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 180.631 is amended by revising the introductory text and table in paragraph (a) to read as follows:

§ 180.631 Pyrasulfotole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide pyrasulfotole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of pyrasulfotole ((5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone) and its desmethyl metabolite (5-hydroxy-3-methyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone), calculated as the stoichiometric equivalent of pyrasulfotole, in or on the commodities:

Commodity	Parts per million
Aspirated grain fractions	0.40
Barley, grain	0.02
Barley, hay	0.30
Barley, straw	0.20
Cattle, fat	0.03
Cattle, liver	3.0
Cattle, meat	0.02
Cattle, meat byproducts, except liver	0.70
Eggs	0.02
Goat, fat	0.03
Goat, liver	3.0
Goat, meat	0.02
Goat, meat byproducts, except liver	0.70
Grass, forage	25
Grass, hay	3.5
Hog, fat	0.02
Hog, liver	0.30
Hog, meat	0.02
Hog, meat byproducts, except liver	0.05
Horse, fat	0.03
Horse, liver	3.0
Horse, meat	0.02
Horse, meat byproducts, except liver	0.70
Milk	0.03
Oat, forage	0.10
Oat, grain	0.08
Oat, hay	0.50
Oat, straw	0.20
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat byproducts	0.20
Rye, forage	0.20
Rye, grain	0.02
Rye, straw	0.20
Sheep, fat	0.03
Sheep, liver	3.0
Sheep, meat	0.02
Sheep, meat byproducts, except liver	0.70
Sorghum, grain, forage	1.5
Sorghum, grain, grain	0.70
Sorghum, grain, stover	0.80
Wheat, forage	0.20
Wheat, grain	0.02
Wheat, hay	0.80
Wheat, straw	0.20

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0267; FRL–8870–9]

Mefenpyr-diethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefenpyr-diethyl in or on multiple commodities. Bayer CropScience LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also moves established tolerances for canola and soybean commodities to correct an administrative error.

DATES: This regulation is effective April 29, 2011. Objections and requests for hearings must be received on or before June 28, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0267. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8072; e-mail address: *benbow.bethany@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 those engaged in the following activities:

- 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 to provide 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 electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–

OPP–2010–0267 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 28, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0267, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 23, 2010 (75 FR 35804) (FRL–8831–3), 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 9F7679) by Bayer CropScience LLC, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.509 be amended by establishing tolerances for residues of the herbicide safener, mefenpyr-diethyl including its metabolites and degradates with compliance to be determined by measuring residues of mefenpyr-diethyl, (1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester) and its dichlorophenyl-pyrazoline metabolites, in or on grass, forage at 1.5 parts per million (ppm); grass, hay at 0.05 ppm; sorghum, forage at 0.1 ppm; sorghum, grain at 0.01 ppm; and sorghum, stover at 0.05 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has increased the proposed tolerance for all proposed commodities as follows: Grass, forage from 1.5 to 1.6 ppm; grass, hay from 0.05 to 0.2 ppm; sorghum, forage from 0.1 to 0.4 ppm; sorghum, grain from 0.01 to 0.04 ppm; and sorghum, stover from 0.05 to 0.2 ppm. The reasons for these changes are explained in Unit IV.C.

In the **Federal Register** of December 10, 2008 (73 FR 74977) (FRL–8390–8), EPA established tolerances for residues of mefenpyr-diethyl in or on canola, seed; soybean, forage; soybean, hay; and soybean, seed. These tolerances were identified as rotational crop tolerances in the final rule; however, they were placed in paragraph (a) of 40 CFR 180.509 in error. They should have been placed in paragraph (d) as tolerances for indirect or inadvertent residues. EPA is moving these tolerances from paragraph (a) to paragraph (d) to correct this administrative error. Moving these tolerances between subsections has no substantive effect, it merely makes them easier to identify as rotational crop tolerances.

III. Aggregate Risk Assessment and Determination of Safety

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. * * *"

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for mefenpyr-diethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mefenpyr-diethyl 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.

Mefenpyr-diethyl has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It is not a dermal irritant but is a slight ocular irritant and dermal sensitizer. Repeated exposure of rats *via* the dermal route did not induce any treatment-related effects at dose levels up to and including the limit dose. Repeated exposure studies *via* the oral route demonstrate that the target organs are the liver and hematopoietic system in dogs, mice, and rats. Effects observed in dogs included increased liver weight and alkaline phosphatase activity (both sexes), focal liver lesions (females), slight anemia (both sexes), decreased mean body weight and body weight gain (females) and decreased food consumption (both sexes). Effects observed in mice included decreased body weight and kidney weight, increased liver weight, and hepatocyte hypertrophy (males), as well as decreased bilirubin and increased lactic acid dehydrogenase values (females). Effects observed in rats included increases in reticulocyte counts (both sexes), and decreased red blood count, hemoglobin, and hematocrit values (females). Mefenpyr-diethyl was negative for carcinogenicity in rats and mice, and is classified as "not likely to be carcinogenic to humans." The available studies did not indicate any genotoxic or neurotoxic potential. Developmental toxicity was not observed in the rat but was observed in the rabbit (abortions) at the same dose level producing maternal toxicity. Mefenpyr-diethyl did not induce any signs of reproductive toxicity. The developmental toxicity studies in rats and rabbits, as well as the reproductive toxicity study in rats, did not demonstrate any pre- or post-natal sensitivity.

