### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180


**Fluroxypyr; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fluroxypyr in or on teff forage, teff grain, teff hay, and teff straw. Intergovernmental Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective June 26, 2018. Objections and requests for hearings must be received on or before August 27, 2018, 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–2017–0225, is available at [http://www.regulations.gov](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](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 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–2017–0225 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 27, 2018. Addressers 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–2017–0225, by one of the following methods:

- Federal eRulemaking Portal: [http://www.regulations.gov](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/contact/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 (FP 793550) 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 herbicide fluroxypyr 1-methylheptyl ester [1-methylheptyl (4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy] acetate] and its metabolite fluroxypyr [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxalacetic acid] in or on teff, forage at 12.0 ppm; teff, grain at 0.5 ppm; teff, straw at 12.0 ppm; acid in or on teff, forage at 12.0 ppm; metabolite fluroxypyr [(4-amino-3,5-pyridinyl)oxy] acetate] and its methylheptyl ester [1-methylheptyl ((4-amino-3,5-pyridinyl)oxy) acetate] and acid in or on teff, forage at 12.0 ppm; teff, grain at 0.5 ppm; teff, straw at 12.0 ppm; acid in or on teff, forage at 12.0 ppm; and teff, hay at 20.0 ppm. That or at 12.0 ppm. That

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 fluroxypyr including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with fluroxypyr follows.

**A. Toxicological Profile**

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The active ingredient used in formulating end-use herbicide products is fluroxypyr 1-methylheptyl ester. However, since the ester form has been shown to rapidly hydrolyze to the acid form, the residues of fluroxypyr 1-methylheptyl ester along with its metabolite fluroxypyr acid metabolite (free and conjugated), are collectively expressed as “fluroxypyr” and are therefore regulated together for tolerance enforcement. In terms of toxicity, the ester and acid forms are considered the same.

Fluroxypyr has low acute toxicity by the oral and dermal routes of exposure and moderate to mild acute toxicity by the inhalation route of exposure, based on lethality studies. Fluroxypyr is not a dermal sensitizer, nor is it irritating to the skin; however, it is a mild eye irritant.

The kidney is the target organ for fluroxypyr following oral exposure to rats, mice, and dogs. In the rat, increased kidney weight, nephrotoxicity, and death were observed in both sexes in the 90-day feeding study, and increased kidney weight and microscopic kidney lesions were observed in both sexes in the chronic study. Increased kidney weight was also observed in the developmental toxicity study, and kidney effects (deaths due to renal failure; increased kidney weight, and microscopic kidney lesions) were observed in both sexes in the 2-generation reproduction study in rats. Although microscopic kidney lesions were observed in dogs in the 28-day feeding study, no kidney effects or other treatment related toxicity were seen in the chronic feeding study in dogs at the same doses used in the 28-day study. Microscopic kidney lesions were observed in mice following long-term exposure.

There was no evidence of increased susceptibility (quantitative/qualitative) following in utero exposure in rats and rabbits, or following pre and/or postnatal exposure in rats. Neither developmental toxicity nor reproductive toxicity was observed in rats. In rabbits, developmental toxicity was not observed following exposure to dose levels that resulted in maternal death; however, abortions were observed in rabbits following exposure to fluroxypyr at the limit dose. There was no evidence of neurotoxicity or neuropathology in any of the studies. An immunotoxicity study in rats found no indication of immunotoxicity. Fluroxypyr is classified “not likely to be carcinogenic to humans” due to lack of evidence to suggest carcinogenicity in the database, and there is no concern for its mutagenicity potential.

Specific information on the studies received and the nature of the adverse effects caused by fluroxypyr 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 “Fluroxypyr: Human Health Risk Assessment to Support Proposed New Use on Teff” on pages 13–16 in docket ID number EPA–HQ–OPP–2017–0225.

**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 fluroxypyr used for human risk assessment is discussed in Unit III.B. of the final rule published in the Federal Register of January 16, 2013 (78 FR 3328) (FRL–9371–1).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to fluroxypyr, EPA considered exposure under the petitioned-for tolerances as well as all existing fluroxypyr tolerances in 40 CFR 180.535. EPA assessed dietary exposures from fluroxypyr 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. No such effects were identified in the toxicological studies for fluroxypyr; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture’s National Health and Nutrition Examination Survey, “What We Eat in America” (NHANES/WWHEIA) dietary survey conducted in 2003–2008. As to residue levels in food, EPA assumed tolerance-level residues with 100 percent crop treated (PCT) for all existing and proposed crop uses and default processing factors for processed commodities.

iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that fluroxypyr does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

3. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluroxypyr in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluroxypyr. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.

Based on the Tier 1 Rice Model and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of fluroxypyr for chronic exposures are estimated to be 540 parts per billion (ppb) for surface water and 0.055 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration value of 540 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, termiteicides, and flea and tick control on pets). Fluroxypyr is currently registered for use on residential turfgrass, golf courses, parks and sports fields. Residential handler exposure was not assessed because all the labels require the use of personal-protective equipment (PPE) and are not intended for application by homeowners.

For post-application exposure, although adults and children performing physical activities on treated turf (e.g., golfing, mowing) may receive dermal exposure to fluroxypyr residues, a quantitative risk assessment for the dermal route of exposure was not conducted since there are no toxicity findings for the short-term route of exposure up to the limit dose. In addition, a quantitative post-application inhalation exposure assessment was not conducted because of the low acute inhalation toxicity, low vapor pressure, and the relatively low use rate.

Young children 1 to <2 years old may receive incidental oral post-application exposure to fluroxypyr from treated turf. The post-exposes for children playing on treated turf resulting in incidental oral exposure as a result of mouthing behaviors were assessed.

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

D. Safety Factor for Infants and Children

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

2. Prenatal and postnatal sensitivity. There is no evidence of increased qualitative or quantitative susceptibility following in utero exposure in rats and rabbits or following pre and/or postnatal exposure in rats.

Fluroxypyr is neither a developmental nor a reproductive toxicant in rats. Fluroxypyr has been evaluated for potential developmental effects in the...
rat and rabbit (gavage administration). Maternal toxicity included death in rats and rabbits. There were no developmental effects in the rat, and while abortions were observed in the rabbit, they occurred only at the limit dose.

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

ii. There is no evidence that fluroxypyr 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.

iii. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilizes tolerance-level residue estimates and assumes 100 PCT for all commodities. This assessment will not underestimate exposure/risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluroxypyr in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposures. These assessments will not underestimate the exposure and risks posed by fluroxypyr.

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, fluroxypyr 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 fluroxypyr from food and water will utilize 3.5% of the cPAD for all infants less than 1-year-old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluroxypyr 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).

Fluroxypyr 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 fluroxypyr.

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 an aggregate MOE of 2,500 for children 1–2 years old. Because EPA’s level of concern for fluroxypyr is a MOE of 100 or below, this MOE is 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, fluroxypyr 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 fluroxypyr.

5. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluroxypyr 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 fluroxypyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate GC/ECD (gas chromatography/electron-capture detection) analytical methods are available to enforce the proposed plant tolerances. The available methods for plant commodities involve extraction of fluroxypyr residues with acetone, partitioning with hexane, purification using a florisil column, and analysis of residues by GC/ECD. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–3310; 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 fluroxypyr on teff.

V. Conclusion

Therefore, tolerances are established for the combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetic acid) in or on teff, forage at 12 ppm; teff, grain at 0.50 ppm; teff, hay at 20 ppm; and teff, straw at 12 ppm.

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 409(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: June 8, 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:


2. In §180.535, add alphabetically the entries “Teff, forage”; “Teff, grain”; “Teff, hay”; and “Teff, straw” to the table in paragraph (a) to read as follows:

§180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

(a) * * *

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