from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 25, 2016.

C.J. Bisignano

Supervisory Bridge Management Specialist, First Coast Guard District.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0569; FRL–9946–07]

Fluensulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluensulfone in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) and Makhteshim Agan of North America, Inc (d/b/a ADAMA) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is June 1, 2016. Objections and requests for hearings must be received on or before August 1, 2016, 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–2015–0569, 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: Susan Lewis, 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–2015–0569 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 August 1, 2016. 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–2015–0569, 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 October 21, 2015 (80 FR 63731) (FRL–9935–29), 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 5E8384) by IR–4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of fluensulfone equivalents (*i.e.,* the sum of thiazole sulfonic acid (TSA) and butene sulfonic acid (BSA) expressed as total fluensulfone equivalents) in or on the raw agricultural commodity vegetable, tuberous and corm, subgroup 1C at 0.6 ppm. That document referenced a summary of the petition prepared by Makhteshim Agan of North America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing, however it related to the chemical propenicol, not fluensulfone.

In the **Federal Register** of March 16, 2016 (81 FR 14030) (FRL–9942–86), 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 5F8351) by Makhteshim Agan of North America, Inc. (d/b/a ADAMA), 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of nematicide fluensulfone, including its metabolites and degradates, in or on berry, low growing, subgroup 13–07G at 0.30 ppm; head and stem *Brassica* subgroup 5A at 1.3 ppm; leafy *Brassica* greens subgroup 5B at 13 ppm; leafy vegetables, group 4, except *Brassica* vegetables at 2.6 ppm; leaves of root and tuber vegetables, group 2 at 20 ppm; radish, oriental at 0.50 ppm; and root vegetables, subgroup

1B, except sugar beet and oriental radish at 3.3 ppm. In addition, the petition requested to amend 40 CFR 180.680 to revise the existing tolerance expression in the introductory paragraph (a) 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 below is to be determined by measuring only 3,4,4-trifluoro-but-3-ene-1-sulfonic acid.'' That document referenced a summary of the petition prepared by Makhteshim Agan of North America, Inc., the registrant, which is available in the docket, EPA–HQ–OPP–2015–0478 at *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for most commodities. 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.

The residue of concern for dietary assessment is the parent compound, fluensulfone. Residues of the metabolites butene sulfonic acid (BSA) and thiazole sulfonic acid (TSA) occur at levels significantly greater than fluensulfone; however, these metabolites are considered non-toxic at levels that may occur from the use of fluensulfone. Based on the available data addressing toxicity of the BSA and TSA metabolites, the Agency has determined that they are not of toxicological concern.

Exposure to fluensulfone results in effects on the hematopoietic system (decreased platelets, increased white blood cells, hematocrit, and reticulocytes), kidneys, and lungs. Body weight and clinical chemistry changes were observed across multiple studies and species. Evidence of qualitative increased susceptibility of infants and children to the effects of fluensulfone was observed in the 2-generation reproduction study in rats, wherein pup death was observed at a dose that resulted in body weight effects in the dams. There was no evidence of either qualitative or quantitative susceptibility in developmental toxicity studies in rats or rabbits.

The most sensitive endpoints for assessing safety of aggregate exposures to fluensulfone under the FFDCA are the increased pup-loss effects for acute dietary exposure; and body weight, hematological and clinical chemistry changes for chronic dietary as well as short/intermediate term dermal exposures.

Decreased locomotor activity in females, and decreased spontaneous activity, decreased rearing, and impaired righting response in both sexes were observed in the acute neurotoxicity study at the lowest dose tested. No other evidence for neurotoxicity was observed in the other studies in the toxicity database, including a subchronic neurotoxicity study. The doses and endpoints chosen for risk assessment are all protective of the effects seen in the acute neurotoxicity study. A developmental neurotoxicity study is not required.

Although the mouse carcinogenicity study showed an association with alveolar/bronchiolar adenomas and carcinomas in the female, EPA has determined that quantification of risk using the chronic reference dose (RfD) will account for all chronic toxicity, including carcinogenicity, that could result from exposure to fluensulfone and its metabolites. That conclusion is based on the following considerations:

1. The tumors occurred in only one sex in one species.

2. No carcinogenic response was seen in either sex in the rat.

3. The tumors in the mouse study were observed at a dose that is almost 13 times higher than the dose chosen for risk assessment.

4. Fluensulfone and its metabolites are not mutagenic.

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 Addressing Label Amendments, Changes to the Residue Definition, and New Uses on Multiple Crops'' on page 43 in docket ID number EPA–HQ–OPP–2015–0569.

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 shown in Table 1 of this unit.

