



Federal Register

**Friday,
July 2, 2004**

Part II

Environmental Protection Agency

**Thiram; Availability of Revised Risk
Assessments; Notice**

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0183; FRL-7366-7]

Thiram; Availability of Revised Risk Assessments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of documents that were developed as part of EPA's process for making pesticide reregistration eligibility decisions and tolerance reassessments consistent with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). These documents are the human health and environmental risk assessments and related documents for thiram. This notice also starts a 60-day public comment period during which the public is encouraged to submit comments on EPA's preliminary assessment of benefits of thiram and risk management ideas or proposals for thiram. This action is in response to a joint initiative between EPA and the U.S. Department of Agriculture (USDA) to increase transparency in the tolerance reassessment process for all pesticides. Comments are to be limited to issues directly associated with thiram and its benefits raised by the risk assessments, potential risk reduction options, or other documents placed in the docket. By allowing access and opportunity for comment on the risk assessments and potential risk reduction options, EPA is seeking to strengthen stakeholder involvement and help ensure that our decisions under FQPA are transparent and based on the best available information.

DATES: Comments, identified by docket ID number OPP-2004-0183, must be received on or before August 31, 2004.

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: Craig Doty, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0122; fax number: (703) 308-8041; e-mail address: doty.craig@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general but may be of interest to a wide range of stakeholders, including environmental, human health, and agricultural advocates; the agrochemical industry; pesticide users; and members of the public interested in pesticide use on food. This list is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. If you have any questions regarding the applicability of this action to you or 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 identification (ID) number OPP-2004-0183. 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-2004-0183. 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-2004-0183. 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-2004-0183.

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-2003-0183. 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

EPA has revised the preliminary assessments of the risks of thiram and identified areas of concern that may require risk mitigation measures. The Agency's dietary, worker, and ecological risk estimates for thiram indicate risks of concern. The Agency's dietary risk estimate indicates acute risk of concern for the general U.S. population and all population subgroups as a result of foliar treatments of apples, peaches, and strawberries. EPA's potential risk mitigation measures for foliar treatments may focus on the apple and strawberry uses because thiram's main foliar uses are on these crops.

For ecological effects, Agency estimates of exposure resulting from thiram's foliar usage and turf applications on sod farms, golf courses, parks, and athletic fields, indicate acute risk to freshwater fish and invertebrates, estuarine/marine fish and invertebrates, reproductive risk to birds, and indirect effects to mammals. These risk estimates also apply to endangered species. Agency estimates of exposure strongly suggest that thiram-treated seed may pose a risk of causing reproductive impairments to wild bird species. EPA received additional information submitted during the Phase 3 comment period pertaining to thiram's use on seed and impact to avian species, but has not completed the review of the data. This additional data may be used to further refine the risk estimates to birds from thiram-treated seed.

Further, worker risks of concern include some loading scenarios for aerial granular application, some handheld equipment use, and a few commercial and on-farm seed treatment scenarios.

EPA has compiled information on thiram's uses and usages, which will be used in conjunction with comments received during the Phase 3 public comment period to perform a benefits analysis. EPA's preliminary findings show several other useful protectant fungicides are available for foliar use based on a review of the USDA Crop Profiles for California, Oregon, and Washington apples, and California and Florida strawberries, and communications with several state crop specialists on the relative importance of thiram in these states.

Thiram's importance for uses on non-residential turf on sod farms and golf courses appears to be relatively low. Thiram's use on golf courses may be less than 0.1% of total golf course acres treated. Thiram's use on sod farms appears to be negligible and may be less than 1% of acres treated.

Thiram's importance for use on seed seems relatively high. Up to 631,000 pounds of thiram (active ingredient) per year are used to treat about 1.3 billion pounds of seed. About 24 million acres are planted with thiram-treated seed. The five crops reflecting the distribution of the acres planted with seed treated with thiram in order of total acres planted are: Cotton, wheat, barley, oats, and sugar beets. These five crops comprise a total of greater than 98% of all acres planted with thiram-treated seed.

EPA has identified some possible preliminary risk reduction options for thiram. The Agency is awaiting additional data on thiram that could be used to refine the acute dietary risk assessment; however, based on the current assessment, eliminating the uses on both strawberries and apples would bring the dietary risk below the Agency's level of concern. This option would also reduce the worker and ecological risks posed by the foliar usage of thiram.

