

Monday, May 3, 2004 (69 FR 24078) relating to the treatment, for purposes of the at-risk limitations, of amounts borrowed from a person who has an interest in an activity other than that of a creditor or from a person (other than the borrower) with such an interest.

**DATES:** This correction is effective May 3, 2004.

**FOR FURTHER INFORMATION CONTACT:** Tara P. Volungis or Christopher L. Trump, (202) 622-3070 (not a toll-free number).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

The final regulations that is the subject of this correction is under section 465 of the Internal Revenue Code.

##### **Need for Correction**

As published, the final regulation contains an error that may prove to be misleading and is in need of clarification.

##### **Correction of Publication**

■ Accordingly, the publication of the final regulations (TD 9124), that were the subject of FR Doc. 04-10010, is corrected as follows:

##### **§ 1.465-8 [Corrected]**

■ In § 1.465-8(b)(4), *Example 1.*, the language, “\$30,000 payable to A. The three partners, B, C, and D, each assumes personal liability for”. is corrected to read “\$30,000 payable to A. Each of the three partners, B, C, and D, assumes personal liability for”.

**Cynthia E. Grigsby,**

*Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedures and Administration).*

[FR Doc. 04-10789 Filed 5-11-04; 8:45 am]

**BILLING CODE 4830-01-P**

#### **POSTAL SERVICE**

##### **39 CFR Part 111**

##### **Permissible Barcode Symbology for Parcels Eligible for the Barcode Discount**

**AGENCY:** Postal Service.

**ACTION:** Withdrawal of final rule.

**SUMMARY:** We are withdrawing the amendment to the Domestic Mail Manual in the final rule published in the **Federal Register** on May 6, 2004 [69 FR 25321], that announced a new requirement for Package Services parcels.

**EFFECTIVE DATE:** May 12, 2004.

**FOR FURTHER INFORMATION CONTACT:** Obataiye B. Akinwale at (703) 292-3643.

**SUPPLEMENTARY INFORMATION:** The Postal Service will issue a further document regarding these mailing standards.

**Neva R. Watson,**

*Attorney, Legislative.*

[FR Doc. 04-10848 Filed 5-10-04; 12:33 pm]

**BILLING CODE 7710-12-P**

#### **ENVIRONMENTAL PROTECTION AGENCY**

##### **40 CFR Part 180**

[OPP-2004-0094; FRL-7358-2]

##### **Pyraflufen-ethyl; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances 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), in or on wheat, forage; wheat, grain; wheat, hay; and wheat, straw. 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 12, 2004. Objections and requests for hearings must be received on or before July 12, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP-2004-0094. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy 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.

**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](mailto: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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers; dairy cattle farmers; livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), 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 E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

## 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(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 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-methylpyrazol-3-yl)-4-fluorophenoxyacetate) and its acid metabolite, E-1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid), expressed as the ester equivalent, in or on wheat forage, wheat grain, wheat hay, and wheat straw at 0.01 parts per million (ppm).

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...."

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 FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for tolerances for combined residues of pyraflufen-ethyl on wheat, forage and wheat, hay at 0.1 ppm; and wheat, grain and wheat, straw at 0.01 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 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of April 30, 2003 (68 FR 23046) (FRL-7300-9).

### B. Toxicological Endpoints

The dose at which no adverse effects are observed (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 adverse effects of 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.

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional

uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor" is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate ( $RfD = NOAEL/UF$ ). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety factor.

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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand ( $1 \times 10^{-5}$ ), one in a million ( $1 \times 10^{-6}$ ), or one in ten million ( $1 \times 10^{-7}$ ). 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<sub>cancer</sub> = point of departure/exposures) is calculated.

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.* 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 one-day or single exposure. No adverse effect attributable to a single exposure (dose) was observed in 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.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID<sup>TM</sup>), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. 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. The exposure for pyraflufen-ethyl residues in food occupies less than 1% of the chronic percent 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, which evaluated the individual food consumption as reported by respondents in the USDA nationwide CSFII 1994–1996 and 1998. The

following assumptions were made for the cancer assessments: 100 PCT and tolerance-level residues for pyraflufen-ethyl on all treated crops. The exposure from pyraflufen-ethyl residues in food results in a cancer risk in the range of 1 in 1 million and is not a 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 FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The 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. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %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 in unit III.E.

