than established during the initial or subsequent performance test or the daily average fan RPM at or above the minimum level established during the initial or subsequent performance test; and

(ii) Checking the static pressure or fan RPM at least every 8 hours to verify the daily average static pressure at the inlet to the control device is at an equal or greater vacuum than established during the initial or subsequent performance test or the daily average fan RPM is at or above the minimum level established during the initial or subsequent performance test and recording the results of each check.

(e) * * *

(2) Operating and maintaining a COMS and collecting and reducing the COMS data according to § 63.7331(j).

* * * * *

(h) For each multicyclone applied to pushing emissions and subject to the operating limit in § 63.7290(b)(4), you must demonstrate compliance by meeting the requirements in paragraphs (h)(1) through (3) of this section.

(1) Maintaining the daily average pressure drop at a level at or below the level established during the initial or subsequent performance test.

(2) Operating and maintaining each CPMS according to § 63.7331(k) and recording all information needed to document conformance with these requirements.

(3) Collecting and reducing monitoring data for pressure drop according to § 63.7331(e)(1) through (3).

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0299; FRL–7681–8]

Mepanipyrim; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of mepanipyrim, 4-methyl-N-phenyl-6-(1-propynyl)-2-pyrimidinamine, and its metabolite, 4-methyl-N-phenyl-6-(2-hydroxypropyl)-2-pyrimidinamine, both free and conjugated in or on grape; grape, raisin; strawberry; and tomato. K-I Chemical U.S.A., Inc., 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 October 13, 2004. Objections and requests for hearings must be received on or before December 13, 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 identification (ID) number OPP–2004–0299. 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, 1801 South Bell St., 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: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of May 26, 2004 (69 FR 29940) (FRL–7357–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E5017) by K-I Chemical U.S.A., Inc., 11 Martine Ave., 9th Floor, White Plains, NY 10606. That notice included a summary of the petition prepared by K-I Chemical U.S.A., the petitioner. One comment from a private citizen was received in response to the notice of filing. The petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide mepanipyrim in or on grape at 2.0 parts per million (ppm); grape, raisin at 4.0 ppm; strawberry at 1.5 ppm; and tomato at 0.5 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 mepanipyrim and its metabolite in or on grape at 1.5 ppm; grape, raisin at 3.0 ppm; strawberry at 1.5 ppm; and tomato at 0.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by mepanipyrim 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 rodents (rat)	NOAEL = ≥ 55.9/61.3 milligrams/kilogram/day LOAEL = Not established
870.3100	90-Day oral toxicity rodents (rat)	NOAEL = Not established LOAEL = 109/120 mg/kg/day, based on increased total bilirubin, alkaline phosphatase, phospholipids, non-esterified fatty acids in males; increased fatty liver changes in both sexes; decreased food efficiency, triglycerides, and phospholipids and increased incidence of hepatic abnormalities (yellowish, malformative nodules, granulation, hepatodiaphragmatic nodule, and fatty change) in females.
870.3100	90-Day oral toxicity rodents (mouse)	NOAEL = 182/224/mg/kg/day LOAEL = 603/675 mg/kg/day (male/female (M/F)), based on increased absolute and relative (to body) liver weights in both sexes, increased severity of anisonucleosis in male liver, and increased food consumption in males.
870.3150	90-Day oral toxicity in nonrodents (dog)	NOAEL = Not established LOAEL = 15 mg/kg/day (M/F), based on increased incidences of minimal pigment deposition in the Kupffer cells and hepatocytes and increased alanine aminotransferase in both sexes.
870.3150	90-Day oral toxicity in nonrodents (dog)	NOAEL = 7.5 mg/kg/day LOAEL = Not established
870.3700	Prenatal developmental in rodents (rat)	Maternal NOAEL = 750/mg/kg/day LOAEL was not established. Developmental NOAEL = 750 mg/kg/day LOAEL was not established.
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL = 90/mg/kg/day LOAEL was not established. Developmental NOAEL = 90 mg/kg/day LOAEL was not established.
870.3800	Reproduction and fertility effects (rats)	Parental/Systemic NOAEL = 3.7/mg/kg/day LOAEL = 11.2/12.7 mg/kg/day, based on increased incidence of periacinar hepatocytic fatty vacuolation in the P and F1 generation males. Reproductive NOAEL = 11.2/12.7 mg/kg/day LOAEL was not established. Offspring NOAEL = 3.7/4.2/mg/kg/day LOAEL = 11.2/12.7 mg/kg/day, based on focal inflammation with associated hepatocytic vacuolation in the males, periacinar/panacinar hepatocytic fatty vacuolation and increased absolute liver eights in the females, and increased relative (to body) liver weights in both sexes.

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

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rats)	Parental/Systemic NOAEL was not established. LOAEL = 10.5/12.0 mg/kg/day (M/F), based on increased incidence of periacinar hepatocytic fatty vacuolation in the F1 males. Reproductive NOAEL = 141.9/165.7/mg/kg/day (M/F) LOAEL was not established. Offspring NOAEL = 3.7/4.2 mg/kg/day (M/F) LOAEL = 10.5/12.0 mg/kg/day (M/F), based on increased liver weights, macroscopic hepatic findings (accentuated lobular pattern and pale liver), and hepatocytic fatty vacuolation.
870.4300	Combined chronic toxicity/ carcinogenicity rodents (rat)	NOAEL = 7.34/9.29/mg/kg/day LOAEL = 100/125 mg/kg/day based on increased incidence of clinical signs of toxicity in males, decreased body weight, body weight gain and food efficiency in both sexes, and evidence of hepatotoxicity, nephrotoxicity, and fatty acid/lipid metabolism disruption in both sexes. Evidence of carcinogenicity, based on hepatocellular adenomas in females.
870.4100	Chronic toxicity dogs	NOAEL = 7.5 mg/kg/day LOAEL = 50 mg/kg/day (M/F), based on decreased body weights, body weight gains, and food consumption in females; increased leukocytes (neutrophils and lymphocytes), decreased erythroid series, and increased myeloid to erythroid ratio in both sexes; and indications of liver toxicity, including increased ALT, alkaline phosphatase, and ornithine carbamyl transferase, and lipofuscin, enlargement, and inflammatory infiltrate in the hepatocytes of both sexes.
870.4300	Carcinogenicity mice	NOAEL = 56/68 (M/F) mg/kg/day LOAEL = 578/681 mg/kg/day (M/F), based on decreased body weights, body weight gains, and food efficiency in males, absolute and relative to body liver weights in both sexes, and gross and microscopic hepatic lesions in both sexes. Evidence of carcinogenicity, based on hepatocellular adenomas and carcinomas in male and female mice.
870.5100	Reverse gene mutation assay in bacteria	There was no evidence of induced mutant colonies over background.
870.5300	Forward gene mutation assay in mammalian cells	There was no evidence that KIF 3535 induced mutant colonies over background in the ± S9 activation.
870.5375	*In vitro* mammalian cytogenetic assay	Not clastogenic with or without S9 activation, at any dose tested.
870.5385	*In vivo* mammalian cytogenetic assay	No increase in aberrant cells were seen in the bone marrow chromosomal aberration assay.
870.5395	*In vivo* mammalian cytogenetic assay	Did not induce micronucleated polychromatic erythrocytes (PMCEs) in bone marrow at any dose.
870.5500	Bacterial DNA damage and repair test	No evidence that DNA damage was induced.
870.5550	UDS synthesis in mammalian cell culture	Did not induce UDS at any dose.
870.7485	Metabolism and pharmacokinetics (rat)	In an unacceptable rat metabolism study mepanipyrim was readily absorbed from the gastrointestinal tract and about 96% of the administered dose was eliminated in feces and urine. Bile was the major route of excretion (72%); and less than 0.1% of the dose was eliminated in expired air. There was no sex difference in absorption and elimination of mepanipyrim. Parent and up to 16 metabolites were purported to be identified; however, > 5% of the administered dose was not accounted or analyzed in the excreta.
Non-guideline	Mechanism of fatty liver (rats)	Dietary administration of 4,000 ppm KIF 3535 to male rats may cause fatty liver by a mechanism inhibiting the synthesis and/or transport and release of VLDL from the liver, as demonstrated by decreased acetate incorporation, decreased serum lipid concentrations, increased liver lipid concentrations, decreased VLDL, LDL, and HDL-triglycerides and HDL-cholesterol levels in serum, and decreased adipose tissue weight.