Specific information on the studies received and the nature of the adverse effects caused by mefenpyr-diethyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document, *Mefenpyr-diethyl (HOE 107892) Safener: Revised Human Health Risk Assessment to Support the New use Petition on Sorghum [grain, stover, and forage] and Grass Grown for Seed (including Conservation Reserve Program areas),* at pages 31–36 in docket ID number EPA–HQ–OPP–2010–0267.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for mefenpyr-diethyl used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MEFENPYR-DIETHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	No hazard was identified in any toxicity study for this duration of exposure.		
Acute dietary (General population including infants and children).	No hazard was identified in any toxicity study for this duration of exposure.		
Chronic dietary (All populations)	NOAEL = 51 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.51 mg/kg/day ..... cPAD = 0.51 mg/kg/day	chronic oral toxicity study (dog). LOAEL = 260 mg/kg/day, based on increased liver weight in both sexes, cholestasis, and increased alkaline phosphatase. chronic toxicity/carcinogenicity study (rat). LOAEL = 252 (males)/318 (females) mg/kg/day, based on statistically significant increases in reticulocyte counts in both sexes, and decreased RBC, hemoglobin, and hematocrit values in females. NOAEL = 48.5 (males)/60 (females) mg/kg/day.
Cancer (oral)	Classification: Not likely to be carcinogenic to humans.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to mefenpyr-diethyl, EPA considered exposure under the petitioned-for tolerances as well as all existing mefenpyr-diethyl tolerances in 40 CFR 180.509. EPA assessed dietary exposures from mefenpyr-diethyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for mefenpyr-diethyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA conducted a highly conservative chronic dietary risk assessment for mefenpyr-diethyl using tolerance level residues and assuming 100% crop treated for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA classified mefenpyr-diethyl as "not likely to be carcinogenic to humans." Therefore, an exposure assessment to evaluate cancer risk is unnecessary for this chemical.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for mefenpyr-diethyl in drinking water. These simulation models take into

account data on the physical, chemical, and fate/transport characteristics of mefenpyr-diethyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW2) models, the estimated drinking water concentrations (EDWCs) of mefenpyr-diethyl for chronic exposures for non-cancer assessments are estimated to be 3 ppb for surface water and 4 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 4 ppb was used to assess the contribution to drinking 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 any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found mefenpyr-diethyl to share a common mechanism of toxicity with any other substances, and mefenpyr-diethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that mefenpyr-diethyl does not have 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 EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is little concern for prenatal toxicity resulting from exposure to mefenpyr-diethyl. There is no evidence of increased susceptibility [qualitative and quantitative] following *in utero* exposure to mefenpyr-diethyl in either the rat or rabbit developmental toxicity study, and there is no evidence of increased susceptibility [qualitative or quantitative] following *in utero* and/or pre-/post-natal exposure in the 2-generation reproduction study in rats. Developmental toxicity was not observed in the rat at the limit dose (1000 mg/kg/day) in one of two available rat developmental studies. In the second study, the only effects observed were decreased body-weight gain and food efficiency during the first week of dosing and increased spleen weights in the maternal animal and a marginal decrease in fetal body weight/body-weight gain during lactation (postnatal study). Developmental toxicity (abortions) was observed in the rabbit at a dose level of 250 mg/kg/day. In the reproduction study, decreased body weight and body-weight gain (parental animal and offspring) and an increase in spleen weight and in the severity (not incidence) of splenic extramedullary hematopoiesis were observed in females. There is no evidence of neurotoxicity, and there are no residual concerns.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA safety factor were reduced to 1X. That decision is based on the following findings:

i. The toxicology database for mefenpyr-diethyl is largely complete, missing only acute and subchronic neurotoxicity studies and an immunotoxicity study. EPA has determined that an additional uncertainty factor is not needed to account for the lack of these studies for the following reasons:

- There is no evidence in the existing studies to suggest that mefenpyr-diethyl targets either the immune system or the nervous system. EPA considered the entire toxicity database (subchronic, chronic, carcinogenicity, developmental and reproductive studies) of mefenpyr-diethyl for evidence of potential immunotoxic and neurotoxic effects. EPA did note that enlarged spleens, more severe hematopoiesis and hemosiderin deposits, and increased spleen weights were observed in mice at doses greater than the limit dose. However, these were determined to be non-specific changes not indicative of immunotoxicity. Additionally, no evidence of neurotoxicity was found. Therefore, based on the above considerations, EPA does not believe that conducting acute and subchronic neurotoxicity or immunotoxicity studies will result in a NOAEL less than the NOAEL of 51 mg/kg/day already set for mefenpyr-diethyl.
- Overall, the toxicity of mefenpyr-diethyl is low. The endpoints were assumed by EPA to be treatment-related, a conservative assumption intended to ensure the risk assessment is protective of potential effects.

