§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Ethylene glycol (CAS Reg. No. 107–21–1)	Without limitation	Encapsulating agent for pesticides being applied post-harvest as residual, and crack and crevice sprays in and around food and nonfood areas of residential and nonresidential structures, including food handling establishments.
* * * * * * *		

■ 3. In § 180.920, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Ethylene glycol (CAS Reg. No. 107–21–1)	Without limitation	Pesticide inert ingredient as a solvent, stabilizer and/or anti-freeze.
* * * * * * *		

[FR Doc. 2011–13577 Filed 5–31–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0426; FRL–8873–5]

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 June 1, 2011. Objections and requests for hearings must be received on or before August 1, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0426. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1243; e-mail address: *montague.kathryn@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr.*

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–2010–0426 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 1, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0426, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 23, 2010 (75 FR 35801) (FRL–8831–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7718) 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-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetate 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 almond hulls at 0.02 parts per million (ppm); nuts, tree, group 14 at 0.01 ppm; pistachio at 0.01 ppm; fruit, pome, group 11 at 0.01 ppm; fruit, stone, group 12 at 0.01 ppm; pomegranates at 0.01 ppm; olives at 0.01 ppm; grapes at 0.01 ppm, and hops at 0.05 ppm. The notice 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 not establishing, at this time, the requested hop tolerance due to the lack of field trial information for the hop study. EPA is updating the proposed crop commodities terminology. The reason for the changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 has low to moderate toxicity from acute exposure and it is not a dermal sensitizer. The liver, kidney, and possibly the hematopoietic system are the target organs for pyraflufen-ethyl in the rat and/or the mouse. There is no evidence of increased sensitivity to the young in developmental and reproductive studies with pyraflufen-ethyl. Pyraflufen-ethyl was not shown to be mutagenic in a battery of tests. Pyraflufen-ethyl was classified as "Likely to be Carcinogenic to Humans" based on male mouse hepatocellular adenomas, carcinomas and/or hepatoblastomas (combined) observed in the mouse carcinogenicity study. The method of quantification was linear cancer slope factor (Q*).

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-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 "Pyraflufen-ethyl: Human Health Risk Assessment for a Section 3 Registration of New Food Uses on Tree Nuts (Crop Group 14), Pistachios, Pome Fruit (Crop Group 11–10), And Stone Fruits (Crop Group 12), Hops, Grapes, Olives And Pomegranates," at page 17 in docket ID number EPA–HQ–OPP–2010–0426.

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 pesticides. 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 the following Table.

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

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	None	An endpoint attributable to a single dose was not identified 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 = 0.2 mg/kg/day	Mouse Carcinogenicity 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 LOAEL = 60 mg/kg/day based on decreases in body weight and food consumption, GI observations, and abortions.
Incidental oral intermediate-term (1 to 6 months).	NOAEL = 20 mg/kg/day UF_A= 10x UF_H= 10x FQPA SF = 1x	LOC for MOE = 100	Mouse Carcinogenicity LOAEL = 98 mg/kg/day based on liver toxicity at interim sacrifice.
Dermal (All Durations)	None	None	In a 28-day dermal toxicity study in rats, no dermal or systemic toxicity was seen at the Limit Dose (1,000 mg/kg/day).
Inhalation (All Durations)	Maternal NOAEL= 20 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE (residential) = 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 x 10^{-2} (mg/kg/day)$^{-1}$		

GI = gastrointestinal. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC = level of concern. Mg/Kg/Day = milligram/kilogram/day.

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 following assumptions: 100 percent crop treated (PCT) and tolerance-level residues for pyraflufen-ethyl on all treated crops except corn, cottonseed, potato, soybean, wheat, pome fruit, stone fruit, pomegranate, olive, grape, tree nuts and pistachio for which one half of the combined Levels of Quantification (LOQs) for the parent and the metabolite were used since all field trial residue levels were less than the LOQ.

iii. *Cancer.* 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 non-linear 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.

In conducting the cancer dietary exposure assessment EPA used the same food consumption data from the U.S. Department of Agriculture (USDA) and assumptions for residue levels in food as the chronic exposure in Unit III. C. 1. ii., above.

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 First Index Reservoir Screening Tool (FIRST), 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 for acute exposures are estimated to be 1,247 parts per trillion (ppt) for surface water and 1.8 ppt for ground water and for chronic exposures for non-cancer and cancer assessments, the EDWCs are estimated to be 281 ppt for surface water and 1.8 ppt for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic and cancer dietary risk assessment, the water concentration of value 281 ppt 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 on the following residential sites that could result in residential exposures: Airports, nurseries, ornamental turf, golf courses, roadsides, railroads, non-crop land, and uncultivated agricultural areas. The risk assessment was conducted using the following residential exposure assumptions: Adults and children may be exposed to residues of pyraflufen-ethyl through short term post application contact with treated residential/recreational areas and residential handlers mixing, loading and applying liquid pyraflufen-ethyl in these areas.

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 pyraflufen-ethyl to share a common mechanism of toxicity with any other substances, and pyraflufen-ethyl does not appear to produce a toxic metabolite 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 reproduction study with pyraflufen-ethyl. EPA concluded there are no residual uncertainties for prenatal 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 except for a 28-day inhalation study, acute and subchronic neurotoxicity studies and immunotoxicity study which are now included under 40 CFR 158.500 as part of the toxicology data requirements for registration of a pesticide (food and non-food uses).

