotoxicity study in mice found no apparent decrease on B-cell activated, T-cell mediated immunoglobulin M (IgM) response to sheep red blood cell (SRBC) at doses as high as 2,383 mg/kg/day.

Fluoxastrobin and major metabolites were negative in a battery of genotoxicity tests. The carcinogenic potential of fluoxastrobin was adequately tested in rats and mice of both sexes. The results demonstrated a lack of treatment-related increase in tumor incidence in rats or mice. There was no mutagenicity concern and no structure activity relationship alert. It was concluded that there was no incidence of carcinogenicity for fluoxastrobin.

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 Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin

of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for fluoxastrobin used for human risk assessment is shown in Table 1. of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOXASTROBIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	None: There was no indication of an adverse effect attributable to a single dose. An aRfD was not established.		
Acute dietary (General population including infants and children).	None: There was no indication of an adverse effect attributable to a single dose. An aRfD was not established.		
Chronic dietary (All populations)	NOAEL = 1.5 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.015 mg/kg/day ... cPAD = 0.015 mg/kg/day	Chronic toxicity in the dog. LOAEL = M/F 8.1/7.7 mg/kg/day based on body weight reductions and hepatocytomegaly and cytoplasmic changes associated with increased serum liver alkaline phosphatase indicative of cholestasis.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 3.0 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day subchronic dog LOAEL = M/F 24.8/24.2 mg/kg/day (800 ppm) based on dose-related reductions in net body weight gain and food efficiency in addition to toxicity findings in the liver (cholestasis) in both sexes, and kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Dermal short-term (1 to 30 days) ..	None: There were no systemic or dermal toxicity findings in a 28-day dermal toxicity study in the rat up to the limit dose (1000 mg/kg/day) and there were no developmental or neurotoxicity concerns raised in other studies.		
Dermal intermediate-term (1 to 6 months).	NOAEL = 3.0 mg/kg/day (dermal absorption rate = 2.3%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day subchronic dog LOAEL = M/F 24.8/24.2 mg/kg/day (800 ppm) based on dose-related reductions in net body weight gain and food efficiency in addition to toxicity findings in the liver (cholestasis) in both sexes, and kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 3.0 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day subchronic dog LOAEL = M/F 24.8/24.2 mg/kg/day (800 ppm) based on dose-related reductions in net body weight gain and food efficiency in addition to toxicity findings in the liver (cholestasis) in both sexes, and kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Cancer (Oral, dermal, inhalation) ..	Classification: ''Not likely to be carcinogenic to humans.''		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluoxastrobin, EPA considered exposure under the petitioned-for tolerance 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 is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted a conservative dietary exposure assessment for fluoxastrobin. The assumptions of this dietary assessment included tolerance level residues and 100 percent crop treated (PCT).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluoxastrobin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* Based on laboratory studies, fluoxastrobin persists in soils for several months to several years and is slightly to moderately mobile in soil.

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 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 fluoxastrobin for chronic exposures for non-cancer assessments are estimated to be 52.9 parts per billion (ppb) for surface water and 0.23 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 53 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). Fluoxastrobin is currently registered for the following uses that could result in residential exposures: Spot treatment and/or broadcast control of diseases on turf, including lawns and golf courses. EPA assessed residential exposure using the following assumptions: Because of the potential for application four times per year, exposure duration is expected to be short-term and intermediate-term. A short-term dermal endpoint was not identified; therefore, only intermediate-term dermal risks as well as short-and intermediate-term inhalation risks were assessed. Homeowner residential applicators are expected to be adults.

There is also the potential for homeowners and their families (of varying ages) to be exposed as a result of entering areas that have previously been treated with fluoxastrobin. Exposure might occur on areas such as lawns used by children or recreational areas such as golf courses used by adults and youths. Potential routes of exposure include dermal (adults and children) and incidental oral ingestion (children). Since no acute hazard has been identified, an assessment of episodic granular ingestion was not conducted. While it is assumed that most residential use will result in short-term (1 to 30 days) post-application exposures, it is believed that intermediate-term exposures (greater than 30 days up to 180 days) are also possible. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found 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 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 toxicity database for fluoxastrobin, including acceptable developmental toxicity studies in rats and rabbits, as well as a 2-generation reproductive toxicity study, provides no indication of prenatal and/or postnasal 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 complete except for a functional immunotoxicity study as required by the recent changes to the pesticide data requirements. The Agency does have an immunotoxicity study for fluoxastrobin but it has deficiencies that make it unacceptable at this time. Nonetheless, the Agency does not believe that conducting a new immunotoxicity study will result in a lower NOAEL than the regulatory dose for risk assessment. First, the available data do not indicate that fluoxastrobin results in primary immune system effects; a NOAEL for decreased spleen weight in the absence of histopathological findings (male rats) was 53 mg/kg/day. Secondly, no apparent decrease in B-cell activated, T-cell mediated IgM response to SRBC was seen in mice at doses as high as

2,383 mg/kg/day. The Agency therefore believes that no additional safety factor is needed to account for the lack of this study, but the registrant will be required to upgrade it.

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 evidence that fluoxastrobin 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 chronic dietary food exposure assessment utilized tolerance-level residues and 100 PCT 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 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 47% of the cPAD for children (1–2 years old), the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluoxastrobin is not expected.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). 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 of adults and children to fluoxastrobin. Because all short- and intermediate-term quantitative hazard assessments (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) in the risk assessments for adults. The Agency believes that most residential exposure will be short-term, based on the use pattern.

There is potential short- and intermediate-term exposure to fluoxastrobin via the dietary (which is considered background exposure) and residential (which is considered primary) pathways. For adults, these pathways lead to exposure via the oral (background), and dermal and inhalation (primary) routes. For children, these pathways lead to exposure via the oral (background), and incidental oral and dermal (primary) routes.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 630 for adults; 170 for children (1–2 years old). Because EPA's level of concern for fluoxastrobin is a MOE of 100 or below, these MOEs are not of concern.

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

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) is available to enforce the tolerance expression. Method No. 00604 is available for plant commodities and Method No. 00691 is available for animal commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; 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.

There are currently no established Mexican, Canadian, or Codex maximum residue limits (MRLs) or tolerances for fluoxastrobin on the squash/cucumber subgroup 9B.

C. Revisions to Petitioned-For Tolerances

EPA converted ''crop subgroup 9B squash/cucumbers'' to ''squash/cucumber subgroup 9B'' to conform it to the Agency's Food and Feed Commodity Vocabulary.

V. Conclusion

Therefore, a tolerance is established for residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]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-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, including its metabolites

and degradates, in or on squash/cucumber subgroup 9B at 0.50 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: August 10, 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 180.609 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Squash/cucumber subgroup 9B	0.50
* * * * *	

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[FR Doc. 2011–20835 Filed 8–16–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0621; FRL–8882–7]

Metconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metconazole in or on the bushberry subgroup 13–07B and the tuberous and corm vegetable subgroup 1C. The Interregional Research Project No. 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 17, 2011. Objections and requests for hearings must be received on or before October 17, 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–2010–0621. 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: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@epa.gov*.