considered). Based on these calculations, the EPA concludes that hog tolerance should be lowered as follows: Hog, meat – 0.50 ppm; hog, fat – 5.0 ppm; and hog, meat byproducts – 2.0 ppm.

As part of the current request, the petitioner submitted a poultry magnitude of the residue study monitoring spinosad residues following both the proposed dermal application scenario (0.9x) and the currently-registered premise treatment (1x). Based on these data and the current poultry MRDB, the EPA concludes that the poultry meat byproducts tolerance should be increased to 0.20 ppm (tolerance for the combined residues of spinosyns A and D). All other poultry tolerances remain adequate.

V. Conclusion

Therefore, tolerances are established for residues of spinosad in or on poultry at 0.20 ppm poultry, meat byproducts; and tolerances are increased as indicated for the following established commodities: Hog, fat 5.0 ppm; hog, meat 0.50 ppm; hog, meat byproducts 2.0 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: September 24, 2010.

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 180.495 is amended by revising the following entries in the table in paragraph (a) to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Hog, fat	5.0
Hog, meat byproducts	2.0
Hog, meat	0.50
* * *	* *
Poultry, meat byproducts	0.20
* * *	* *

* * * * *

[FR Doc. 2010–24573 Filed 9–29–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0677; FRL–8845–7]

Fluoxastrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluoxastrobin in or on multiple commodities which are identified and discussed later in this document. Arysta LifeScience North America, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 30, 2010. Objections and requests for hearings must be received on or before November 29, 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–2007–0677. 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 (7504P), 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*.

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–2007–0677 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 November 29, 2010. 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–2007–0677, 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 Tolerances

In the **Federal Register** of October 7, 2009 (74 FR 51597) (FRL–8792–7), 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 9F7567) 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 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-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 in or on aspirated grain fractions at 15 parts per million (ppm); meat byproducts (cattle, goat, horse, sheep) at 0.2 ppm; sweet corn, forage at 13 ppm; sweet corn (kernels plus cob with husks removed) at 0.02 ppm; sweet corn, stover at 10 ppm; wheat, bran at 0.2 ppm; wheat, forage at 7.0 ppm; wheat, grain at 0.09 ppm; wheat, hay at 17 ppm; and wheat, straw at 11 ppm. The proposed tolerance in or on aspirated grain fractions is actually a decrease in the pre-existing tolerance for fluoxastrobin and its Z isomer in 40 CFR 180.609 of 20 ppm. The proposed meat byproduct tolerances are actually changes in the tolerance expression from fluoxastrobin, its Z isomer, and its phenoxy-hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol to fluoxastrobin and its Z isomer and an increase in the pre-existing tolerance levels in 40 CFR 180.609 of 0.10 ppm for meat byproducts of cattle, goat, horse, and sheep. 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 tolerances. Minor changes have been made to several commodity names to conform them to the Agency's Food and Feed Commodity Vocabulary. The tolerance expression for the meat byproduct commodities has been corrected to add the phenoxy-hydroxypyrimidine metabolite. The proposed tolerance of 0.02 ppm in or on sweet corn, kernels plus cob with husks removed and of 0.2 ppm in or on wheat, bran have been reduced and the proposed tolerance of 15 ppm in or on aspirated grain fractions has been increased. 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 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 phospatase (ALP). In addition, several phase I and phase II liver drug metabolizing enzymes were induced. Other toxicity in dogs included body weight loss or reduced gain, decreased food efficiency, and effects on kidneys including increased relative weight in females and degeneration of proximal tubular epithelium in males. The no observed adverse effect level (NOAEL) of 1.5 milligrams/kilograms/day (mg/kg/day) in the 1–year dog study was used for setting the chronic reference dose (RfD).

The liver appeared to be a target organ in other studies, as well, but the toxicological relevance of liver findings in species other than the dog is questionable. For example, among the changes noted in the treated animals were increased liver weight in the mouse and rat, and hypertrophy and cytoplasmic changes in the mouse, but there were no increases in any of the serum liver enzymes including ALP.

In the 90–day oral toxicity study in rats, the urinary system in males was a target organ as evidenced by increased kidney weight and histopathology findings in kidneys, urinary bladder, and urethra including the presence of calculi in the urethra and kidneys. In another rat study, there were markedly increased urinary pHs in males in addition to increased urinary calcium excretion in the form of calcium oxalate crystals. Kidney changes were also seen in a 90–day mouse feeding study with increased kidney weights and tubular hypertrophy in females. Following 90–day administration in dogs, there was degeneration of the proximal tubular epithelium in males.

The adrenal glands seem to be another target organ in males of the 90–day rat study where vacuolation was seen in the zona fasciculata of the adrenal cortex. In another 30–day rat feeding study, adrenal cortical cytomegaly with fine vacuolization was seen in all high dose males and the responses were comparable between the groups treated with the pure fluoxastrobin E- or 2:1 E/Z-isomers. The adrenal changes are not likely to be endocrine related effects.