In the absence of a route specific inhalation toxicity study, a point of departure (POD) for inhalation exposure risk assessment has been extrapolated from an oral study. EPA does not believe the aggregate risk assessment is under-protective of adult handlers. Residential handler MOEs based on the extrapolated endpoint are quite high (greater than 35 million), and the contribution of residential exposure to aggregate risk is small. Therefore, even if an inhalation study were to provide a lower POD than the oral study, it's not expected to have a significant impact on aggregate risk.

ii. Pyraflufen-ethyl primarily impacts the parameters of food consumption, decreased body weight, and histopathological changes in the liver. There is no evidence that pyraflufen-ethyl causes neurotoxic effects in any of the available toxicity studies. Evidence of immunotoxic potential is limited to an adverse effect on the spleen reported in one study at a dose level (1,489 mg/kg/day) which is above the limit dose, and also caused death. EPA does not believe that conducting immunotoxicity and acute/subchronic neurotoxicity testing will result in a NOAEL less than 20 mg/kg/day, which is presently used as the POD for chronic risk assessment.

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% of the crop treated and a conservative estimate of residues in food. 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 postapplication exposure of children as well as incidental oral exposure of toddlers. 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 less than 1% of the cPAD for all population groups. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 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.

A short-term aggregate risk assessment was performed for residential handler exposure, children's incidental post-application oral exposure (from residential treatment) and dietary exposure to food and water (considered to be a background exposure level). The anticipated exposure level for children ages 1–2 years old (the highest exposed population) is below EPA's level of concern, with a MOE greater than 60,000.

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).

Pyraflufen-ethyl is not registered for any use patterns that would result in intermediate-term residential exposure. No residential handler exposure is expected and post application inhalation exposure is expected to be negligible. Post application exposure to infants and children over the intermediate term duration (1–6 months) is not likely based on the use pattern. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to pyraflufen-ethyl through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* The aggregate cancer risk assessment for the general population takes into account exposure estimates from dietary consumption of pyraflufen-ethyl from food and drinking water sources. Average food plus water source dietary exposure was used. Estimated cancer risk for the U.S. population includes infants and children. The aggregate cancer risk estimate for pyraflufen-ethyl is 2.8×10^{-6}. This risk estimate is based, in part, on the conservative assumption that 100% of all crops for which pyraflufen-ethyl is registered or proposed for registration are treated. Additional refinement using PCT estimates would result in a lower estimate of cancer risk.

EPA generally considers cancer risks in the range of one in one million (1×10^{-6}) or less to be negligible. The precision which 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 described above, 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 percent of registered crops are treated. Accordingly, EPA has concluded the cancer risk for all existing pyraflufen-ethyl uses and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus negligible.

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 with 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; e-mail 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 U.N. 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. Canada has not established MRLs for the proposed use sites for pyraflufen-ethyl.

C. Revisions to Petitioned-for Tolerances

In the **Federal Register** of December 8, 2010 (75 FR 76284) (FRL–8853–8), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised the existing pome fruit group 11. Changes to crop group 11 included adding azarole; medlar; Asian pear; Chinese quince; Japanese quince; and tejocote; creating subgroups; revising the representative commodities; and naming the new crop group, Pome Fruit Group 11–10. Therefore, consistent with this rule, EPA is establishing tolerances for pyraflufen-ethyl residues on Pome Fruit Group 11–10 instead of the requested Pome Fruit Group 11 and is correcting the crops proposed in the Notice of Filing to the crop commodities specified in 40 CFR 180.41: grape; nut, tree, group 14; olive and pomegranate.

V. Conclusion

Therefore, previously established tolerances are amended and new tolerances are established for residues of pyraflufen-ethyl, including its metabolites and degradates, as set forth in the regulatory text.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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, 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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 (Pub. L. 104–4).

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, Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: May 18, 2011.

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. Section 180.585 is amended by revising the introductory text of paragraph (a) and by alphabetically adding commodities to the table in 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 tolerance levels specified below is to be determined by measuring pyraflufen-ethyl, ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetate, and its acid metabolite, *E*-1, 2-[2-chloro-5-(4-chloro-5-(difluoromethoxy)-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxy]acetic acid, in or on the commodity:

Commodity	Parts per million	Expiration/ revocation date
Almond, hulls	0.02	None.
* * * * * * *		
Fruit, pome, group 11–10	0.01	None.
Fruit, stone, group 12	0.01	None.
Grape	0.01	None.
* * * * * * *		
Nut, tree, group 14	0.01	None.
Olive	0.01	None.
Pistachio	0.01	None.
Pomegranate	0.01	None.
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[FR Doc. 2011–13587 Filed 5–31–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0268; FRL–8873–9]

Bromoxynil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises established tolerances for residues of bromoxynil in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 1, 2011. Objections and requests for hearings must be received on or before August 1, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0268. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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–2010–0268 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 1, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0268, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 23, 2010 (75 FR 35801) (FRL–8831–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7678) by Bayer CropScience LLC, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.324 be amended by increasing existing tolerances for residues of the herbicide bromoxynil, 3,5-dibromo-4-hydroxybenzonitrile, in or on sorghum, grain, grain from 0.05 parts per million (ppm) to 0.2 ppm; grass, hay from 3.0 ppm to 5.0 ppm; and grass, forage from 3.0 ppm to 18 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience 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.

Based upon review of the data supporting the petition, EPA has determined that the existing tolerances for aspirated grain fractions, milk, and grain sorghum forage must also be increased as a result of the proposed changes to the use patterns for sorghum and grasses. The reasons for these changes are explained in Unit IV.C.