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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0226; FRL-9979-81]

Florasulam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of florasulam in or on teff forage, teff grain, teff hay, and teff straw. Interregional Research Project Number 4 (IR-4) 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-2017-0226, is available at *http://www.regulations.gov* or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0226 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-2017-0226, 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 23, 2017 (82 FR 49020) (FRL-9967-37), 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 7E8549) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide florasulam N-(2,6-difluorophenyl)-8-fluoro-5-methoxy (1,2,4)triazolo(1,5-c)pyrimidine-2-sulfonamide in or on the raw agricultural commodities

teff, forage at 0.05 parts per million (ppm); teff, grain at 0.01 ppm; teff, straw at 0.05 ppm; and teff, hay at 0.05 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov*. A comment was received on the notice of filing. EPA's response to this comment is discussed 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 florasulam including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with florasulam 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.

There was slight nephrotoxicity (increased kidney weights, hypertrophy, and degeneration/regeneration and inflammation of the descending portion of proximal tubules) observed in the kidneys of rats (both sexes) after subchronic exposure to florasulam (90 days) at or greater than 500 milligrams/kilogram/day (mg/kg/day). Chronic exposure in rats led to slight nephrotoxicity (increased kidney weights, hypertrophy, and slight multi-focal mineralization of the papilla) at 250 and 500 mg/kg/day in males only. Additionally, at 500 mg/kg/day, papillary necrosis and hyperplasia of the transitional epithelium (papilla) were observed in the kidney (males). Decreases in body weight and body weight gain were also observed in females after subchronic (500 mg/kg/day) and chronic exposure (250 mg/kg/day). Liver toxicity was observed in dogs (both sexes) in the form of increased alkaline phosphatase activity (59-127%), increased liver weights, hypertrophy, and hepatic vacuolation at 50 mg/kg/day after 90 days. After 1 year, there were increases in alkaline phosphatase (233-783%) in dogs (both sexes) but no changes in liver weights or gross or microscopic pathology at 50

mg/kg/day. Additionally, there were decreases in body weight, body weight gain and food consumption, as well as vacuolation of the zona reticularis and zona fasciculate in the adrenal gland (consistent with fatty change) in both sexes. There were no adverse effects noted after subchronic/chronic exposure to florasulam in mice up to the limit dose of 1,000 mg/kg/day.

There was no evidence of developmental toxicity or indications of neonatal sensitivity in the developmental and reproduction toxicity studies (rats and rabbits). In the rat developmental toxicity study, decreased body weights and decreased food consumption were observed. There were also slight decreases observed in fetal body weight and delays in ossification observed in fetuses at the high dose. However, the minor differences were not considered adverse since there was no clear dose-response relationship and the values (both findings) fell within historical control values. Furthermore, the findings were attributed to the associated decreases in maternal body weights. There were no treatment-related effects observed in dams or offspring in the developmental toxicity study in rabbits. In the reproduction toxicity study in rats, there were decreased body weights, body weight gains, and food consumption, as well as increased kidney weights and hypertrophy in both sexes at 500 mg/kg/day. Additionally, at 500 mg/kg/day, transient decreases in pup body weights were observed on post-natal day 4 pre-culling (F1 and F2 males) and post-natal day 7 (F1 females and F2 males and females); however, by post-natal day 21, all treated groups were similar to controls. The decreases observed were associated with decreased maternal body weight and food consumption and were transient in nature; thus, they were not considered adverse.

Dermal exposure to florasulam did not result in systemic toxicity up to the limit dose of 1,000 mg/kg/day. There is no evidence of neurotoxicity, mutagenicity, or carcinogenicity after exposure to florasulam. In addition, there is no evidence of endocrine related toxicity.

Specific information on the studies received and the nature of the adverse effects caused by florasulam 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 "*Florasulam: Human Health Risk Assessment for proposed use on Turfgrass*" ("2009 Florasulam Turfgrass Assessment") on pages 35-39 in docket ID number EPA-HQ-OPP-2017-0226. The Agency is relying on this risk assessment because the toxicological profile for florasulam has not changed since that risk assessment was conducted and as indicated in a more recent assessment for use on teff, the Agency has concluded that registering use on teff would not alter the Agency's previously assessed exposure estimates for florasulam. *See "Florasulam: Human Health Risk Assessment for Proposed Use on Teff"* (Dec. 6, 2017) ("2017 Florasulam Teff Assessment"), which can also be found in *http://www.regulations.gov* in docket ID number EPA-HQ-OPP-2017-0226.

