or incurred in taxable years for which the period of limitation on credit or refund under section 6511 has not expired. For expenses paid or incurred on or after October 1, 2014, a taxpayer’s local lodging expenses are personal expenses and are not deductible unless they qualify as deductible expenses under section 162. Except as permitted under section 162 or 212, the costs of a taxpayer’s meals not incurred in traveling away from home are nondeductible personal expenses.

Heather C. Maloy, Acting Deputy Commissioner for Services and Enforcement.

Approved: August 22, 2013.

Mark J. Mazur, Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2014–23306 Filed 9–30–14; 8:45 am]

BILLING CODE 4303–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


DATES: This regulation is effective October 1, 2014. Objections and requests for hearings must be received on or before December 1, 2014, 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–2012–0576, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Blvdg., 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 is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: RDFRNotices@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–2012–0576 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 1, 2014. 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–2012–0576, 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.
• Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
• Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Summary of Petitioned-For Tolerance

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 to 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.

Following repeated exposure, fluoxastrobin has mild or low toxicity in all tested species except for the dog. Repeated oral administration to dogs resulted in adverse liver toxicity at considerably lower doses than those noted in other species. Based on species sensitivity, the effects observed in the dog were used as endpoints for risk assessment. In both the 90-day and 1-year oral feeding studies in dogs, the liver appeared to be the target organ. In dogs, mice, and rats, the kidney was another target organ. There was no indication of an adverse effect attributable to a single dose. Based on developmental toxicity studies (rat and rabbit) and a 2-generation reproduction study (rat), there was neither increased susceptibility of pre-/postnatal exposure to fluoxastrobin, nor adverse effects on reproduction. Furthermore, neurotoxic effects were not seen in an acute neurotoxicity study in rats up to the limit dose of 2,000 mg/kg/day. In a subchronic neurotoxicity study in rats, fluoxastrobin did not elicit any neurotoxic effects. Repeated dose studies of fluoxastrobin in the database did not show immunotoxic effects in rats. Results of genotoxicity testing were negative and there were no treatment-related carcinogenicity findings in adequately performed carcinogenicity studies in rats and mice. Therefore, fluoxastrobin is classified as “not likely to be carcinogenic to humans.” 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 can be found at http://www.regulations.gov in document Fluoxastrobin. Aggregate Human Health Risk Assessment for the Proposed New Uses on Melon Subgroup 9A and Sorghum, Along with Establishment of Permanent Tolerances on Wheat, and Amendments to Established Tolerances on Milk and Milk Fat on page 26 in docket ID number EPA–HQ–OPP–2012–0576.

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 considers 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.


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. A slightly refined chronic dietary exposure assessment was performed for fluoxastrobin using tolerance-level residues, average field trial residues, and 100% crop treated (CT). This risk assessment was conducted using the DEEM–FCID Version 3.16. This model uses 2003–2008 food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWELA).

   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, average field trial residues, and/or 100% CT were assumed for all food commodities.
2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluoxastrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluoxastrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www.epa.gov/oppefed1/models/water/index.htm. In addition to evaluating the EDWCs from the proposed uses, EDWCs were reevaluated for all existing uses with Pesticide Root Zone Model Ground Water (PRZM–GW), which models continued use of fluoxastrobin over many years. For the chronic dietary assessment, the ground water EDWC (137 μg/L) was more conservative than the surface water EDWC (18.6 μg/L); the ground water EDWC was based on an existing turf use modeled with a 100-year simulation of 100 years of repeated applications, using the highest single maximum application rate and the highest yearly application rate.

3. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-diary 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: Broadcast control of diseases on turf, including lawns and golf courses. EPA assessed residential exposure using the following assumptions:

i. Residential handler exposure. 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.

ii. Post-application 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. Residential post-application exposure for adults and children is expected to be short-term only because residues are not expected to be present for longer periods of time. Exposure might occur on areas such as lawns, borders or pathways, 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)(B)(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 safer 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 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. 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.

ii. 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. The rat developmental study was tested up to the limit dose (1,000 mg/kg/day), and the rabbit developmental study was tested up to 400 mg/kg/day (highest dose tested). At the highest dose tested, there were decreases in food consumption and body weight in the maternal animals, but there were no developmental effects. Furthermore, in the rat reproduction study, there was no sensitivity in the offspring of the pups relative to the parental animals.

iv. The exposure databases are estimated based on data that reasonably account for potential exposures. The chronic dietary food exposure assessment was slightly refined but still based on 100 PCT assumptions, tolerance-level residues, some average field-trial residues, and conservative ground water modeling estimates. New 2012 Residential Standard Operating Procedures (SOPs) were used to assess post-application exposure to children including incidental oral exposure. In addition, the Agency has obtained a Turf Transferable Residue (TTR) study, which provides slightly refined chemical-specific assumptions to estimate exposure for the hand-to-mouth post-application assessment. The assessment is still considered highly conservative because it assumes maximum application rates and conservative day zero hand-to-mouth activities.
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 30% of the cPAD for the general population, and 66% of the cPAD for all infants <1 year old, the population subgroup with the highest estimated chronic dietary exposure to fluoxastrobin. 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-term risk. Short-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 uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluoxastrobin. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 610 for adults and 110 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. Intermediate-term risk. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, fluoxastrobin is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluoxastrobin.

5. 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.

6. 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 livestock 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; email 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 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 no Codex maximum residue limits (MRLs) established for fluoxastrobin.

C. Revisions to Petitioned-for Tolerances

The petition requested a tolerance of 4.0 ppm for residues of fluoxastrobin and its Z-isomer on sorghum forage and stover. Based on the available residue data and using the Organisation for Economic Co-operation and Development (OECD) tolerance calculation procedure, the Agency is establishing a tolerance for these commodities at 5.0 ppm. In addition, the Agency is revising the commodity names to “sorghum, grain, grain”, “sorghum, grain, forage”, and “sorghum, grain, stover” to be consistent with the commodity vocabulary EPA generally uses for tolerances.

V. Conclusion

Therefore, tolerances are established for combined residues of fluoxastrobin and its Z-isomer in or on melon subgroup 9A and sorghum, grain, grain at 1.5 ppm; and in or on sorghum, grain, forage and sorghum, grain, stover at 5.0 ppm.

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 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 Communities.”
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(n)(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 “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.

Dated: September 24, 2014.

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, add alphabetically “melon subgroup 9A”; “sorghum, grain, forage”; “sorghum, grain, grain”; and “sorghum, grain, stover” to the table in paragraph (a)(1) as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) General. (1) * * *

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[FR Doc. 2014–23398 Filed 9–30–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Tetraacetylethylenediamine and Its Metabolite, Diacetylethylenediamine; Exemption From the Requirement of a Tolerance

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:

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