possess, carry, and transport concealed, loaded, and operable firearms within a national wildlife refuge in accordance with the laws of the state in which the wildlife refuge, or that portion thereof, is located, except as otherwise prohibited by applicable Federal law.

Dated: December 5, 2008.

Lyle Laverty,

Assistant Secretary of the Interior for Fish and Wildlife and Parks.

[FR Doc. E8–29249 Filed 12–9–08; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 41

[Docket No.: PTO–P–2007–0006]

RIN 0651–AC12

Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals; Delay of Effective and Applicability Dates

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule; delay of effective and applicability dates.

SUMMARY: On June 10, 2008, the United States Patent and Trademark Office (Office) published the final rule that amends the rules governing practice before the Board of Patent Appeals and Interferences (BPAI) in *ex parte* patent appeals. The final rule states that the effective date is December 10, 2008, and that the final rule shall apply to all appeals in which an appeal brief is filed on or after the effective date. On June 9, 2008, the Office published a 60-Day **Federal Register** Notice requesting the Office of Management and Budget (OMB) to establish a new information collection for BPAI items in the final rule and requesting public comment on the burden impact of the final rule under the provisions of the Paperwork Reduction Act (PRA). On October 8, 2008, the Office published a 30-Day **Federal Register** Notice stating that the proposal for the collection of information under the final rule was being submitted to OMB and requesting comments on the proposed information collection be submitted to OMB. The proposed information collection is currently under consideration by OMB. Since the review by OMB has not been completed, the Office is hereby notifying the public that the effective and applicability date of the final rule is not December 10, 2008. The effective and applicability dates will be identified in a subsequent notice.

DATES: The effective date for the final rule published at 73 FR 32938, June 10, 2008, is delayed, pending completion of OMB review of the proposed information collection under the PRA. The Office will issue a subsequent notice identifying a revised effective date on which the final rule shall apply.

FOR FURTHER INFORMATION CONTACT: Allen MacDonald, Administrative Patent Judge, at (571) 272–9797, or Kimberly Jordan, Chief Trial Administrator, at (571) 272–4683, Board of Patent Appeals and Interferences, directly by phone, or by facsimile to (571) 273–0043, or by mail addressed to: Mail Stop Board of Patents Appeals and Interferences, P.O. Box 1450, Alexandria, VA 22313–1450.

SUPPLEMENTARY INFORMATION: On June 10, 2008, the United States Patent and Trademark Office (Office) published the final rule that amends the rules governing practice before the Board of Patent Appeals and Interferences (BPAI) in *ex parte* patent appeals. *See Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals;* Final Rule, 73 FR 32938 (June 10, 2008), 1332 *Off. Gaz. Pat. Office* 47 (July 1, 2008) (hereinafter ''BPAI final rule 2008''). The BPAI final rule 2008 states that the effective date is December 10, 2008, and that the final rule shall apply to all appeals in which an appeal brief is filed on or after the effective date.

On June 9, 2008, the Office published a new information collection request for OMB to review several BPAI items in the BPAI final rule 2008 as subject to the PRA. *See Board of Patent Appeals and Interferences Actions;* New Collection, Comment Request, 73 FR 32559 (June 9, 2008) (hereinafter ''60-Day Notice''). In addition to requesting OMB to establish a new information collection, the 60-Day Notice invited comments from the public and other Federal agencies on the burden impact of the proposed information collection under the provisions of the PRA. The 60-Day Notice specified that comments were to be submitted on or before August 8, 2008.

On October 8, 2008, the Office published a notice that the proposed information collection was being submitted to OMB and public comments on the proposed collection were to be submitted to OMB on or before November 7, 2008. *See Submission for OMB Review; Comment Request;* 73 FR 58943 (October 8, 2008) (hereinafter ''30-Day Notice''). On October 9, 2008, the Office filed a Supporting Statement with OMB (*http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=200809–0651–003*). The Supporting Statement included the Office's response to comments received following the 60–Day Notice. The 30–Day Notice requested public comments be submitted to OMB on or before November 7, 2008.

The proposed information collection request is currently under consideration for approval by OMB. The review by OMB has not been completed. Therefore, the effective and applicability dates of the BPAI final rule 2008 will not be December 10, 2008. The Office will notify the public when the revised effective and applicability dates are set. In the subsequent notification, the Office will provide at least a 30-day time period before the BPAI final rule 2008 becomes effective.

On November 20, 2008, the Office published a clarification notice on the effective date provision. *See Clarification of the Effective Date Provision in the Final Rule for Ex Parte Appeals,* 73 FR 70282 (November 20, 2008). As indicated in the clarification notice, the Office will not hold an appeal brief as non-compliant solely for following the new format even though it is filed before the effective date. Thus, appeal briefs filed before the effective date of the BPAI final rule 2008 (yet to be determined) must either comply with current 37 CFR 41.37 (which remains in effect) or revised 37 CFR 41.37 (the effective date of which has yet to be determined). Furthermore, the Office has posted a list of questions and answers on the USPTO Web site (at *http://www.uspto.gov/web/offices/dcom/bpai/rule.html*) regarding the implementation of the BPAI final rule 2008. These questions and answers will be revised accordingly.