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 florasulam used for human risk assessment is shown in Table 1 of this unit.

Table 1. - Summary of Toxicological Doses and Endpoints for Florasulam 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)	No appropriate endpoint identified		
Chronic dietary	NOAEL= 5 mg/kg/day	Chronic RfD = 0.05	**<u>Chronic toxicity – dogs</u>** LOAEL = 50 mg/kg/day,

(All populations)	UF_A = 10x UF_H = 10x FQPA SF = 1x	mg/kg/day cPAD = 0.05 mg/kg/day	based on decreased body weights (17%), body weight gains (68%), and food consumption in the females; adverse liver alterations; slight vacuolation of the zona reticularis and zona fasciculata in the adrenal gland (fatty change) in both sexes.
Incidental oral short-term (1-30 days)	NOAEL= 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	**Subchronic toxicity – dogs** LOAEL = 50 mg/kg/day based on hepatotoxicity (increases in alkaline phosphatase activity and hepatic vacuolation) observed in both sexes
Inhalation short-term (1-30 days)	Oral study NOAEL= 5 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	**Subchronic toxicity – dogs** LOAEL = 50 mg/kg/day based on hepatotoxicity (increases in alkaline phosphatase activity and hepatic vacuolation) observed in both sexes
Cancer (Oral, dermal, inhalation)	Not Likely to be Carcinogenic to Humans		

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*. EPA's most recent quantitative dietary assessment was conducted in connection with the registration of turfgrass uses for florasulam. *See* 2009 Florasulam Turfgrass Assessment. That document considered dietary exposure for residues of florasulam in food associated with the all existing florasulam tolerances in 40 CFR 180.633 as described in Unit III.C.1. of the 2007 rulemaking establishing those tolerances. 72 FR 55073 (Sept. 28, 2007). EPA has determined that approval of the use on teff will not change those dietary exposure estimates for residues of florasulam in or on food. The Agency expects residues on teff to be similar to those residues in or on wheat because of the similarity in use pattern and application rates. Teff is prepared like other whole grains, such as rice and barley, and may also be used to make flour in a manner similar to wheat and other cereal grains. As a flour, the Agency expects that teff will likely substitute in the diet for cereal grain foods rather than add to dietary exposure. With respect to livestock commodities, residues of florasulam in teff livestock feeds are expected to be similar to those in other forages, hays, and silages for which florasulam is currently registered. Therefore, there would be no increase in the livestock dietary burden should teff be substituted in the livestock diet for other hays and silages; residues in meat, milk, poultry and eggs will remain the same.

2. *Dietary exposure from drinking water*. In the 2009 Florasulam Turfgrass Assessment, the Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for florasulam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of florasulam. 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.*

To arrive at the total EDWC (estimated drinking water concentrations), the maximum surface water and ground water values for the parent was added to the maximum surface water and ground water value for the major degradate. Based on the FQPA Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of florasulam use on turfgrass for chronic exposures are estimated to be 1.36 parts per billion (ppb) for surface water and 0.06 ppb for ground water.

The Agency has concluded that the teff use will not increase drinking water exposure estimates because the teff use pattern is similar to the use patterns on wheat and barley. The wheat and barley use patterns yield EDWCs that are approximately nine times lower than the use on turfgrass and thus would not be used to assess dietary exposure. Therefore, the Agency used the same modeled estimates of drinking water concentrations from the 2009 Florasulam Turfgrass Assessment: for the chronic dietary risk assessment, the water concentration of value 1.36 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).

Florasulam is currently registered for the following uses that could result in residential exposures: turf. The new use on teff is not a residential use. Therefore, EPA

is relying on its 2009 Florasulam Turfgrass Assessment to assess residential exposures. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposure is expected to handlers as a result of applying florasulam to turf. There is no short-term dermal endpoint for florasulam, and therefore, no dermal risks were assessed for residential handlers. The scenarios assessed for handlers was mixing/loading/applying florasulam to turf with various application equipment.

For post-application, the Agency determined there is a potential for exposure from entering florasulam-treated residential areas, such as lawns, sports fields, and golf courses that could lead to post-application exposures to adults and children. No short-term dermal point of departure was identified for florasulam. Therefore, no dermal risks were assessed for residential post-application exposures.

