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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0593; FRL-9914-35]

Fluensulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluensulfone in or on cucurbit vegetables and fruiting vegetables. Makhteshim Agan of North American Inc. (MANA), doing business as (dba) ADAMA, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2012-0593, 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: Lois Rossi, 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*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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-2012-0593 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2012-0593, 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 September 28, 2012 (77 FR 59578) (FRL-9364-6), 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 2F8019) by Makhteshim Agan of North America, Inc. (MANA), dba ADAMA, 3120 Highwoods Blvd, Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the nematicide fluensulfone, {5-Chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole}, in or on cucurbit vegetables at 1.0 parts per million (ppm) and fruiting vegetables at 0.6 ppm. That document referenced a summary of the petition prepared by MANA, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels of 1.0 and 0.6 ppm for cucurbits and fruiting vegetables to 0.50 and 0.50 ppm, respectively. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the

tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with 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. Fluensulfone has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant but is a skin sensitizer. Acute oral toxicity studies were also conducted with the metabolites thiazole sulfonic acid (TSA), butene

sulfonic acid (BSA), and methyl sulfone (MeS). The results indicated TSA and BSA were of low toxicity (Toxicity Category III), while MeS was of moderate toxicity (Toxicity Category II) by the oral route of exposure. The acute oral toxicity studies indicated that BSA and TSA were comparably less toxic than fluensulfone. Twenty-eight-day oral toxicity studies conducted with BSA and TSA were submitted and also indicated that both metabolites are of much lower toxicity than the parent compound. 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.

Dietary and inhalation studies in rats showed evidence of portal-of-entry effects in the forestomach, pharynx, epiglottis, and nasal cavity. The most sensitive endpoints for assessing human health risk are the increased pup-loss effects for acute dietary exposure; body weight, hematological and clinical chemistry changes for chronic dietary as well as short/intermediate term dermal exposures; and clotting time, decreased thymus weight, and portal-of-entry effects (histopathology of the epiglottis and nasal cavity) for inhalation exposures (short/intermediate term).

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 document Fluensulfone: New Active Ingredient Human Health Risk Assessment of Proposed Uses on Cucurbit Vegetables and Fruiting Vegetables on pages 32-46 in docket ID number EPA-HQ-OPP-2012-0593.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for fluensulfone used for human risk assessment is shown in the Table of this unit.

Table -- 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 = 16.2/23 mg/kg/day (M/F) 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 = 122.0/169.1 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= 3.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.03 mg/kg/day cPAD = 0.03 mg/kg/day	Co-critical 90-day dog and chronic dog Chronic: LOAEL = 16 mg/kg/day based on decreased body weight, increased mean hemoglobin concentration distribution width, and increased relative and absolute reticulocyte counts in both sexes, decreased prothrombin time in males and increased platelets in females. Subchronic: NOAEL = 1.6 mg/kg/day LOAEL = 17.1 mg/kg/day based on decreased body weight in females and increased relative and absolute reticulocyte counts, decreased bilirubin, decreased albumin, decreased A/G ratio, increased TSH, and pigmented Kupffer cells in 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. 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 in 40 CFR part 180. 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. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003-2008. As described in Units IV and V, tolerances for fluensulfone are in terms of the BSA metabolite. However, as previously noted, the BSA metabolite is not of toxicological concern. Therefore, as to residue levels in food, EPA assumed 100 percent crop treated (PCT); limit-of-quantitation residues of fluensulfone, as reflected in crop field trials (equivalent to a fluensulfone-based tolerance); and empirically derived processing factors.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) which used food consumption data from the USDA NHANES.WWEIA 2003-2008. As described in Units IV and V, tolerances for fluensulfone are in terms of the BSA metabolite. However, as previously noted, the BSA metabolite is not of toxicological concern. Therefore, as to residue levels in food, EPA assumed 100 PCT; limit-of-quantitation residues of fluensulfone, as reflected in crop

field trials (equivalent to a fluensulfone-based tolerance); and empirically derived processing factors.

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 percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for fluensulfone. Residues equivalent to a fluensulfone-based tolerance 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://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model Ground Water (PRZMGW), the estimated drinking water concentrations (EDWCs) of fluensulfone and its metabolites of toxic concern for acute exposures are estimated to be 11.80 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 acute dietary risk assessment, the water concentration value

of 77.6 ppb was used to assess the contribution to drinking water. For 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 not registered for any specific use patterns that would result in residential exposure.

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://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold

effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA 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*. There was no evidence of quantitative or qualitative susceptibility in developmental toxicity studies in rats and rabbits. Offspring effects in those studies occurred in the presence of maternal toxicity and were not considered more severe than the parental effects. However, there was evidence of increased qualitative susceptibility of pups in the 2-generation reproduction study in rats. Maternal effects observed in that study were decreases in body weight and body weight gain; at the same dose, effects in offspring were decreased pup weights, decreased spleen weight, and increased pup death.