Dated: December 5, 2008.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E8–29297 Filed 12–9–08; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0672; FRL–8390–8]

Mefenpyr-diethyl and Metabolites; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the herbicide safener, mefenpyr-diethyl (CAS Reg. No. 135590–91–9), also known as 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester and its 2,4-dichlorophenyl-pyrazoline metabolites, applied at a rate no greater than 0.053 pounds safener per acre per growing season, in or on the rotational crop commodities soybean seed, soybean hay, soybean forage and canola seed. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 10, 2008. Objections and requests for hearings must be received on or before February 9, 2009, 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–2007– 0672. 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: Karen Samek, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347-8825; e-mail address: *samek.karen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2007–0672 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 February 9, 2009.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0672, 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. Petition for Tolerance

In the **Federal Register** of August 22, 2007 (72 FR 47008) (FRL–8145–1), 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 7E7224) by Bayer CropScience, 2 T.W., Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.509 be amended for 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 by increasing the maximum allowable seasonal use rate to 0.053 lb safener/acre(A), as well as, establishing rotation crop tolerances on soybean seed at 0.02 parts per million (ppm); soybean forage at 0.1ppm; soybean hay at 0.1 ppm; and canola seed at 0.02 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the Notice of Filing.

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 the petitioned-for tolerances for residues of the herbicide safener, mefenpyr-diethyl, in or on soybean seed at 0.02 ppm, soybean forage at 0.1 ppm, soybean hay at 0.1 ppm, and canola seed at 0.02 ppm; as well as the petitioned-for request to increase the maxium allowable seasonal use rate from 0.026 lb safener/A to 0.053 lb safener/A. EPA's assessment of exposures and risks associated with establishing 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.

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 dermal sensitizer and ocular irritant. Metabolism studies indicate that mefenpyr-diethyl is rapidly metabolized, widely distributed, and primarily excreted via the urine. Repeat exposure 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 demonstrated that the target organs are the liver and hematopoietic system in dogs, mice, and rats. Mefenpyr-diethyl was negative for carcinogenicity in rats and mice, and classified as ''not likely to be carcinogenic to humans.'' Mefenpyr-diethyl did not show any genotoxic potential. Developmental toxicity was not observed in the rat at the limit dose (1,000 milligrams/kilogram/day (mg/kg/day)) 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 or neurotoxic potential. The developmental toxicity studies in rats and rabbits, as well as the reproductive toxicity study in rats, did not demonstrate any prenatal or postnatal sensitivity. There is a lack of evidence of neurotoxicity in any study on mefenpyr-diethyl and therefore there is no concern for neurotoxicity resulting from exposure to mefenpyr-diethyl.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 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 DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

Exposure/Scenario	Point of Departure and Uncertainty Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population, including infants and children)	No hazard was identified in any toxicity study for this duration of exposure.		
Acute Dietary (Females 13–49 years of age)	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 phosphates.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MEFENPYR-DIETHYL FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS—Continued

Exposure/Scenario	Point of Departure and Uncertainty Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer	Classification: Not likely to be carcinogenic to humans.		

Point of Departure = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF=uncertainty factor. UF_A = extrapolated from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

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. The residue of concern for both risk assessment and tolerance setting purposes in plants and animals is the parent compound, mefenpyr-diethyl, and its 2,4-dichlorophenyl-pyrazoline metabolites. 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*. A highly conservative chronic dietary risk assessment was conducted for food and drinking water for mefenpyr-diethyl. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals. As to residue levels in food, EPA assumed that 100% of crops with requested uses of mefenpyr-diethyl are treated and that all treated crops contain residues at the tolerance level.

No new magnitude of the residue data, reflecting the new proposed seasonal rate of 0.053 lb safener/A, were submitted for the primary crop commodities. It is, however, noted that the field trial data that were previously submitted in support of the petition to establish tolerances for primary crops were conducted at an exaggerated rate of 0.089 lb/safener/A. Therefore, the Agency has determine that the established tolerances for primary crop commodities remain adequate to support the proposed higher application rate.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified mefenpyr-diethyl as a ''Not likely to be carcinogenic to humans;'' therefore, an exposure assessment for assessing cancer risk is unnecessary for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for mefenpyr-diethyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

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-GROW) models, the estimated drinking water concentrations (EDWCs) of mefenpyr-diethyl and its transformation products for chronic exposures for non-cancer assessments are estimated to be 3 parts per billion (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). No products containing mefenpyr-diethyl are available for sale in the residential market because of the crops specified on the applicable labels. As such, a residential risk assessment was not conducted.

