Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1 paragraph (34)(g), of the instruction, from further environmental documentation because this rule is not expected to result in any significant environmental impact as described in NEPA. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.

■ 2. From 8 a.m. on May 11, 2003 through 8 p.m. on November 15, 2003 add temporary § 165.T09–214 to read as follows:

§ 165.T09–214 Regulated Navigation Area; Des Plaines River, Joliet, Illinois

(a) *Regulated navigation area.* The following waters are a Regulated Navigation Area (RNA): All portions of the Des Plaines River between mile 287.3 (McDonough St. Bridge) and mile 288.7 (Ruby Street Bridge).

(b) *Applicability.* This section applies to operators of all southbound tows transiting beneath the Jefferson Street Bridge (mile 287.9), Joliet, Illinois with barge configurations of over 89 feet in overall width and more than 800 feet in length.

(c) *Regulations.* (1) All southbound tows to which this section applies must use an assist tug when transiting through the RNA.

(2) The general regulations contained in 33 CFR 165.13 apply to this section.

(3) Deviation from this section is prohibited unless specifically authorized by the Commander, Ninth Coast Guard District or his designated representatives. Designated representatives include the Captain of the Port Chicago.

Dated: May 9, 2003.

Ronald F. Silva,

Rear Admiral, Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 03–12687 Filed 5–20–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0163; FRL–7306–1]

