

The sum of these adjustments is a decrease of 57,855 responses and 7,134,152 burden hours from the current approved total. According to the procedures prescribed in 5 CFR 1320.12, EPA has submitted this ICR to OMB for review and approval. Any comments related to the renewal of this ICR should be submitted within 30 days of this notice, as described above.

Dated: November 22, 2002.

Oscar Morales,

Director, Collection Strategies Division, Office of Environmental Information.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0250; FRL-7274-7]

Fenarimol; Availability of the Risk Assessments on FQPA Tolerance Reassessment Progress and Tolerance Reassessment Decision (TRED)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's tolerance reassessment decision and related documents for fenarimol including the *Fenarimol Overview*, *Fenarimol Summary*, *Fenarimol Decision Document (TRED)*, and supporting risk assessment documents. EPA has reassessed the 42 tolerances, or legal limits, for residues of fenarimol in or on raw agricultural commodities. These tolerances are now considered safe under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: Comments on the tolerance reassessment decision or on the human health effects risk assessment for fenarimol, identified by docket ID number OPP-2002-0250, must be received by EPA on or before January 3, 2003. In the absence of substantive comments, the tolerance reassessment decision will be considered final.

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. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0250 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Tom Myers, Special Review and

Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8589; e-mail address: myers.tom@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, but will 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 use of pesticides. The Agency has not attempted to describe all the persons or entities who may be interested in or affected by this action. If you have questions in this regard, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

You can obtain copies of the TRED and related documents discussed in this notice on EPA's website at <http://www.epa.gov/pesticides/reregistration/status.htm>. Information on pesticide reregistration and tolerance reassessment, including the purpose and status of Agency programs to complete Reregistration Eligibility Decisions (REDs), Interim REDs, and tolerance reassessment decisions (TREDs), is available at <http://www.epa.gov/pesticides/reregistration>. General information is available on the Office of Pesticide Programs' home page, <http://www.epa.gov/pesticides/>.

2. *In person.* The Agency has established an official record for this action under docket ID numbers OPP-2002-0250. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official

record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0250 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described in this unit. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0/9.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0250. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that

you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record 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 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 notice 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. What Action is the Agency Taking?

EPA has reassessed the risks associated with current food uses of the pesticide fenarimol, reassessed 42 existing tolerances, and reached a tolerance reassessment and risk management decision. The Agency is issuing for comment the resulting report on FQPA tolerance reassessment progress, including the *Fenarimol Overview, Fenarimol Summary, Fenarimol Decision Document (TRED)*, and supporting risk assessment documents.

EPA must review tolerances and tolerance exemptions that were in effect when FQPA was enacted in August 1996, to ensure that these existing pesticide residue limits for food and

feed commodities meet the safety standard established by the new law. Tolerances are considered reassessed once the safety finding has been made or a revocation occurs. EPA has reviewed and made the requisite safety finding for the tolerances and exemptions included in this notice. EPA approved registration of products containing fenarimol as an active ingredient prior to the 1996 enactment of the Food and Quality Protection Act; therefore, while no reregistration decision is required at present, risks from non-occupational exposure to fenarimol through food, drinking water, and residential uses must be reassessed. The Agency has evaluated the dietary risk associated with fenarimol and has determined that there is a reasonable certainty, with appropriate mitigation, that no harm to any population subgroup will result from aggregate exposure to fenarimol when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Residential post-application exposure was of concern for children and infants from fenarimol products applied in residential settings. To mitigate this risk, the registrant has agreed to remove the residential uses from their labels until they conduct a special developmental toxicity study that will assess possible effects of fenarimol on the adult and juvenile rat hormonal systems. Once these data are submitted and reviewed, the Agency will make a determination regarding the reinstatement of the residential uses. For chronic drinking water risk from surface water, potential (average) estimated environmental concentrations (EECs) of fenarimol (84 parts per billion (ppb)) exceeds the chronic drinking water level of comparison (DWLOC) for all populations.

The 84 ppb value includes all residential uses and the golf course use of fenarimol. However, with the residential uses removed from the label, a correction factor of 0.31 can be applied to the 84 ppb surface water number to account for the use of fenarimol only on tees, greens, and fairways on golf courses. This would reduce the chronic EEC to 26 ppb. Infants and children, the most sensitive population subgroups would still exceed the chronic DWLOC of 20. However, the chronic EECs were estimated using Tier I modeling and only slightly exceed the DWLOC. Additional data are being required that will provide important information on the mobility of fenarimol and its degradates. These studies will help to

refine the chronic surface water, ground water, and drinking water risk assessments. The Agency has reassessed all 42 tolerances for fenarimol and can make a FQPA safety determination. In addition, available residue chemistry data support the establishment of a 0.02 part per million (ppm) permanent tolerance for fenarimol residues in filberts under 40 CFR 180.421 (a). The Agency has sufficient residue data for reassessing the tolerances for fenarimol. The chronic dietary exposure assessment for fenarimol is highly refined using anticipated residues based on 1996–1999 Food and Drug Administration (FDA) monitoring data for apples, bananas, cherries, grapes, and pears. Field trial residue data were used for pecans and filberts. Percent crop treated information and processing factors, where available, were used in the assessment. There were no U.S. Department of Agriculture Pesticide Data Program monitoring data available for fenarimol. Residues of fenarimol *per se* were non-detectable (below the method limit of detection (LOD)) in all 1996–1999 FDA monitoring samples of apples, bananas, grapes, and pears (a total of more than 3,000 samples). Out of 214 cherry samples, three had detectable residues. Residues of fenarimol *per se* were non-detectable <LOD in/on all but one pecan nut meat sample from seven trials. There were no detectable residues in filbert samples from four field trials. Chronic dietary risks from exposure do not exceed the Agency's level of concern.

EPA works with affected parties to reach the tolerance reassessment decisions. The Agency therefore is issuing the fenarimol decision as a final decision with a public comment period. All comments received during the public comment period will be carefully considered by the Agency. If any comment significantly affects the Agency's decision, EPA will publish an amendment to the decision in the **Federal Register**. In the absence of substantive comments, the tolerance reassessment decisions reflected here will be considered final.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: November 15, 2002.

Betty Shackelford,

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

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