Based on these considerations, EPA does not expect the required studies to provide lower points of departure than those currently selected for risk assessment, and an additional uncertainty factor is not needed to account for the lack of these studies.

ii. There is no evidence of neurotoxicity in the available toxicology database and no evidence of significant developmental toxicity in either the rat or rabbit developmental toxicity studies. Based on these considerations, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence of increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to mefenpyr-diethyl in drinking water. These assessments will not underestimate the exposure and risks posed by mefenpyr-diethyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, mefenpyr-diethyl is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to mefenpyr-diethyl from food and water will utilize less than 1% of the cPAD for infants, less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for mefenpyr-diethyl.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because mefenpyr-diethyl does not have residential uses that would result in residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for, mefenpyr-diethyl.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because mefenpyr-diethyl does not have residential uses that would result in residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for, mefenpyr-diethyl.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, mefenpyr-diethyl is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to mefenpyr-diethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. An enforcement method for plants entitled "An Analytical Method for Determination of Residues of AE F107892 (mefenpyr-diethyl) and its Metabolites in Wheat and Barley by Gas Chromatography using Mass Selective Detection" is available. Radiovalidation and independent laboratory validation (ILV) data have been submitted for the plant method. The Agency determined that this method is suitable for food tolerance enforcement of mefenpyr-diethyl and the three metabolites AE F094270, AE F113225, and/or AE F109453.

This 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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for mefenpyr-diethyl.

C. Revisions to Petitioned-for Tolerances

EPA has revised the sorghum commodity terms and the tolerances levels for both sorghum and grass commodities. The sorghum commodity terms have been revised from "sorghum, grain;" "sorghum, forage;" and "sorghum, stover" to "sorghum, grain, grain;" "sorghum, grain, forage;" and "sorghum, grain, stover" respectively to agree with the accepted terminology in the Agency's Food and Feed Vocabulary. EPA has increased the proposed tolerance for all proposed commodities as follows: Grass, forage from 1.5 to 1.6 ppm; grass, hay from 0.05 to 0.2 ppm; sorghum, grain, forage from 0.1 to 0.4 ppm; sorghum, grain, grain from 0.01 to 0.04 ppm; and sorghum, grain, stover from 0.05 to 0.2 ppm. The grass, forage tolerance was increased from 1.5 ppm to 1.6 ppm because total mefenpyr-diethyl resides were detected up to 1.59 ppm at the proposed pre-harvest interval of 0 days in crop field trials. Since there were no detectible residues of parent or metabolites in the crop field trials for grass (hay) or sorghum, grain (forage; grain; or stover), the tolerances are being set based on the sum of the lowest level of method validation (LLMV) of the parent (mefenpyr-diethyl) and the three metabolites. The LLMV is 0.05 ppm for grass, hay and sorghum, grain, stover; 0.10 ppm in sorghum, grain, forage; and 0.01ppm in sorghum, grain, grain.

Finally, as noted in Unit II, the petitioner requested that the proposed tolerances be established for residues of mefenpyr-diethyl, including its metabolites and degradates, but that compliance with the tolerance levels be determined by measuring only the sum of mefenpyr-diethyl and its dichlorophenyl-pyrazoline metabolites, calculated as the stoichiometric equivalent of mefenpyr-diethyl, in or on the commodities. EPA is revising the tolerance expression for existing tolerances in 40 CFR 180.509 to agree with the tolerance expression proposed in this petition. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of the safener, mefenpyr-diethyl, including its metabolites and degradates, in or on grass, forage at 1.6 ppm; grass, hay at 0.2 ppm; sorghum, grain, forage at 0.4 ppm; sorghum, grain, grain at 0.04 ppm; and sorghum, grain, stover at 0.2 ppm. Compliance with these tolerances is to be determined by measuring the sum of mefenpyr-diethyl, (1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester) and its dichlorophenyl-pyrazoline metabolites, calculated as the stoichiometric

equivalent of mefenpyr-diethyl, in or on the commodity.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children From Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.,* 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination With Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 21, 2011.

Lois Rossi,

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), 346a and 371.

■ 2. Section 180.509 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 180.509 Mefenpyr-diethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the safener, mefenpyr-diethyl, including its metabolites and degradates, when applied at a rate no greater than 0.053 pound safener per acre per growing season in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of 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, calculated as the stoichiometric equivalent of mefenpyr-diethyl, in or on the commodity.

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
Grass, forage	1.6
Grass, hay	0.2
Hog, meat byproducts	0.1
Horse, meat byproducts	0.1
Sheep, meat byproducts	0.1
Sorghum, grain, forage	0.4
Sorghum, grain, grain	0.04
Sorghum, grain, stover	0.2
Wheat, forage	0.2
Wheat, grain	0.05
Wheat, hay	0.2
Wheat, straw	0.5

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of mefenpyr-diethyl, including its metabolites and degradates, when applied at a rate no greater than 0.053 pound safener per acre per growing season in or on the commodities identified in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of 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, calculated as the stoichiometric equivalent of mefenpyr-diethyl, in or on the commodity.

Commodity	Parts per million
Canola, seed	0.02
Soybean, forage	0.1
Soybean, hay	0.1
Soybean, seed	0.02

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