ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0572; FRL–9992–69]

Fluensulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes and amends tolerances for residues of fluensulfone in or on multiple commodities which are identified and discussed later in this document. Makhteshim Agan of North America (d/b/a ADAMA) requested these tolerances and tolerance amendments under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 24, 2019. Objections and requests for hearings must be received on or before July 23, 2019, 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–2017–0572, 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 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 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main 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?

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.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0572 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 July 23, 2019. 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–2017–0572, 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

In the **Federal Register** of February 27, 2018 (83 FR 8408) (FRL–9972–17), 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 7F8614) by Makhteshim Agan of North America d/b/a ADAMA, 3120 Highlands Blvd., Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the nematicide, fluensulfone, including its metabolites and degradates, in or on the following commodities: Citrus dried pulp at 0.4 parts per million (ppm); Crop Group 10–10, citrus fruit at 0.15 ppm; peanut at 0.15 ppm; peanut, hay at 8.0 ppm; and peanut, meal at 0.30 ppm. That document referenced a summary of the petition prepared by Makhteshim Agan of North America, the registrant, which is available in docket ID number EPA–HQ–OPP–2017–0572 at *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

In the **Federal Register** of May 18, 2018 (83 FR 23247) (FRL–9976–87), 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 7F8650) by Makhteshim Agan of North America, d/b/a ADAMA, 3120 Highlands Blvd., Suite 100, Raleigh, NC 27604. The petition requested to amend the tolerances in 40 CFR 180.680 for residues of the nematicide, fluensulfone and its metabolite BSA expressed as fluensulfone equivalents, in or on Berry, low growing, subgroup 13–07G at 0.5 parts per million (ppm); *Brassica,* head and stem, subgroup 5A at 1.5 ppm; *Brassica,* leafy greens, subgroup 5B at 20 ppm; Potato, chips at 2 ppm; Potato, granules/flakes at 2 ppm; Tomato, paste at 1.5 ppm; Vegetables, cucurbits, group 9 at 0.7 ppm; Vegetables, fruiting, group 8–10 at 0.7 ppm; Vegetables, leafy, except *Brassica,* group 4 at 4 ppm; Vegetables, leaves of root and tuber, group 2, except sugar beet at 50 ppm;

Vegetables, root, except sugar beet, subgroup 1B at 4 ppm; and Vegetables, tuberous and corm, subgroup 1C at 0.8 ppm. That document referenced a summary of the petition prepared by Makhteshim Agan of North America, the registrant, which is available in docket ID number EPA–HQ–OPP–2018–0030 at *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

In the **Federal Register** of March 18, 2019 (84 FR 9737) (FRL–9989–71), 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 7F8650) by Makhteshim Agan of North America, d/b/a ADAMA, 3120 Highlands Blvd., Suite 100, Raleigh, NC 27604. The petition requested to: (1) Amend the tolerance expression in 40 CFR 180.680 paragraphs (a) and (d) to read ''Tolerances are established for residues of the nematicide fluensulfone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the following table below is to be determined by measuring only the sum of fluensulfone, 5-chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole and its metabolite, 3,4,4-trifluoro-but-3-ene-1-sulfonic acid, calculated as the stoichiometric equivalent of fluensulfone, in or on the commodity''; and (2) amend the tolerances in 40 CFR 180.680 for residues of the nematicide, fluensulfone and its metabolite BSA expressed as fluensulfone equivalents, on the raw agricultural commodities as follows: Almond hulls at 5 parts per million (ppm); Fruit, pome, group 11 at 0.4 ppm; Fruit, small vine climbing subgroup 13–07D at 0.8 ppm; Fruit, stone, group 12 at 0.1 ppm; Grain cereal, forage, fodder and straw, group 16 at 3 ppm; and, rotated wheat (inadvertent residues with 90-day PBI): Grain, cereal, group 15 at 0.05 ppm; Molasses at 0.3 ppm; and, rotated cereal grains (inadvertent residues with 10-month PBI): Nut, tree, group 14 at 0.04 ppm; Sugarcane at 0.05 ppm and Wheat grain (includes triticale) (Barley grain; Buckwheat grain; Oat grain; and Teosinte grain) at 0.1 ppm; Wheat bran (Barley bran) at 0.14 ppm; Wheat forage (Oat forage) at 6 ppm; Wheat germ at 0.10 ppm; Wheat hay (Barley hay and Oat hay) at *15* ppm; Wheat middlings at 0.10 ppm; Wheat shorts at 0.11 ppm; and, Wheat straw (Barley straw and Oat straw) at 6 ppm. That document referenced a summary of the petition prepared by Makhteshim Agan of North America, the registrant, which is available in docket ID number EPA–HQ–OPP–2018–0793 at *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has modified the levels at which tolerances are being established as well as which commodities will have tolerances. The reasons 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 fluensulfone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluensulfone 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.

A summary of the toxicological effects of fluensulfone are discussed in the final rule published in the **Federal Register** of April 13, 2018 (83 FR 15971) (FRL–9975–76).

Specific information on the studies received and the nature of the adverse effects caused by fluensulfone 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 the document titled ''*Fluensulfone—Aggregate Human Health Risk Assessment in Support of Section 3 Registration of New Uses on Citrus and Peanut, and Change in the Tolerance Expression*'' on pages 39–49 in docket ID number EPA–HQ–OPP–2017–0572.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for fluensulfone used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 1, 2016 (81 FR 34898) (FRL–9946–07).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluensulfone, EPA considered exposure under the petitioned-for tolerances as well as all

existing fluensulfone tolerances in 40 CFR 180.680. EPA assessed dietary exposures from fluensulfone 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.

Such effects were identified for fluensulfone. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute dietary risk assessment assumed tolerance-equivalent residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption information from the USDA's NHANES/WWEIA. As to residue levels in food, the chronic dietary risk assessment assumed tolerance-equivalent residues and 100 PCT.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to fluensulfone. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for fluensulfone. Tolerance-equivalent residue levels 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 fluensulfone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluensulfone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW) models, the estimated drinking water concentrations (EDWCs) for acute exposures are estimated to be 11.8 parts per billion (ppb) for surface water and 77.6 ppb for ground water and for chronic exposures are estimated to be 0.173 ppb for surface water and 52.5 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 77.6 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 52.5 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).

Fluensulfone is currently registered for the following uses that could result in residential exposures: Golf courses and residential lawns. EPA assessed residential exposure using the following assumptions: No residential handler exposure for fluensulfone is expected because the products are not intended for homeowner use. The product label requires that handlers wear specific clothing (*e.g.,* long sleeve shirt/long pants) and/or personal protective equipment (PPE). The Agency has made the assumption that the product is not for homeowner use and is intended for use by professional applicators. As a result, a residential handler assessment has not been conducted.

For adult residential post-application exposure, the Agency evaluated dermal post-application exposure only to outdoor turf/lawn applications (high contact activities). The Agency also evaluated residential post-application exposure for children via dermal and hand-to-mouth routes of exposure, resulting from treated outdoor turf/lawn applications (high contact activities). Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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 fluensulfone to share a common mechanism of toxicity with any other substances, and fluensulfone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluensulfone 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rats and rabbits. Fetal effects in those studies occurred in the presence of maternal toxicity and were not considered more severe than the maternal effects. However, there was evidence of increased qualitative, but not quantitative, susceptibility of pups in the 2-generation reproduction study in rats. Maternal effects observed in that study were decreased body weight; at the same dose, effects in offspring were decreased pup weights, decreased spleen weight, and increased pup loss (post-natal day 1–4). Although there is evidence of increased qualitative susceptibility in the 2-generation reproduction study in rats, there are no residual uncertainties with regard to pre- and post-natal toxicity following in utero exposure to rats or rabbits and pre- and post-natal exposures to rats. Considering the overall toxicity profile, the clear NOAEL for the pup effects observed in the 2-generation reproduction study, and that the doses selected for risk assessment are protective of all effects in the toxicity database including the offspring effects,

the degree of concern for the susceptibility is low.

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 fluensulfone is complete.

ii. Evidence of potential neurotoxicity was only seen following acute exposure to fluensulfone and the current PODs chosen for risk assessment are protective of the effects observed. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no indication of quantitative susceptibility in the developmental and reproductive toxicity studies, and there are no residual uncertainties concerning pre- or post-natal toxicity. In addition, the endpoints and doses chosen for risk assessment are protective of the qualitative susceptibility observed in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-equivalent residue levels. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluensulfone in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluensulfone.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluensulfone will occupy 9.4% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluensulfone from food and water will utilize 4.1% of the cPAD for all infants less than 1 year 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 fluensulfone 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).