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 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 control and treated animals in spleen cell count, macrophage activities after PMA stimulation and plaque-forming cell assay after challenge with sheep erythrocytes. Slight decreases were noted in IgG 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 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 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 can be found in "Fluoxastrobin. Human Health Risk Assessment for Proposed Uses on Sweet Corn, Field Corn/Sweet Corn Grown for Seed, and Wheat; Revised Tolerances on Peanut and Refined Peanut Oil Based on a Peanut Processing Study; and Label Revision Allowing Homeowner Residential Application to Turf Grasses," p. 23 in docket ID number EPA–HQ–OPP–2007–0677.

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 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 performed an unrefined (food and drinking water) exposure assessment. The assumptions of this dietary assessment included tolerance level residues and 100% crop treated. Based on processing studies, the processing factors for tomato puree, potato chips, dry potato (granules/flakes), and potato flour were reduced to 1. Separate tolerances were set for peanut oil, wheat bran and tomato paste; therefore, the processing factors for these commodities were set at 1. For all other processed commodities, Dietary Exposure Evaluation Model version 7.81 default processing factors were assumed.

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.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for floxastrobin. Tolerance level residues and 100 PCT 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 First 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 33 parts per billion (ppb) for surface water and less than 1 ppb for ground water. The modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 33 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 has previously been registered for the following uses that could result in post-application residential exposures: Turf, including lawns and golf courses. However, applications to residential turf have previously been restricted to certified pest control operators. Under consideration in the current risk assessment is a proposed label that would allow homeowner residential application to turf, which would result in residential handler exposure. Residential handlers may be exposed via loading and applying granular fluoxastrobin for spot treatments and/or broadcast control of turf diseases.

EPA assessed residential application 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 so only intermediate-term dermal risks were assessed. Short- and intermediate-term inhalation risks were also 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) postapplication exposures, it is believed that intermediate-term exposures (greater than 30 days up to 180 days) are also possible. The best data and methodology currently available were used in the fluoxastrobin residential assessment. Since chemical-specific data were not available, the Agency used the current approaches for residential assessment, many of which include recent upgrades to the standard operating procedures (SOPs). For example, for the hand-to-mouth calculations for children (three to less than six years old), a 5% transferability factor was applied to calculate residue levels appropriate for this exposure pathway. Overall, the Agency believes that the calculated risks represent screening level estimates. Estimates are thought to be conservative, even when measures of central tendency (e.g., most transfer coefficients) are used, because values that would be considered to be in the lower percentile aspect of any input parameter have not been used in the calculations. In addition, maximum application rates have been used for all scenarios. The risk estimates also assume no dissipation of residues after day zero and do not take into account the periodic growth and cutting of the grass. Actual residues should be considerably lower, which is why intermediate-term exposures are unlikely. Further, because a short-term dermal toxicity endpoint was not identified, the intermediate-term

endpoint was used for all dermal risk estimates, even though the residential exposure duration is believed to be mostly short-term based on the use pattern. Finally, based on the Agency's current practices, a quantitative post-application inhalation exposure assessment was not performed at this time, primarily because fluoxastrobin has a very low vapor pressure. 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 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 Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF 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 is adequately protected if the FQPA SF is 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 because available data showed no apparent decrease in B-cell activated, T-cell mediated immunoglobulin M (IgM) response to sheep red blood cells (SRBC) 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 assessments 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 acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. 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 42% of the cPAD for children (1-2 years old), the population subgroup 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 of adults and children 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 a background exposure level). 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.

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 result in aggregate MOEs of 470 for adult males; 510 for adult females (13-

49 years old); 220 for children (1-2 years old), short-term; and 210 for children (1-2 years old), intermediate-term. Residential exposure for adults is intermediate-term dermal exposure from application of the product plus post-application dermal exposure plus short- and intermediate-term inhalation exposure from application of the product. Short-term residential exposure for children is incidental oral exposure. Intermediate-term residential exposure for children is post-application dermal exposure and post-application incidental oral exposure. Because EPA's level of concern for fluoxastrobin is a MOE of 100 or below, these residential MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* As is explained in Unit III.A., 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) 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 Codex or Canadian maximum residue limits (MRLs) or tolerances for fluoxastrobin in or on sweet corn or wheat.