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, railroads, noncrop 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 postapplication 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 does not have, at this time, available data to determine whether pyraflufen-ethyl has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyraflufen-ethyl and 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 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 policy statements

released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at <http://www.epa.gov/pesticides/cumulative/>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

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.* There is a complete toxicity data base 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 wheat, while some of which may be limited in geographic representation, indicate that residues of pyraflufen-ethyl are expected to be

below the levels of quantitation. The likelihood of finite residues to occur in these crops is quite low. 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 PCT 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 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 body weights. Default body weights and consumption values as used by the EPA's 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 body weights 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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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 reference dose 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 Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRAFLUFEN-ETHYL

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

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRAFLUFEN-ETHYL—Continued

Population Subgroup <sup>1</sup>	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC <sup>2</sup> (ppb)	Ground Water EEC <sup>2</sup> (ppb)	Chronic DWLOC <sup>3</sup> (ppb)
Females (13–50 years)	0.20	< 1	0.28	0.002	6,000
Children (1–6 years)	0.20	< 1	0.28	0.002	2,000

<sup>1</sup> Subgroups with the highest food-source dietary exposure were selected for adult males, adult females, and children. The following body weights were used (70 kg adult male; 60 kg adult females; 10 kg child).

<sup>2</sup> The crop producing the highest level was used (potatoes, 0.009 lb ai/acre).

<sup>3</sup> Chronic DWLOC (ppb) = maximum chronic water exposure (mg/kg/day) × body weight (kg) ÷ water consumption (L) × 10<sup>-3</sup> mg/μg.

3. *Short-term risk.* The short-term aggregate risk assessment estimates risks likely to result from 1 to 30 day 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 PCT information were used).

A short-term risk aggregate assessment was 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 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 (considered to be a background exposure level).

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 120,500 for children (3–5 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 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PYRAFLUFEN-ETHYL

Population Subgroup	Aggregate MOE <sup>1</sup> (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC <sup>2</sup> (ppb)	Ground Water EEC <sup>2</sup> (ppb)	Short-Term DWLOC <sup>3</sup> (ppb)
Children (3–5 years)	120,500	100	0.28	0.002	2,000

<sup>1</sup> Aggregate MOE = NOAEL ÷ (Avg food exposure + Residential exposure).

<sup>2</sup> The crop producing the highest level was used (potatoes, 0.009 lb ai/acre).

<sup>3</sup> DWLOC (ppb) = maximum water exposure (mg/kg/day) × body weight (kg) ÷ body weight: Children-10 kg ÷ water consumption (L) × 10<sup>-3</sup> mg/μg.

4. *Intermediate-term risk.* The intermediate-term aggregate risk assessment estimates risks likely to result from 1 to 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 risk aggregate assessment is not required 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 required for

infants and children because postapplication exposure over the intermediate-term duration is not likely based on the use pattern. Therefore, an intermediate-term aggregate risk assessment was not performed.

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  $3.32 \times 10^{-2}$  (mg/kg/day)<sup>-1</sup>). Using the exposure assumptions discussed in this unit for cancer, the carcinogenic risk is determined for the U.S. population (total) only. The estimated exposure from food to pyraflufen-ethyl is  $4.3 \times 10^{-5}$  mg/kg/day. Applying the  $Q_1^*$  of 0.0332 (mg/kg/

day)<sup>-1</sup> to the exposure value results in a cancer risk estimate in the range of 1 in 1 million. This assessment substantially overstates risk because it is based on the assumption that all commodities covered by pyraflufen-ethyl tolerances contain tolerance level residues of pyraflufen-ethyl. Potential exposure from pyraflufen-ethyl in drinking water will, at most, only marginally increase dietary exposure. As the table below indicates, the DWLOC, estimated using a cancer risk of 3 in 1 million (considered to be in the range of 1 in 1 million), is not exceeded by estimated levels of pyraflufen-ethyl in drinking water.

