

will meet on Monday, October 6, 1997, from 8:30 a.m. to 5:00 p.m. Tuesday, October 7, 1997, from 8:30 a.m. to 12:00 p.m.

ADDRESSES: The meeting will be held at: the National Airport Doubletree Hotel, 300 Army Navy Drive, Arlington-Crystal City, VA, 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Elaine Y. Lyon, Office of Pesticide Programs (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: (703) 305-5306; (703) 308-1850 (fax); e-mail: Lyon.elaine@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The tentative agenda of the SFIREG Working Committee on Water Quality and Pesticide Disposal includes the following:

1. Surface Water - storm water retention ponds and sanitary waste water treatment facilities.
2. Lysimeters technology.
3. Update on state management plan rule.
4. Update on restricted use product rule.
5. Measures of success.
6. Rinse water reuse.
7. Reports from committee members.
8. Other topics as appropriate.

List of Subjects

Environmental protection.

Dated: September 22, 1997.

Jay Ellenberger,

Acting Director, Field and External Affairs Division, Office of Pesticide Programs.

[FR Doc. 97-25757 Filed 9-25-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-760; FRL-5740-2]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-760, must be received on or before October 27, 1997.

ADDRESSES: By mail submit written comments to: Public Information and

Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. W-57, 4th floor, CS #1, Westfield Building North Tower, 2800 Crystal Drive, Arlington, VA 22202, 703-308-8371, e-mail: gairola.indira@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-760] (including comments and data submitted electronically as described

below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-760] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 16, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

AgrEvo

PP 7F4850

EPA has received a pesticide petition (PP 7F4850) from AgrEvo, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of herbicide safener Mefenpyr-diethyl (HOE 107892) on wheat and barley

commodities. The proposed analytical method involves homogenization, filtration, partition and cleanup with analysis by high performance liquid chromatography using UV detection. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCa; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The fate of mefenpyr-diethyl has been determined in young barley plants and the nature of the residue is understood. Residues of concern are mefenpyr-diethyl and its 2,4-dichlorophenyl-pyrazoline metabolites, all of which are detected and quantified by the analytical method described above.

Residue trials have been conducted in the United States in 1995 and 1996. When applied as a single application at a rate of 0.089 lb. of safener per acre, combined residues in wheat or barley grain did not exceed 0.04 ppm. In wheat or barley straw, combined residues did not exceed 0.67 ppm, and in wheat or barley hay combined residues did not exceed 0.35 ppm. In these same trials, combined residues did not exceed 0.55 ppm in wheat forage. Thus, the proposed tolerances of 0.05 ppm in barley and wheat grain, 0.75 ppm in wheat straw and forage, 0.5 ppm in wheat and barley hay, and 1.0 ppm in barley straw are adequate.

2. *Analytical method.* A practical analytical method utilizing gas chromatography and a mass selective detector is available for detecting and measuring levels of mefenpyr-diethyl and its 2,4-dichlorophenyl-pyrazoline containing metabolites in wheat grain and straw. The limit of quantitation (LOQ) is 0.01 mg/kg (ppm) in wheat and barley grain, 0.05 mg/kg (ppm) in wheat and barley straw and wheat hay, and 0.1 ppm in wheat forage.

3. *Magnitude of residues.* The fate of mefenpyr-diethyl has been determined in young barley plants and the nature of the residue is understood. Residues of concern are mefenpyr-diethyl and its 2,4-dichlorophenyl-pyrazoline metabolites, all of which are detected and quantified by the analytical method described above.

Residue trials have been conducted in the United States in 1995 and 1996. When applied as a single application at a rate of 0.089 lb. of safener per acre, combined residues in wheat or barley grain did not exceed 0.04 ppm. In wheat

or barley straw, combined residues did not exceed 0.67 ppm, and in wheat or barley hay combined residues did not exceed 0.35 ppm. In these same trials, combined residues did not exceed 0.55 ppm in wheat forage. Thus, the proposed tolerances of 0.05 ppm in barley and wheat grain, 0.75 ppm in wheat straw and forage, 0.5 ppm in wheat and barley hay, and 1.0 ppm in barley straw are adequate.

