



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2016-0167; FRL-9944-32]**

### **Chlorpyrifos, Diazinon, and Malathion Registration Review; Draft Biological Evaluations; Notice of Availability**

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

**ACTION:** Notice.

**SUMMARY:** EPA is announcing the availability of the draft biological evaluations for the registration reviews of all uses of chlorpyrifos, diazinon, and malathion 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. Through the registration review program, EPA is ensuring that each pesticide's registration is based on the most current scientific methods. Furthermore, EPA is meeting its obligation under section 7 of the Endangered Species Act by ensuring that each pesticide's registration is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of designated critical habitat.

**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-2016-0167, 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 for the pesticide of interest identified in the following table.

<b>Registration Review Case Name and Number</b>	<b>Pesticide Docket ID Number</b>	<b>Chemical Review Manager, Telephone Number, Email Address</b>
Chlorpyrifos, 100	EPA-HQ-OPP-2008-0850	Dana Friedman, 703-347-8827, <a href="mailto:friedman.dana@epa.gov">friedman.dana@epa.gov</a>
Diazinon, 238	EPA-HQ-OPP-2008-0351	Khue Nguyen, 703-347-0248, <a href="mailto:nguyen.khue@epa.gov">nguyen.khue@epa.gov</a>
Malathion, 248	EPA-HQ-OPP-2009-0317	Steven Snyderman, 703-347-0249, <a href="mailto:Snyderman.steven@epa.gov">Snyderman.steven@epa.gov</a>

*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](mailto: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, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides and/or the potential impacts of pesticide use on listed species and designated critical habitat. 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 for the pesticide of interest identified under **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 pesticides discussed in this document, compared to the general population.

## **II. Executive Summary**

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

EPA is providing an opportunity for public review of its draft biological evaluations for the registration reviews of chlorpyrifos, diazinon, and malathion. 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. As part of the registration review process, the Agency has completed comprehensive draft biological evaluations for all chlorpyrifos, diazinon, and malathion uses.

These draft biological evaluations represent the first ever nationwide assessments of these pesticides to federally endangered and threatened species (*i.e.*, listed species) and designated critical habitat. The interim scientific methods used in these draft biological evaluations were developed collaboratively with the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS), hereafter referred to as the Services, based on recommendations from the April 2013 National Academy of Sciences (NAS) report "Assessing Risks to Endangered and Threatened Species from Pesticides." As

part of this effort, the U.S. Department of Agriculture has provided expertise on crop production and pesticide uses and assistance with the use of the National Agricultural Statistics Service Cropland Data Layer to help define the footprint of agricultural use patterns.

After reviewing comments received during the public comment period, EPA will issue revised final biological evaluations, explain any changes, respond to comments, and may request public input on risk mitigation before completing proposed registration review decisions for chlorpyrifos, diazinon, and malathion. For those species and designated critical habitats where registered uses of the pesticides are “likely to adversely affect” species and/or habitat, USFWS and NMFS will utilize the analyses and data from the biological evaluations in their final Biological Opinions for each of the three chemicals.

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

EPA is conducting its registration review of chlorpyrifos, diazinon, and malathion pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA 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.

EPA develops endangered species biological evaluations and consults with the

Services pursuant to section 7(a)(2) of the Endangered Species Act (ESA), 16 U.S.C. 1531 *et seq.*, and the implementing regulations at 50 CFR Part 402.

### **III. Registration Reviews**

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations for chlorpyrifos, diazinon, and malathion to ensure that these registrations continue to satisfy the FIFRA standard for registration—that is, that chlorpyrifos, diazinon, and malathion can still be used without unreasonable adverse effects.

