

Dated: November 19, 1996.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 96-29918 Filed 11-21-96; 8:45 am]

BILLING CODE 6560-50-P

[FRL-5654-5]

Community-Based Environmental Protection Committee of the National Advisory Council for Environmental Policy and Technology; Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act, Public Law 92-463, EPA gives notice of a two-day meeting of the Community-Based Environmental Protection Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT). NACEPT provides advice and recommendations to the Administrator of EPA on a broad range of environmental policy issues, and the Community-Based Environmental Protection Committee was formed to identify opportunities for harmonizing environmental policy, economic activity, and ecosystem management.

The meeting is being held to discuss recommendations the Committee plans to submit to EPA. Scheduling constraints preclude oral comments from the public during the meeting. Written comments can be submitted by mail, and will be transmitted to Committee members for consideration.

DATES: The public meeting will be held on Tuesday, December 17, 1996, and Wednesday, December 18, 1996, at the Dupont Plaza Hotel, 1500 New Hampshire Avenue, N.W., Washington, D.C. On Tuesday, December 17, the Committee will meet from 9:00 a.m. to 5:00 p.m., and on Wednesday, December 18, the Committee will meet from 9:00 a.m. to 4:00 p.m.

ADDRESSES: Written comments should be sent to: Deborah Ross, Office of Cooperative Environmental Management, U.S. EPA (1601F), 401 M Street SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Deborah Ross, Designated Federal Officer, Direct line (202) 260-9752, Secretary's line (202) 260-9744.

Dated: November 7, 1996.

Deborah Ross,

Designated Federal Officer.

[FR Doc. 96-29927 Filed 11-21-96; 8:45 am]

BILLING CODE 6560-50-M

[FRL-5654-2]

Science Advisory Board Notification of Public Advisory Open Committee Meeting

Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Ecological Risk Subcommittee of the Science Advisory Board's (SAB) Integrated Risk Project will meet on December 10-12, 1996, at the Bourbon Orleans Hotel, 717 Orleans Street, New Orleans, LA, 70116, telephone (504) 523-2222. The meeting is open to the public and will begin at 8:30 a.m. on December 10 and at 8:00 a.m. on December 11 and 12. Due to limited space, seating at the meeting will be on a first-come basis.

The main purpose of the meeting is to: (1) complete discussion of a methodology for identifying and ranking ecological risks as part of the SAB's Integrated Risk Project; and (2) meet with representatives of the IRP Human Exposure and Health Subcommittee to discuss integration of methodologies for ranking human health and ecological risks.

Background on the Integrated Risk Project: In a letter dated October 25, 1995, to Dr. Matanoski, Chair of the SAB Executive Committee, Deputy Administrator Fred Hansen charged the SAB to: (1) develop an updated ranking of the relative risk of different environmental problems based upon explicit scientific criteria; (2) provide an assessment of techniques and criteria that could be used to discriminate among emerging environmental risks and identify those that merit serious, near-term Agency attention; (3) assess the potential for risk reduction and propose alternative technical risk reduction strategies for the environmental problems identified; and (4) identify the uncertainties and data quality issues associated with the relative rankings. Since that time, five SAB panels, working at the direction of an ad hoc Steering Committee established by the Executive Committee, have been discussing methods for: (1) Assessing relative risks; (2) selecting suites of risk reduction options; and (3) conducting economic analysis of various risk management options. A final report is expected in early summer of 1997.

Single copies of *Reducing Risk* can be obtained by contacting the SAB's Committee Evaluation and Support Staff (1400), 401 M Street, SW, Washington, DC 20460, telephone (202) 260-8414, or fax (202) 260-1889. Members of the public desiring additional information

about the meeting, including an agenda, should contact Ms. Constance Valentine, Staff Secretary, Science Advisory Board (1400F), US EPA, 401 M Street, SW, Washington DC 20460, by telephone at (202) 260-8414, fax at (202) 260-7118, or via The INTERNET at: Valentine.Connie@EPAMAIL.EPA.GOV.

Providing Oral or Written Comments: Anyone wishing to make an oral presentation at the meeting should contact Stephanie Sanzone, Designated Federal Official for the Subcommittee, no later than 4:00 p.m., December 2, 1996, at (202) 260-6557 or via the Internet at Sanzone.Stephanie@epamail.epa.gov. The request should identify the name of the individual who will make the presentation and an outline of the issues to be addressed. At least 35 copies of any written comments to the Committee are to be given to Ms. Sanzone no later than the time of the presentation for distribution to the Committee and the interested public. The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. Each individual or group making an oral presentation will be limited to a total time of five minutes.