Pyraflufen-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of pyraflufen-ethyl in or on cotton. Nichino America Incorporated requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 21, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0163, must be received on or before July 21, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), 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 an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification ID number OPP–2003–0163. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of November 20, 2002 (67 FR 70073) (FRL–7184–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (1F6428) by Nichino America Incorporated, 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. That notice included a summary of the petition prepared by Nichino America Incorporated, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.585 be amended by establishing tolerances for combined 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 as the ester equivalent in or on cotton undelinted seed at 0.05 parts per million (ppm) and cotton gin byproduct at 1.5 ppm.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997) (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the 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, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of pyraflufen-ethyl on cotton undelinted seed at 0.04 ppm and cotton gin byproduct at 1.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyraflufen-ethyl are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–day oral toxicity in rats	NOAEL = 5,000 parts per million (ppm) (456–499 milligrams/kilograms/day (mg/kg/day)). LOAEL = 15,000 ppm (1,489–1,503 mg/kg/day) based on clinical signs, death, effects on erythrocytes, changes in clinical chemicals for liver function and splenomegaly.
870.3150	90–day oral toxicity in dogs	NOAEL = 1,000 mg/kg/day. LOAEL not established, no effects observed.
870.3200	28–Day dermal toxicity in rats	NOAEL = 1,000 mg/kg/day. LOAEL not established; no effects observed.
870.3700	Prenatal developmental in rats	Maternal NOAEL ≥ 1,000 mg/kg/day Maternal LOAEL not determined; no effects observed. Developmental NOAEL ≥ 1,000 mg/kg/day. Developmental LOAEL not determined; no effects observed.
870.3700	Prenatal developmental in rabbits	Maternal NOAEL = 20 mg/kg/day. Maternal LOAEL= 60 mg/kg/day based on mortality. Developmental = 60 mg/kg/day. Developmental LOAEL = 150 mg/kg/day based on increased incidence of abortion.
870.3800	Reproduction and fertility effects	Parental NOAEL = 1,000 ppm (70.8–82.3 mg/kg/day (M); 80.1–91.2 (F). Parental LOAEL = 10,000 ppm (721–844 and 813–901 mg/kg/day) based on decreased body weight (bwt) and bwt gains of F_0 and F_1(M) and F_1(F), gross and microscopic liver lesions of (M) and (F)-both generations. Reproductive NOAEL ≥ 10,000 ppm (721–844 and 813–901 mg/kg/day). Reproductive LOAEL not determined; no effects observed. Offspring NOAEL = 1,000 ppm (70.8–82.3 mg/kg/day (M); 80.1–91.2 (F). Offspring LOAEL = 10,000 ppm (721–844 and 813–901 mg/kg/day) based on decreased bwt and bwt gains of the F_1 and F_2 pups.
870.4100	Chronic toxicity in dogs	NOAEL ≥ 1,000 mg/kg/day. LOAEL not determined; no effects observed.
870.4200	Carcinogenicity in mice	NOAEL = 200 ppm (20.99 mg/kg/day (M); 19.58 mg/kg/day (F). LOAEL = 1,000 ppm (109.7 mg/kg/day (M); 98.3 mg/kg/day (F) based on liver toxicity, hepatocellular tumors at 5,000 ppm; possibly hemangioma/ hemangioasarcomas.
870.4300	Chronic toxicity in rodents/carcinogenicity in rats	NOAEL = 2,000 ppm (86.7 mg/kg/day (M); 111.5 mg/kg/day (F). LOAEL = 10,000 ppm (468.1 mg/kg/day (M); 578.5 mg/kg/day (F) based on decreased bwt and bwt gain in males and microcytic anemia, liver lesions and kidney toxicity (both sexes); possible increase pheochromocytomas in females.
870.5100	Gene nutation	Non-mutagenic when tested up to 5,000 μg/plate, in presence and absence of metabolic activation (S9-mix), in *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *E.coli* strain WP2(uvrA). There was no evidence of induced mutant colonies over background.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5300	Gene mutation	In mammalian cell gene mutation assays at the TK locus, L5178Y mouse lymphoma cells cultured *in vitro* were exposed to pyraflufen-ethyl in dimethylsulfoxide (DMOS) in the absence of mammalian metabolic activation (S9-mix) and with S9-mix. Concentrations 160 μg/mL were insoluble; cytotoxicity was seen at 80 μg/mL -S9 and 160 μg/mL +S9. There was no increase in the number of mutant colonies over background in the absence of S9-mix but a non-reproducible dose-related increase in the number of mutant colonies was seen in the presence of S9-mix. In mammalian cell gene mutation assays at the TK locus, L5178Y mouse lymphoma cells cultured *in vitro* were exposed to pyraflufen-ethyl in DMSO in the absence of mammalian metabolic activation (S9-mix) and with S9-mix. There was no evidence of induced mutant colonies over background up to cytotoxic concentrations (50 μg/mL-S9; and 350 μg/mL +S9.
870.5375	Chromosomal aberration	In a mammalian cell cytogenetics assay, human primary lymphocyte cultures were exposed to pyraflufen-ethyl in DMSO without metabolic activation (S9-mix) or with S9-mix. Compound precipitation occurred at 2,600 μg/mL +/-S9. There was no evidence of chromosomal aberration induction over background.
870.5395	Cytogenetics	In a CD-1 mouse bone marrow micronucleus assay, five mice/sex/dose/harvest time were treated via oral gavage with pyraflufen-ethyl in corn oil. ET-751 was tested to the limit (LTD) dose of 5,000 mg/kg bwt. Signs of compound toxicity were limited to piloerection, hunched posture in one female, and piloerection and hunched posture in one male receiving 5,000 mg/kg. No bone marrow cytotoxicity was seen at any dose. There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any dose or treatment time.
870.5500	Bacillus subtilis	In a differential killing/growth inhibition assay in bacteria, strains H17 (rec+) and M45 (rec-) of *B. subtilis* were exposed to pyraflufen-ethyl in DMSO in the presence and absence of metabolic activation (S9-mix). There was no evidence of greater growth inhibition or cell killing in repair-defective strains compared to repair competent strains up to the limit of test material solubility.
870.5550	Unscheduled DNA synthesis (UDS)	In an *in vivo/in vitro* UDS assay in rat hepatocytes, pyraflufen-ethyl was administered to five SPF outbred albino Hsd/Ola Sprague-Dawley male rats per test group by oral gavage (four of the five rats were used for hepatocyte culture). No signs of overt toxicity to the test animals or cytotoxic effects to the target cells were seen up to the LTD (2,000 mg/kg). The mean net nuclear grain count was below zero for both doses at both treatment times indicating no induction of UDS as tested in this study.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics	Pyraflufen-ethyl was readily absorbed and excreted within 96 hours following a single or repeated oral dose of 5 mg/kg (plasma $t_{1/2}$ of 3–3.5 hours). However, at a dose of 500 mg/kg, absorption was saturated as indicated by C_{max} values which did not reflect the 100-fold dose differential (2.7–2.8 Fg eq/g for the low-dose group and 100–107 Fg eq-hr/g for the high-dose group). Following single or multiple oral low doses (5 mg/kg) of pyraflufen ethyl, urinary excretion accounted for 27–33% of the administered radioactivity suggesting that a multiple exposure regimen did not affect the absorption/excretion processes. Urinary excretion was reduced to only 5–7% following a single 500 mg/kg dose. Excretion via the feces accounted for the remainder of the administered radioactivity in all treatment groups. Analysis of biliary excretion following a single 5 mg/kg dose showed that 36% of the administered dose appeared in the bile. Based upon the excretion data, total bioavailability of a low dose was approximately 56%. Biliary excretion data were not available for a high-dose group which prevented a definitive assessment of bioavailability. Excretory patterns did not exhibit gender-related variability. However, plasma and blood clearance was more rapid in females than in males as shown by plasma/blood radioactivity time-course and the greater AUC values for males (32.3 vs 18.4 Fg eq-hr/g for the low-dose group and 2,738 vs 1,401 Fg eq-hr/g for the high-dose group). Radioactivity concentrations indicated tissue concentrations at or near detection limits (generally <0.01 Fg eq/g and never exceeding 0.02 Fg eq/g) at 96 hrs postdose for any tissues. Therefore, neither pyraflufen-ethyl nor its metabolites appear to undergo significant sequestration. Tissue burden data following compound administration did not suggest a specific target beyond those tissues, namely liver and kidney, which are associated with absorption and elimination of orally administered xenobiotics.