Fluensulfone 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 fluensulfone.

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 5300 for adults and 2500 for children. Because EPA's level of concern for fluensulfone 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, fluensulfone 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 fluensulfone.

5. *Aggregate cancer risk for U.S. population.* EPA assessed cancer risk using a non-linear approach (*i.e.,* RfD) since it adequately accounts for all chronic toxicity, including carcinogenicity, that could result from exposure to fluensulfone. As the chronic dietary endpoint and dose are protective of potential cancer effects, fluensulfone is not expected to pose an aggregate cancer risk.

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 fluensulfone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An enforcement analytical method for the BSA metabolite was previously submitted and found to be acceptable. The method extracts residues from matrices into an acetonitrile-based solvent, involves minimal cleanup, and uses high-performance liquid chromatography with tandem mass spectrometric detection (LC–MS/MS) in negative-ion mode to isolate, identify and quantify residues. For all matrices and analytes, the limit of quantitation (LOQ), defined as the lowest level of method validation (LLMV), was 0.01 ppm. With the change to the tolerance expression, an enforcement method is now needed for parent fluensulfone. A method for analysis of fluensulfone residues was previously submitted and has been found to be suitable for enforcement. The method is essentially identical to that used for BSA analysis but omits the cleanup step and uses LC–MS/MS in the positive-ion mode for isolation, identification, and quantification of residues.

The FDA multi-residue protocols are not suitable for the analysis of fluensulfone or its metabolites BSA and TSA. The Agency notes that QuEChERS multi-residue method may be suitable for the analysis of these compounds, based on extraction solvents and clean-up strategies being similar to the analytical method described above.

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.

The Codex has not established a MRL for fluensulfone for citrus.

The Codex has established MRLs for fluensulfone in or on some of the commodities or parts of some of the crop groups that are being revised in this document. The U.S. tolerances are harmonized with the Codex MRLs to the extent possible. In several cases (below), there is disharmony between U.S. crop group tolerances and Codex MRLs for individual commodities covered by the crop group. Because EPA has data supporting the establishment of the crop groups and no data that indicate a need to establish separate individual commodities, the effect is that tolerances for some individual commodities are not harmonized with Codex MRLs.

Commodity	Tolerance (ppm) U.S.	MRL (mg/kg) Codex
Brassica, leafy green, subgroup 5B	20	1 (Group of leafy vegetables) 9 (Komatsuna).
Vegetables, cucurbits, group 9	0.70	0.3 (Melons, except watermelon).
Vegetables, leafy, except Brassica, group 4	4.0	1 (Group of leafy vegetables).
Vegetables, leaves of root and tuber, group 2, except sugar beet.	50	1 (Group of leafy vegetables) 10 (Turnip greens).
Vegetables, root, except sugar beet, subgroup 1B	4.0	3 (Root and tuber vegetables).

C. Response to Comments

One comment generally opposing the use of fluensulfone was received in response to the notice of filing for citrus and peanut uses (EPA–HQ–OPP–2017–0572). Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these fluensulfone tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

One comment was received in response to the notice of filing to amend the tolerance expression for fluensulfone to harmonize with the Codex residue definition (EPA–HQ–OPP–2018–0793). The commenter supported the federal government regulating the chemicals in pesticides and specifically wanted EPA to set higher safety standards for pesticides. As explained in the previous paragraph, EPA evaluated fluensulfone using the existing safety standard in the FFDCA and has determined that these fluensulfone tolerances are safe.

D. Revisions to Petitioned-For Tolerances

For stone fruit (Crop Group 12–12) and sugarcane, the tolerances being established by the Agency are derived using the Organization for Economic Cooperation and Development (OECD) MRL calculation procedures and based on available residue data.

The tolerance for tree nuts is based on the requested revision to the tolerance expression. As such, it is the combination of 0.01 ppm BSA and 0.01 ppm fluensulfone, resulting in the level of 0.02 ppm as opposed to the proposed 0.04 ppm.

Inadvertent tolerances in barley bran and wheat bran are being revised to 0.15 ppm (based on the OECD calculation procedure rounding classes), rather than the proposed tolerances at 0.14 ppm.

