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: February 20, 2013.

Lois Rossi,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.659:

■ a. Add alphabetically the following commodities to the table in paragraph (a)(2).

■ b. Add a new paragraph (a)(3).

The additions read as follows.

§ 180.659 Pyroxasulfone; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Soybean, forage	1.0
Soybean, hay	2.0

(3) Tolerances are established for residues of the herbicide pyroxasulfone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolites, 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1*H*-pyrazol-4-carboxylic acid (M–3); [5-(difluoromethoxy)-3-(trifluoromethyl)-1*H*-pyrazol-4-yl]methanesulfonic acid (M–25); and 3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid (M–28), calculated as the stoichiometric equivalent of pyroxasulfone, in or on the commodity.

Commodity	Parts per million
Soybean, seed	0.06

* * * * *

[FR Doc. 2013–04559 Filed 2–26–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–1002; FRL–9379–6]

Pyraflufen-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraflufen-ethyl in or on multiple commodities which are identified and discussed later in this document. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 27, 2013. Objections and requests for hearings must be received on or before April 29, 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–2011–1002, 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–2011–1002 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 April 29, 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–2011–1002, 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 Tolerance

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL–9335–9), 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 1F7944) by Nichino America, Inc., 4550 New Linden Hill Road Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR 180.585 be amended by establishing tolerances for residues of the herbicide pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1*H*-pyrazol-3-yl]-4-fluorophenoxy] acetate and its acid metabolite, E–1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetic acid, expressed in terms of the parent, in or on hop, dried cone at 0.01 parts per million (ppm); peanut at 0.01 ppm; peanut, hay at 0.07 ppm; peanut, meal at 0.01 ppm; and peanut, refined oil at 0.01 ppm. That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances for peanut and peanut, hay but not establishing tolerances for hop, dried cone; peanut, meal; or peanut, refined oil. In addition, the current time-limited tolerances established for combined residues of pyraflufen-ethyl and metabolite E–1 in milk and the meat by-products of cattle, goat, horse, and sheep at 0.02 ppm are being revised to permanent tolerances for combined residues of pyraflufen-ethyl and metabolites E–1 and E–9 at 0.03 ppm. Finally, permanent tolerances for combined residues of pyraflufen-ethyl and metabolites E–1 and E–9 are also being set for the fat and meat of cattle, goat, horse, and sheep at 0.03 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyraflufen-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraflufen-ethyl 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. Pyraflufen-ethyl exhibits relatively low acute toxicity from oral, dermal, and inhalation exposure. It produces moderate eye

irritation and is not a dermal irritant or a dermal sensitizer. Following repeated short-term and chronic oral dosing, the liver, kidney, and hematopoietic system are the target organs for pyraflufen-ethyl in the rat and/or mouse. The rabbit appears to be the most sensitive species in the toxicity database with adverse effects, including mortality. Adverse effects were not noted in the dog following oral exposure or in the rat following dermal exposure. There was no evidence of increased susceptibility following pre-natal exposure to rats and rabbits in the developmental toxicity studies or following pre- and post-natal exposure to rats in the multi-generation reproduction study. Although not mutagenic in the mutagenicity battery or carcinogenic in the rat, pyraflufen-ethyl is classified as ''Likely to be Carcinogenic to Humans'' due to a compound-related increase in incidence of hepatocellular adenomas, carcinomas, and/or hepatoblastomas in male and female mice. A linear low-dose extrapolation approach is used to estimate human cancer risk (Q_1*) based on combined hepatocellular adenomas, carcinomas, and/or hepatoblastomas seen in male mice.

Since the last risk assessment, the neurotoxicity battery was reviewed and determined to be negative for both acute and subchronic neurotoxicity. Additionally, the Agency reviewed an immunotoxicity study that showed a decreased immune response (decreases of anti-sheep red blood cell (SRBC) antibody forming cell (AFC) response in male rats), only at a dose level approaching the limit dose.

Specific information on the studies received and the nature of the adverse effects caused by pyraflufen-ethyl as well as the no observed adverse effect levels (NOAELs) and the lowest observed adverse effect levels (LOAELs) from the toxicity studies can be found at *http://www.regulations.gov* in document Pyraflufen-ethyl—Human Health Risk Assessment for a Section 3 Registration of New Food Uses on Hops and Peanuts at pages 44–48 in docket ID number EPA–HQ–OPP–2011–1002.