B. Toxicological Endpoints

The dose at which no observed adverse effects levels are (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which observed adverse effects of levels concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for pyraflufen-ethyl used for human risk assessment is shown in Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRAFLUFEN-ETHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose (mg/kg/day) UF/MOE	Hazard Based Special FQPA Safety Factor	Endpoint for Risk Assessment
Dietary Risk Assessments			
Acute dietary	Not applicable	Not applicable	No adverse effect attributable to a single exposure (dose) was observed in oral toxicity studies, including the developmental toxicity studies in rats and rabbits.
Chronic dietary	NOAEL= 20 UF = 100 Chronic RfD = 0.20 mg/kg/day	1X	Mouse carcinogenicity. LOAEL = 98 mg/kg/day based on liver toxicity.
Incidental oral short-term (1–30 days) residential only	NOAEL= 20 UF = 100 MOE=100	1X	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 (1–6 months) residential only	NOAEL= 20 UF = 100 MOE=100	1X	Mouse carcinogenicity. LOAEL = 98 mg/kg/day based on liver toxicity at interim sacrifice.
Non-Dietary Risk Assessments			
Dermal short-term and intermediate-term	Not applicable	Not applicable	In a 28-dermal toxicity study in rats, no dermal or systemic toxicity was seen at the LTD (1,000 mg/kg/day). The physical and chemical characteristics (e.g., Kow is low) indicate that dermal absorption is not expected to occur to any appreciable extent. There is no concern for prenatal and/or postnatal toxicity. Therefore, no hazard was identified and quantification of dermal risk is not required.
Residential	MOE = not applicable	Not applicable	
Occupational	MOE = not applicable	Not applicable	
Inhalation[1] short-term (1–30 days)	Oral NOAEL= 20	1X	Developmental toxicity-rabbit. LOAEL = 60 mg/kg/day based on decreases in bwt and food consumption, GI observations, and abortions.
Residential	MOE = 100		
Occupational	MOE= 100		
Inhalation[1] intermediate-term (1–6 months)	Oral NOAEL= 20	1X	Mouse carcinogenicity. LOAEL = 98 mg/kg/day based on liver toxicity at interim sacrifice.
Residential	MOE = 100		
Occupational	MOE= 100		
Inhalation[1] long-term (< 6 months)	Oral NOAEL= 20	1X	Mouse carcinogenicity. LOAEL = 98 mg/kg/day based on liver toxicity.
Residential	MOE =100		
Occupational	MOE= 100		
Cancer	Classification: ''Likely to be Carcinogenic to Humans'' by the oral route Q_1* = 3.32 x 10^{-2} (mg/kg/day)$^{-1}$		