Dated: November 14, 1996.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 96-29871 Filed 11-21-96; 8:45 am]

BILLING CODE 6560-50-P

[PF-674; FRL-5574-2]

Pesticide Tolerance Petition; Notice of Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice is a summary of a pesticide petition proposing the establishment of a regulation for residues of spinosad in or on cotton.

DATES: Comments, identified by the docket number [PF-674], must be received on or before December 23, 1996.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted electronically by sending

electronic mail (E-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data on this notice of filing may be filed online at many Federal Depository Libraries. In person, bring comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as comments 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

George LaRocca (PM 13), Rm. 204, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 6F4735) from DowElanco 9330 Zionsville Road, Indianapolis, IN 46268-1054 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the insecticide spinosad in or on the raw agricultural commodity cottonseed at 0.02 ppm. Spinosad is a fermentation derived tetracyclic macrolide product produced by the actinomycete, *Saccharopolyspora spinosa* and consists of two structurally related compounds, namely spinosyn A and spinosyn D which provide the insect control activity for this new product. The two spinosyns only differ from each other in the substitution of a hydrogen by a methyl group and have structures consisting of a basic amine group, two sugars, and a larger complex hydrophobic ring. This new active ingredient that has been accepted by EPA as a reduced risk product is being proposed for registration as a broad

spectrum worm control product on cotton. The proposed analytical method is based on high performance liquid chromatography (HPLC) with ultraviolet (UV) detection.

Pursuant to section 408(d)(2)(A)(i) of the FFDCFA, as amended, DowElanco has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by DowElanco and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

I. Petition Summary

A. Residue Chemistry

The metabolism of spinosad in plants (cotton) and animals (goats and poultry) is adequately understood for the purposes of this tolerance. A rotational crop study showed no carryover of measurable spinosad related residues in representative test crops. Residues in the magnitude of residue study were non-detectable in or on cottonseed. Residues of spinosad did not concentrate in process fractions in samples treated at a 6X application rate. There is a practical method (HPLC with UV detection) for detecting (0.004 ppm) and measuring (0.01 ppm) levels of spinosad in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set for this tolerance. The method has had a successful method tryout in EPA's laboratories.

B. Toxicological Profile

1. *Acute toxicity.* Spinosad has low acute toxicity. The rat oral LD50 is 3738 mg/kg for males and >5000 mg/kg for females, whereas the mouse oral LD50 is >5000 mg/kg. The rabbit dermal LD50 is >5000 mg/kg and the rat inhalation LC50 is >5.18 mg/l air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits. End use formulations of spinosad that are water-based suspension concentrates have similar low acute toxicity profiles.

2. *Genotoxicity.* Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* mammalian gene mutation assay using mouse lymphoma cells, an *in vitro* assay for DNA damage and repair in rat hepatocytes, and an *in vivo* cytogenetic assay in the mouse bone marrow (micronucleus test) have been

conducted with spinosad. These studies show a lack of genotoxicity.

3. *Reproductive and developmental toxicity.* Spinosad caused decreased body weights in maternal rats given 200 mg/kg/day by gavage (highest dose tested). This was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOELs for maternal and fetal effects in rats were 50 and 200 mg/kg/day, respectively. A teratology study in rabbits showed that spinosad caused decreased body weight gain and a few abortions in maternal rabbits given 50 mg/kg/day (highest dose tested). Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOELs for maternal and fetal effects in rabbits were 10 and 50 mg/kg/day, respectively. The NOEL found for maternal and pup effects in a rat reproduction study was 10 mg/kg/day. Neonatal effects at 100 mg/kg/day (highest dose tested in the rat reproduction study) were attributed to maternal toxicity.

4. *Subchronic toxicity.* Spinosad was evaluated in 13-week dietary studies and showed NOELs of 4.9 mg/kg/day in dogs, 6 mg/kg/day in mice, and 8.6 mg/kg/day in rats. No dermal irritation or systemic toxicity occurred in a 21-day repeated dose dermal toxicity study in rabbits given 1000 mg/kg/day.

5. *Chronic toxicity.* Based on chronic testing with spinosad in the dog and the rat, a reference dose (RfD) of 0.025 mg/kg/day is proposed for spinosad. The RfD has incorporated a 100-fold safety factor to the NOELs found in these two chronic tests. The NOELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOELs shown in the rat chronic study were 2.4 and 3.0 mg/kg/day, respectively for male and female rats.

6. *Carcinogenicity.* Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that spinosad be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18-month mouse feeding study and a 24-month rat feeding study at all dosages tested. The NOELs shown in the mouse oncogenicity study were 11.4 and 13.8 mg/kg/day, respectively for male and female mice. The NOELs shown in the rat chronic/oncogenicity study were 2.4 and 3.0 mg/kg/day, respectively for male and female rats. A maximum tolerated dose was achieved at the top dosage level tested in both of these

studies based on excessive mortality. Thus, the doses tested are adequate for identifying a cancer risk. Accordingly, DowElanco concludes that a cancer risk assessment should not be necessary.

7. *Neurotoxicity.* Spinosad did not cause neurotoxicity in rats in acute, subchronic, or chronic toxicity studies.

8. *Endocrine effects.* There is no evidence to suggest that spinosad has an effect on any endocrine system.

9. *Animal metabolism.* There were no major differences in the bioavailability, routes or rates of excretion, or metabolism of spinosyn A and spinosyn D following oral administration in rats. In addition, the routes and rates of excretion were not affected by repeated administration.

10. *Metabolite toxicity.* The residue of concern for tolerance setting purposes is the parent material (spinosyn A and spinosyn D). Thus, DowElanco concludes there is no need to address metabolite toxicity.

C. Aggregate Exposure

1. *Dietary exposure.* For purposes of assessing the potential dietary exposure from use of spinosad on cotton, a conservative estimate of aggregate exposure is determined by TMRC assuming that 100% of the cotton crop has a residue of spinosad at the tolerance level of .02 ppm. The potential dietary exposure is obtained by multiplying the tolerance residue level on cottonseed (0.02 ppm) by the consumption data which estimates the amount of cottonseed products consumed by various population subgroups. Cottonseed is fed to animals; thus exposure to residues in cottonseed might result if such residues are transferred to meat, milk, poultry, or eggs. However, based on the results of animal metabolism studies in goat and poultry and the level of spinosad residues expected in animal feeds (<0.02 ppm), DowElanco concludes that there is no reasonable expectation that measurable residues of spinosad will occur in meat, milk, poultry or eggs under the terms of the proposed use of spinosad on cotton. There are no other established U.S. tolerances for spinosad and no other registered uses for spinosad on food or feed crops in the United States. The use of a tolerance level and 100% of crop treated clearly results in an overestimate of human exposure and a safety determination for the use of spinosad on cotton that is based on a conservative exposure assessment. Another potential source of dietary exposure are residues in drinking water. Based on the available environmental studies conducted with spinosad wherein it's properties show

little or no mobility in soil DowElanco concludes, there is no anticipated exposure to residues of spinosad in drinking water. In addition, there is no established Maximum Concentration Level for residues of spinosad in drinking water.

2. *Non-dietary exposure.* There are no other uses currently registered for spinosad. The proposed use on cotton involves application of spinosad to crops grown in an agriculture environment. Thus, the potential for non-occupational exposure to the general population is not expected to be significant.

D. Cumulative Effects

The potential for cumulative effects of spinosad and other substances that have a common mechanism of toxicity is also considered. In terms of insect control, spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism that is clearly novel and unique among known insecticidal compounds. Spinosad also has effects on the GABA receptor function that may contribute further to its insecticidal activity. Based on results found in tests with various mammalian species, spinosad appears to have a mechanism of toxicity like that of many amphiphilic cationic compounds. There is no reliable information to indicate that toxic effects produced by spinosad would be cumulative with those of any other pesticide chemical. Thus DowElanco believes it is appropriate to consider only the potential risks of spinosad in an aggregate exposure assessment.

E. Safety Determinations

1. *U.S. population in general.* Using the conservative exposure assumptions and the proposed RfD described above, the aggregate exposure to spinosad use on cotton will utilize 0.004% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Thus, DowElanco concludes that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues (<0.02 ppm) on cottonseed.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of spinosad, data from developmental toxicity studies in rats and rabbits and

a 2-generation reproduction study in the rat are considered. 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 effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of pups.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for spinosad relative to pre- and post-natal effects for children is complete. Further, for spinosad, the NOELs in the chronic feeding studies which were used to calculate the RfD (0.025 mg/kg/day) are already lower than the NOELs from the developmental studies in rats and rabbits by a factor of more than 10-fold.