The metabolism of mefenpyr-diethyl in poultry is adequately understood. Laying hens were fed the compound at a level approximately 5-times the worst case dietary burden for 14-days. Low levels of residues of mefenpyr-diethyl were detected in fat, and low levels of residues of mefenpyr-diethyl and its 2,4-dichlorophenyl-pyrazoline containing metabolites were detected in liver and eggs.

The metabolism of mefenpyr-diethyl in ruminants is also adequately understood. A lactating goat was dosed with the compound at a level approximately 56-times the worst case dietary burden for 7-days. Low levels of residues of mefenpyr-diethyl and/or its 2,4-dichlorophenyl-pyrazoline containing metabolites were detected in liver and eggs.

B. Toxicological Profile

1. *Acute toxicity.* The acute oral LD₅₀ of mefenpyr-diethyl was greater than 5,000 mg/kg in both rats and mice. The acute rat dermal LD₅₀ was greater than 4,000 mg/kg, and the acute rat inhalation LC₅₀ (4-hour) was greater than 1.32 mg/l. Mefenpyr-diethyl was slightly irritating to the eyes of rabbits. It was not irritating to rabbit skin in a standard dermal irritation study but was a weak dermal sensitizer in a guinea pig maximization study. Evidence of photoirritation, but no photosensitization, was observed in other studies with guinea pigs. Based on these results, mefenpyr-diethyl is expected to be classified as TOXICITY CATEGORY IV for acute oral toxicity and skin irritation, and TOXICITY CATEGORY III for acute dermal and inhalation toxicity, and eye irritation.

2. *Genotoxicity.* No evidence of genotoxicity was observed in a battery of studies including *Salmonella* and *E. coli* bacterial gene mutation assays, an HGPRT gene mutation assay in Chinese hamster cells, a mouse micronucleus assay, an *in vitro* chromosome aberration assay, and an *in vitro* unscheduled DNA synthesis assay.

3. *Reproductive and developmental toxicity.* Two rat developmental toxicity studies have been conducted with mefenpyr-diethyl. In the first study, Wistar rats were administered

mefenpyr-diethyl by gavage at dose levels of 0 and 1,000 mg/kg body weight/day on gestation days 7 to 16. The fetuses were delivered by cesarean section on gestation day 21 and evaluated for external, visceral and/or skeletal anomalies. No maternal or developmental effects were noted in this study. Thus, the NOEL for maternal and developmental effects was considered to be 1,000 mg/kg bodyweight. In the second study, Wistar rats were again administered mefenpyr-diethyl by gavage at dose levels of 0 and 1,000 mg/kg body weight/day on gestation days 7 to 16, but the dams were then allowed to deliver normally and the offspring were evaluated for up to 44-days post-partum. No maternal effects were observed in this study. There was a marginal decrease in the body weight of the offspring at birth and during lactation but no other changes in physical, functional, or behavioral endpoints were observed.

In a rabbit developmental toxicity study, mefenpyr-diethyl was administered by gavage to Himalayan rabbits at dose levels of 0, 40, 100, and 250 mg/kg body weight/day on gestation days 6 to 18. The highest dose tested was toxic to both dams and embryos, as evidenced by a decreased food and water consumption, decreased maternal body weights, abortions, and increased incidences of intrauterine death. No morphological effects on the offspring were noted. The NOEL for maternal and embryonic toxicity was considered to be 100 mg/kg body weight.

A 2-generation reproduction study was conducted in Wistar rats fed diet containing mefenpyr-diethyl at dietary concentrations of 0, 200, 1,000, and 5,000 ppm for 70-days then continuously through successive generations. Effects observed at 5,000 ppm consisted of decreased food consumption, decreased body weight gain, increased spleen weights and increased splenic hematopoiesis in the parental animals, and decreased body weights in the pups during lactation. No effects on reproductive parameters were noted. Thus, the overall study NOEL for both parents and the progeny was considered to be 1,000 ppm, equivalent to a mean daily substance intake of 75 and 99 mg/kg bodyweight for the males and females, respectively.

4. *Subchronic toxicity.* In a 90-day feeding study, mefenpyr-diethyl was administered to Wistar rats at concentrations of 0, 100, 500, 2,500, and 7,500 ppm in the diet. Based on slight reduction in body weight at 7,500 ppm and minimal to slight anemia at 2,500 and 7,500 ppm, the NOEL was considered to be 500 ppm, equivalent to

a mean daily test substance intake of 42 mg/kg body weight.

In a 90-day feeding study in beagle dogs, mefenpyr-diethyl was administered in the diet at concentrations of 0, 400, 2,000, and 10,000 ppm. Effects observed at 10,000 ppm included decreased food consumption and body weight gain, increased liver weights, anemia, and alterations in several clinical chemistry parameters. There were no histopathological changes. Increased liver weight and increases in two serum enzymes were noted at 2,000 ppm. Thus, the NOEL was considered to be 400 ppm, equivalent to a mean daily test substance intake of 15 mg/kg body weight.

In a 90-day feeding study in NMRI mice, mefenpyr-diethyl was administered in the diet at concentrations of 0, 100, 500, 2,500, and 7,500 ppm. Effects noted at 7,500 ppm included decreased food consumption and body weight gain, slight anemia, alterations in several hematology and clinical chemistry parameters, slightly increased spleen weights, and markedly increased liver weights. Histopathological evaluation revealed hepatocellular hypertrophy in the liver, and increased hemosiderin deposits and compensatory hematopoiesis in the spleen. Effects noted at 2,500 ppm included decreased weight gain, minor alterations in several clinical pathology parameters, slight increases in liver weights, and hepatocellular hypertrophy. The NOEL for this study was considered to be 500 ppm, equivalent to a mean daily substance intake of 89 mg/kg body weight.

In a subchronic dermal toxicity study, mefenpyr-diethyl was applied to Wistar rats at dose levels of 0, 100, 300, and 1,000 mg/kg body weight for six hours per day, 5-days a week, for a total of 21-days over a period of 30-days. Based on slight anemia observed among the females at 1,000 mg/kg body weight, the NOEL was considered to be 300 mg/kg bodyweight.

5. Chronic toxicity. A 2-year feeding chronic toxicity/carcinogenicity study was conducted in Wistar rats with mefenpyr-diethyl at dietary concentrations of 0, 40, 200, 1,000, and 5,000 ppm. No evidence of carcinogenicity was observed in this study. Based on slight reductions in female body weights and slight anemia in both sexes at 5,000 ppm, the NOEL was considered to be 1,000 ppm, equivalent to a mean daily substance intake of 48 and 60 mg/kg bodyweight in males and females, respectively.

A 2-year feeding chronic toxicity/carcinogenicity study was conducted in

NMRI mice with mefenpyr-diethyl at dietary concentrations of 0, 20, 100, 500, and 2,500 ppm. No evidence of carcinogenicity was observed in this study. Slight but consistently reduced body weights and slight increases in liver weight were noted in male mice at 2,500 ppm. Hepatocellular hypertrophy was noted in both sexes at 2,500 ppm, in male mice only at 500 ppm, and in a few males at 100 ppm. Hematology, serum biochemistry and urinalysis parameters were unaffected. Because of the low incidence and severity of the hepatocellular hypertrophy at 100 ppm, the NOAEL for this study was considered to be 500 ppm, equivalent to a mean daily intake of 71 mg/kg body weight.

A 1-year feeding study was conducted in beagle dogs with mefenpyr-diethyl at dietary concentrations of 0, 60, 300, 1,500, and 7,500 ppm. There was a slight decrease in food consumption in males at 7,500 ppm, but body weights were unaffected. Other effects at this dose level consisted of slight anemia, a slight increase in platelet count, alterations in several clinical chemistry parameters, moderately to markedly increased liver weights, slightly increased thyroid weights, slightly decreased prostate weights, and minimal intrahepatic cholestasis. The NOEL for this study was considered to be 1,500 ppm, equivalent to a mean daily test substance intake of 55 mg/kg body weight.

6. Animal metabolism. The metabolism of mefenpyr-diethyl in poultry is adequately understood. Laying hens were fed the compound at a level approximately 5-times the worst case dietary burden for 14-days. Low levels of residues of mefenpyr-diethyl were detected in fat, and low levels of residues of mefenpyr-diethyl and its 2,4-dichlorophenyl-pyrazoline containing metabolites were detected in liver and eggs.

The metabolism of mefenpyr-diethyl in ruminants is also adequately understood. A lactating goat was dosed with the compound at a level approximately 56-times the worst case dietary burden for 7-days. Low levels of residues of mefenpyr-diethyl and/or its 2,4-dichlorophenyl-pyrazoline containing metabolites were detected in kidney, liver, fat, and milk.

Based on the results observed in these metabolism studies, secondary residues in animal commodities are not expected to be of concern in terms of dietary risk to consumers.

C. Aggregate Exposure

Mefenpyr-diethyl is intended for use on agricultural crops as a herbicide safening agent. As such, non-occupational exposures to mefenpyr-diethyl would be limited to potential exposures via residues in food or water. There are no acute toxicity concerns with mefenpyr-diethyl. Therefore, only chronic exposures are being addressed here.

Dietary exposure—1. Food. Potential dietary exposures from food under the proposed tolerances were estimated using the Exposure 1 software system (TAS, Inc.) and the 1977-78 USDA consumption data. For the purposes of this risk assessment, AgrEvo USA Company has made the overly conservative assumption that 100% of all wheat and barley commodities will contain residues of mefenpyr-diethyl and that all of those residues will be at the proposed tolerance level. Further, default concentration factors are assumed for processed wheat and barley commodities. Thus, this estimate should result in a gross overestimation of actual human exposure, allowing administration. Metabolite profiles were similar following oral and dermal exposures, with the route of metabolism being hydrolysis of the two carboxylic acid ester groups, and decarboxylation of one of the carboxylic acid groups resulting in the aromatization of the heterocyclic ring.

2. Drinking water. The potential for mefenpyr-diethyl to leach into groundwater has been assessed in various laboratory studies. These experiments clearly demonstrate that mefenpyr-diethyl is rapidly degraded in the environment, chiefly via metabolism in biologically active soils. Aerobic degradation half-lives of 3-days or less were observed under a wide range of experimental conditions. Clear degradation of metabolites was also observed, with soil photolysis accelerating the process. Mefenpyr-diethyl was stable to hydrolysis under acid conditions, but was rapidly degraded at mildly alkaline pH values. Rapid photodegradation was observed under those aqueous conditions where mefenpyr-diethyl is stable to hydrolysis. The compound sorbed readily to soil organic matter, therefore, leaching is not of concern. Based on these environmental fate data and the anticipated conditions of use, the potential for movement of mefenpyr-diethyl is considered to be low. As such, the potential contribution of any residues of the compound in water to the total dietary intake of mefenpyr-diethyl will be negligible.

D. Cumulative Effects

The potential for mefenpyr-diethyl to leach into groundwater has been assessed in various laboratory studies. These experiments clearly demonstrate that mefenpyr-diethyl is rapidly degraded in the environment, chiefly via metabolism in biologically active soils. Aerobic degradation half-lives of 3– days or less were observed under a wide range of experimental conditions. Clear degradation of metabolites was also observed, with soil photolysis accelerating the process. Mefenpyr-diethyl was stable to hydrolysis under acid conditions, but was rapidly degraded at mildly alkaline pH values. Rapid photodegradation was observed under those aqueous conditions where mefenpyr-diethyl is stable to hydrolysis. The compound sorbed readily to soil organic matter, therefore leaching is not of concern. Based on these environmental fate data and the anticipated conditions of use, the potential for movement of mefenpyr-diethyl is considered to be low. As such, the potential contribution of any residues of the compound in water to the total dietary intake of mefenpyr-diethyl will be negligible.

E. Safety Determination

1. *U.S. population.* A Reference Dose value (RfD) of 0.48 mg/kg body weight/day is appropriate for chronic dietary risk assessments of mefenpyr-diethyl. This RfD is based on the 2–year rat chronic toxicity study in which the NOEL was 1,000 ppm, equivalent to 48 mg/kg body weight for males, and a 100–fold safety factor to account for interspecies extrapolation and intraspecies variation.