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 pyraflufen-ethyl used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRAFLUFEN-ETHYL 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 (General population including infants and children).	None		An endpoint attributable to a single dose was not identified for pyraflufen-ethyl from the available data.
Chronic dietary (All populations)	NOAEL = 20 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.20 mg/kg/day ..... cPAD = 0.20 mg/kg/day.	Mouse carcinogenicity study. LOAEL = 98 mg/kg/day based on liver toxicity.
Incidental oral short-term (1 to 30 days).	NOAEL = 20 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental toxicity—rabbit. Maternal LOAEL = 60 mg/kg/day based on decreases in body weight and food consumption, gastro-intestinal (GI) observations, and abortions.
Dermal short-term (1 to 30 days); Dermal intermediate-term (1 to 6 months).	None		28-day dermal toxicity—rats. No dermal or systemic toxicity was seen at the limit dose (1,000 mg/kg/day).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRAFLUFEN-ETHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation short-term (1 to 30 days) and Intermediate and long term (1–6 months).	Inhalation (or oral) study NOAEL = 20 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Developmental toxicity-rabbit. LOAEL = 60 mg/kg/day based on decreases in body weight and food consumption, GI observations, and abortions.
Cancer (Oral, dermal, inhalation)	Classification: ''Likely to be Carcinogenic to Humans'' by the oral route. $Q_1^* = 3.32 \times 10^{-2}$ (mg/kg/day)$^{-1}$		

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 pyraflufen-ethyl, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraflufen-ethyl tolerances in 40 CFR 180.585. EPA assessed dietary exposures from pyraflufen-ethyl 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 pyraflufen-ethyl; 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 (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA incorporated all current and proposed tolerances for combined residues of pyraflufen-ethyl and metabolite E–1 in plants and residues of pyraflufen-ethyl, metabolite E–1 and metabolite E–9 in animals and assumed 100% of crops were treated. The commodities of corn, wheat, soybeans, cottonseed, potatoes, pome fruit, stone fruit, pomegranates, olives, grapes, tree nuts, and pistachios were analyzed at ½ the combined levels of quantitation (LOQs) of the parent and metabolites for the residue values in the dietary assessment because the field trials showed that residues were lower than the LOQ. All other established and proposed commodities were analyzed using tolerance-level residues. Because the commodity-specific processing studies did not show pyraflufen-ethyl concentration after processing, the chronic dietary exposure assessment did not incorporate processing factors for the following commodities: Treated corn grain, soybean seeds, wheat grain, apples, and grapes. However, default processing factors were used for dry potatoes (6.5X), peanut butter (1.89X), dried beef (1.92X), and corn syrup (1.5X). An empirical processing factor of 0.6X was used for cotton seed oil. The anticipated residue in meat, milk, fat, and meat byproducts was calculated to be 0.001 ppm. Chronic (non-cancer) dietary exposure from drinking water was determined based on a Tier 2 (surface water) drinking water estimate provided by the Environmental Fate and Effects Division (EFED). The chronic (annual average) estimate for drinking water was incorporated directly into the dietary assessment for the combined residues of pyraflufen-ethyl and its metabolic products, E–1, E–2, and E–3, which are the major residues present in the supporting studies.

iii. *Cancer.* Pyraflufen-ethyl is classified as ''Likely to be Carcinogenic to Humans'' by the oral route; therefore, a cancer dietary risk assessment was conducted. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that pyraflufen-ethyl should be classified as ''Likely to be Carcinogenic to Humans'' and a linear approach has been used to quantify cancer risk.

All exposure inputs for the cancer assessment were the same as for the chronic dietary exposure assessment, except the estimated drinking water concentrations (EDWC). A Tier 2 drinking water (surface water) of a (30-year average) estimate for pyraflufen-ethyl and its metabolic products, E–1, E–2, and E–3, was incorporated directly into the dietary assessment to estimate chronic carcinogenic risk from drinking water containing pyraflufen-ethyl.

iv. *Anticipated residue information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyraflufen-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyraflufen-ethyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of pyraflufen-ethyl acute exposures are estimated to be 0.640 parts per billion (ppb) for surface water and 0.0018 ppb for ground water. The estimated drinking water concentrations (EDWCs) of pyraflufen-ethyl for non-cancer chronic exposures are estimated to be 0.295 ppb for surface water and 0.0018 ppb for ground water. The EDWCs of pyraflufen-ethyl for chronic exposures for cancer assessments are estimated to be 0.268 ppb for surface water and 0.0018 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.295 ppb was used to assess the contribution to drinking water. For cancer dietary risk assessment, the water concentration of value 0.268 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).