The petitioner had requested a higher tolerance for inadvertent residues on teosinte grain than the tolerance level set for crop group 15, based on the residue data used to establish the higher tolerance for wheat grain. These higher tolerances are based on residue data that indicate higher tolerances are necessary for crops for which the pesticide label permits a shorter plant-back interval (*i.e.,* wheat, barley, buckwheat, oats). For other crops, including teosinte, the pesticide label establishes a longer plant-back interval, and associated residue data indicate that such intervals result in lower residues on those crops. It is this latter set of residue data and the pesticide label instructions for plant-back intervals that support the crop group 15 tolerance as well as the Agency's conclusion that residues in teosinte will be covered by the crop group 15 tolerance. A tolerance in wheat milled byproducts is being established at 0.15 ppm (based on the OECD calculation procedure rounding classes); because a tolerance on wheat milled byproducts covers residues in both wheat shorts and wheat middlings, tolerances on those individual commodities are unnecessary.

Although the petitioner did not request a revision of the existing grape, raisin tolerance, EPA is modifying that tolerance to 1.5 ppm. As noted in 40 CFR 180.40(f)(1), EPA will not establish crop group tolerances unless necessary tolerances for processed foods are also established. In this action, the petitioner has requested an increase in the tolerance for subgroup 13–07D, which includes grape. Based on available data, EPA has determined that an amended tolerance for grape, raisin would be necessary. This tolerance is derived from the revised highest average field trial (HAFT) of 0.49 ppm from the grape field trials, using the revised residue definition (fluensulfone + BSA, in terms of fluensulfone), multiplied by the median processing factor for raisins from the processing study (2.7X), resulting in 1.32 ppm; therefore, a tolerance of 1.5 ppm in raisin is appropriate.

For citrus, EPA used processing factors of 233X for fluensulfone and <0.5X for BSA in citrus oil. Application of these processing factors and OECD MRL rounding classes indicates that residues will concentrate in dried pulp at higher levels than requested as well as in citrus oil. In accordance with 40 CFR 180.40(f)(1), EPA is establishing a tolerance for fruit, citrus, group 10–10, oil at 15 ppm. Based on the Agency's calculations, EPA is also establishing the proposed tolerance for citrus, dried pulp as a tolerance for fruit, citrus, group 10–10, dried pulp at 0.9 ppm, rather than 0.4 ppm.

Although the petitioner requested tolerances on peanut commodities, after EPA determined that the submitted field trial data were not adequate to support a tolerance the petitioner withdrew its request for those tolerances; therefore,

EPA is not establishing tolerances for residues on peanut; peanut, hay; or peanut, meal.

V. Conclusion

Therefore, tolerances are established for residues of fluensulfone, and its metabolite BSA expressed as fluensulfone equivalents, in or on fruit, citrus, group 10–10 at 0.3 ppm; fruit, citrus, group 10–10, dried pulp at 0.9 ppm; and fruit, citrus, group 10–10, oil at 15 ppm.

Additionally, existing tolerances under paragraphs (a) and (d) are revised as follows for residues of fluensulfone, and its metabolite BSA expressed as fluensulfone equivalents, as follows: *Paragraph (a):* Almond, hulls at 5 ppm; berry, low growing, subgroup 13–07G at 0.5 ppm; *Brassica,* head and stem, subgroup 5A at 1.5 ppm; *Brassica,* leafy greens, subgroup 5B at 20 ppm; fruit, pome, group 11–10 at 0.4 ppm; fruit, small, vine climbing, subgroup 13–07D at 0.8 ppm; fruit, stone, group 12–12 at 0.15 ppm; grape, raisin at 1.5 ppm; nut, tree, group 14–12 at 0.02 ppm; potato, chips at 2 ppm; potato, granules/flakes at 2 ppm; sugarcane, cane at 0.06 ppm; sugarcane, molasses at 0.3 ppm; tomato, paste at 1.5 ppm; vegetables, cucurbits, group 9 at 0.7 ppm; vegetables, fruiting, group 8–10 at 0.7 ppm; vegetables, leafy, except *Brassica,* group 4 at 4 ppm; vegetables, leaves of root and tuber, group 2, except sugar beet at 50 ppm; vegetables, root, except sugar beet, subgroup 1B at 4 ppm; and vegetables, tuberous and corm, subgroup 1C at 0.8 ppm; *Paragraph (d):* barley, bran at 0.15 ppm; barley, grain at 0.1 ppm; barley, hay at 15 ppm; barley, straw at 6 ppm; buckwheat, grain at 0.1 ppm; grain, cereal, forage, fodder and straw, group 16 at 3 ppm; grain, cereal, group 15 at 0.05 ppm; oat, forage at 6 ppm; oat, grain at 0.1 ppm; oat, hay at 15 ppm; oat, straw at 6 ppm; wheat, bran at 0.15 ppm; wheat, forage at 6 ppm; wheat, germ at 0.1 ppm; wheat, grain at 0.1 ppm; wheat, hay at 15 ppm; wheat, milled byproducts at 0.15 ppm; and wheat, straw at 6 ppm.