Concerning the reproduction study in rats, the pup effects shown at the highest dose tested were attributed to maternal toxicity. Therefore, DowElanco concludes that an additional uncertainty factor is not needed and that the RfD at 0.025 mg/kg/day is appropriate for assessing risk to infants and children.

Using the conservative exposure assumptions previously described, the percent RfD utilized by the aggregate exposure to residues of spinosad on cottonseed is 0.012% for children 1 to 6 years old, the most sensitive population subgroup. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, DowElanco concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on cottonseed.

F. International Tolerances

There are no Codex maximum residue levels established for residues of spinosad on cottonseed or any other food or feed crop.

II. Administrative Matters

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the docket control number, PF-674. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4

p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket number PF-674 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, Crystal Mall 2, 1921 Jefferson Davis Highway Arlington, VA 22202.

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. The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

List of Subjects

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

Dated: November 15, 1996.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96-29929 Filed 11-21-96; 8:45 am]

BILLING CODE 6560-50-F

[PF-673; FRL-5573-8]

Pesticide Tolerance Petition; Notice of Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice is a summary of a pesticide petition proposing the establishment of a regulation for residues of thiazopyr in or on orange and grapefruit. This summary was prepared by the petitioner.

DATES: Comments, identified by the docket number [PF-673], must be received on or before, December 23, 1996.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide 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 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments on this notice may be filed on-line at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as a comments 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Joanne Miller (PM-23) Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703) 305-6224. e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP) 3F4187 from Rohm and Haas Company, Philadelphia, PA, 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 the herbicide thiazopyr in or on the raw agricultural commodity orange (whole fruit) and grapefruit (whole fruit) at 0.05 ppm. The proposed analytical method is gas chromatography using mass selective detection.

Pursuant to section 408(d)(2)(A)(i) of the FFDC, as amended, Rohm and Haas Company has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was

prepared by Rohm and Haas Company and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioners and not necessarily EPAs and to remove certain extraneous material.

I. Rohm & Haas Petition Summary

A. Residue Chemistry

1. *Plant metabolism.* Metabolism studies were conducted on peanuts, cotton and lemon. The metabolism of thiazopyr in all crops was extensive. Little thiazopyr was observed in crop tissues. About 10 metabolites were identified and quantified in each study. In peanuts, cotton, and lemon, any individual metabolite represented less than 13-, 9-, and 10-percent of the total dosage, respectively. The metabolic pathway for all three crops is the same.

2. *Analytical method.* A gas-liquid chromatographic analytical method using mass selective detection has been validated in citrus for enforcement purposes. This method converts thiazopyr and its metabolites to a common moiety which is quantified. The limit of quantitation of the method is 0.025 ppm for citrus whole fruit and processed fractions.

3. *Magnitude of residues.* The maximum application rate of 2 pounds of the active ingredient per acre was applied 3 months prior to harvest in 20 field trials. No detectable thiazopyr residue was found above the limit of quantitation of the residue method in whole fruit. After a single application of thiazopyr at 10 pounds per acre 3 months prior to harvest, processed commodities of citrus were produced and analyzed. No residue was found above the limit of quantitation of the method in the processed fractions.

B. Toxicological Profile

1. *Acute toxicity.* Thiazopyr technical was practically non-toxic by ingestion of a single dose (LD₅₀ > 5.0 g/kg) in rats and was practically non-toxic by dermal application (LD₅₀ > 5.0 g/kg in rats). Thiazopyr technical was not significantly toxic to rats after a 4-hr inhalation exposure, with an LC₅₀ value of > 1.2 mg/L (highest concentration attainable) for both sexes. Thiazopyr technical was classified as slightly irritating to the eye and no more than slightly irritating to the skin. Thiazopyr technical was not a dermal sensitizer.

2. *Genotoxicity.* Thiazopyr technical was negative (non-mutagenic) in the Ames microbial mutation assay with and without hepatic enzyme activation. Thiazopyr technical was negative in a hypoxanthine guanine phosphoribosyl