Pyraflufen-ethyl is currently registered for the following uses that could result in residential exposures: Established ornamental turf lawns (residential, industrial, and institutional), parks, cemeteries, athletic fields, golf courses, sod farms, nurseries, ornamental plantings, and Christmas trees. EPA assessed residential handler exposure using the following assumptions: (1) Most residential uses will result in short-term (1–30 day) exposures, (2) residential handlers are assumed to be wearing short-sleeved shirts, short pants, shoes, and socks during pyraflufen-ethyl application, (3) various application methods may be used such as manually pressurized handwands, backpack sprayers, and hose-end sprayers.

When determining the potential for residential post-application exposure, the Agency considers residues from leaf to skin/hand residue transfer, children's hand-to-mouth transfer, and exposure time. Because exposure to treated gardens and turf could be expected within the same day, adult post-application cancer exposure to treated trees and retail plants and turf were combined. The exposure assessment for treated plants is considered extremely conservative in that the plants are assumed to be treated the same day that residential post-application contact occurs, with no residue transfer between treatment and purchase of the plants. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/opp00001/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.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 pyraflufen-ethyl to share a common mechanism of toxicity with any other substances, and pyraflufen-ethyl does not appear to produce a toxic metabolite which is also produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyraflufen-ethyl 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 susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with pyraflufen-ethyl. There is no evidence of increased susceptibility of young rats in the pyraflufen-ethyl reproduction study and there are no residual uncertainties for pre- and/or postnatal exposure.

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 pyraflufen-ethyl is complete.

ii. There is no indication that pyraflufen-ethyl 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 pyraflufen-ethyl 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% crop treated (CT) and tolerance-level residues for the proposed commodities, and residue inputs of ½ LOQ as refined estimates of the currently registered commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraflufen-ethyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of adults and children as well as incidental oral exposure of children. In addition, the residential exposure assessment is based on the updated 2012 Residential Standard Operating Procedures (SOPs) employing surrogate study data, including conservative exposure assumptions based on day 0 dermal/oral contact to turf and surfaces treated at the maximum application rate. These data are reliable and are not expected to underestimate risks to adults or children. The Residential SOPs are based upon reasonable ''worst-case'' assumptions and are not expected to underestimate risk. Although some of the residue values used in the dietary exposure assessment were refined, these assessments will not underestimate the exposure and risks posed by pyraflufen-ethyl.

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, pyraflufen-ethyl 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 pyraflufen-ethyl from food and water will utilize < 1% of the cPAD for children 1–2 years 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 pyraflufen-ethyl 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). Pyraflufen-ethyl 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 pyraflufen-ethyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined chronic dietary and short-term residential exposures result in an adult (inhalation) non-cancer aggregate MOE of 290,000. The aggregate MOE for children 1–2 years old, including incidental oral exposures from treated turf, is 9,600. Because EPA's level of concern for pyraflufen-ethyl 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, pyraflufen-ethyl 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 pyraflufen-ethyl.

5. *Aggregate cancer risk for U.S. population.* The aggregate cancer risk assessment for the general U.S. population considers exposure estimates from dietary consumption of pyraflufen-ethyl in food and drinking water and exposure through residential uses of pyraflufen-ethyl. Exposures from residential uses are based on the lifetime average daily dose and assume an exposure period of 2 days per year and 35 years of exposure over a 78 year lifetime. Average food and water exposure to pyraflufen-ethyl was used in the aggregate assessment. Estimated cancer risk for the general U.S. population includes infants and children; therefore, a children's cancer risk estimate was not reported separately. The aggregate cancer risk estimate for pyraflufen-ethyl is 2.6×10^{-6}. EPA generally considers cancer risks in the range of one in one million (1×10^{-6}) or less to be negligible. The precision that can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure just described, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Although the pyraflufen-ethyl exposure risk assessment is somewhat refined, it retains significant conservatism due, among other things, to the assumption that 100% of registered crops are treated in the dietary cancer assessment and 100% dermal absorption was assumed in the residential exposure cancer assessment. Accordingly, EPA has concluded the cancer risk for all existing pyraflufen-ethyl uses and the uses associated with the tolerances established in this action falls within the range of 1×10^{-6} to 3×10^{-6} and is thus negligible. Therefore, the aggregate cancer risk estimate from pyraflufen-ethyl residues in food and drinking water is not of concern for the general U.S. population.

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 pyraflufen-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography-mass spectrometry (GC/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residue methods@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 pyraflufen-ethyl.