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

Guideline No.	Study Type	Results
Non-guideline	Oxidative damage to hepatic DNA (females rats and mice)	Measurement of liver 8-hydroxyguanine were inconsistent and not accompanied by vehicle control data, therefore, interpretation of the results were inconclusive.
Non-guideline	Induction of lipid peroxidation (female rats and mice)	Oral or dietary administration of the test compound did not induce hepatic lipid peroxidation as measured by thiobarbituric acid-reactive compounds in either female rats or mice in this study.
Non-guideline	Induction of mixed function oxidase (female rats and mice)	Dietary administration of mepanipyrim induced cytochrome P-450 and aminopyrine N-demthylase activities in the female rat and aminopyrine N-demthylase activity in female mice.
Non-guideline	Promotion of liver carcinogenesis (rats)	Liver is the target organ, consistent with other studies. The test compound may/or may not act as a tumor promoting agent in the two-stage model of hepatic carcinogenesis utilized in the current study.
Non-guideline	Liver enzyme induction (mice)	Single oral administration of 5000 mg/kg or multiple administrations of 3000 mg/kg/day KIF-3535 to male mice causes hepatotoxicity (increased liver weights, cellular hypertrophy, and increase in cell proliferation) and increase in liver metabolic enzymes (cytochrome P-450).
Non-guideline	Liver enzyme induction (rat)	Single administration of 5,000 mg/kg or multiple administrations of 2,000 mg/kg KIF-3535 to rats caused decrease in body weights, hepatotoxicity (increased liver weights, discoloration, cellular hypertrophy, fatty changes, elevated GPT and GOT, and increase in cell proliferation) and increase in mild increase in liver metabolic enzymes (cytochrome P-450).

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 (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-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^{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for mepanipyrim used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MEPANIPYRIM HUMAN HEALTH 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	Not available	None	An endpoint of concern attributable to a single dose was not identified. An acute RfD was not established.
Chronic Dietary all populations	NOAEL= 7.3 mg/kg/day UF = 100 Chronic RfD = 0.073 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD FQPA SF = 0.073 mg/kg/day	Chronic Toxicity - Rat Systemic Toxicity LOAEL = 100 mg/kg/day, based on increased incidence of clinical signs of toxicity in males, decreased body weight, body weight gain and food efficiency in both sexes, and evidence of hepatotoxicity, nephrotoxicity, and fatty acid/lipid metabolism disruption in both sexes.
Cancer (oral, dermal, inhalation)			EPA concluded that mepanipyrim is ''likely to be carcinogenic to humans.'' For risk assessment purposes EPA derived a Q_1*= 1.35 x 10^{-2}, based on mouse liver combined adenomas and carcinomas.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Mepanipyrim is a new chemical and these are the first tolerances to be proposed for this chemical. Risk assessments were conducted by EPA to assess dietary exposures from mepanipyrim 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. There were no toxic effects attributable to a single dose. An endpoint of concern was not identified to quantitate acute dietary risk to the general population, including infants and children, or to the subpopulation females 13–50 years old. Therefore, a quantitative acute exposure 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™), 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 chronic exposure assessments: It was assumed that 100% of the crop imported from Western Europe was treated and that anticipated residues based on average field trial data occurred on all commodities. Since the petitioner provided pesticide product labels limited to use in Western Europe only, it was assumed that use of mepanipyrim would be limited to Western Europe.

iii. *Cancer*. For the cancer exposure assessment, the same assumptions as identified in the chronic exposure unit, Unit III.C.1.ii., were used. Applying the Q_1* of 0.0135 $(mg/kg/day)^{-1}$ to the exposure value results in a cancer risk estimate of 2.6 x 10^{-7}.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) of FFDCA require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: The percentage of imported crops from Western Europe which are consumed by the United States are as follows: Grapes, fresh - 1%; grape, juice - 1%; grape, raisin - 3.3%; strawberry, fresh - 1%; strawberry, juice - 31.5%; tomatoes, fresh - 1.3% and tomatoes, processed - 4%.

The Agency believes that the three conditions listed in Unit III. have been met. With respect to Condition 1, the PCT estimates were derived from the U.S. Department of Agriculture's Economic Service and the U.S. Census Bureau for the period of 1981–2000 to determine the imported share of U.S. consumed food. Additionally, import data from the Foreign Agricultural Trade of the United States (FATUS) database which is used as the official United States source of import and export data served as the source to determine the percentage of imported grapes, strawberries, and tomatoes imported from Western Europe. Import data from the years 2000 to 2003 was analyzed and averaged in order to estimate the percentage of imports. The Agency believes this data is reliable as the import data was stable over a 3 year period, and the United States has other major sources favored for import of these commodities. As to Conditions 2 and 3, regional consumption information and consumption

information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which mepanipyrim may be applied in a particular area.

2. *Dietary exposure from drinking water.* The proposed tolerances are for imported commodities only, and there are no current or proposed U.S. registrations for this chemical. Therefore, there is no potential for exposure to mepanipyrim through drinking water, and a drinking water assessment was not performed.

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). There are no products containing mepanipyrim proposed or registered for residential use or that may be applied by commercial applicators to residential sites. Therefore, a residential exposure assessment was not performed.

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.''

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 mepanipyrim and any other substances and mepanipyrim 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 mepanipyrim 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. 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 quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to mepanipyrim in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility to mepanipyrim following pre-/postnatal exposure in a 2-generation reproduction study. There is no concern for developmental neurotoxicity resulting from exposure to mepanipyrim. Since there was no observed evidence of developmental neurotoxicity in short and long-term toxicity studies in rats, mice, and dogs, a developmental neurotoxicity (DNT) study is not required.

3. *Conclusion.* There is a complete toxicity database for mepanipyrim and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. There is no evidence of susceptibility following *in utero* exposure in the developmental toxicity studies in rats or rabbits, and in the 2-generation rat reproduction study. There are no residual uncertainties concerning pre- and postnatal toxicity and no neurotoxicity concerns. The chronic and cancer dietary food exposure assessments utilizes ARs calculated from field trial data and percent crop imported from Western Europe data for all commodities. Although refined, the assessments are based on reliable data and will not underestimate exposure/risk. There is no potential for drinking water exposure. There is no potential for residential exposure. Based on these data and conclusions, EPA reduced the FQPA Safety Factor to 1X and a developmental neurotoxicity study will not be required.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* An acute endpoint was not identified in any of the toxicity studies. Therefore, no acute risk is expected from exposure to mepanipyrim.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to mepanipyrim from food will utilize < 1% of the cPAD for the U.S. population, < 1% of the cPAD for all infants < 1 year old, and < 1 % of the cPAD for children 1–2 years old. There are no residential uses for mepanipyrim that result in chronic residential exposure to mepanipyrim. There are no current or proposed U.S. registrations of mepanipyrim for the United States and, as a result, there is no expectation of exposure through drinking water. Therefore, EPA does not expect the aggregate exposure (dietary) to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF CHRONIC DIETARY EXPOSURE AND RISK FOR MEPANIPYRIM

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
		DEEM-FCID	DEEM-FCID
General U.S. Population	0.73	19	<1

TABLE 3.—SUMMARY OF CHRONIC DIETARY EXPOSURE AND RISK FOR MEPANIPYRIM—Continued

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
		DEEM-FCID	DEEM-FCID
All Infants <1 year old)	0.73	0.000006	<1
Children 1–2 years old	0.73	0.000051	<1
Children 3–5 years old	0.73	0.000053	<1
Children 6–12 years old	0.73	0.000028	<1
Youth 13–19 years old	0.73	0.000013	<1
Adults 20–49 years old	0.73	0.000015	<1
Adults 50+ years old	0.73	0.000017	<1
Females 13–49 years old	0.73	0.000015	<1

3. *Aggregate cancer risk for U.S. population*. Applying the Q_1* of 0.0135 $(mg/kg/day)^{-1}$ to the exposure value results in a cancer risk estimate of 2.6×10^{-7}. Therefore, estimated cancer risk is below the Agency's level of concern of risk in the range of 1×10^{-6}.

4. *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 toinfants and children from aggregate exposure to mepanipyrim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromotography/nitrogen-phosphorus detector (GC/NPD) method and multi-residue method (MRM)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no established Codex, Canadian or Mexican maximum residue limits (MRLs) for mepanipyrim.

V. Conclusion

Therefore, the tolerances are established for combined residues of mepanipyrim, 4-methyl-N-phenyl-6-(1-propynyl)-2-pyrimidinamine, and its metabolite, 4-methyl-N-phenyl-6-(2-hydroxypropyl)-2-pyrimidinamine, both free and conjugated in or on grape at 1.5 ppm; grape, raisin at 3.0 ppm; strawberry at 1.5 ppm; and tomato at 0.5 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–2004–0299 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 December 13, 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 (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. *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–2004–0299, 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: September 30, 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 180.604 is added to subpart C to read as follows:

§ 180.604 Mepanipyrim; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect of inadvertent residues.* [Reserved]

(e) *Revoked tolerances subject to the channel of trade provisions.* [Reserved]

(f) *Import tolerances.* Tolerances are established for the combined residues of mepanipyrim, 4-methyl-N-phenyl-6-(1-propynyl)-2-pyrimidinamine, and its metabolite, 4-methyl-N-phenyl-6-(2-hydroxypropylk)-2-pyrimidinamine,

both free and conjugated in or on the following commodities:

Commodity	Parts per million
Grape	1.5
Grape, raisin	3.0
Strawberry	1.5
Tomato	0.5

[FR Doc. 04–22963 Filed 10–12–04; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 031126297–3297–01; I.D. 100604A]

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 630 of the Gulf of Alaska

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

ACTION: Modification of a closure.

SUMMARY: NMFS is opening directed fishing for pollock in Statistical Area 630 of the Gulf of Alaska (GOA) for 48 hours. This action is necessary to fully use the 2004 total allowable catch (TAC) of pollock specified for Statistical Area 630.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), October 7, 2004, through 1200 hrs, A.l.t., October 9, 2004.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

NMFS closed the directed fishery for pollock in Statistical Area 630 of the GOA under § 679.20(d)(1)(iii) on October 2, 2004 (69 FR 59834, October 6, 2004).

NMFS has determined that, approximately 2,767 mt of pollock remain in the 2004 directed fishing allowance. This amount is large enough to provide for a manageable directed pollock fishery in Statistical Area 630. Therefore, in accordance with 679.25(a)(2)(i)(C) and (a)(2)(iii)(D), and to fully utilize the 2004 TAC of pollock specified for Statistical Area 630, NMFS is terminating the previous closure and is reopening directed fishing for pollock in Statistical Area 630 of the GOA. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will be reached after 48 hours. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 630 of the GOA effective 1200 hrs, A.l.t., October 9, 2004.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the opening of pollock in Statistical Area 630.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: October 6, 2004.

Alan D. Risenhoover,

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

[FR Doc. 04–22938 Filed 10–7–04; 1:46 pm]

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