TABLE 3.—CANCER DRINKING WATER LEVELS OF COMPARISON CALCULATIONS FOR THE U.S. POPULATION

Q <sub>1</sub> * (mg/kg/day) <sup>-1</sup>	Negligible Risk Level <sup>1</sup>	Chronic Food Exposure mg/kg/day	Ground Water EEC <sup>2</sup> (ppb)	Surface Water EEC <sup>2</sup> (ppb)	Cancer DWLOC <sup>3</sup> (ppb)
0.0332	3.0E-6	4.3E-5	0.002	0.28	1.65

<sup>1</sup> 3.0E-6 is statistically within the range that EPA generally accepts as "negligible risk."

<sup>2</sup> The crop producing the highest level was used (potatoes).

<sup>3</sup> Cancer DWLOC (ppb) = maximum water exposure (mg/kg/day) × body weight (kg) ÷ water consumption (L) × 10<sup>-3</sup> mg/μg.

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 Incorporated has submitted a petition method validation (PMV) and an independent laboratory validation for a Gas Chromatography and Mass Selective (GC/MS) method proposed for the enforcement of tolerances for residues of pyraflufen-ethyl and its acid metabolite, E-1, on wheat.

##### B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits, for residues of pyraflufen-ethyl in/on wheat. Harmonization is not an issue for this petition.

##### C. Conditions

The following data are being required by the Agency to complete the database requirements prior to approval of an unconditional registration of pyraflufen-ethyl:

- Submit a separate copy of a detailed description of the methodology used to quantify residues of pyraflufen-ethyl and E-1 (measured as E-15, the methyl ester of E-1) for this tolerance request without confidentiality claims. The results for E-15 should be calculated in terms of parent compound. Once the separate detailed description of the methodology is received and accepted, it will be sent to the Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual Volume II (PAM II) as a lettered method.

#### V. Conclusion

Therefore, the 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 as the ester equivalent, in or on wheat, forage and wheat, hay at 0.1 ppm; wheat, grain and wheat, straw at 0.01 ppm.

#### VI. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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 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-2004-0094 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 12, 2004.

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](mailto: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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0094, 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 **ADDRESSES**. 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 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 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

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: April 29, 2004.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR part 180 is amended as follows:



**PART 180—[AMENDED]**

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

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

■ 2. 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
* * *	* *
Wheat, forage .....	0.1
Wheat, grain .....	0.01
Wheat, hay .....	0.1
Wheat, straw .....	0.01

\* \* \* \* \*

[FR Doc. 04-10455 Filed 5-11-04; 8:45 am]

BILLING CODE 6560-50-S

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[DA 04-1026; MB Docket No. 03-77; RM-10660, RM-10835]

**Radio Broadcasting Services; Ashland, AL; Atlanta, GA; Coaling, Cordova, Decatur, Dora, Holly Pond, and Midfield, AL; Pulaski, TN; Sylacauga and Tuscaloosa, AL**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In response to a petition for rule making in this proceeding filed by Cox Radio, Inc. and CXR Holdings, Inc. and a counterproposal jointly filed by Kea Radio, Inc. and Pulaski Broadcasting, Inc. this document grants multiple channel substitutions and changes of community of license in Alabama, Georgia and Tennessee. See 68 FR 17592, April 10, 2003. Specifically, this document substitutes Channel 239C2 for Channel 239C1 at Tuscaloosa, Alabama, reallots Channel 239C2 to Midfield, Alabama, and modifies the Station WBHJ license to specify operation on Channel 239C2 at Midfield. In order to accommodate the Channel 239C2 allotment at Midfield, this document reallots Channel 238A from Holly Pond, Alabama, Hackleburg, Alabama, and modifies the Station WFMH-FM license to specify Hackleburg as the community of license.

