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) (Public Law 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 (NTTAA), 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: August 25, 2008.

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 180.474 is amended in paragraph (a)(1) by alphabetically adding the commodity pistachio to the table to read as follows:

§180.474 Tebuconazole; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * * * *	
Pistachio	0.05
* * * * *	

* * * * *

[FR Doc. E8–20625 Filed 9–4–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007-0366; FRL–8377–6]

Pyraflufen-ethyl; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for residues of pyraflufen-ethyl in or on grass, forage, group 17; and grass, hay, group 17; establishes time-limited tolerances for milk; cattle, meat byproducts; goat, meat byproducts; horse, meat byproducts and sheep, meat byproducts, and revises the existing tolerances for soybean, forage; soybean, hay; wheat, forage and wheat, hay. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The time-limited tolerances expire on October 15, 2012.

DATES: This regulation is effective September 5, 2008. Objections and requests for hearings must be received on or before November 4, 2008, 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–2007-0366. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP 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: Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703-305-6224; e-mail address: *miller.joanne@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:

- 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 provides 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing

Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2007-0366 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 4, 2008

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007-0366, 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'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. Petition for Tolerances

In the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL–8133–4), 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 7F7190) 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-1H-pyrazol-3 -yl)-4-fluorophenoxyacetate; and its acid metabolite, E-1, 2-chloro-5-4-chloro-5-difluoromethoxy-(1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, expressed in terms of the parent in or on food commodities: Soybeans, forage at 0.05 parts per million (ppm); soybean, hay at 0.10 ppm; grass, forage, crop group 17 at 1.0 ppm; and grass, hay, crop group 17 at 1.2 ppm.

In the **Federal Register** of June 13, 2008 (73 FR 33814) (FRL–8367–3), EPA issued a second notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7190) 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 new tolerances for residues of the herbicide, pyraflufen-ethyl, ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetate, and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, expressed in terms of the parent, in or on food commodities grass, forage, group 17 at 1.0 ppm; grass, hay, group 17 at 1.4 ppm; milk at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm, and by revising existing tolerances for residues of the herbicide, pyraflufen-ethyl, ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetate, and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, expressed in terms of the parent, in or on food commodities soybean, seed to 0.05 ppm; soybean, hay to 0.10 ppm; wheat, forage to 0.02 ppm; and wheat, hay to 0.01 ppm.These notices referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notices of filing. Tolerances for milk at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm expire on October 15, 2012. A time limitation been imposed because of the requirement for a cattle feeding study conducted to determine residues of the E-9 metabolite in milk and cattle tissues.

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 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 the petitioned-for tolerances for residues of pyraflufen-ethyl and its metabolite expressed in terms of the parent on grass, forage, group 17 at 1.0 ppm; grass, hay, group 17 at 1.4 ppm; milk at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm, and by revising existing tolerances for soybean, forage to 0.05 ppm; soybean, hay to 0.10 ppm; wheat, forage to 0.02 ppm; and wheat, hay to 0.01 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances 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. Specific information on the studies received and the nature of the toxic 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.

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.

Specific information on the studies received and the nature of the toxic 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 document Pyraflufen-ethyl: Human Health Risk Assessment for Pyraflufen-ethyl: Proposed New Use on Pasture and Rangeland Grasses (PP 7F7190) and Amendment to Allow Early Season Postemergence Broadcast Uses to Corn (excluding sweet corn), Soybeans and Wheat at page 13 in docket ID number EPA–HQ–OPP–2007–0366.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs/safety factors) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in document Pyraflufen-ethyl: Human Health Risk Assessment for Pyraflufen-ethyl: Proposed New Use on Pasture and Rangeland Grasses (PP#7F7190) and Amendment to Allow Early Season Postemergence Broadcast Uses to Corn (excluding sweet corn), Soybeans and Wheat at page 13 in docket ID number EPA–HQ–OPP–2007-0366. Also, a summary of the toxicological endpoints for pyraflufen-ethyl used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 30, 2003 (68 FR 23046) (FRL–7300–9).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pyraflufen-ethyl, EPA considered exposure from 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 USDA 1994–1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, the following assumptions were made for the chronic exposure assessments: 100 percent crop treated (PCT) and tolerance-level residues for pyraflufen-ethyl on all treated crops except corn, cottonseed, potato, soybean and wheat for which one half of the combined Levels of Quantification (LOQs) for the parent and the metabolite were used since all field trial data were less than the LOQ.

iii. *Cancer*. For the cancer dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, the following assumptions were made for the chronic exposure assessments: 100 percent crop treated (PCT) and tolerance-level residues for pyraflufen-ethyl on all treated crops except corn, cottonseed, potato, soybean and wheat for which one-half of the combined LOQs for the parent and the metabolite were used since all field trial data were less than the LOQ.

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) 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. Chronic exposures for cancer assessments 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 dietary risk assessment, the water concentration value of 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 non-dietary 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 areas which may include residential/recreational areas.

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 website 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 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% 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 post-application 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute 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.* Pyraflufen-ethyl is currently registered for use(s) 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.