C. Revisions to Petitioned-For Tolerances

Based on a lack of adequate residue data, the Agency is not granting tolerances for hops at this time. As permitted under 40 CFR 180.8, the petitioner has withdrawn its request for hop, dried cone tolerances.

In addition, the requested tolerances for peanut, meal and peanut, refined oil are not being granted since those residues will be covered by the proposed tolerance for peanut. Because peanut hay is fed to livestock and may affect residue levels, upon review of the data supporting the petitions, EPA determined that several livestock tolerances should be revised (from residues of the parent and metabolite E-1 in milk and meat by-products of cattle, goat, horse, and sheep at 0.02 ppm to residues of the parent and metabolites E-1 and E-9 at 0.03 ppm) and several new livestock tolerances should be established (residues of the parent and metabolites E-1 and E-9 in the fat and meat of cattle, goat, horse and sheep at 0.03 ppm). The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation.

Finally, based on data submitted with this petition, EPA is removing the time-limitations for these tolerances.

V. Conclusion

Therefore, permanent tolerances are established for the combined residues of pyraflufen-ethyl, metabolite E-1, and metabolite E-9 in or on (cattle, goat, horse, sheep) fat, meat, and meat by-products at 0.03 ppm; milk at 0.03 ppm; and new tolerances are established for the combined residues of pyraflufen-ethyl and metabolite E-1 in or on peanut at 0.01 ppm; and peanut, hay at 0.07 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: February 20, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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 § 180.585, revise paragraph (a) to read as follows:

§ 180.585 Pyraflufen-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, pyraflufen-ethyl, including its metabolites and degradates, in the commodities in the table below. Compliance with the plant commodity tolerance levels specified in the table is to be determined by measuring only the sum of the parent pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1*H*-pyrazol-3-yl]-4-fluorophenoxy] acetate, and its acid metabolite, E–1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetic acid, calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the commodity. Compliance with the livestock commodity tolerance levels specified in the table is to be determined by measuring only the sum of the parent pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1*H*-pyrazol-3-yl]-4-fluorophenoxy] acetate and its acid metabolites: E–1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetic acid, and E–9, 2-chloro-5-(4-chloro-5-difluoromethoxy-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetic acid, both calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the commodity.

Commodity	Parts per million
Almond, hulls	0.02
Cattle, fat	0.03
Cattle, meat	0.03
Cattle, meat byproducts	0.03
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.04
Fruit, pome, group 11–10	0.01
Fruit, stone, group 12	0.01
Goat, fat	0.03

Commodity	Parts per million
Goat, meat	0.03
Goat, meat byproducts	0.03
Grape	0.01
Grass, forage, group 17	1.0
Grass, hay, group 17	1.4
Horse, fat	0.03
Horse, meat	0.03
Horse, meat byproducts	0.03
Milk	0.03
Nut, tree, group 14	0.01
Olive	0.01
Peanut	0.01
Peanut, hay	0.07
Pistachio	0.01
Pomegranate	0.01
Potato	0.02
Sheep, fat	0.03
Sheep, meat	0.03
Sheep, meat byproducts	0.03
Soybean, forage	0.05
Soybean, hay	0.10
Soybean, seed	0.01
Wheat, forage	0.02
Wheat, grain	0.01
Wheat, hay	0.01
Wheat, straw	0.01

* * * * *

[FR Doc. 2013–04555 Filed 2–26–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0302; FRL–9377–6]

Acetochlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends inadvertent tolerances for residues of acetochlor in or on crop groups 15 and 16 for cereal grains by dropping the exclusion for rice grain and straw. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 27, 2013. Objections and requests for hearings must be received on or before April 29, 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–2012–0302, 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: Hope Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–5410; email address: *johnson.hope@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–2012–0302 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 April 29, 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–2012–0302, 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.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 Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL–9353–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F7996) by Monsanto Company, 1300 I St. NW., Suite 450 East, Washington, DC 20005. The petition requested revisions to the current tolerances for residues of the herbicide acetochlor, 2-chloro-2′-methyl-6′-ethyl-*N*-ethoxymethylacetanilide and its metabolites containing either the 2-ethyl-6-methylaniline (EMA) or the 2-(1-hydroxyethyl)-6-methyl-aniline (HEMA) moiety, at 40 CFR 180.470 for grain, cereal, group 15, except corn, grain sorghum, rice, and wheat, grain and grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw.

Specifically the petition requested that crop groups 15 and 16 be amended