

9. Report on Salt River Pima Maricopa Indian Community Pesticide Program.
10. OPP Tribal Strategy - final review.
11. TPPC outreach power point.
12. Federal Credential (questions and answers).
13. Presentation and questions and answers by EPA Office of Enforcement and Compliance Assurance.
14. Section 18 and 24c pilot project - soybean rust.
15. Instructions on preparing forms to include the Form 5700.
16. Region 8 and 9 reports.
17. Performance Measures - panel/ reports from working groups and discussion of performance for Tribes.
18. Strategic planning for the TPPC Environmental Protection.

#### List of Subjects

Environmental protection, Pesticide and pests.

Dated: August 10, 2005.

Jay S. Ellenberger,

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

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#### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0385 FRL-7734-4]

#### Permethrin; Notice of Availability of Risk Assessments and Opening of Docket

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of EPA's preliminary human health and ecological risk assessments and related documents for permethrin, a synthetic pyrethroid insecticide, and opens a public comment period on these documents. The public is encouraged to provide information to refine assessed risks, and suggest risk management ideas or proposals to address the risks identified. At this time, EPA is intending to develop a Reregistration Eligibility Decision (RED) for permethrin through a modified 4-phase public participation process that the Agency uses to involve the public in developing pesticide reregistration and tolerance assessment decisions. For permethrin, a modified 4-Phase process with one public comment period and ample opportunity for public consultation seems appropriate in view of the number and level of risk concerns identified in the preliminary risk assessment. However, if as a result of

comments received during this comment period EPA finds that additional issues warranting further discussion are raised, the Agency may consider an additional comment period, as needed. Through this program, EPA is ensuring that all pesticides meet current health and safety standards. This notice is phase-3 of the 4-phase process.

**DATES:** Comments, identified by docket identification (ID) number OPP-2004-0385 must be received on or before October 31, 2005.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

#### FOR FURTHER INFORMATION CONTACT:

Jacqueline Guerry, Chemical Review Manager, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-0024; e-mail address: [guerry.jacqueline@epa.gov](mailto:guerry.jacqueline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2004-0385. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the

collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide

a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

### C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit

comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2004-0385. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-2004-0385. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2004-0385.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP-2004-0385. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

### D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then

identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

### E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we propose, new approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the rule or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Background

### A. What Action is the Agency Taking?

EPA is releasing for public comment its preliminary human health and environmental fate and effects risk assessments and related documents for the synthetic pyrethroid insecticide,

permethrin, and is encouraging the public to provide information to refine identified risks, and suggest risk management ideas or proposals. EPA is ensuring that pesticides meet current standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Permethrin is registered for use on sites in agricultural, commercial, and residential settings. In addition to its pesticidal uses, permethrin also has non-FIFRA pharmaceutical use as a pediculicide for the treatment of head lice and scabies. The Food and Drug Administration (FDA) approves use of the pesticidal-containing pharmaceutical products under FFDCA.

The preliminary risk assessments have identified potential residential postapplication noncancer chronic risks of concerns for toddlers; residential handlers and postapplication cancer risks; occupational handler and postapplication noncancer chronic and cancer risks; and potential acute and chronic ecological risks of concern. EPA is providing an opportunity, through this notice, for interested parties to provide comments and input on the Agency's risk assessments for permethrin. Such comments and input could address the potential risks of concern.

All elements of the Agency's risk assessments for permethrin are open for public comment; however, we are particularly seeking public comment and input on data that could help refine those scenarios where uncertainties exist and risk estimates exceed the level of concern, which are identified in the Agency's risk assessments available in the docket. Specifically, there is uncertainty regarding the residential handler and postapplication cancer risks. In order to identify the residential exposure scenarios that may pose risks of concern, the Agency is seeking public comment on the typical number of applications associated with those homeowner scenarios assessed. Additionally, the Agency is looking for consumer information on the market segments that utilize impregnated clothing and the use pattern of these products (i.e. types of impregnated clothing purchased and worn, number of times the article of clothing is worn and washed, etc.). Refer to the Permethrin Overview document available in the docket for further discussion of uncertainties and data needs regarding residential uses. Further, the only occupational risks of concern identified resulted from use of permethrin in mushroom houses. The

Agency is seeking typical use information on permethrin applied in mushroom houses (i.e. current level of personal protective equipment worn, application rate, and percent crop treated, etc.), as well as benefits of this use, and potential risk mitigation ideas. Additionally, the Agency is interested in obtaining data or information that would assist in refining the risks identified in the ecological assessment, such as the typical use of buffer zones in areas where permethrin is applied close to bodies of water. Finally, additional data are being requested regarding the potential ecological risk resulting from permethrin formulations that contain the synergist piperonyl butoxide (PBO). Few toxicity studies are available on formulations of permethrin/PBO. In order to assess any increased toxicity of permethrin active ingredient when formulated with a synergist, the Agency is requesting the submission of existing permethrin/PBO toxicity studies, and public comment on additional studies that may need to be generated to address this issue. Refer to the Overview document for more discussion of this matter.

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to permethrin, compared to the general population.

EPA is releasing for public comment its risk assessments for permethrin, to provide an opportunity for interested parties to also provide risk management proposals or otherwise comment on risk management. Such comments and proposals should further discuss ways to manage permethrin's occupational, residential, and/or ecological risks resulting from its many uses, as discussed in the Agency's risk assessments.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** on May 14, 2004, explains that in conducting these programs, the Agency is tailoring its public participation process to be

commensurate with the level of risk, extent of use, complexity of the issues, and degree of public concern associated with each pesticide. At this time for permethrin, a modified 4-Phase process with one public comment period and ample opportunity for public consultation seems appropriate in due to the number and level of risk concerns. However, if as a result of comments received during this comment period EPA finds that additional issues warranting further discussion are raised, the Agency may consider an additional comment period, as needed.

All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. Comments will become part of the Agency Docket for permethrin. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

#### *B. What is the Agency's Authority for Taking this Action?*

Section 4(g)(2) of FIFRA as amended directs that, after submission of all data concerning a pesticide active ingredient, "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration," before calling in product specific data on individual end-use products and either reregistering products or taking other "appropriate regulatory action."

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

#### **List of Subjects**

Environmental protection, Pesticides and pests.

Dated: August 25, 2005.

#### **Debra Edwards,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs*  
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