C. Revisions to Petitioned-For Tolerances

EPA converted "aspirated grain fractions" to "grain, aspirated grain fractions"; "sweet corn (kernels plus cob with husks removed)" to "corn, sweet, kernel plus cob with husks removed"; "sweet corn, forage" to "corn, sweet, forage"; "sweet corn, stover" to "corn, sweet, stover"; "meat byproducts (cattle, goat, horse, sheep)" to "cattle, meat byproducts", "goat, meat byproducts", "horse, meat byproducts", and "sheep, meat byproducts" to conform them to the Agency's Food and Feed Commodity Vocabulary. EPA also corrected the tolerance expression for the meat byproduct commodities from fluoxastrobin and its Z isomer to fluoxastrobin, its Z isomer, and its phenoxy-hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol. The proposed tolerance of 0.02 ppm in or on sweet corn, kernels plus cob with husks removed has been reduced to 0.01 ppm in or on corn, sweet, kernel plus cob with husks removed, based on the highest observed residues in the sweet corn crop field trials and the limit of quantitation of the residue method of 0.01 ppm for combined residues of fluoxastrobin and its Z isomer. The proposed tolerance of 0.2 ppm in or on wheat, bran has been reduced to 0.15 ppm and the proposed tolerance of 15 ppm in or on aspirated grain fractions has been increased to 60 ppm in or on grain, aspirated grain fractions because the wheat field trials indicate that the highest average field trial residue of 0.11 ppm for wheat grain is 0.11 ppm and the wheat processing study indicates that residues of fluoxastrobin may concentrate in wheat, bran (1.3x) and aspirated grain fractions (518x). This is also an increase in the pre-existing tolerance of 20 ppm for fluoxastrobin in or on aspirated grain fractions.

V. Conclusion

Therefore, tolerances are established for 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-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, in or on corn, sweet, forage at 13 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 10 ppm; wheat, bran at 0.15 ppm; wheat, forage at 7.0 ppm; wheat, hay at 17 ppm; and wheat, straw at 11 ppm. A pre-existing tolerance for the residues of fluoxastrobin and its Z isomer in or on grain, aspirated grain fractions is increased from 20 ppm to 60 ppm. Pre-existing tolerances are also increased for the residues of fluoxastrobin, its Z isomer, and its phenoxy-hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, in cattle, meat byproducts from 0.10 ppm to 0.20 ppm; in goat, meat byproducts from 0.10 ppm to 0.20 ppm; in horse, meat byproducts from 0.10 ppm to 0.20 ppm; and in sheep, meat byproducts from 0.10 ppm to 0.20 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: September 24, 2010.

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:

i. Removing "Aspirated grain fractions" in paragraph (a)(1) in the table;

ii. Adding alphabetically the following commodities to the table in paragraph (a)(1); and

iii. Revising the entries for Cattle, meat byproducts; Goat, meat byproducts; Horse, meat byproducts; and Sheep, meat byproducts in the table in paragraph (a)(2).

The amendments read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

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

Commodity	Parts per million
* * *	* *
Corn, sweet, forage	13
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	10
Grain, aspirated grain fractions	60
* * *	* *
Wheat, bran	0.15
Wheat, forage	7.0
Wheat, hay	17
Wheat, straw	11

(2) * * *

Commodity	Parts per million
* * *	* *
Cattle, meat byproducts	0.20
* * *	* *
Goat, meat byproducts	0.20
* * *	* *
Horse, meat byproducts	0.20
* * *	* *
Sheep, meat byproducts	0.20

* * * * *

[FR Doc. 2010–24575 Filed 9–29–10; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 173, and 178

[Docket No. PHMSA–06–25736 (HM–231)]

RIN 2137–AD89

Hazardous Material; Miscellaneous Packaging Amendments

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Final rule.

SUMMARY: On February 2, 2010, the Pipeline and Hazardous Materials Safety Administration published a final rule amending the Hazardous Materials Regulations to: Revise several packaging related definitions; add provisions to allow more flexibility when preparing and transmitting closure instructions, including conditions under which closure instructions may be transmitted electronically; add a requirement for shippers to retain packaging closure instructions; incorporate new language that allows for a practicable means of stenciling the United Nations (UN) symbol on packagings; and clarify a requirement to document the methodology used when determining whether a change in packaging configuration requires retesting as a new design or may be considered a variation of a previously tested design. The February 2 final rule also incorporated requirements for the construction, maintenance, and use of Large Packagings. This final rule responds to one petition for reconsideration and four appeals submitted in response to the February 2 final rule and also corrects several errors that occurred in that rulemaking.

DATES: *Effective Date:* October 1, 2010.

Voluntary Compliance Date: Compliance with the requirements adopted herein is authorized as of September 30, 2010. However, persons voluntarily complying with these regulations should be aware that appeals may be received and as a result of PHMSA's evaluation of these appeals, the amendments adopted in this final rule correction may be revised accordingly.

FOR FURTHER INFORMATION CONTACT: Eileen Edmonson, Office of Hazardous Materials Standards, (202) 366–8553, or Ben Moore, Office of Hazardous Materials Technology, (202) 366–4545; Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey