environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–1092, to read as follows:

§ 165.T05–1092 Safety Zone Within the Lower Portion of Anchorage #9, Mantua Creek Anchorage; Paulsboro, NJ.

Location: The southern one-third of the Anchorage #9 (Mantua Creek Anchorage), below position 39° 51.573 N—075° 13.557 W.

(a) *Enforcement period:* This rule will be enforced from December 20, 2012 until January 31, 2013, unless cancelled earlier by the Captain of the Port.

(b) *Regulations:* All persons are required to comply with the general regulations governing safety zones in 33 CFR 165.23 of this part.

(1) All persons and vessels utilizing the southern one-third portion of the anchorage must be authorized by the Captain of the Port or her representative.

(2) All persons or vessels wishing to anchor within the safety zone must request authorization to do so from the Captain of the Port or her representative 24 hours prior to the intended time of transit.

(3) Vessels granted permission to anchor must do so in accordance with the directions provided by the Captain of the Port or her representative to the vessel.

(4) To seek permission to anchor in the safety zone, the Captain of the Port or her representative can be contacted via Sector Delaware Bay Command Center (215) 271–4940.

(5) This section applies to all vessels wishing to anchor in the safety zone within Mantua Creek Anchorage except vessels that are engaged in the following operations:

(i) Enforcing laws;

(ii) Servicing aids to navigation, and

(iii) Emergency response vessels.

(6) No person may enter a safety zone unless authorized by the COTP or the District Commander;

(7) No person may bring or cause to be brought into a safety zone any vehicle, vessel, or object unless authorized by the COTP or the District Commander;

(8) No person may remain in a safety zone or allow any vehicle, vessel, or object to remain in a safety zone unless authorized by the COTP or the District Commander; and

(9) Each person in a safety zone who has notice of a lawful order or direction shall obey the order or direction of the COTP or District Commander issued to carry out the purposes of this subpart.

(c) *Definitions.*

(1) *The Captain of the Port* means the Commanding Officer of Sector Delaware Bay or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on her behalf.

(2) [Reserved]

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the Safety Zone by Federal, State, and local agencies.

Dated: December 20, 2012.

T.C. Wiemers,

Captain, U.S. Coast Guard, Alternate Captain of the Port Delaware Bay.

[FR Doc. 2013–00845 Filed 1–15–13; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0962; FRL–9371–1]

Fluroxypyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluroxypyr in or on rice bran and rice grain. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2013. Objections and requests for hearings must be received on or before March 18, 2013, 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–2011–0962, 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), EPA West 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: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–8072; email address: *benbow.bethany@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–2011–0962 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 March 18, 2013. 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–2011–0962, 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 Confidential Business Information (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.htm.*

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 Tolerances

In the **Federal Register** of December 30, 2011 (76 FR 82238) (FRL–9331–1), 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 1F7928) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.535 be amended by establishing tolerances for residues of the herbicide, fluroxypyr 1–MHE and its acid metabolite, fluroxypyr, in or on rice at 1.5 parts per million (ppm) and rice bran at 3.0 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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 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 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 maternal rats 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 document ''Fluroxypyr. Human Health Risk Assessment to Support Proposed New

Use on Rice,'' p. 15 in docket ID number EPA–HQ–OPP–2011–0962.

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 fluroxypyr used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUROXYPYR 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 adverse effects were identified following a single oral dose and there are no developmental concerns noted in the database.		
Chronic dietary (All populations)	NOAEL = 100 mg/kg/day. UF_A = 10× UF_H = 10× FQPA SF = 1×	Chronic RfD = 1 mg/kg/day. cPAD = 1 mg/kg/day	Chronic/Carcinogenicity-Rat LOAEL = 500 mg/kg/day, based on kidney effects (increased kidney weights, alterations in clinical chemistry parameters indicative of impaired renal functions, and increase in severity of chronic progressive glomerulonephropathy in both sexes).
Incidental oral (Short- and Intermediate term).	NOAEL = 100 mg/kg/day. UF_A = 10× UF_H = 10× FQPA SF = 1×	LOC for MOE = 100	Chronic/Carcinogenicity-Rat LOAEL = 500 mg/kg/day, based on kidney effects (increased kidney weights, alterations in clinical chemistry parameters indicative of impaired renal functions, and increase in severity of chronic progressive glomerulonephropathy in both sexes).
Inhalation (all durations)	Inhalation (or oral) study NOAEL = 100 mg/kg/day (inhalation and oral toxicity assumed to be equivalent). UF_A = 10× UF_H = 10× FQPA SF = 1×	LOC for MOE = 100	Chronic/Carcinogenicity-Rat LOAEL = 500 mg/kg/day, based on kidney effects (increased kidney weights, alterations in clinical chemistry parameters indicative of impaired renal functions, and increase in severity of chronic progressive glomerulonephropathy in both sexes).
Cancer (Oral)	Classified as a ''Not Likely'' human carcinogen.		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 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/WWEIA) 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.* 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.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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://www.epa.gov/oppefed1/models/water/index.htm.

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 acute and chronic exposures are both 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 acute and 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, termiticides, and flea and tick control on pets).

Fluroxypyr is currently registered for the following uses that could result in residential exposures: Residential turfgrass, golf courses, parks and sports fields. EPA assessed residential exposure using the following assumptions: Residential handler exposure is expected to be short-term. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Since there are no toxicity findings for the short-term dermal route of exposure up to the limit dose, only inhalation exposure was assessed for residential handlers of fluroxypyr. The following exposure scenarios were assessed for residential handlers: Loading and applying liquids with manually pressurized hand-wands, hose-end sprayers, and backpack applicators.

For residential post-application exposure and risk estimates, EPA assumed that young children 1 to <2 years old may receive incidental oral post-application exposure to fluroxypyr from treated turf.

A residential bystander post-application inhalation exposure assessment was not performed for fluroxypyr at this time because the chemical has low vapor pressure, is applied at a low rate, and is not applied via airblast. Although a quantitative residential post-application inhalation exposure assessment was not performed as a result of pesticide drift from neighboring treated agricultural fields, an inhalation exposure assessment was performed for flaggers. This exposure scenario, for which no risks of concern were identified, is representative of a worse case inhalation (drift) exposure and may be considered protective of most outdoor agricultural and commercial post-application inhalation exposure scenarios. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 Web site 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 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. The toxicity database for fluroxypyr is complete.

ii. There is no indication that fluroxypyr 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 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.

iv. 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 exposure of toddlers. 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 (<1 year old), the population group receiving the greatest exposure.

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 aggregate MOEs of 2,500 for adult handlers using a backpack sprayer, and 2,400 for children's postapplication oral exposure. Because EPA's level of concern for fluroxypyr 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, 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 enforcement methodology (gas chromatography/electron capture detection (GC/ECD methods GRM 96.02 and 96.03)) are available to enforce the tolerance expression. Fluroxypyr was previously tested through FDA's Multiresidue Methodology, Protocols C, D, and E and was found to be recovered. The results have been published in the FDA Pesticide Analytical Manual, Volume I. The GRM 96.02 and 96.03 methods 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.

There are no Maximum Residue Limits (MRLs) established by Codex, Canada, or Mexico for any of the proposed commodities for fluroxypyr.

V. Conclusion

Therefore, tolerances are established for the combined residues of fluroxypyr 1–MHE and its acid metabolite fluroxypyr, in or on rice at 1.5 ppm and rice bran at 3.0 ppm.

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 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 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: January 7, 2013.

Lois Rossi,

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 § 180.535, in paragraph (a), revise the introductory text and add alphabetically the following commodities to the table to read as follows:

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

(a) *General.* Tolerances are established for 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 the following raw agricultural commodities. Compliance with the established tolerance levels is determined by measuring only the sum 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] calculated as the stoichiometric equivalent of fluroxypyr.

Commodity	Parts per million
* * * * *	
Rice, bran	3.0
Rice, grain	1.5
* * * * *	

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[FR Doc. 2013–00562 Filed 1–15–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0038; FRL–9374–3]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spiromesifen in or on tea, dried. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2013. Objections and requests for hearings must be received on or before March 18, 2013, 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–2012–0038, 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), EPA West 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: Jennifer Gaines, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–5967; email address: *Gaines.Jennifer@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://ecfr.gpoaccess.gov/cgi/t/text/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–2012–0038 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 March 18, 2013. 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–2012–0038, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/