Prepublication Copy Notice:

The Director of the Pesticide Re-Evaluation Division in the Office of Pesticide Programs signed the following *Federal Register* document on September 14, 2016:

Title:	Registration Review; Draft Malathion Human Health Risk Assessment; Notice of Availability
Action:	Notice
FRL:	9952-53
Docket No.:	EPA-HQ- OPP-2009-0317

This is a **prepublication version** of the document that EPA is submitting for publication in the *Federal Register*. While the Agency has taken steps to ensure the accuracy of this prepublication version of the document, **it is not the official version** of the document for purposes of public comment or judicial review. Please refer to the official version of the document that will appear in a forthcoming *Federal Register* publication, which is currently expected to occur within 10 work days of the signature date.

Once the official version of the document publishes in the *Federal Register*, the prepublication version of the document posted on the agency's internet will be replaced with a link to the document that appears in the *Federal Register* publication. At that time, you will also be able to access the on-line docket for this *Federal Register* document at *http://www.regulations.gov*.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2009-0317; FRL-9952-53]

Registration Review; Draft Malathion Human Health Risk Assessment; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health risk assessment for the registration review of malathion (case 0248) for public review and comment. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed a comprehensive draft human health risk assessment for malathion. After reviewing comments received during the public comment period, EPA may issue a revised human health risk assessment, explain any changes to the draft risk assessment, respond to comments, and may request public input on risk mitigation before completing its proposed registration review decision for malathion. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number

EPA-HQ-OPP-2009-0317, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact the Chemical Review Manager*: Steven Snyderman at telephone number: (703) 347-0249; email address: *snyderman.steven@epa.gov*.

For general questions on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8015; email address: *dumas.richard@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, farm worker, 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 Chemical Review Manager identified in **FOR FURTHER INFORMATION CONTACT.**

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

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, 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 or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

II. Authority

EPA is conducting its registration review of malathion pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. FIFRA section 3(g) provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Review

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations for malathion to ensure that they continue to satisfy the FIFRA standard for registration—that is, that malathion can still be used without unreasonable adverse effects on human health or the environment. Information concerning the registration review of malathion (case 0248) is in the docket, under Docket ID No. EPA-HQ-OPP-2009-0317.

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's

draft human health risk assessment for malathion. Such comments and input could address, among other things, the Agency's risk assessment methodologies and assumptions, as applied to this draft human health risk assessment. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to the draft human health risk assessment. EPA will then issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments. In the **Federal Register** notice announcing the availability of the revised risk assessment, if the revised risk assessment indicates risks of concern, the Agency may provide a comment period for the public to submit suggestions for mitigating the risk identified in the revised risk assessment before developing a proposed registration review decision for malathion.

1. *Other related information*. Additional information on the registration review status of malathion, as well as information on the Agency's registration review program and on its implementing regulation is available at *https://www.epa.gov/pesticide-reevaluation*.

2. *Information submission requirements*. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

• To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.

• The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

• Submitters must clearly identify the source of any submitted data or information.

• Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq.*

Dated: 9/14/2015

Yu-Ting Guilaran

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.