4. *Cumulative effects*. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to mefenpyr-diethyl and 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 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(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*. The prenatal and postnatal toxicity database for mefenpyr-diethyl includes rat and rabbit developmental toxicity studies and a two-generation reproduction toxicity study in rats. There was no evidence of increased

susceptibility of *in utero* rats or rabbits in the prenatal developmental studies or of young rats in the two-generation reproduction study.

Developmental toxicity was not observed in the rat at the limit dose (1,000 mg/kg/day). The only effects observed in the rat developmental toxicity study 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). In the rabbit developmental toxicity study, developmental toxicity (abortion) was observed at the same dose level producing maternal toxicity (250 mg/kg/day).

In the reproduction study, parental toxicity consisted of decreased body weight and body-weight gain, and an increase in spleen weight and in the severity (not incidence) of splenic extramedullary hematopoiesis in females. In the pups, decreased body weight and body-weight gains were observed at the same dose levels as the parental animals. The NOAEL is 82 mg/kg/day (1,000 ppm) for both the parental animal and offspring.

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

i. The toxicity database for mefenpyr-diethyl is complete, with the exception of immunotoxicity studies which are new data requirements under the revised Part 158 Toxicology Data Requirements (40 CFR part 158). In the absence of these studies, EPA has evaluated the available toxicity data for mefenpyr-diethyl and determined that an additional database uncertainty factor is not needed, based on the following conclusions:

No acute and subchronic Neurotoxcity studies are available, however there is no evidence of neurotoxicity in the toxicology database on mefenpyr-diethyl, which includes subchronic, chronic, developmental toxicity, and reproduction studies performed at dose of 250 mg/kg/day and above. Therefore, based on the above considerations, the Agency does not believe that conducting acute and subchronic neurotoxicity studies will result in a NOAEL less than the NOAEL of 51 mg/kg/day already set for mefenpyr-diethyl; therefore additional neurotoxicity studies are not necessary and the 10x safety factor can be reduced to 1x.

Considering that the application of mefenpyr-diethyl will be by either aerial application or spray boom equipment, the 28–day inhalation study is required as confirmatory data. However, the additional uncertainty factor for database uncertainties does not need to be applied since the MOE is >1,000 and significant inhalation exposures of concern are not anticipated.

EPA considered the entire toxicity database for mefenpyr-diethyl for potential adverse effects on the thymus and spleen as indications of potential immunotoxicity and noted 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. Therefore, based on the above considerations, EPA does not believe that conducting a special series (Harmonized Guideline 870.7800), immunotoxicity study will result in a NOAEL less than the NOAEL of 51 mg/kg/day already set for mefenpyr-diethyl and an additional uncertainty factor for database uncertainties does not need to be applied.

ii. There is no indication that mefenpyr-diethyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that mefenpyr-diethyl results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming 100 PCT 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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

2. *Chronic risk*. Exposure to mefenpyr-diethyl food and drinking water results in an estimated risk equivalent to <1% of the cPAD for the general population and all regulated subpopulations, including infants and children as well.

There are no residential uses for mefenpyr-diethyl, therefore the aggregate risk assessments include the contribution of risk from dietary (food and water) sources only.

3. *Aggregate cancer risk for U.S. population*. Mefenpyr-diethyl was negative for carcinogenicity in rats and mice and thus is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

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 (Report Supplement to EPA MRID 45457401)'' is available. Radiovalidation and independent laboratory validation (ILV) data have been submitted for the plant method. The Agency analytical lab has concluded that this method is suitable for food tolerance enforcement of mefenpyr-diethyl and its 2,4-dichlorophenyl-pyrazoline metabolites. 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 Tolerances

No Codex, Canadian, or Mexican maximum residue limits are established for residues of mefenpyr-diethyl and its metabolites in crop or livestock commodities; therefore, there are no issues with international harmonization raised by this action.

V. Conclusions

Therefore, 40 CFR 180.509 is amended for 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 by increasing the maximum allowable seasonal use rate to 0.053 lb safener/A, as well as rotation crop 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 in or on soybean seed at 0.02 ppm; soybean forage at 0.1 ppm; soybean hay at 0.1 ppm; and canola seed at 0.02 ppm.

It should be noted that no new magnitude of the residue data, reflecting the new proposed seasonal rate of 0.053 lb safener/A, were submitted for the primary crop commodities. However, field trail data that were previously submitted in support of the petition to establish tolerances for primary crops were conducted at an exaggerated rate of 0.089 lb safener/A. Therefore, the Agency determined that the established tolerances for primary crop commodities remain adequate to support the proposed higher application rate.

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, *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) (Public Law 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: December 2, 2008.

Donald R. Stubbs,

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), 346a 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, when applied at a rate no greater than 0.053 pound safener per acre per growing season in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.2
Barley, straw	0.5
Canola, seed	0.02
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
Soybean forage	0.1
Soybean, hay	0.1
Soybean, seed	0.02

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

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

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

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