1-Oral endpoints were selected because inhalation studies were unavailable. Absorption via the inhalation route is presumed to be equivalent to oral absorption.

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.585) for the combined residues of 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 as the ester equivalent in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from pyraflufen-ethyl in food as follows:

i. *Acute exposure*. Acute dietary 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 adverse effect attributable to a single exposure (dose) of pyraflufen-ethyl was observed in the oral toxicity studies, including the developmental toxicity studies in rats and rabbits. Therefore, EPA did not identify an acute dietary endpoint and an acute dietary assessment was not performed because no acute risk is expected.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United State Department of Agriculture (USDA) nationwide Continuing Surveys of Food Intake by Individuals (CSFII) 1989–1992 and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% crop treated (PCT) and tolerance-level residues for pyraflufen-ethyl on all treated crops. This assessment was Tier I analysis. The exposure from pyraflufen-ethyl residues in food occupies less than 1% of the chronic population adjusted dose (cPAD) for all population subgroups and is not a concern.

iii. *Cancer*. The cancer dietary exposure assessment was conducted using the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA nationwide CSFII 1989–1992 and accumulated exposure to the chemical for each commodity. The following assumptions were made for the cancer assessments: 100% PCT and tolerance-level residues for pyraflufen-ethyl on all treated crops. The estimated exposure to the U.S. population (total) to pyraflufen-ethyl is 2×10^{-5} mg/kg/day. Applying the Q_1^* of 0.0332 $(mg/kg/day)^{-1}$ to the exposure value results in a cancer risk estimate of 6.6×10^{-7}. Therefore, the lifetime cancer risk to the U.S. population is below EPA's level of concern.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyraflufen-ethyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the chemical and physical characteristics of pyraflufen-ethyl.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a PCT crop area factor as an adjustment to account for the maximum PCT crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a percent referance dose (%RfD) or percent population adjusted dose (%PAD). Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to pyraflufen-ethyl they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of pyraflufen-ethyl for acute exposures are estimated to be 1.25 parts per billion (ppb) for surface water and 0.002 ppb for ground water. The EECs for chronic exposures are estimated to be 0.28 ppb for surface water and 0.002 ppb for ground 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 use on the following residential non-dietary sites: Airports, nurseries, ornamental turf, golf courses, roadsides, and railroads. The risk assessment was conducted using the following residential exposure assumptions: adults and children may be exposed to residues of pyraflufen-ethyl through postapplication contact with treated areas which may include residential/recreational areas.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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 does not have, at this time, available data to determine whether pyraflufen-ethyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyraflufen-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyraflufen-ethyl has 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 the final rule for

Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety (MOS) 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 that a different MOS will be safe for infants and children. MOS are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

