Dated: April 11, 2003.

Alexis Strauss,

Acting Regional Administrator, Region IX.

■ Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(21)(vi)(D), (c)(41)(ii)(F), (c)(103)(ii)(E), (c)(176)(i)(B)(*2*), (c)(182)(i)(E)(*2*), (c)(307)(i)(C), and (c)(308)(i)(B) to read as follows:

§ 52.220 Identification of plan.

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(c) * * *

(21) * * *

(vi) * * *

(D) Previously approved on May 11, 1977 in paragraph (c)(21)(vi)(A) of this section and now deleted Rules 105, 106, 107, 110, 111, and 112 (now replaced by Rule 101).

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(41) * * *

(ii) * * *

(F) Previously approved on August 31, 1978 in paragraph (c)(41)(ii)(A) of this section and now deleted Rule 104 (now replaced by Rule 101).

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(103) * * *

(ii) * * *

(E) Previously approved on July 6, 1982 in paragraph (c)(103)(ii)(B) of this section and now deleted Rule 109 (now replaced by Rule 101).

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(176) * * *

(i) * * *

(B) * * *

(*2*) Previously approved on October 23, 1989 in paragraph (c)(176)(i)(B)(*1*) of this section and now deleted Section 442 (now replaced by Section 436).

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(182) * * *

(i) * * *

(E) * * *

(*2*) Previously approved on March 11, 1988 in paragraph (c)(182)(i)(E)(*1*) of this section and now deleted Rules 101, 102, 103, and 108 (now replaced by Rule 101).

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(307) * * *

(i) * * *

(C) San Diego County Air Pollution Control District.

(*1*) Rule 101, adopted on September 25, 2002.

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(308) * * *

(i) * * *

(B) Lake County Air Quality Management District.

(*1*) Sections 226.5, 232.1, 238.5, 249.3, 250.5, 433.5, 436, and 436.5, adopted on October 1, 2002 and Sections 431.5, 431.7, 432.5, and 433, amended on October 1, 2002.

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[FR Doc. 03–10426 Filed 4–29–03; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0077; FRL–7297–9]

Mefenpyr-Diethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of mefenpyr-diethyl also known chemically as 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester in or on wheat and barley commodities. Bayer CropScience formerly doing business as Aventis CropScience and/or AgrEvo Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0077, must be received on or before June 30, 2003.

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

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–8380; e-mail address: gandhi.bipin@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:

- Industry (NAICS 111), e.g., crop production
- Industry (NAICS 112), e.g., animal production
- Industry (NAICS 311), e.g., food manufacturing
- Industry (NAICS 32532), e.g., pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0077. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

II. Background and Statutory Findings

In the **Federal Register** of September 26, 1997 (62 FR 50610) (FRL–5740–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 7F4850) by AgrEvo. Since 1997, by a series of mergers, AgrEvo became Aventis Crop Science and then Bayer CropScience. That notice included a summary of the petition prepared by AgrEvo, now doing business as Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.509 be amended by establishing permanent tolerances for the combined residues of the herbicide safener, mefenpyr-diethyl, 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester, in or on wheat and barley commodities.

In the **Federal Register** of August 8, 1997 (62 FR 42678) (FRL–5731–7), EPA, on its own initiative, pursuant to section 408(e) and (1)(6) of the FFDCA, established time-limited tolerances for the inert ingredient herbicide safener, mefenpyr-diethyl, and its 2,4-dichlorophenyl-pyrazoline metabolites in or on wheat grain and wheat straw. This action was in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of mefenpyr-diethyl on wheat grain and wheat straw in North Dakota and Montana.

Similarly, mefenpyr-diethyl time-limited tolerances were established by the Agency in the **Federal Register** of September 9, 1998 (63 FR 48116) (FRL–6024–7), in or on barley grain, barley hay, barley straw, and the processed by-products of barley grain: pearled barley, bran and flour. This action was in response to EPA's granting of an emergency exemption under FIFRA section 18 authorizing use of mefenpyr-diethyl on barley in North Dakota.

These time-limited tolerances have been extended as the petitioner has continued data generation. (See the **Federal Register** of May 6, 1998 (63 FR 24939) (FRL–5788–1); the **Federal Register** of November 22, 1999 (64 FR 63711) (FRL–6385–5); and the **Federal Register** of December 14, 2001 (66 FR 64768) (FRL–6814–2)). The extensions of these time-limited tolerances were consistent with the safety standard (FFDCA section 408(b)(2)) and FIFRA section 18. Currently, the time-limited tolerances under 40 CFR 180.509(b) expire on December 31, 2003. As the permanent tolerances are established, these emergency exemption time-limited tolerances are no longer necessary and will be revoked.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (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 the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for combined residues of mefenpyr-diethyl on wheat and barley commodities. EPA's assessment of exposures and risks associated with establishing the 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 mefenpyr-diethyl 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	Subchronic feeding studies in mouse	NOAEL = 89.3/105.4 mg/kg/day (milligram/kilogram/day), male and female (M/F) LOAEL = 449.0/523.5 mg/kg/day (M/F) based on decreased body and kidney weight, increased liver weight and hepatocyte hypertrophy in males; decreased bilirubin and increased lactic acid dehydrogenase values in females

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

Guideline No.	Study Type	Results
870.3100	Subchronic feeding studies in rats	NOAEL = 206.7/223.0 mg/kg/day (M/F) LOAEL = 660.6/708.9 mg/kg/day(M/F) based on decreased body weight (bwt) gains; decreased erythrocyte counts, hemoglobin and hematocrit values; and increased reticulocyte counts and mean corpuscular volume
870.3150	Subchronic feeding-dogs	NOAEL = 80.5/81.2 mg/kg/day (M/F) LOAEL = 341.0/336.1 mg/kg/day (M/F) based on increased absolute and relative liver weights and alkaline phosphatase activities in both sexes; focal liver lesions in females; slight anemia in both sexes; decrease in mean bwt and bwt gain in females and decreased food consumption in both sexes
870.3200	28–Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day highest dose tested (HDT) LOAEL was not determined, but would be greater than the NOAEL
870.3700	Developmental toxicity in rodents (rat)	Maternal NOAEL < 1,000 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decrease in body weight gain and food efficiency during the first week of treatment and on increase in absolute and relative spleen weights Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL = Not determined but would be greater than the NOAEL. Note that only one dose was tested
870.3700	Postnatal developmental toxicity in rodents (rat)	Maternal NOAEL < 1,000 mg/kg/day Maternal NOAEL = 1,000 mg/kg/day based on decrease in bwt gain and food efficiency during the first week of treatment Developmental NOAEL < 1,000 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on marginal decreases in fetal bwt and bwt gain during lactation. Note that only one dose was tested
870.3700	Developmental Toxicity in nonrodents (rabbit)	Maternal NOAEL= 100 mg/kg/day Maternal LOAEL = 250 mg/kg/day based on higher rate of abortions and marginal decreases in body-weight gain, food efficiency index and food consumption Developmental NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day based on higher rate of abortions
870.3800	Reproduction and fertility effects	Parental-Offspring/Systemic NOAEL = 57.3/76.0 mg/kg/day (M/F) Parental-Offspring/Systemic LOAEL= 306.0/392.0 mg/kg/day (M/F) based on decrease mean bwt and mean bwt gain in parents and offspring and an increase in mean spleen weight an increase in the severity (but not in the incidence) of splenic extramedullary hematopoiesis in females. Reproductive NOAEL = 306.0/392.0 mg/kg/day (M/F): HDT Reproductive LOAEL was not determined but would be greater than the NOAEL
870.4100	Chronic-feeding toxicity-dogs	NOAEL = 51.4/57.6 mg/kg/day (M/F) LOAEL = 260.2/282.2 mg/kg/day (M/F) based on high ALP levels and increased absolute and relative liver weights in both sexes and grade 1 (minimal) intrahepatic cholestasis in the liver: 2/sex
870.4300	Chronic Toxicity-Carcinogenicity rats	NOAEL = 48.5/60.0 mg/kg/day (M/F) LOAEL = 251.6/318.0 mg/kg/day (M/F) based on significant increases in reticulocyte counts
870.4300	Carcinogenicity mice	NOAEL = 350.8/463.4 mg/kg/day (M/F) LOAEL = (M/F) not determined, however, study considered adequate for carcinogenicity based on results of subchronic study
870.5265	Gene Mutation *Salmonella* and *E. Coli*	Non-mutagenic with or without activation
870.5300	Gene Mutation HGPRT with V79 cells	Non-mutagenic with or without activation
870.5375	Chinese Hamster Lung Fibroblast Assay	No clastogenic response with or without activation

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

Guideline No.	Study Type	Results
870.5395	Micronucleus Assay	No clastogenic response at any dose or sacrifice time
870.5550	Unschedule DNA synthesis	No clear evidence of genotoxicity. However, study not acceptable
870.7485	Metabolism and pharmacokinetics	Single dose of 1 or 100 mg/kg bwt: Urinary excretion - 76–88% of administered radioactivity with 59–72% excreted within first 24 hours. Fecal excretion ranged from 13–32%. 83–91% of administered dose excreted (urine and feces) by 24 hours and 91 to > 99% excreted by 48 hours. At least 68–88% of administered dose absorbed. Recovery in tissues/animal: 0.24% of administered radioactivity (range: 0.07 – 0.51%). General order of concentration plasma > whole blood > lungs > subcutaneous fat > heart > kidneys > retroperitoneal fat > liver > gonads > pancreas > skeletal muscle. No volatile radioactivity detected 0–24 hours after dosing. Between 100–106% of administered radioactivity recovered. Single dose of 1 or 100 mg/kg bwt: Radioactivity rapidly excreted: total of 78–92% excreted by 48 hours. Renal excretion predominant route of elimination (65–72% by 48 hours), indicating that at least 65–72% of the administered dose was absorbed. None of test material found in its original form in urine. Three metabolites identified in urine: 13–26% of the radioactivity was recovered in the feces by 48 hours. The same three metabolites identified in urine were also present in the feces: Proposed metabolic steps: Consecutive hydrolysis (saponification) of the two carboxylic acid ester groups and a decarboxylation of one of the carboxylic groups, resulting in an aromatization of the pyrazoline ring. Enterohepatic circulation is unlikely to play a major role. In males, there appears to be either lower intestinal absorption or a higher biliary excretion when compared to females.

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

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

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

A summary of the toxicological endpoints for mefenpyr-diethyl used for human risk assessment is discussed in this unit: The Agency has determined that there is no acute toxicological concern. No appropriate endpoint was identified from oral toxicity studies including the developmental toxicity studies in rats and rabbits. No short-term or intermediate-term dermal or systemic toxicity was observed up to 1,000 mg/kg/day and no development effects were observed in the developmental rat study at 1,000 mg/kg/day. Therefore, no endpoint was identified for risk assessment for the short- and intermediate-term risk assessments. Based on the current use-pattern (i.e. one application per season) long-term exposure via the dermal route is not expected. Therefore, a long-term dermal end-point was not identified. Similarly, no endpoint was identified for carcinogenicity since this chemical is not classified as a human carcinogen.

For chronic dietary risk assessment the NOAEL of 57.3 mg/kg/day in a 2–generation reproduction toxicity study was identified as an appropriate end point. Taking into account the UF of 100, the chronic RfD is 0.57 mg/kg/day (NOAEL 57.3/ UF 100 = 0.57). The Agency has used a FQPA Factor of 1 and therefore, the chronic population adjusted dose (PAD) is 0.57 mg/kg/day (RfD 0.57/FQPA 1 = 0.57) for mefenpyr-diethyl.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been previously established (40 CFR 180.509(b)) under FIFRA section 18, the Emergency Exemption Program, for the combined residues of mefenpyr-diethyl. To establish permanent tolerances, risk assessments were conducted by EPA to assess dietary exposures from mefenpyr-diethyl in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

An acute dietary risk assessment was not performed because no appropriate acute toxicological endpoint could be identified in any of the oral toxicity studies including the developmental studies in rats and rabbits.

ii. *Chronic exposure.* The chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the

Food Commodity Intake Database (DEEM-FCID®, Version 1.3), which incorporates consumption data from USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–96 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods ''as consumed'' (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or not specified (N/S); baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg bwt/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

The DEEM-FCID® analyses estimate the dietary exposure of the U.S. population and various population subgroups. The analysis assumed tolerance-level residues. No processing studies were required due to the fact that field trials conducted at exaggerated rate (greater than 5X) showed no detectable residues in wheat and barley grains. Therefore, no tolerance is needed for processed commodities. A default processing factor of 1.92 was used for dried beef in this dietary exposure analysis. No other commodities in this analysis used DEEM default processing factors. No percent crop treated or anticipated residues were used.

iii. *Cancer*. The Agency has determined that mefenpyr-diethyl is ''not likely to be a human carcinogen.'' This was based on weight-of-the-evidence from negative rat and mouse carcinogenicity studies as well as negative mutagenicity studies. Therefore, a carcinogenic dietary assessment was not performed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for mefenpyr-diethyl 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 mefenpyr-diethyl.

The Agency used the FQPA Index Reservoir Screening Tool (FIRST) to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW2) model is used to predict pesticide concentrations in shallow ground water. FIRST is a tier 1 model that uses a specific high-end runoff scenario for pesticides. It incorporates an index reservoir environment, but does include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

Neither FIRST nor SCI-GROW2 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 models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since FIRST and SCI-GROW2 is considered to be a screening tool 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 mefenpyr-diethyl, they are further discussed in the aggregate risk sections see Unit III.E.

The EECs for a single application of mefenpyr-diethyl at an exaggerated rate of 0.090 kg/hectare (ha) (0.080 lb/acre) results in the peak and chronic concentrations of combined parent and metabolites of 5 parts per billion (ppb) and 3 ppb, respectively for surface water and 4 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). Mefenpyr-diethyl 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 the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether mefenpyr-diethyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, mefenpyr-diethyl 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 mefenpyr-diethyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines 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*. In the prenatal developmental toxicity study in rats, no evidence of developmental toxicity was seen, even in the presence of maternal toxicity. In the developmental toxicity study in

rabbits, developmental toxicity was seen in the presence of maternal toxicity. A higher rate of abortions occurred at the highest dose level tested (250 mg/kg/day). An examination of the individual litter data provided no evidence as to whether or not the higher rate was due to maternal toxicity or developmental toxicity. Therefore, both the maternal and developmental NOAELs and LOAELs were based on this effect. In the 2–generation reproduction study and in the postnatal developmental toxicity study in rats, effects in the offspring were observed only at or above treatment levels which caused parental toxicity. Developmental (Offspring) effects in these two studies consisted of decreases in bwt and bwt gain of the pups in the presence of either decreased bwt and bwt gain or hematopoietic effects in the parents. There does not appear to be any increased susceptibility in rats or rabbits to *in utero* and/or postnatal exposure to mefenpyr-diethyl. Developmental effects were only observed at levels which were parentally toxic.

3. *Conclusion*. There is a complete toxicity data base for mefenpyr-diethyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed (i.e., reduced to 1) because there is no indication of increased susceptibility to infants and children, dietary exposure estimates are likely to result in an overestimate of the actual exposure, estimates for ground and surface source drinking water exposure are upper-bound concentrations and there are currently no registered residential uses and thus, this type of exposure to infants and children is not expected.

E. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which the Agency has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because the Agency 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, the Agency will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No acute endpoint was identified, therefore, no acute risk is expected.

2. *Chronic risk*. EPA has concluded that exposure to mefenpyr-diethyl from food will utilize less than 1% of the cPAD for the U.S. population and all population subgroups. (Table 2). There are no residential uses for mefenpyr-diethyl that result in chronic residential exposure to mefenpyr-diethyl. The following table represents the results of the Tier 1 chronic dietary (food only) exposure analysis for mefenpyr-diethyl proposed uses on barley and wheat.

TABLE 2.—EXPOSURE AND RISK ESTIMATES FOR DIETARY (FOOD ONLY) EXPOSURE TO MEFENPYR-DIETHYL.

Population Subgroup	Estimated Dietary Exposure, mg/kg bwt/day	% cPAD
U.S. population	0.000113	<1%
All infants (< 1 year)	0.000068	<1%
Children (1–2 years)	0.000295	<1%
Children (3–5 years)	0.000273	<1%
Children (6–12 years)	0.000186	<1%
Youth (13–19 years)	0.000107	<1%
Adults (20–49 years)	0.000091	<1%
Females (13–49 years)	0.000082	<1%
Adults (50+ years)	0.000074	<1%

This exposure analysis and cPAD represents a conservative estimate of dietary (food only) exposure and risk from the use of mefenpyr-diethyl on barley and wheat. Further refinement, through the use of anticipated residues, percent-of-crop treated estimates and/or monitoring data, would result in a reduction in the exposure estimates and the associated risk. However, in this analysis, even without further refinement, the risk estimate for all population subgroups is less than 1% of the cPAD. This is below the Agency's level of concern (100% of the cPAD) for the general U.S. population and all population subgroups.

However, there is potential for chronic dietary exposure to mefenpyr-diethyl in drinking water. The EECs for surface water and ground water are less than the DWLOC. Thus, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 below.

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

Population Subgroup	cPAD (mg/kg/day)	% cPAD (food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.57	0.000113	3	4	20,000
All infants (< 1 year old)	0.57	0.00007	3	4	5,700
Children (1–2 years old)	0.57	0.000295	3	4	5,700
Females (13–49 years old)	0.57	0.00008	3	4	17,000

3. *Short-term risk and intermediate-term risk*. Mefenpyr-diethyl is not registered for use on any sites that would result in residential exposure.

4. *Aggregate cancer risk for U.S. population*. Mefenpyr-diethyl is not classified as a human carcinogen and thus is not expected to pose a cancer risk.

5. *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 mefenpyr-diethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has submitted an analytical method for mefenpyr-diethyl and its metabolites in wheat and barley using Gas Chromatography with a Mass Selective Detection (GC/MSD). This enforcement method has been reviewed by the Agency and fulfills the guidelines.

The petitioner also submitted an analytical method for mefenpyr-diethyl and its metabolites in Beef Liver also using GC/MSD. The petitioner also submitted an Independent Laboratory Validation of the method.

Adequate enforcement methodology GC/MSD 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 no CODEX, Canadian or Mexican limits for residues of mefenpyr-diethyl in wheat and barley. However, Italy has established an MRL (maximum residue limit) of 0.05 ppm in wheat grain for residues of mefenpyr-diethyl and its metabolites which is consistent with the wheat grain tolerance established today.

C. Conditions

Based on the residue uptake results of the confined rotational studies at 90 gram/hectare (0.80 lb/acre) residue uptakes, the Agency would usually establish a 30–day plantback interval for leafy, fruiting, and root vegetables, and 12–month plantback interval for all other crops other than wheat and barley, which can be replanted at any time. However, at this time, the petitioner has indicated that the application rate will not exceed 30 gram/hectare or 0.0267 lb/acre. Given this reduction to one–third of the application rate used in the study, the Agency believes that a 30–day plantback interval is appropriate for all crops except cereal grains and grasses. The plant back interval for cereal grains and grasses, except wheat and barley, (which can be replanted at any time) is 12–months.

V. Conclusion

Therefore, tolerances are established for the combined residues of mefenpyr-diethyl, 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester, in or on wheat and barley commodities.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0077 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 June 30, 2003.

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

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

2. *Tolerance fee payment*. If you file an objection or request a hearing, you

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0077, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the

agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 17, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.509 is revised to read as follows:

§ 180.509 Mefenpyr-diethyl; tolerance for residues.

(a) *General.* Tolerances are established for residues of the herbicide safener mefenpyr-diethyl (1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester) and its 2,4-dichlorophenyl-pyrazoline metabolites at a rate of 0.0267 pound safener per acre per growing season in or on following commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.2
Barley, straw	0.5
Cattle, meat byproducts	0.1
Goat, meat byproducts	0.1
Hog, meat byproducts	0.1
Horse, meat byproducts	0.1
Sheep, meat byproducts	0.1
Wheat, forage	0.2
Wheat, grain	0.05
Wheat, hay	0.2
Wheat, straw	0.5

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

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

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

[FR Doc. 03–10263 Filed 4–29–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0110; FRL–7300–9]

Pyraflufen-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of pyraflufen-ethyl in or on field corn, potato, and soybean. 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 April 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0110, must be received on or before June 30, 2003.

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

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS Code 111)
- Animal production (NAICS Code 112)
- Food manufacturing (NAICS Code 311)
- Pesticide manufacturing (NAICS Code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0110. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/4 0cfr180_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm.*

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