EPA-APPROVED IOWA SOURCE-SPECIFIC ORDERS/PERMITS—Continued

Name of source	Order/permit No.	State effective date	EPA approval date	Comments
Blackhawk Foundry and Machine Company.	Permit No. 72–A–060–S5 (Cupola).	8/19/02	6/10/2004 [FR page citation].	Provisions of the permit that relate to pollutants other than PM_{10} are not approved by EPA as part of this SIP.

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[FR Doc. 04–13177 Filed 6–9–04; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0174; FRL–7362–9]

Fenpyroximate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fenpyroximate and its metabolites in or on cotton gin byproducts; cotton undelinted seed; fruit pome group 11; grape; liver and kidney of cattle, goat, horse, and sheep; meat, fat, and meat byproducts (excluding liver and kidney) of cattle, goat, horse, and sheep; and milk. The Interregional Research Project Number 4 and Nichino America, Incorporated requested these tolerances 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 June 10, 2004. Objections and requests for hearings, identified by docket ID number OPP–2004–0174, must be received on or before August 9, 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–2004–0174. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either 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. Attention: Docket ID Number OPP–2004–0174. 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: Melody Banks, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5413; e-mail address: *banks.melody@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and 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 processing (NAICS 3110), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturers (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 on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of July 11, 2003 (68 FR 41345) (FRL–7314–8), 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 pesticide petitions (PP 3E6519) by Interregional Research Project Number 4, 681 U.S. Highway No. 1 South, North Brunswick, NJ 08902 and (PP 2F6437) by Nichino America, Incorporated, 4550 New Linden Hill Rd., Wilmington, DE 19808. That notice included a summary of the petition prepared by Nichino America, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.566 be amended by establishing tolerances for combined residues of the insecticide fenpyroximate, benzoic acid, 4-[[[(E)-[1,3-dimethyl-5-phenoxy-1H-pyrazol-4 yl)methylene]amino]oxy]methyl]-, 1,1-dimethylethyl ester, in or on fruit pome group 11 at 0.3 parts per million (ppm) (PP 3E6519); apple fruit at 0.8 ppm, grape at 0.3 ppm, cotton undelinted seed at 0.1 ppm, cotton gin byproducts at 9.0 ppm, milk at 0.01 ppm, liver and kidney of cattle, goat, hog, horse, and sheep at 0.50 ppm, and meat, fat, and meat byproducts (excluding liver and

kidney) of cattle, goat, hog, horse, and sheep at 0.02, 0.08, and 0.01 ppm, respectively (PP 2F6437).

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 fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate and its Z-isomer, (Z)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate on fruit pome group 11 at 0.40 ppm, grape at 1.0 ppm, cotton undelinted seed at 0.10 ppm, cotton gin byproducts at 10.0 ppm; for combined residues of fenpyroximate and its metabolites ((E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methyleneaminooxymethyl benzoic acid and (E)-1,1-dimethylethyl-2-hydroxyethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl] benzoate, calculated as the parent compound in milk at 0.015 ppm, meat, fat, and meat byproducts (excluding liver and kidney) of cattle, goat, horse, and sheep at 0.03 ppm; and for combined residues of fenpyroximate and its metabolite ((E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methyleneaminooxymethyl benzoic acid, calculated as the parent compound in kidney and liver of cattle, goat, horse and sheep at 0.25 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fenpyroximate 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 (rodent)	NOAEL = 1.5 milligrams/kilogram/day (mg/kg/day) (20 ppm) LOAEL = 7.4 mg/kg/day (100 ppm) for rats, based on decreased body weight gains in both sexes.
870.3150	90-Day oral toxicity (non-rodent)	NOAEL < 2 mg/kg/day LOAEL= 2 mg/kg/day, based on slight bradycardia and an increased incidence of diarrhea in both sexes; and reduced food consumption, body weight, body weight gain, emaciation, and torpor in females.
870.3200	21-Day dermal toxicity (rat)	NOAEL < 1,000 mg/kg/day highest dose tested (HDT) LOAEL = 1,000 mg/kg/day (the limit dose and the only dose tested) based on decreased body weight gains in males and females and increased liver weights in the females.
870.3200	21-Day dermal toxicity (rat)	NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day (limit dose) based on clinical signs in the females, decreased body weights, body weights gains, and food consumption in both sexes, increased absolute liver weights and a possible increase in hepatocellular necrosis in the females.
870.3700	Prenatal developmental toxicity (rodent)	Maternal NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on marginal decrease in body weight gain and food consumption. Developmental NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on increased incidence of additional thoracic ribs.
870.3700	Prenatal developmental (rabbit)	Maternal NOAEL = 5 mg/kg/day LOAEL > 5 mg/kg/day Developmental NOAEL = 5 mg/kg/day LOAEL > 5 mg/kg/day

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

Guideline No.	Study type	Results
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 1.99 mg/kg/day for males 2.44 mg/kg/day for and females LOAEL = 6.59 and 8.60 mg/kg/day for males and females, respectively, based on decreased body weights during the premating period Reproductive NOAEL = 6.59 and 8.60 mg/kg/day for males and females, respectively LOAEL was not established Offspring NOAEL = 2.44 mg/kg/day LOAEL = 8.60 mg/kg/day, based on decreased lactational weight gain in both generations of pups
870.4100	Chronic toxicity (dog)	NOAEL = 5 mg/kg/day LOAEL = 15 mg/kg/day in both sexes, based on diarrhea, bradycardia, decrease cholesterol, body weight gain, and food consumption (males); vomiting, diarrhea, excess salivation, and decrease cholesterol in females.
870.4200	Carcinogenicity (mice)	NOAEL = Males: 2.4 mg/kg/day; Females: 2.5 mg/kg/day LOAEL = Males: 9.5 mg/kg/day; Females: 10 mg/kg/day based on decreased body weights and food consumption. No evidence of carcinogenicity.
870.4300	Combined chronic/carcinogenicity (rat)	NOAEL = Males: 0.97 mg/kg/day; Females: 1.16 mg/kg/day LOAEL = Males: 3.08 mg/kg/day; Females: 3.79 mg/kg/day based on decreased mean body weight gain. No evidence of carcinogenicity.
870.5100	Bacterial reverse mutation	At limit concentration(5,000 μg/plate) inhibition of growth was observed in strains TA98, TA1537, TA1538, and WP2uvrA. The positive controls induced the appropriate responses in the corresponding strains. There was no evidence of induced mutant colonies over background.
870.5300	*In vitro* mammalian cell gene mutation	Not cytotoxic up to 330 μg/ml, the limit of solubility. There was no evidence of mutagenic effect at any dose level with or without metabolic activation. The positive controls induced the appropriate response.
870.5375	*In vitro* mammalian chromosome aberration (helacells)	Tested up to limit of solubility (up to 330 μg/ml). For metaphase analysis, the highest concentration (20 μg/ml) produced moderate toxicity (mitotic index ~57% of solvent control). Two lower concentrations produces mitotic indices 25% and 12.5% of the high concentration. Positive controls induced the appropriate response. The results of this study provide sufficient evidence to consider NNI-850 negative in this assay.
870.5395	Mammalian micronucleus (mouse)	There was suggestive evidence that NNI-850 was cytotoxic to the target cell at the highest dose level. The positive control induced significant increases in micronucleated polychromatic erythrocytes (MPCEs). There was no significant increase in the frequency of MPCEs in bone marrow after any NNI-850 treatment time. Fenpyroximate is considered negative in this micronucleus assay.
870.5500	DNA damage/repair *REC* assay	Did not cause any inhibitory zone in either strain at any dose level in the presence or absence of metabolic activation. The negative and positive controls induced the appropriate responses.
870.5550	Unscheduled DNA synthesis (rat primary hepatocyte)	Fenpyroximate was negative. The positive control induced the appropriate response.
870.6100	Acute delayed neurotoxicity (hen)	NOAEL ≥ 5,000 mg/kg/day LOAEL was not observed
870.7485	Metabolism and pharmacokinetics (rat)	The majority of the radioactivity from the single and repeated low doses was excreted in the feces within 24 hours of dosing. In contrast, fecal excretion of the majority of the high dose was delayed until 96–144 hours, and at 24 hours the major portion of the single high dose (53.4–63.9%) remained in the stomach contents. The maximum concentration in blood (at the maximum time (tmax)) was reached at 7–11 hours following a single low dose compared with 29–101 hours after a single-high dose. The low doses were eliminated from blood within 96 hours, whereas the high dose persisted through 168 hours. A total of 20 metabolites, each accounting for <10% of the dose, were characterized from excreta (urine and feces) of low dosed rats. The preponderance of metabolites and low levels of parent in the feces at the 2 mg/kg dose indicates absorption from the digestive tract, extensive metabolism by the liver, and biliary excretion of the low dose (2 mg/kg). The high dose of 400 mg/kg causes as a toxic effect delayed excretion and decreased absorption and metabolism.

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

Guideline No.	Study type	Results
870.7600	Dermal penetration (rat)	Mean absorption based on urinary/fecal excretion, blood, carcass, and cage wash ranged from 0 to 5.3% (0.0 to 5.3% low dose, 0.5 to 2.5% mid dose and 0.52 to 1.5% high dose). Dermal absorption factor is 5%

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 intra species differences.

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (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 fenpyroximate used for human risk assessment is shown in Table 2 of this unit:

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

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute dietary Females 13–49 years of age	NOAEL = 5.0 mg/kg/day UF = 100 Acute RfD = 0.05 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.05 mg/kg/day	Prenatal Developmental-Toxicity Study—rat LOAEL = 25 mg/kg/day based on increase in the fetal incidence of additional thoracic ribs.
Chronic dietary All populations	NOAEL= 0.97 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.01 mg/kg/day	Combined Oral Chronic Toxicity/carcinogenicity Study—rat LOAEL = 3.1 mg/kg/day based on decreased body weights, accompanied by reduced food efficiency and a slight decrease in mean food consumption.

* 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 180.566) for the combined residues of fenpyroximate and its metabolites, in or on a variety of raw agricultural commodities. Time-limited tolerances have been established for imported wine grapes and imported hops. Risk assessments were conducted by EPA to assess dietary exposures from fenpyroxymate 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. In conducting this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the 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 acute exposure assessments: Tolerance-level residues and 100% crop treated information for all registered and proposed uses of fenpyroximate were used to conduct an unrefined acute dietary-exposure assessment for females 13–49 years old. The acute dietary-exposure estimate for females 13–49

years old represents 5% of the aPAD and is below EPA's level of concern. Since an effect of concern attributable to a single dose in toxicity studies was not identified for the general U.S. population, an acute dietary-exposure assessment was not performed for this population.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment EPA used DEEM-FCID™ which incorporates food consumption data as reported by respondents in CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance-level residues and 100% crop treated information for all registered and proposed uses of fenpyroximate were used to conduct an unrefined, Tier 1 chronic dietary-exposure assessment for the general U.S. population and various population subgroups. The chronic dietary-exposure estimates range from 4% to 29% of the cPAD. These estimates are below EPA's level of concern The most highly-exposed population subgroup is children 1–2 years old at 29% cPAD.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenpyroximate 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 physical characteristics of fenpyroximate.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Sreening Concentration in Groundwater (SCI-GROW), which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes 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) from these models 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 fenpyroximate they are further discussed in the aggregate risk sections in Unit E.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of fenpyroximate for acute exposures are estimated to be 1.5 parts per billion (ppb) for surface water and <0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.13 ppb for surface water and <0.006 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).

Fenpyroxymate is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to 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 fenpyroximate 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 fenpyroximate and any other substances and fenpyroximate 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 fenpyroximate 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 Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website 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 database on toxicity and exposure unless EPA determines 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.

2. *Prenatal and postnatal sensitivity*. EPA evaluated the potential for increased susceptibility of infants and children from exposure to fenpyroximate according to the February 2002 OPP 10X guidance document. EPA concluded that there are no concerns or residual uncertainties for prenatal and postnatal toxicity.

3. *Conclusion*. Based on these data, EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because:

- There are no concerns or residual uncertainties for pre- or postnatal toxicity.
- The toxicological database is complete for the assessment of toxicity and susceptibility following pre- and/or postnatal exposures. No clinical signs of neurotoxicity or neuropathology were observed in the database.
- There are no residual concerns regarding completeness of the exposure database.
- The dietary food exposure assessment is Tier 1, screening level,

which is based on tolerance level residues and assumes 100% of all crops will be treated with fenpyroximate. By using these screening-level assessments, actual exposures/risks will not be underestimated.

- The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded.
- There are currently no registered or proposed residential uses of fenpyroximate.

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 body weights. Default body weights and consumption values as used by 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 groundwater 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fenpyroximate will occupy 5% of the aPAD for females 13–49 years old. In addition, there is potential for acute dietary exposure to fenpyroximate and its M-1 and M-3 metabolites 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 aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FENPYROXIMATE

Population subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Acute DWLOC (ppb)
Females 13–49 years old	0.05	5	1.5	< 0.006	1,400

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenpyroximate from food will utilize 8% of the cPAD for the U.S. population, 18% of the cPAD for all infants (< 1 year old) and 29% of the cPAD for children 1–2 years old. In addition, there is potential for chronic dietary exposure to fenpyroximate 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 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FENPYROXIMATE

Population subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.01	8	0.13	< 0.006	320
All infants (< 1 year old)	0.01	18	0.13	< 0.006	82
Children 1–2 years old	0.01	29	0.13	< 0.006	71
Children 3–5 years old	0.01	21	0.13	< 0.006	79
Children 6–12 years old	0.01	10	0.13	< 0.006	90
Youth 13–19 years old	0.01	4	0.13	< 0.006	290
Adults 20–49 years old	0.01	6	0.13	< 0.006	330
Females 13–49 years old	0.01	6	0.13	< 0.006	280
Adults 50+ years old	0.01	5	0.13	< 0.006	330

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenpyroximate is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenpyroximate is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Fenpyroximate is classified as not likely to be carcinogenic to humans; therefore, an aggregate cancer risk assessment was not performed.

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 fenpyroximate residues.

IV. Other Considerations

International Residue Limits

Codex maximum residue levels (MRLs) are established for residues of fenpyroximate per se in/on grapes, apple and cattle commodities. There are no established or proposed tolerances for fenpyroximate in or on grapes in Canada and Mexico. Harmonization with the Codex MRLs is not possible as the U.S. tolerance expressions include additional metabolites/isomers.

V. Conclusion

Therefore, tolerances are established for combined residues of fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate and its Z-isomer, (Z)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate on fruit pome group at 0.40 ppm, grape at 1.0 ppm, cotton undelinted seed at 0.10 ppm, cotton gin byproducts at 10.0 ppm; for combined residues of fenpyroximate and its metabolites ((E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methyleneaminooxymethyl] benzoic acid and (E)-1,1-dimethylethyl-2-hydroxyethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene]amino]oxy]methyl] benzoate, calculated as the parent compound in milk at 0.015 ppm, meat, fat, and meat byproducts (excluding liver and kidney) of cattle, goat, horse, and sheep at 0.03 ppm; and for combined residues of fenpyroximate and its metabolite ((E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methyleneaminooxymethyl] benzoic acid, calculated as the parent compound in kidney and liver of cattle, goat, horse, and sheep at 0.25 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of 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 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 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–2004–0174 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 August 9, 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 issue(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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564–6255.

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 PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0174, 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 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 issue(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 record keeping requirements.

Dated: May 28, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.566 is amended by designating the text of paragraph (a) as paragraph (a)(1) and by adding paragraphs (a)(2), (a)(3), and (a)(4) to read as follows:

§ 180.566 Fenpyroximate; tolerances for residues.

(a) * * *

(2) Tolerances are established for residues of the insecticide fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl -5-phenoxy-1H-

pyrazol-4-yl) methylene] amino]oxy]methyl] benzoate and its Z-isomer, (Z)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5- phenoxy-1H- pyrazol-4-yl)methylene] amino]oxy] methyl]benzoate in or on the following commodities:

Commodity	Parts per million
Cotton, gin byproducts	10
Cotton undelinted seed	0.10
Fruit pome group 11	0.40
Grape	1.0
Hop[1]	10

[1]There are no U.S. registrations on hop.

(3) Tolerances are established for residues of the insecticide fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5 -phenoxy-1H-pyrazol-4-yl) methylene] amino]oxy]methyl] benzoate and its metabolites, (E)-4- [(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methylene aminooxymethyl]benzoic acid and (E)-1,1-dimethylethyl-2-hydroxyethyl 4-[[[[(1,3-dimethyl -5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl] benzoate, calculated as the parent compound in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.03
Cattle, meat	0.03
Cattle, meat byproduct (excluding liver and kidney)	0.03
Goat, fat	0.03
Goat, meat	0.03
Goat, meat byproducts (excluding liver and kidney	0.03
Horse, fat	0.03
Horse, meat	0.03
Horse, meat byproducts (excluding liver and kidney)	0.03
Milk	0.015
Sheep, fat	0.03
Sheep, meat	0.03
Sheep, meat byproducts (excluding liver and kidney	0.03

(4) Tolerances are established for residues of the insecticide fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl] benzoate and its metabolite, (E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methylene aminooxymethyl]benzoic acid, calculated as the parent compound in the following commodities:

Commodity	Parts per million
Cattle, kidney	0.25
Cattle, liver	0.25
Goat, kidney	0.25
Goat, liver	0.25
Horse, kidney	0.25
Horse, liver	0.25
Sheep, kidney	0.25
Sheep, liver	0.25

* * * * *

[FR Doc. 04–13146 Filed 6–9–04; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 10, 12, and 15

[USCG–1999–5610]

RIN 1625–AA24 (Formerly RIN 2115–AF83)

Training and Qualifications for Personnel on Passenger Ships

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule adopts without changes the interim rule published on October 30, 2002, which established requirements of training and certification for masters, certain licensed officers, and certain crewmembers on most vessels inspected under subchapter H, T, or K. It is intended to help reduce human error, improve the ability of crewmembers to assist passengers during emergencies, and promote safety.

DATES: This final rule is effective July 12, 2004.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–1999–5610 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this rule, call Mark Gould, Project Manager, Commandant (G–MSO–1), Coast Guard, telephone (202) 267–6890. If you have questions on viewing the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, telephone (202) 366–0271.

SUPPLEMENTARY INFORMATION:

Interim Rule

On October 30, 2002, we published an interim rule with request for comments (67 FR 66063; effective January 28, 2003). The interim rule established training and certification requirements for masters, certain licensed officers, and certain crewmembers on ships inspected under 46 CFR subchapters H, T, and K. It did not apply to roll-on/roll-off passenger ships carrying more than 12 passengers on international voyages, or to passenger ships on domestic voyages. The interim rule implemented Regulation V/3 of the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended in 1997.

We issued an interim rule instead of a final rule in order to give the public time to comment on a change we made in 46 CFR 12.35–5 subsequent to publication of the Notice of Proposed Rulemaking (NPRM; 65 FR 37507, June 15, 2000). That section provides general requirements for unlicensed persons who serve on passenger ships and perform duties that involve safety or care for passengers. The public comment period for the interim rule ended December 20, 2002.

We received no comments in response to our interim rule and request for comments. Because no reason to change the rule has been brought to our attention, we now announce our decision to finalize the interim rule. Pursuant to the Administrative Procedure Act, 30 days must elapse before the final rule takes effect, and during that period the interim rule will continue to be in effect.

Regulatory Evaluation

The analyses we conducted in connection with the interim rule all remain unchanged, and the Analysis Documentation prepared for the interim rule remains in the docket. This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget (OMB) has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). Please consult the Regulatory Evaluation provided in the interim rule for further information.

Collection of Information

As described in the NPRM and in the Analysis Documentation, the interim rule contained three added