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). A short-term risk aggregate assessment was not performed for adults because no handler exposure is expected and post-application inhalation exposure is expected to be negligible (and there are no dermal endpoints of concern). A short-term aggregate risk assessment was performed for infants and children because there is a potential for oral post-application exposure resulting from contact with treated areas which may include residential/recreational areas. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water. Short term aggregate risk is based on children's incidental oral exposure (from residential post-application treatment) and dietary exposure (food and drinking water). The anticipated exposure level for children, 1-2 years (the highest exposed population) is below EPA's level of concern, with a Margin of Exposure (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 to 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 form dietary consumption of pyraflufen-ethyl from food, residential, and drink water sources. Exposures from residential uses are based on the lifetime average daily dose and assume an exposure period of 5 days per year and 50 years of exposure in a lifetime (70 years). 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 2.9 x 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 Percent Crop Treated estimates would result in a lower estimate of cancer risk.

EPA generally considers cancer risks in the range of 1 in 1 million (1 x 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 3.16 x 10^{-7} and 3.16 x 10^{-6} are expressed as risks in the range of 1 x 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 LOC of the range of 1 x 10^{-6} until the calculated risk exceeds approximately 3 x 10^{-6}. Since the calculated cancer risk for pyraflufen-ethyl does not exceed this level, estimated cancer risk is considered to be 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 and 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

There are currently no established Codex, Canadian or Mexican maximum residue limits, for residues of pyraflufen-ethyl in/on grass, milk, meat byproducts, soybean and wheat.

V. Conclusion

Therefore, permanent tolerances are established for residues of pyraflufen-ethyl and its metabolite expressed in terms of the parent on grass, forage, group 17 at 1.0 ppm; grass, hay, group 17 at 1.4 ppm. Time-limited tolerances are established for milk at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm. Existing tolerances are revised for soybean, forage to 0.05 ppm; soybean, hay to 0.10 ppm; wheat, forage to 0.02 ppm; and wheat, hay to 0.01 ppm.

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, *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 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 (UMRA) (Public Law 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 (NTTAA), 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: August 25, 2008.

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 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, ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetate, and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, expressed in terms of the parent in or on the following food commodities:

Commodity	Parts per million	Expiration/ revocation date
Cattle, meat by-products	0.02	10/15/12
Corn, field, forage	0.01	None
Corn, field, grain	0.01	None
Corn, field, stover	0.01	None
Cotton, gin by-products	1.5	None
Cotton, undelinted seed	0.04	None
Goat, meat by-products	0.02	10/15/12
Grass, forage, group 17	1.0	None
Grass, hay, group 17	1.4	None
Horse, meat by-products	0.02	10/15/12
Milk	0.02	10/15/12
Potato	0.02	None
Sheep, meat by-products	0.02	10/15/12
Soybean, forage	0.05	None
Soybean, hay	0.10	None
Soybean, seed	0.01	None
Wheat, forage	0.02	None
Wheat, grain	0.01	None
Wheat, hay	0.01	None
Wheat, straw	0.01	None

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[FR Doc. E8–20515 Filed 9–4–08; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 070717340–8451–02]

RIN 0648–XK16

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Closure of the Directed Butterfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that the directed fishery for butterfish in the Exclusive Economic Zone (EEZ) will be closed effective 0001 hours, September 5, 2008. Vessels issued a Federal permit to harvest butterfish may not retain or land more than 250 lb (0.11–mt) of butterfish per trip for the remainder of the year (through December 31, 2008). This action is necessary to prevent the fishery from exceeding its domestic annual harvest (DAH) of 500 mt and to allow for effective management of this stock.

DATES: Effective 0001 hours, September 5, 2008, through 2400 hours, December 31, 2008.

FOR FURTHER INFORMATION CONTACT: Don Frei, Fishery Management Specialist, 978–281–9221, Fax 978–281–9135.

SUPPLEMENTARY INFORMATION: Regulations governing the butterfish fishery are found at 50 CFR part 648. The regulations require specifications for maximum sustainable yield, initial optimum yield, allowable biological catch, domestic annual harvest (DAH), domestic annual processing, joint venture processing, and total allowable levels of foreign fishing for the species managed under the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan. The procedures for setting the annual initial specifications are described in § 648.21.

The 2008 specification of DAH for butterfish was set at 500 mt (73 FR 18443, April 4, 2008).

Section 648.22 requires NMFS to close the directed butterfish fishery in the EEZ when 80 percent of the total annual DAH has been harvested. If 80 percent of the butterfish DAH is projected to be landed prior to October 1, a 250–lb (0.11–mt) incidental butterfish possession limit is put in effect for the remainder of the year, and if 80 percent of the butterfish DAH is projected to be landed on or after October 1, a 600–lb (0.27–mt) incidental butterfish possession limit is put in effect for the remainder of the year. NMFS is further required to notify, in advance of the closure, the Executive Directors of the Mid-Atlantic, New England, and South Atlantic Fishery Management Councils; mail notification of the closure to all holders of butterfish permits at least 72 hr before the effective date of the closure; provide adequate notice of the closure to recreational participants in the fishery; and publish notification of the closure in the **Federal Register**. The Administrator, Northeast Region, NMFS, based on dealer reports and other available information, has determined that 80 percent of the DAH for butterfish in 2008 fishing year will be harvested. Therefore, effective 0001 hours, September 5, 2008, the directed fishery for butterfish fishery is closed and vessels issued Federal permits for butterfish may not retain or land more than 250 lb (0.11 mt) of butterfish during a calendar day. The directed fishery will reopen effective 0001 hours, January 1, 2009, when the 2009 DAH becomes available.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 2, 2008.

Allan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E8–20600 Filed 9–2–08; 4:15 pm]

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