To address the ecological risks posed by thiram's usage on turf, an option would be to limit the use of thiram to golf course tees and greens. In relation to addressing these risk concerns, the technical registrant has submitted a voluntary letter of cancellation that eliminates the uses of thiram for turf applications to parks, athletic fields, and commercial landscapes; and all homeowner and retail uses as for animal repellency on residential lawns or turf, turf being grown for sale or other commercial use such as sod.

To address the risk concerns for workers, an option would be to add additional levels of personal protection (e.g., the use of a respirator) or to eliminate certain application methods

(e.g., high pressure handwand), or use sites (e.g., on-farm seed treatment). In relation to addressing these risk concerns, the technical registrant has submitted a voluntary letter of cancellation that eliminates the on-farm seed treatment of peanuts.

EPA is investigating additional risk reduction options to mitigate ecological risks of concern posed by the seed treatment uses of thiram. Commenters are encouraged to discuss the feasibility of restricting the broadcasting of treated seed and means to ensure that spillage from drilled seeding applications is removed from the field or buried, as has been required by the European Union. Alternatively, restrictions could be placed on which types of seed are treated, the areas of the country where thiram-treated seed could be planted, and/or the time of year it is planted. The Agency encourages stakeholders to submit risk management proposals.

EPA has identified the areas of risk posed by thiram as it is currently labeled and seeks stakeholder input on how thiram use and usages can be modified to reduce these risks. EPA encourages stakeholder input on the following items to assist in developing a risk mitigation plan:

1. Describe how you use thiram during your production cycles. What production changes would you make if thiram were not available including alternative fungicides? What specific pests are being targeted?
2. How effective are the alternatives to thiram? What are the differences in costs associated with the use of thiram alternatives? What impact, if any, do you observe to quality or yield?
3. What is the maximum application rate that you use and how often do you use it?
4. How important is thiram for the foliar, turf, and seed treatment uses?
5. How can the Agency reduce ecological risks posed by thiram-treated seed?
6. How can the Agency reduce occupational risks posed by thiram (e.g., sewing bags of commercially treated seed or applying thiram with high pressure handwand)?

III. What Action is the Agency Taking?

EPA is providing an opportunity, through this notice, for interested parties to provide written comments and input to the Agency on the risk assessments and preliminary risk reduction options for thiram. These documents have been developed as part of the public participation process that EPA and USDA are using to involve the public in the reassessment of pesticide tolerances under FQPA, and the

reregistration of individual pesticides under FIFRA. A goal of the public participation process has been to find a more effective way for the public to participate at critical junctures in the Agency's development of pesticide risk assessments and risk management decisions. EPA and USDA began implementing this pilot process in August 1998, to increase transparency and opportunities for stakeholder consultation. The documents being released to the public through this notice provide information on the revisions that were made to the thiram preliminary risk assessments, which were released to the public on January 26, 2004 (69 FR 3581) (FRL-7341-2), through notices in the **Federal Register**. The Agency's human health and environmental risk assessments and other related documents for thiram are available in the individual pesticide docket. As additional comments, reviews, and risk assessment modifications become available, these will also be docketed for thiram.

In addition, this notice starts a 60-day public participation period during which the public is encouraged to submit risk management proposals or other comments on risk management for thiram. The Agency is providing an opportunity, through this notice, for interested parties to provide written comments on risk management proposals or ideas for thiram. Such comments and proposals could address ideas about how to manage dietary, occupational, or ecological risks on specific thiram use sites or crops across the United States or in a particular geographic region of the country. To address dietary risk, for example, commenters may choose to discuss the feasibility of modifications in use, and usages of thiram or suggest alternative measures to reduce residues contributing to dietary exposure. For occupational risks, commenters may suggest personal protective equipment or technologies to reduce exposure to workers and pesticide handlers. For ecological risks, commenters may suggest ways to reduce environmental exposure, e.g., exposure.

All comments should be submitted by August 31, 2004, using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**. Comments will become part of the Agency record for thiram.

List of Subjects

Environmental protection, Thiram, Pesticides, Tolerance reassessment.

Dated: June 29, 2004.

Debra Edwards,

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

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