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

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations, including infants and children and females 13–49 years of age).	NOAEL = 16.2 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.16 mg/kg/day. aPAD = 0.16 mg/kg/day	2-generation reproduction—rat offspring. LOAEL = 122.0 mg/kg/day based on an increase in pup loss between PND 1 and 4 in the F1 and F2 offspring with the majority of deaths occurring on day 2.
Chronic dietary (All populations)	NOAEL= 9.6 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.10 mg/kg/day. cPAD = 0.10 mg/kg/day	2-year toxicity/carcinogenicity-rat. LOAEL = 57.7 mg/kg/day based on decreased body weight in males, and hematology changes, clinical chemistry changes and histopathological effects in the lung and esophagus of both sexes.
Incidental oral short-term (1 to 30 days).	NOAEL= 9.6 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-year toxicity/carcinogenicity-rat. LOAEL = 57.7 mg/kg/day based on decreased body weight in males, and hematology changes, clinical chemistry changes and histopathological effects in the lung and esophagus of both sexes.
Dermal short-term (1 to 30 days).	Oral study NOAEL = 9.6 mg/kg/day (dermal absorption factor = 9.5%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-year toxicity/carcinogenicity-rat. LOAEL = 57.7 mg/kg/day based on decreased body weight in males, and hematology changes, clinical chemistry changes and histopathological effects in the lung and esophagus of both sexes.
Cancer (Oral, dermal, inhalation).	EPA has determined that quantification of risk using the chronic RfD will adequately account for all chronic toxicity, including carcinogenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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. Parent fluensulfone occurs at residue levels well below those of the BSA metabolite, the residue defined for the enforcement of tolerances. As previously noted, the BSA metabolite is not of toxicological concern. Since tolerances do not include fluensulfone itself, EPA has used the Organization for Economic Cooperation and Development (OECD) maximum residue limit (MRL) calculation procedures to derive tolerance-equivalent residue levels for fluensulfone. For foods where the level of fluensulfone is expected to be below the limit of quantification (LOQ), 0.01 ppm, the Agency has assumed that residues occur at the LOQ. For foods with quantifiable levels of fluensulfone, EPA has assumed that residues occur at the tolerance-equivalent level. 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's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute dietary risk 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 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.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for fluensulfone. Tolerance-equivalent level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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: Turf/lawns. EPA assessed residential exposure using the following assumptions: For residential handlers, a quantitative exposure/risk assessment was not developed because the product is not intended to be applied by homeowners. 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 Web site 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 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 and body weight gain; at the same dose, effects in offspring were decreased pup weights, decreased spleen weight, and increased pup loss (PND 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-level residues. 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 9.3% 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 3.9% 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 5,700 for adults and 3,000 for children 1–2 years old. 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

Adequate enforcement methodology (acetonitrile/water (1:1, v/v) extraction and analysis by reverse-phase high-performance liquid chromatography-mass spectrometry (HPLC–MS/MS)) is available to enforce the tolerance expression.

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 any MRLs for fluensulfone for the commodities covered by this document.

C. Response to Comments

Three comments were submitted in response to the March 16, 2016 Notice of Filing. Two of them opposed the petition generally due to there being too many toxic chemicals being used in America without citing any specific human health concerns about fluensulfone itself. The Agency understands the commenters' concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

The second comment was from the Center for Food Safety and primarily concerned about Agency compliance with any relevant obligations under the Endangered Species Act. This comment is not relevant to the Agency's evaluation of safety of the fluensulfone tolerances; section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

D. Revisions to Petitioned-For Tolerances

Most of the petitioned-for tolerance levels differ from those being established by the Agency. In the cases of the tolerances proposed by ADAMA, it is not clear to the Agency how the tolerance levels proposed in the March 16, 2016 Notice of Filing (**Federal Register** 2016–05952) were derived. EPA's tolerance levels are based on residues of BSA only, without any conversion to fluensulfone equivalents. The Agency used the OECD MRL procedures to derive the levels being established in today's action. For crop groups, and per EPA's current policy, tolerance levels for each representative commodity were calculated separately, and then the maximum value within each crop group was selected as the tolerance level. For root vegetables except sugar beet (Subgroup 1B), the tolerance level is based on data from radish root (including Oriental radish root). Although a separate listing for Oriental radish was requested, EPA is not establishing a separate tolerance level since that crop is a member of crop subgroup 1B. For leaves of root and tuber vegetables (Crop Group 2), EPA is establishing a tolerance for residues in/on the leaves of root and tuber vegetable, except sugar beet because the petitioned-for uses do not include a use on sugar beet; the tolerance is based on data from radish tops (including Oriental radish tops). The tolerance for residues in/on leafy vegetables except *Brassica* vegetables (Group 4) is based on data from leaf lettuce and spinach, assessed separately. For head and stem *Brassica* (Subgroup 5A), the tolerance is

based on data from cabbage. For *Brassica* leafy greens (Subgroup 5B), data from mustard greens, komatsuna (Japanese mustard spinach), and mizuna (Japanese mustard) were combined to derive the tolerance level. All of EPA's tolerance levels are expressed to provide sufficient precision for enforcement purposes, and this may include the addition of trailing zeros (*e.g.,* 0.30 ppm rather than 0.3 ppm).

