provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.11442 Halogenated alkylbenzoic acid, ethyl ester (generic) (P–19–108).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as halogenated alkylbenzoic acid, ethyl ester (PMN P–19–108) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: Skin irritation; respiratory complications; central nervous system effects; internal organ effects; reproductive effects; developmental effects; eye irritation. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q). It is a significant new use to manufacture or process the substance without including the engineering controls/processes described in the premanufacture notice.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=14.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.11443 Halogenated benzoic acid, ethyl ester (generic) (P–19–110).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as halogenated benzoic acid, ethyl ester (PMN P–19–110) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: Skin irritation; respiratory complications; central nervous system effects; internal organ effects; reproductive effects; developmental effects; eye irritation. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q). It is a significant new use to manufacture or process the substance without including the engineering controls/processes described in the premanufacture notice.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=14.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0118; FRL–8653–01–OCSPP]

Fluensulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerance for residues of fluensulfone in or on soybean, seed. Makhteshim Agan of North America (d/b/a ADAMA) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 18, 2021. Objections and requests for hearings must be received on or before October 18, 2021, 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–2020–0118, 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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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 Publishing 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(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–2020–0118 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 October 18, 2021. 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–2020–0118, 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 April 15, 2020 (85 FR 20910) (FRL–10006–54), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP 9F8799) by Makhteshim Agan of North America (d/b/a ADAMA), 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR 180.680 be amended by establishing tolerances for residues of the nematicide fluensulfone, in or on soybean, seed at 0.1 parts per million (ppm); soybean, forage at 7.0 ppm; and soybean, hay at 20 ppm. That document referenced a summary of the petition prepared by Makhteshim Agan of North America, the petitioner, which is available in the docket, *http://www.regulations.gov.* Two 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 is establishing a tolerance that varies from what is requested. The reason for these changes is 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 therein, 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 tolerance established by this action. EPA's assessment of exposures and risks associated with fluensulfone follows.

In an effort to streamline **Federal Register** publications, EPA is not reprinting here summaries of its analyses that have previously appeared in the **Federal Register** in previous tolerance rulemakings for the same pesticide. To that end, this rulemaking refers the reader to several sections from the April 13, 2018 tolerance rulemaking for residues of fluensulfone that remain unchanged for an understanding of the Agency's rationale in support of this rulemaking. See 83 FR 15971 (FRL–9975–76). Those sections are: Units III.A (Toxicological Profile); III.B. (Toxicological Points of Departure/Levels of Concern); and III.C. (Exposure Assessment), except as explained in the next paragraphs; III.D. (Safety Factor for Infants and Children).

Exposure assessment updates. EPA's exposure assessments have been updated to include the additional exposure from use of fluensulfone on soybeans. EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure from drinking water and from residential sources. The new use does not result in an increase in the estimated residue levels in drinking water or in exposure from residential sources relative to those used in the last assessment.

Further information about EPA's risk assessment and determination of safety supporting the new fluensulfone tolerance can be found at *http://www.regulations.gov* in the document titled ''Fluensulfone. Human Health Risk Assessment for a New Use on Soybean.'' in docket ID EPA–HQ–OPP–2020–0118.

Assessment of aggregate risks. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern: The acute dietary risk estimate is 21% of the aPAD for infants (<1 year old), the group with the highest exposure. Chronic dietary risks are below the Agency's level of concern: 4.8% of the cPAD for infants (<1 year old), the group with the highest

exposure. EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposure above the level of concern of 100 for all scenarios assessed and are not of concern. EPA has determined that quantification of cancer risk using a non-linear approach (*i.e.,* reference dose) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fluensulfone; the chronic aggregate assessment did not result in risk estimates of concern.

Determination of safety. Therefore, based on the risk assessments and information described above, EPA concludes 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. More detailed information on this action to establish a tolerance on soybean can be found in the document entitled, ''Fluensulfone. Human Health Risk Assessment for a new use on Soybean'' by going to the docket established by this action, which is described under **ADDRESSES**.

IV. Other Considerations

A. Analytical Enforcement Methodology

There are adequate residue analytical methods for enforcing tolerances for fluensulfone residues of concern in/on the registered plant and livestock commodities. These methods include two high-performance liquid chromatography methods with tandem mass-spectroscopy detection (HPLC/MS/MS) for determining residues in/on plant and livestock matrices.

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). 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 on soybean.

C. Response to Comments

EPA received two comments from anonymous sources. One comment cited concern regarding fluoride; this comment is not relevant to the Agency's evaluation of a tolerance for the proposed new use of fluensulfone on soybean. The other comment expresses concern about pesticides in general, and requests that the Agency deny use of fluensulfone without specifically mentioning the new use on soybean. While the agency recognizes that some people do not like pesticides, the Agency has evaluated the aggregate risk of fluensulfone and has determined 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.

D. Revisions to Petitioned-For Tolerances

The agency has determined that tolerances are not needed for soybean, forage and soybean, hay, as the label contains a feeding restriction for those commodities, and the commodities will not be in the channels of trade. Further, the agency has recommended amending the proposed tolerance for soybean, seed from 0.1 ppm to 0.07 ppm based upon the OECD MRL/Tolerance Calculation Procedures.

V. Conclusion

Therefore, a tolerance is established for residues of fluensulfone on soybean, seed at 0.07 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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: August 6, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.680, amend the table 1 to § 180.680 by adding in alphabetical order in paragraph (a) the entry ''Soybean, seed'' to read as follows:

§ 180.680 Fluensulfone; tolerances for residues.

(a) * * *

TABLE 1 TO § 180.680

Commodity	Parts per million
* * * * * * *	
Soybean, seed	0.07
* * * * * * *	

* * * * *

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