To replace the loss of the sole local service at Holly Pond, this document reallots Channel 245C from Decatur, Alabama, to Holly Pond, and modifies the license of Station WRSA to specify Holly Pond as the community of license. In order to accommodate Channel 239C2 at Midfield, it reallots Channel 237A from Cordova, Alabama, Coaling, Alabama, and modifies the Station WFFN license to specify Coaling as the community of license. To replace the loss of the sole local service at Cordova, this document also reallots Channel 223A from Dora, Alabama, to Cordova, and modifies the Station WQOP-FM license to specify Cordova as the community of license. See Supplementary Information.

**DATES:** Effective June 4, 2004.

**FOR FURTHER INFORMATION CONTACT:** Robert Hayne, Mass Media Bureau (202) 418-2177.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the *Report and Order* in MM Docket No.03-77 adopted April 14, 2004, and released April 19, 2004. The full text of this decision is available for inspection and copying during normal business hours in the FCC Reference Information Center at Portals II, CY-A257, 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or via e-mail [qualixint@aol.com](mailto:qualixint@aol.com).

This document reallots Channel 238A from Ashland, Alabama, to Hobson City, Alabama, and modifies the Station WASZ license to specify Hobson City as its community of license. To replace the loss of the sole local service at Ashland, this document reallots Channel 252A from Sylacauga, Alabama, to Ashland, and modifies the Station WTRB-FM license to specify Ashland as its community of license. This document also reclassifies the Channel 253C allotment at Atlanta, Georgia, to Channel 253C0 and modifies the Station WSB-FM license to specify operation on Channel 253C0. This document substitutes Channel 252C3 for Channel 252A at Scottsboro, Alabama, and modifies the Station WKEA license to specify operation Channel 252C3. In order to accommodate the Channel 252C3 allotment at Scottsboro, this document substitutes Channel 252C3 for Channel 252A at Pulaski, Tennessee, reallots Channel 252C3 to Killen, Alabama, and modifies the Station WKSJ-FM license to specify operation on Channel 252C3 at Killen. The

reference coordinates for the Channel 239C2 allotment at Midfield, Alabama, are 33-24-50 and 87-01-05. The reference coordinates for the Channel 238A allotment at Hackleburg, Alabama, are 34-13-15 and 87-45-00. The reference coordinates for the Channel 245C allotment at Holly Pond, Alabama, are 34-29-23 and 86-37-38. The reference coordinates for the Channel 237A allotment at Coaling, Alabama, are 33-04-58 and 87-27-02. The reference coordinates for the Channel 223A allotment at Cordova, Alabama, are 33-38-55 and 87-09-19. The reference coordinates for the Channel 238A allotment at Hobson City, Alabama, are 33-29-30 and 85-52-55. The reference coordinates for the Channel 252A allotment at Ashland, Alabama, are 33-13-30 and 85-53-40. The reference coordinates for the Channel 253C0 allotment at Atlanta, Georgia, are 33-45-33 and 84-20-05. The reference coordinates for the Channel 252C3 allotment at Scottsboro, Alabama, are 34-30-40 and 86-01-54. The reference coordinates for the Channel 252C3 allotment at Killen, Alabama, are 34-58-40 and 87-36-05.

### List of Subjects in 47 CFR Part 73

Radio, Radio Broadcasting.

■ Part 73 of the Code of Federal Regulations is amended as follows:

### PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

#### § 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Alabama, is amended by removing Channel 238A and by adding Channel 252A at Ashland, by adding Coaling, Channel 237A, by removing Channel 237A and by adding Channel 223A at Cordova, by removing Channel 245C at Decatur, by removing Dora, Channel 223A, by adding Hackleburg, Channel 238A, by adding Hobson City, Channel 238A, by adding Holly Pond, Channel 245C, by adding Killen, Channel 252C3, by adding Midfield, Channel 239C2, by removing Channel 252A and by adding Channel 252C3 at Scottsboro, by removing Sylacauga, Channel 252A, and by removing Tuscaloosa, Channel 239C1.

■ 3. Section 73.202(b), the Table of FM Allotments under Georgia, is amended by removing Channel 253C and by adding Channel 253C0 at Atlanta.

■ 4. Section 73.202(b), the Table of FM Allotments under Tennessee, is