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*. There is a complete toxicity database for pyraflufen-ethyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The field trial data on cotton, while some of which may be limited in geographic representation or lack of early season application, indicate that residues of pyraflufen-ethyl are expected to be finite. EPA determined that the 10X SF to protect infants and children should be removed and instead, a different additional safety factor of 1X should be used. The FQPA factor is removed because: 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; there are no residual uncertainties identified in the exposure databases; the dietary food exposure assessment is expected to be conservative, tolerance-level residues and 100% crop treated information were used; and dietary drinking water exposure is based on conservative modeling estimates.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and bwts. Default bwts and consumption values as used by the United States Environmental Protection Agency Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default bwts and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No adverse effect attributable to a single exposure (dose) of pyraflufen-ethyl was observed in the oral toxicity studies, including the developmental toxicity studies in rats and rabbits. Therefore, an acute RfD was not established and no acute risk is expected.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyraflufen-ethyl from food will utilize <1% of the cPAD for the U.S. population and <1% of the cPAD for children (1–6 years). Based on the use pattern, chronic residential exposure to residues of pyraflufen-ethyl is not expected. In addition, there is potential for chronic dietary exposure to pyraflufen-ethyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO PYRAFLUFEN-ETHYL

Population Subgroup[1]	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)[2]	Ground Water EEC (ppb)[2]	Chronic DWLOC (ppb)[3]
U.S population	0.20	<1	0.28	0.002	7,000
Males (20+ years old)	0.20	<1	0.28	0.002	7,000
Females (13–50 years old)	0.20	<1	0.28	0.002	6,000
Children (1–6 years old)	0.20	<1	0.28	0.002	2,000
Males (13–19 years old)	0.20	<1	0.28	0.002	7,000

[1] Subgroups with the highest food-source dietary exposure were selected for adult males, adult females and children. The following bwts were used (70 kg adult male; 60 kg adult females; 10 kg child).

[2] The crop producing the highest level was used (potatoes, 0.009 lb active ingredient/acre).

[3] Chronic DWLOC (ppb) = [maximum chronic water exposure (mg/kg/day) x bwt (kg)] ÷ [water consumption (L) x 10^{-3} mg/kg]).

3. *Short-term risk*. The short-term aggregate risk assessment estimates risks likely to result from 1–30 days exposure to pyraflufen-ethyl residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used in the short-term aggregate assessment, while average (chronic) values are used to account for dietary (food only) exposure. The short-term aggregate risk assessment is considered conservative because food-source dietary exposure is based on a Tier 1 DEEM assessment (tolerance level residues and 100% crop treated information were used).

A short-term aggregate risk assessment is not performed for adults because no handler exposure is expected and postapplication inhalation exposure is expected to be negligible. A short-term aggregate risk assessment is required for infants and children because there is a potential for oral post-application exposure resulting from residential uses.

Pyraflufen-ethyl is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for pyraflufen-ethyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 170,000 for children (1–6 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of pyraflufen-ethyl in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PYRAFLUFEN-ETHYL

Population Subgroup	Aggregate MOE (Food + Residential)[1]	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)[2]	Ground Water EEC (ppb)[2]	Short-Term DWLOC (ppb)[3]
Children (1–6 years old)	170,000	100	0.28	0.002	2,000

[1] Aggregate MOE = NOAEL (Avg Food Exposure + Residential Exposure).
[2] The crop producing the highest level was used (potatoes, 0.009 lb ai/acre).
[3]DWLOC(ppb) = [maximum water exposure (mg/kg/day) x bwt (kg)] ÷ [water consumption (L) x 10^{-3} mg/kg]
*(bwt: Children-10 kg).

4. *Intermediate-term risk*. The intermediate-term aggregate risk assessment estimates risks likely to result from 1–6 months of exposure to pyraflufen-ethyl residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used in the intermediate-term assessment, while average values are used for food and drinking water exposure.

An intermediate-term aggregate risk assessment is not preformed for adults because no handler exposure is expected and postapplication inhalation exposure is expected to be negligible. Also, an intermediate-term aggregate risk assessment is not preformed for infants and children because postapplication exposure over the intermediate-term duration is not likely based on the use pattern.