EPA has been collaborating with the Services to develop interim scientific approaches to assess the impact of pesticides on listed species and designated critical habitat, as required by ESA and as recommended by the April 2013 NAS report. Chlorpyrifos, diazinon, and malathion were selected for the development and implementation of these interim approaches because these pesticides were included in the first Biological Opinion issued by NMFS in response to litigation brought by the Washington Toxics Coalition (WTC) with regard to salmonids in the Pacific Northwest. This Biological Opinion was later remanded to NMFS by the U.S. Court of Appeals for the 3<sup>rd</sup> Circuit. The interim scientific approaches used in the draft biological evaluations for chlorpyrifos, diazinon, and malathion were developed based on a collaborative effort among the agencies, and will be refined based on the public comments received on the draft biological evaluations as well as input from an ESA stakeholder workshop planned for the summer of 2016. More information on this process is available at <https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and>.

Chlorpyrifos is an organophosphate (OP) insecticide, acaricide, and miticide used to control a variety of insects on a variety of food and feed crops. Currently registered uses

include a variety of fruits, nuts, vegetables, grains, and non-agricultural areas (such golf course turf, industrial sites, greenhouses and nurseries, sod farms, and wood products). Public health uses include aerial and ground-based fogger treatments to control mosquitoes. There are also residential uses of ant and roach bait products and fire ant mound treatments. EPA has completed a draft biological evaluation to assess whether all registered uses of chlorpyrifos may affect listed species and designated critical habitat. The chlorpyrifos draft biological evaluation is viewable at: <https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos>. Comments on the draft biological evaluation for chlorpyrifos should be submitted to the chlorpyrifos registration review docket (EPA-HQ-OPP-2008-0850) at <http://www.regulations.gov>.

Diazinon is a restricted use OP insecticide currently registered for use on a number of fruits, vegetables, nuts, ornamentals, and in cattle ear tags. All residential uses were phased out as part of risk mitigation during reregistration, and there are currently no residential uses. EPA has completed a draft biological evaluation to assess whether all registered uses of diazinon may affect listed species and designated critical habitat. The diazinon draft biological evaluation is viewable at: <https://www.epa.gov/endangered-species/biological-evaluation-chapters-diazinon>. Comments on the draft biological evaluation for diazinon should be submitted to the diazinon registration review docket (EPA-HQ-OPP-2008-0351) at <http://www.regulations.gov>.

Malathion is a non-systemic, wide spectrum OP. It is used in the agricultural production of a wide variety of food/feed crops to control insects such as aphids, leafhoppers, and Japanese beetles. Malathion is also used in USDA's Cotton Boll Weevil Eradication Program, Fruit Fly (Medfly) Control Program, and for mosquito-borne disease control. It is

also registered for outdoor residential uses which include vegetable gardens, home orchards, and ornamentals. EPA has completed a draft biological evaluation to assess whether all registered uses of malathion may affect listed species and designated critical habitat. The draft malathion biological evaluation is viewable at: <https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion>. Comments on the draft biological evaluation for malathion should be submitted to the malathion registration review docket (EPA-HQ-OPP-2009-0317) at <http://www.regulations.gov>.

#### **IV. Public Review and Comment Opportunity**

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 biological evaluations for chlorpyrifos, diazinon, and malathion. Such comments and input could address, among other things, the Agency's risk assessment methodologies and assumptions, as applied to these draft biological evaluations. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to the draft biological evaluations. EPA will then issue final biological evaluations, explain any changes to the draft biological evaluations, and respond to comments. For those species and designated critical habitats where registered uses of the pesticides are "likely to adversely affect" species and/or habitat, USFWS and NMFS will utilize the analyses and data from the biological evaluations in their final Biological Opinions for each of the three chemicals. The final Biological Opinions for the three chemicals are currently scheduled for December 2017. In the Federal Register notice announcing the availability of the final biological evaluations, if the final biological evaluations indicate risks of concern, the Agency may provide a comment period for the public to submit suggestions for mitigating the risk identified in the

final biological evaluations before developing proposed registration review decisions for chlorpyrifos, diazinon, and malathion.

1. *Other related information.* Additional information on endangered species risk assessment and the NAS report recommendations are available at

<https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and>. Information on the Agency's registration review program and 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: March 28, 2016.

Michael Goodis,

Acting *Director*,

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

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