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/or post-natal toxicity following *in utero* exposure to rats or rabbits and pre- and/or 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 and endpoints selected for risk assessment are equal to or less than the NOAEL from that study, the degree of concern for the susceptibility observed in the 2-generation

reproduction study is low. The selected POD will be protective of these developmental effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the 10X FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluensulfone is complete.

ii. 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.

iii. There is no evidence that fluensulfone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. However, there was evidence of increased qualitative susceptibility of young rats in the 2-generation reproduction study. For the reasons discussed in Unit III.D.2., EPA concludes that the 10X FQPA SF is not necessary to adequately protect infants and children.

iv. There are no residual uncertainties identified in the exposure databases. The current dietary assessment is based on high-end assumptions such as maximum residue levels from field trials of the parent compound in food, 100 PCT, and modeled estimates of residues in drinking water. EPA made conservative (protective) assumptions in the groundwater and surface water modeling used to assess exposure to fluensulfone in

drinking water. Furthermore, there are no proposed residential uses. 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 aPAD and 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 7.4% of the aPAD for all infants, 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 9.5% of the cPAD for all infants, the population group receiving the greatest exposure. There are no residential uses for fluensulfone.

3. *Short- and intermediate-term risk*. Short-and intermediate-term risk are assessed based on short-term residential exposure plus chronic dietary exposure. A short- and intermediate-term adverse effect was identified; however, fluensulfone is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Because there is no short-term or 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 short-term risk), no

further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fluensulfone**.**

4. *Aggregate cancer risk for U.S. population*. Based on the data summarized in Unit III.C.1.iii., EPA has concluded that the cPAD is protective of potential cancer effects. Given the results of the chronic risk assessment, fluensulfone is not expected to pose a cancer risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluensulfone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Suitable methods for tolerance enforcement have been developed and independently validated. For all matrices and analytes, the limit of quantitation (LOQ), defined as the lowest spiking level where acceptable precision and accuracy data were obtained, was determined to be 0.01 milligram/kilogram (mg/kg). The limit of detection (LOD) was defined to be 30% of the LOQ (i.e. 0.0003 mg/kg). The Food and Drug Administration (FDA) multi-residue methods are not suitable for detection and enforcement of fluensulfone residues (as the sulfonic acid metabolite BSA) in non-fatty matrices.

Adequate enforcement methodology (reverse-phase high performance liquid chromotography-mass spectrometry/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 MRLs for fluensulfone.

C. Revisions to Petitioned-For Tolerances

The proposed tolerance levels, 1.0 and 0.6 ppm for cucurbits and fruiting vegetables, respectively, differ from those being established by EPA. Although both the petitioner and EPA have used the OECD calculation procedures to obtain tolerance levels, the residue definitions being used are different. The petitioner's proposed levels are based on residues of BSA and TSA, combined and expressed as parent fluensulfone whereas the EPA-calculated tolerances are based on residues of only the BSA metabolite, expressed as parent fluensulfone. Furthermore, the petitioner combined residue data from

the representative commodities to obtain their proposed tolerances. In accordance with policy, EPA calculated separate tolerance levels for each representative commodity and then selected the maximum tolerance estimate within each group, resulting in tolerance levels of 0.80 ppm and 0.70 ppm for cucurbits and fruiting vegetables, respectively.

However, in order to mitigate estimated worker risks associated with chemigation operations, Makhteshim has reduced the proposed application rate from 3.5 lb. fluensulfone per acre to 2.5 lb. per acre. For purposes of establishing a tolerance that is reflective of the revised application rate, the residue data were re-evaluated. The resulting tolerance level for both cucurbit vegetables and fruiting vegetables is 0.50 ppm.

V. Conclusion

Therefore, tolerances are established for residues of the nematicide fluensulfone, including its metabolites and degradates, in or on vegetables, cucurbit, group 9 at 0.50 ppm and vegetables, fruiting, group 8-10 at 0.50 ppm. Compliance with the tolerance levels specified below is to be determined by measuring only 3,4,4-trifluoro-but-3-ene-1-sulfonic acid, calculated as the stoichiometric equivalent of fluensulfone.

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 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 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 "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 11, 2014.

Jack Housenger,
Director, 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 added to to subpart C 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, calculated as the stoichiometric equivalent of fluensulfone.

Commodity	Parts per million
Vegetables, cucurbits, group 9	0.50
Vegetables, fruiting, group 8-10	0.50

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

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

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

[FR Doc. 2014-22466 Filed 09/23/2014 at 8:45 am; Publication Date: 09/24/2014]