Lastly, the tolerance expressions for fluensulfone currently established under 40 CFR 180.680 (a) and (d) are revised to read as follows ''Tolerances are established for residues of the nematicide fluensulfone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the following table below is to be determined by measuring only the sum of fluensulfone, 5-chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole and its metabolite, 3,4,4-trifluoro-but-3-ene-1-sulfonic acid, calculated as the stoichiometric equivalent of fluensulfone, in or on the commodity.''

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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 action has been exempted from review under Executive Order 12866, this action 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action 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 tolerances 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 action 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 ''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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (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: May 16, 2019.

Michael Goodis,

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. Revise § 180.680 to read as follows:

§ 180.680 Fluensulfone; tolerances for residues.

(a) *General.* Tolerances are established for residues of the nematicide fluensulfone, including its metabolites and degradates, in or on the commodities in the table 1 to § 180.680. Compliance with the tolerance levels specified in the following table below is to be determined by measuring only the sum of fluensulfone, 5-chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole and its metabolite, 3,4,4-trifluoro-but-3-ene-1-sulfonic acid, calculated as the stoichiometric equivalent of fluensulfone, in or on the commodity.

TABLE 1 TO § 180.680

Commodity	Parts per million
Almond, hulls	5
Berry, low growing, subgroup 13–07G	0.5
Brassica, head and stem, subgroup 5A	1.5
Brassica, leafy greens, subgroup 5B	20
Fruit, citrus, group 10–10	0.3
Fruit, citrus, group 10–10, dried pulp	0.9
Fruit, citrus, group 10–10, oil	15
Fruit, pome, group 11–10	0.4
Fruit, small, vine climbing, subgroup 13–07D	0.8
Fruit, stone, group 12–12	0.15
Grape, raisin	1.5
Nut, tree, group 14–12	0.02
Potato, chips	2
Potato, granules/flakes	2
Sugarcane, cane	0.06
Sugarcane, molasses	0.3
Tomato, paste	1.5
Vegetables, cucurbits, group 9	0.7
Vegetables, fruiting, group 8–10	0.7
Vegetables, leafy, except *Brassica,* group 4	4
Vegetables, leaves of root and tuber, group 2, except sugar beet	50
Vegetables, root, except sugar beet, subgroup 1B	4
Vegetables, tuberous and corm, subgroup 1C	0.8

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the nematicide fluensulfone, including its metabolites and degradates, in or on the commodities in table 2 to § 180.680. Compliance with the tolerance levels specified in the following table below is to be determined by measuring only the sum of fluensulfone, 5-chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole and its metabolite, 3,4,4-trifluoro-but-3-ene-1-sulfonic acid, calculated as the stoichiometric equivalent of fluensulfone, in or on the commodity.

TABLE 2 TO § 180.680

Commodity	Parts per million
Barley, bran	0.15
Barley, grain	0.1
Barley, hay	15
Barley, straw	6
Buckwheat, grain	0.1
Grain, cereal, forage, fodder and straw, group 16	3
Grain, cereal, group 15	0.05
Oat, forage	6
Oat, grain	0.1
Oat, hay	15
Oat, straw	6
Wheat, bran	0.15
Wheat, forage	6
Wheat, germ	0.1
Wheat, grain	0.1
Wheat, hay	15
Wheat, milled byproducts	0.15
Wheat, straw	6

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