The Agency assumed that inhalation exposures are minimal following outdoor applications of an active ingredient with low vapor pressure. Since the proposed use of florasulam include only outdoor applications and florasulam has a low vapor pressure, post-application inhalation exposures and risks were not assessed. The scenario resulting in the highest exposure was short-term incidental oral risks for toddlers after applications of florasulam to lawns. The exposure scenarios include hand to mouth, object to mouth, incidental soil ingestion and the combination of all three of these scenarios.

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 florasulam to share a common mechanism of toxicity with any other substances, and florasulam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that florasulam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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 developmental toxicity or indications of neonatal sensitivity in the developmental and reproduction toxicity studies (rats and rabbits). In the rat developmental toxicity study (750 mg/kg/day) body weights were decreased by 4-6% during gestation days 6-19, resulting in a 16% decrease in body weight gains during treatment (gestation days 6-16); food consumption was also decreased (not statistically analyzed) by 6-13% during the treatment period. Additionally, at this dose, absolute and relative (to body weight) kidney weights were increased ($p<=0.05$) by 8 and 12%, respectively. At 250 and 750 mg/kg/day, slight decreases (3-4%) were observed in fetal body weight. Additionally, there were delays in ossification observed in fetuses at 750 mg/kg/day. However, the minor differences were not considered adverse since there was no clear dose-response and the values (both findings) fell within historical control values. Furthermore, the findings were attributed to the associated decreases in maternal body weights. There were no treatment-related effects observed in dams or offspring in the developmental toxicity study in rabbits. In the reproduction toxicity study in rats, there were decreased body weights, body weight gains, and food consumption, as well as increased kidney weights and hypertrophy in both sexes at 500 mg/kg/day. Additionally, at 500 mg/kg/day, transient decreases in pup body weights were observed on post-natal day 4 pre-culling (F1 and F2 males) and post-natal day 7 (F1 females and F2 males and females); however, by post-natal day 21, all treated groups were similar to controls. The

decreases observed were associated with decreased maternal body weight and food consumption and were transient in nature; thus, they were not considered adverse

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 florasulam is complete.

ii. There is no indication that florasulam is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that florasulam results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to florasulam 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 florasulam.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, florasulam is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to florasulam from food and water will utilize less than 1% of the cPAD for all population groups. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of florasulam 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).

Florasulam 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 florasulam.

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 14,000 for children, 98,000 for the general U.S. population, and 114,000 for adult females. Because EPA's level of concern for florasulam 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**,** florasulam 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 florasulam**.**

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, florasulam is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromatography and mass selective detection (GC-MSD)) 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 a MRL for florasulam on teff.

C. Response to Comments

A single comment was received that appeared to be in support of the petition and read in part that "the proposed regulation of pesticide residuals is…a very reasonable proposal." The commenter also expressed concern regarding the consequences for not meeting the residue levels. The commenter's concern is outside the scope of this rulemaking, which is concerned with assessing the safety of these tolerances.

V. Conclusion

Therefore, tolerances are established for residues of florasulam, including its metabolites and degradates, in or on teff, forage at 0.05 ppm; teff, grain at 0.01 ppm; teff, hay at 0.05 ppm; and teff, straw at 0.05 ppm.

In addition, in accordance with Agency policy, EPA is revising the introductory language in paragraph (a) to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of florasulam not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

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), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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: July 16, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.633:

i. Revise paragraph (a) introductory text; and

ii. Add alphabetically the commodities "Teff, forage," "Teff, grain," "Teff, hay," and "Teff, straw" to the table in paragraph (a).

The revision and additions read as follows:

§ 180.633 Florasulam; tolerances for residues.

(a) *General*. Tolerances are established for residues of the herbicide florasulam, including its metabolites and degradates, in or on the commodities below. Compliance with the tolerance levels specified below is to be determined by measuring only florasulam, N-(2, 6-difluorophenyl)-8-fluoro-5-methoxy (1, 2, 4) triazole (1, 5-*c*)pyrimidine-2-sulfonamide, in or on the commodities.

Commodity	Parts per million
****	***
Teff, forage	0.05
Teff, grain	0.01
Teff, hay	0.05

Teff, straw	0.05
****	***

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