ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


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 poultry, liver, hog, fat; hog, meat byproducts; and rice, grain. Arysta LifeScience, North America, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 24, 2012. Objections and requests for hearings must be received on or before December 24, 2012, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2009–0677, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket Center (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the OPP Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket Center (EPA/DC) is (703) 308–0034; email 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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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


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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0677 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 December 24, 2012. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0677, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
II. Summary of Petitioned-For Tolerance

In the Federal Register issue of October 5, 2011 (76 FR 61647) (FRL–8890–5), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F78970) 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 tolerances for combined residues of the fungicide fluoxastrobin, (1E,2S)-[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-chlorophenoxo)]-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime, in or on rice, grain at 6.0 ppm and established additional tolerances for hog, fat; hog, meat byproducts; and poultry, liver. The petition supported the petition, EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance on rice, grain to 4.0 ppm and established additional tolerances for hog, fat; hog, meat byproducts; and poultry, liver. The reason for these changes are explained in Unit IV.D.

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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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.

The most recent human health risk assessment for fluoxastrobin was conducted for use on the squash/cucumber crop subgroup 9B. Since that time, an adequate functional immunotoxicity study has been submitted and reviewed. In accordance with 40 CFR part 158—Data Requirements for Pesticides, a subchronic inhalation study is also required for fluoxastrobin. However, the Agency has waived the inhalation toxicity study data requirement at this time. The hazard characterization and toxicity endpoints for risk assessment remain unchanged.

Fluoxastrobin and its major metabolites were evaluated in a battery of genotoxicity tests and results were negative. 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 that established a tolerance for residues of fluoxastrobin in or on squash/cucumber subgroup 9B. That rule was published in the Federal Register issue of August 17, 2011 (76 FR 50893) (FRL–8884–4).

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 factors (UFs)/safety factors (SFs) 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 the final rule published in the Federal Register issue of August 17, 2011, p. 50895.

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 Nationwide 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). The Dietary Exposure Evaluation Model (DEEM) software version 7.81 default processing factors were assumed except for where tolerances were established for processed commodities or when processing studies showed no concentration. Based on processing studies, the processing factors for dried potato (granules/flakes), potato chips, potato flour, and tomato puree were reduced to 1.15. Default processing factors were set for peanut oil, tomato paste, and wheat bran; therefore, the processing factors for these commodities were set at 1.

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 fluoxastrobin. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

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 Tier 1 Rice Model and Screening Concentration in Ground Water (SC–GROW) models, the estimated drinking water concentrations (EDWCs) of fluoxastrobin for chronic exposures for non-cancer assessments are estimated to be 93 parts per billion (ppb) for surface water and 0.038 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 value of 93 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, termiteicides, 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: Residential handler exposure for adults is expected to be short-term only. Intermediate-term and chronic exposures are not likely because of the intermittent nature of applications by homeowners. Since there are no toxicity findings for the short-term dermal route of exposure up to the limit dose, the residential handler assessment only includes the inhalation route of exposure.

There is also 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. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: http://www.epa.gov/pesticides/science/residential-exposure-sop.html.

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. 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 (Food Quality Protection Act) 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 available studies used to evaluate pre- and postnatal exposure susceptibility do not indicate increased susceptibility of rats or rabbits to fluoxastrobin. These studies include the following:

i. Developmental toxicity studies in rats.

ii. Developmental toxicity studies in rabbits.

iii. A 2-generation reproduction study in rats.

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.

ii. There is no indication that fluoxastrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UF 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. The exposure databases are estimated based on data that reasonably account for potential exposures. The
chronic dietary food exposure assessment was conservatively based on 100 PCT assumptions, tolerance-level residues, and conservative ground and surface drinking water modeling estimates. New 2012 Residential Standard Operating Procedures (SOPs) were used to assess post-application exposure to children including incidental oral exposure. The residential post-application assessment assumes maximum application rates and conservative day zero hand-to-mouth activities. All of the exposure estimates for fluoxastrobin are based on conservative high-end assumptions and are not likely to result in underestimated risk.

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 36% of the cPAD for the general population, and 75% 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 takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fluoxastrobin is currently registered for use as a fumigant on rice, grain at 6.0 ppm; and poultry, liver at 0.06 ppm. The comment was a request that the Agency request a tolerance level of 4.0 ppm for rice, grain. In the notice of filing, the Agency has revised the tolerance level from 6.0 ppm to 4.0 ppm for rice, grain based on the data used to support the risk assessment. The petitioner has subsequently submitted a revised notice of filing to the Agency requesting a tolerance level of 4.0 ppm for rice, grain.

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 United Nations 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 MRLs or tolerances for fluoxastrobin.

C. Response to Comment

One comment was received to the docket from the City of Sacramento, CA. The comment was a request that the EPA thoroughly review the request to register fluoxastrobin for use on rice with regard to its potential to affect drinking water quality. The Agency has determined that dietary risks for fluoxastrobin are below the Agency’s concern for dietary exposure and risk.

D. Revisions to Petitioned-For Tolerances

The petitioner requested a tolerance level of 6.0 ppm for rice, grain in the notice of filing. The Agency has revised the tolerance level from 6.0 ppm to 4.0 ppm for rice, grain based on the data used to support the risk assessment. The petitioner has subsequently submitted a revised notice of filing to the Agency requesting a tolerance level of 4.0 ppm for rice, grain.

The use of fluoxastrobin on rice, grain will result in a slight increase in the dietary burden to ruminant tissues; however secondary residues in ruminant commodities are not expected to exceed the established tolerances for milk and ruminant tissues. The increased dietary burden to swine and poultry results in slight residues in animal tissues. The increased dietary burden to swine and poultry results in slight residues in animal tissues. The increased dietary burden to swine and poultry results in slight residues in animal tissues.
VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) 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 19985, 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 FFDCA section 408(d), 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 FFDCA section 408(b)(4). 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) (2 U.S.C. 1501 et seq.).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), 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 the rule in the Federal Register. This action 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.


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:


2. In §180.609:

i. Add alphabetically the commodity “Rice, grain” to the table in paragraph (a)(1).

ii. Add alphabetically the following commodities to the table in paragraph (a)(2). The additions read as follows:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
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<tbody>
<tr>
<td>Poultry, liver</td>
<td>0.06</td>
</tr>
<tr>
<td>Hog, fat</td>
<td>0.03</td>
</tr>
<tr>
<td>Hog, meat byproducts</td>
<td>0.06</td>
</tr>
<tr>
<td>Rice, grain</td>
<td>4.0</td>
</tr>
</tbody>
</table>

[FR Doc. 2012–26086 Filed 10–23–12; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 648
[Docket No. 120330235–2014–01]
RIN 0648–BC04
Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Emergency Rule Extension, Closure of the Delmarva Access Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary final rule; emergency action extension.

SUMMARY: NMFS extends the emergency closure of the Delmarva Access Area (DMV) published on May 14, 2012, which is scheduled to expire on November 10, 2012. Specifically, this temporary rule extends the 180-day closure of the DMV in fishing year (FY) 2012 for an additional 186 days, through May 13, 2013.

DATES: This rule is effective from November 10, 2012, through May 14, 2013. The expiration date of the temporary rule published May 14, 2012 (77 FR 28311), is extended to May 14, 2013, unless superseded by another action which will publish in the Federal Register.

ADDRESSES: The Environmental Assessment (EA) is available by request from: John K. Bullard, Regional Administrator, National Marine Fisheries Service, Northeast Region, 55 Great Republic Drive, Gloucester, MA 01930–2276, or via the Internet at http://www.nmfs.noaa.gov.


SUPPLEMENTARY INFORMATION: