

have sufficient professional qualifications, including training and experience, to be capable of providing expert comments as to the impact on health and the environment of regulatory actions under sections 6(b) and 25(a) of FIFRA. The Deputy Administrator appoints seven individuals to serve on the FIFRA SAP for staggered terms of 4 years, based on recommendations from the National Institutes of Health and the National Science Foundation.

Section 104 of FQPA (Public Law 104-170) established the FQPA Science Review Board (SRB). These scientists shall be available to the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP.

B. Public Meeting

The FIFRA SAP will meet to consider and review plant-incorporated protectants based on virus coat protein genes: science issues associated with a review of proposed rules. A plant-incorporated protectant (PIP) is a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. The term includes both active and inert ingredients. PIPs are regulated as pesticides by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) because they meet the FIFRA definition of a pesticide, being intended for preventing, destroying, repelling, or mitigating a pest. Residues of PVCP-PIPs in or on food are also subject to FFDCA section 408 because PIPs meet the FFDCA definition of a pesticide chemical.

PIPs may occur naturally or be introduced into plants by conventional breeding or genetic engineering. PVCP-PIPs are PIPs in which inserted genetic material is derived from a plant virus sequence that encodes a plant virus coat protein. Plant virus coat proteins encapsidate the viral nucleic acid and are known to have a role in nearly every stage of viral infection including replication, movement throughout an infected plant, and transport from plant to plant. Incorporation of plant virus coat protein gene sequences into plant genomes has been found to confer resistance to the virus from which it was derived and often to related viruses.

EPA is seeking the assistance of the FIFRA SAP in evaluating several issues associated with the review of proposed rules that would exempt certain PVCP-PIPs from regulation under FFDCA and/or FIFRA. These issues include the potential human health effects from exposure to residues of PVCP-PIPs, the

potential for non-target impacts, and the potential environmental consequences associated with gene flow and recombination.

C. FIFRA SAP Meeting Minutes

The FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency in approximately 90 days after the meeting. The meeting minutes will be posted on the FIFRA SAP web site or may be obtained by contacting the PIRIB at the address or telephone number listed in Unit I.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 19, 2005.

Clifford J. Gabriel,

Director, Office of Science Coordination and Policy.

[FR Doc. 05-19129 Filed 9-22-05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0348; FRL-7733-5]

Malathion; Revised Risk Assessments, Notice of Availability, and Solicitation of Risk Reduction Options

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's revised human health risk assessment and as well as the start of a 60-day comment period ecological risk assessment for the organophosphate pesticide malathion. A revised human health assessment on malathion was conducted to incorporate toxicity data which EPA received after 2000. Since no additional ecological data on malathion has been received after 2000, EPA's ecological risk characterization has remained unchanged. This notice also solicits information or data from stakeholders and interested parties to help refine the malathion risk assessment, and encourages parties to suggest risk management ideas or proposals to address the potential risks which have been identified. EPA is developing an Interim Reregistration Eligibility Decision (IREED) for malathion through the full, 6-Phase public participation process, which in this case includes reissuing the revised risk assessment for an additional Phase 5 public comment period. The Agency uses this process to involve the public in developing

pesticide reregistration and tolerance reassessment decisions. Through these programs, EPA is ensuring that all pesticides meet current health and safety standards.

DATES: Comments must be received on or before November 22, 2005.

ADDRESSES: Comments, identified by identification (ID) number OPP-2004-0348, 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: Tom Moriarty, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5035; fax number: (703) 308-8005; e-mail address: moriarty.thomas@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-2004-0348. 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, to 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. 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-2004-0348. 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, Attention: Docket ID Number OPP-2004-0348. 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-2004-0348.

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-2004-0348. 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?

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 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 your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Background

A. What Action is the Agency Taking?

EPA is making available the Agency's revised human health risk assessment, and ecological risk assessment on malathion. Previously completed risk assessments were issued for public comment through a **Federal Register** notice published on December 12, 2000 (65 FR 77624) (FRL-6756-7), along with EPA's response to comments; and related documents for malathion. EPA has updated its human health risk assessment since 2000 by incorporating data received since that time. However, since no additional ecological data regarding malathion has been received since 2000, the ecological risk assessment currently being made available is the same assessment

completed in 2000. EPA developed the risk assessments for malathion as part of its public process for making pesticide reregistration eligibility and tolerance reassessment decisions. Through these programs, 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).

Malathion is characterized as a non-systemic, broad spectrum organophosphate pesticide with numerous commercial agricultural uses, residential uses and, as well as several wide area uses. Malathion's wide area applications include use as a public health mosquitocide, use to control fruit flies, and use in eradication programs such as the U.S. Department of Agriculture's Boll Weevil Eradication Program. Malathion is also formulated into a pharmaceutical product (Ovide® Lotion) which is approved by the Food and Drug Administration for the control of head lice and their ova.

EPA's revised human health risk assessment has identified potential risks of concern from various uses of malathion, some of which are derived mainly from potential exposure to malathion's oxygen metabolite, malaoxon. Concerns include potential exposure to malaoxon through drinking water, and from drift as a result of wide area applications. The Agency also has potential risk concerns for adults and children who may be exposed to malathion *per se* from the home fogger use of malathion. EPA has also included an analysis of the pharmaceutical use of malathion. The analysis of the pharmaceutical use presents the proposed safety findings on malathion as a pharmaceutical and a pesticide product from the joint perspective of both the Food and Drug Administration and EPA.

The Agency is interested in receiving information which would help refine the identified risks, and information on effective and practical measures to mitigate potential risk. Information or data that could refine uncertainties, or risk estimates that exceed the Agency's level of concern are of particular concern to the Agency. Because EPA notes that estimated dietary risks differ significantly between calculations made with maximum and typical application parameters, the Agency is interested in information on typical use patterns (rates, number of applications, or application intervals) for commercial agricultural crops. EPA notes that in conducting its occupational assessment, exposure data were unavailable for two

specific application scenarios, (1) power dusters, and (2) plant dipping scenarios, and is requesting additional information on either of these application scenarios. In addition, information is requested on the feasibility of the levels of protection assessed for pesticide handlers, and the maximum restricted entry intervals being evaluated, as well as the type of post-application activities which need to be performed for the scenarios assessed. With respect to the estimated risk from wide area treatments, EPA notes that additional data on the transformation of malathion to malaoxon could potentially refine this portion of the malathion risk assessment. Additional toxicity data on malaoxon may also be a help to EPA. EPA is also interested in information on typical storage conditions, or information on malathion's product life cycle, such as how long a product is typically stored before it is used.

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 (69 FR 26819) (FRL-6756-7), explains that in conducting these programs, EPA is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. As mentioned earlier, a revised risk assessment on malathion was previously published in 2000 during Phase 5 of the 6-Phase process. However, due to new data and revised risk characterization, EPA is reissuing its current revised risk assessment during a second Phase 5 public comment period.

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

After considering comments received, EPA will develop and issue the Malathion IRED. The decisions presented in this IRED may be supplemented by further risk mitigation measures when EPA considers its cumulative assessment of the organophosphate pesticides.

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: September 14, 2005.

Debra Edwards,

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

[FR Doc. 05-18705 Filed 9-22-05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0013; FRL-7696-1]

Pesticide Reregistration Performance Measures and Goals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's progress in meeting its performance measures and goals for pesticide reregistration during fiscal year 2004. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to publish information about EPA's annual achievements in this area. This notice discusses the integration of tolerance reassessment with the reregistration process, and describes the status of various regulatory activities associated with reregistration and tolerance reassessment. The notice gives total numbers of chemicals and products reregistered, tolerances reassessed, Data Call-Ins issued, and products registered under the "fast-track" provisions of FIFRA. Finally, this notice contains the schedule for completion of activities for specific chemicals during fiscal years 2005 through 2008.

DATES: This notice is not subject to a formal comment period. Nevertheless, EPA welcomes input from stakeholders and the general public. Written

comments, identified by the docket ID number [OPP-2005-0013], should be received on or before November 22, 2005.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Carol P. Stangel, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone: (703) 308-8007; e-mail: stangel.carol@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who are interested in the progress and status of EPA's pesticide reregistration and tolerance reassessment programs, 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 information in this notice, 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-2005-0013. 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.

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