In the case of the tolerance proposed by IR–4, the petitioned-for tolerance is based on the sum of residues of BSA and TSA, expressed as fluensulfone, rather than on residues of BSA only, which is how the tolerance expression currently describes measurement of residues for compliance purposes. Basing enforcement on BSA alone provides a suitable marker of use, simplifies residue analysis, and avoids enforcement complications that may result from the potential for TSA to carry over in treated soil from one year to the next. Furthermore, IR–4 did not propose tolerances for residues of fluensulfone in processed potato commodities. The submitted potato processing study indicates that during processing, residues of BSA in chips and in granules/flakes are likely to concentrate to levels greater than in tubers. Therefore, EPA is establishing separate tolerances to cover residues in those commodities.

V. Conclusion

Therefore, tolerances are established for residues of fluensulfone in or on berry, low growing, subgroup 13–07G at 0.30 ppm; *Brassica,* head and stem, subgroup 5A at 1.50 ppm; *Brassica,* leafy greens, subgroup 5B at 9.0 ppm; potato, chips at 0.60 ppm; potato, granules/flakes at 0.80 ppm; vegetables, leafy, except *Brassica,* group 4 at 2.0 ppm; vegetable, leaves of root and tuber, group 2, except sugar beet at 30 ppm; vegetables, root, except sugar beet, subgroup 1B at 3.0 ppm; and vegetables, tuberous and corm, subgroup 1C at 0.50 ppm. Also, the time-limited Section 18 tolerance for ''carrot'' is removed since it is now covered by the permanent tolerance for ''vegetables, root, except sugar beet, subgroup 1B.'' And lastly, the tolerance expression is changed as requested by the petitioner.

VI. Statutory and Executive Order Reviews

This action 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 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). 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 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 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 19, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.680 is revised 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 below. Compliance with the tolerance levels specified below is to be determined by measuring only 3,4,4-trifluoro-but-3-ene-1-sulfonic acid.

Commodity	Parts per million
Berry, low growing, subgroup 13–07G	0.30
Brassica, head and stem, subgroup 5A	1.50
Brassica, leafy greens, subgroup 5B	9.0
Potato, chips	0.60
Potato, granules/flakes	0.80
Tomato, paste	1.0
Vegetables, cucurbits, group 9	0.50
Vegetables, fruiting, group 8–10	0.50
Vegetables, leafy, except *Brassica,* group 4	2.0
Vegetables, leaves of root and tuber, group 2, except sugar beet	30
Vegetables, root, except sugar beet, subgroup 1B	3.0
Vegetables, tuberous and corm, subgroup 1C	0.50

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

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

(d) *Indirect or inadvertant residues.* [Reserved]

[FR Doc. 2016–12722 Filed 5–31–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0212; FRL–9943–73]

Aldicarb, Alternaria destruens, Ampelomyces quisqualis, Azinphos-methyl, Etridiazole, Fenarimol, et al.; Tolerance and Tolerance Exemption Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking certain tolerances in follow-up to canceled product registrations or uses for acephate, aldicarb, azinphos-methyl, etridiazole, fenarimol, imazamethabenz-methyl, tepraloxydim, thiazopyr, and tralkoxydim, and is revoking tolerance exemptions for certain pesticide active ingredients. However, EPA will not revoke the thiacloprid tolerances at this time that had been previously proposed for revocation. Also, EPA is making minor revisions to the section heading and introductory text for *Pythium oligandrum* DV 74. In addition, in accordance with current Agency practice, EPA is making revisions to the tolerance expression for imazamethabenz-methyl, and removing expired tolerances and tolerance exemptions for certain pesticide active ingredients.

DATES: This regulation is effective November 28, 2016. Objections and requests for hearings must be received on or before August 1, 2016, 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–2015–0212, 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: Joseph Nevola, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8037; email address: *nevola.joseph@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 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 the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g), 21 U.S.C. 346a(g), 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–2015–0212 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 August 1, 2016. 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–2015–0212, 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. Background

A. What action is the Agency taking?

In the **Federal Register** of July 22, 2015 (80 FR 43373) (FRL–9929–12), EPA issued a proposed rule to revoke certain tolerances for acephate, aldicarb, azinphos-methyl, etridiazole, fenarimol, imazamethabenz-methyl, tepraloxydim, thiacloprid, thiazopyr, and tralkoxydim, and tolerance exemptions for certain pesticide active ingredients, in follow-up to canceled product registrations or uses. Also, EPA proposed to make minor revisions to the section heading and introductory text for *Pythium oligandrum* DV 74. In addition, in accordance with current Agency practice, EPA proposed to make minor revisions to the tolerance expression for imazamethabenz-methyl, and remove expired tolerances and tolerance exemptions for certain pesticide active ingredients. The proposal provided a 60-day comment period.

Since the proposed rule of July 22, 2015, amendments for the last two acephate labels with succulent bean use (revising succulent bean to a non-food use) were approved by EPA, as anticipated and discussed in the