5. *Aggregate cancer risk for U.S. population*. Pyraflufen-ethyl has been classified as a ''Likely to be Carcinogenic to Humans'' by the oral route of exposure (Q_1* of 3.32 x 10^{-2} $(mg/kg/day)^{-1}$). Using the exposure assumptions discussed in this unit for cancer, the cancinogenic risk is determined for the U.S. population (total) only. The aggregate cancer DWLOC (2.3 ppb) is greater than EPA's estimates of pyraflufen-ethyl residues in drinking water. Therefore, the aggregate cancer risk from residues of pyraflufen-ethyl in food and drinking water does not exceed EPA's level of concern as shown in the following Table 5:

TABLE 5.—CANCER DWLOC CALCULATIONS FOR THE U.S. POPULATION

Q_1* $(mg/kg/day)^{-1}$	Negligible Risk Level[1]	Aggregate cancer risk (food and residential	Ground Water EEC[2] (ppb)	Surface Water EEC[2] (ppb)	Cancer DWLOC[3] (ppb)
0.0332	3.0E-6	8.3E-7	0.002	0.28	2.3

[1] Negligible risk is that below 10^{-6}. 3.0E-6 is statistically within the range that EPA generally accepts as ''negligible risk''.
[2] The crop producing the highest level was used (potatoes).
[3]Cancer DWLOC (ppb) = [maximum water exposure (mg/kg/day) x bwt (kg)] ÷ [water consumption (L) x 10^{-3} mg/kg]

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, and to infants and children from aggregate exposure to pyraflufen-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Nichino America, Inc. has submitted a petition method validation (PMV) and an independent laboratory validation for a Gas Chromatography/Mass Spectometry (GC/MS) method proposed for the enforcement of tolerances for residues of *pyraflufen ethyl* and its acid metabolite, E-1. The proposed plant method is adequate for enforcement of tolerances in/on cotton.

Adequate enforcement methodology (example—GC) 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 is neither a Codex proposal, nor Canadian or Mexican limits, for residues of pyraflufen-ethyl in/on cotton. Harmonization is not an issue for this petition.

C. Conditions

A risk assessment for human health has been conducted for this proposed use. Using the proposed or recommended tolerances, the chronic estimates are well below the Agency's level of concern and the cancer risk estimate is also within Agency's level of concern. The following data are being required by the Agency to complete the database requirements prior to approval of an unconditional registration of pyraflufen-ethyl on cotton:

- Product label contain a statement limiting use to commercial applicators only so that possible use by homeowners on residential turf would be minimized and/or include a restriction prohibiting use by homeowners for the turf and ornamental use sites.
- Proposed uses in farmyards, farm buildings, fence lines, dry ditches and ditch banks be removed from the label due to the potential for residues to contact food sources in these use sites.
- The label for pyraflufen ethyl should clearly state the allowable number of applications per season.

V. Conclusion

Therefore, tolerances are established for combined residues of 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 pyraflufen-ethyl in or on cotton undelinted seed at 0.04 ppm and cotton gin byproduct at 1.5 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0163 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 July 21, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0163, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual

issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 7, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.585 is amended by alphabetically adding commodities in the table in paragraph (a) to read as follows:

§ 180.585 Pyraflufen-ethyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
Cotton, gin byproduct	1.5
Cotton, undelinted seed	0.04

* * * * *

[FR Doc. 03–12359 Filed 5–20–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0151; FRL–7305–2]

Indoxacarb; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of indoxacarb and its R-enantimomer in or on collards. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on collards. This regulation establishes a maximum permissible level for residues of indoxacarb in this food commodity. The tolerance will expire and is revoked on June 30, 2006.

DATES: This regulation is effective May 21, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0151, must be received on or before July 21, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *Madden.Barbara@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 a federal or state government agency (NAICS 9241) involved in administration of environmental quality programs (i.e., Departments of Agriculture, Environment, etc).

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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0151. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the insecticide indoxacarb [(S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno [1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate] and its R-enantimomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno [1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate in or on collards at 3.0 parts per million (ppm). This tolerance will expire and is revoked on June 30, 2006. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18-related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State