Under the conservative (worst-case) dietary exposure assumption described above in paragraph D.1., chronic dietary exposures will utilize only 0.11% of the RfD for the general U.S. population. There is generally no concern for exposures below 100% of the RfD since it represents the level at or below which no appreciable risks to human health is posed. Thus, there is reasonable certainty that no harm will result to the U.S. population in general from aggregate exposure to mefenpyr-diethyl residues.

2. *Infants and children.* Data from rat and rabbit development toxicity studies and rat multigeneration reproduction studies are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal

development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from pre-natal and post-natal exposure to the pesticide.

FFDCA Section 408 provides that the Agency may apply an additional safety factor for infants and children to account for pre- and post-natal toxicity or incompleteness of the database. However, the toxicology database for mefenpyr-diethyl regarding potential pre- and post-natal effects in offspring is complete according to existing Agency data requirements and does not indicate any particular developmental or reproductive concerns. No reproductive effects were noted in any of the studies and the NOEL's for the parents and offspring were the same in three of the four studies. A marginal decrease in pup weights was noted at a non-maternally toxic dose level in the second rat developmental toxicity study, but only at a dose level of 1,000 mg/kg/day. Thus, there does not appear to be any significant difference in sensitivity to mefenpyr-diethyl between adults and offspring. Furthermore, the proposed RfD of 0.48 mg/kg/day, which is based on a 48 mg/kg/day NOEL from the 2–year rat feeding study, already provides for a safety factor of 208 relative to the 100 mg/kg/day developmental NOEL from the rabbit developmental toxicity study. Thus, the RfD of 0.48 mg/kg/day is considered to be appropriate for assessing potential risks to infants and children and an additional uncertainty factor is not warranted.

Using the conservative assumptions described above, aggregate exposure to mefenpyr-diethyl is expected to utilize 0.25% of the reference dose in the population subgroups children 1–6 years old and 0.18% of the reference dose in the population subgroup children 7–12 years old. These numbers would, in all likelihood, be significantly lower if an adjustment for actual percent of crop treated was considered.

F. International Tolerances

Italy has established an MRL (maximum residue limit) of 0.05 ppm in wheat grain for residues of mefenpyr-diethyl and metabolites.

[FR Doc. 97–25656 Filed 9–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5899–2]

Clean Water Act Class II: Proposed Administrative Penalty Assessment and Opportunity To Comment Regarding ProSoCo, Inc., Kansas City, KS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed administrative penalty assessment and opportunity to comment regarding ProSoCo, Inc., Kansas City, Kansas.

SUMMARY: EPA is providing notice of opportunity to comment to the proposed assessment.

Under 33 U.S.C. 1321(b)(6), EPA is authorized to issue orders assessing civil penalties for various violations of the Act. EPA may issue such orders after filing a Complaint commencing either a Class I or Class II penalty proceeding. EPA provides public notice of the proposed assessment pursuant to 33 U.S.C. 1321(b)(6)(C).

Class II proceedings are conducted under EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 CFR part 22. The procedures by which the public may submit written comment on a proposed Class II order or participate in a Class II proceeding, and the procedures by which a respondent may request a hearing, are set forth in the Consolidated Rules. The deadline for submitting public comment on a proposed Class II order is thirty (30) days after issuance of public notice.

On August 6, 1997, EPA commenced the following Class II proceeding for the assessment of penalties by filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, (913) 551–7630, the following Complaint:

In the Matter of ProSoCo, Inc., Kansas City, Kansas, EPCRA Docket No. VII–97E–44 and CWA Docket No. VII–97–W–0017.

The Complaint proposes a penalty of Ten Thousand Dollars (\$10,000) under the Clean Water Act for the release and discharge of a hazardous substance into waters of the United States in violation of section 103(a) of CERCLA and section 311(b)(3) of the Clean Water Act.

FOR FURTHER INFORMATION CONTACT:

Persons wishing to receive a copy of EPA's Consolidated Rules, review the Complaint or other documents filed in this proceeding, comment upon the