

## PRE-PUBLICATION NOTICE

On May 10, 2019, Alexandra Dapolito Dunn, EPA's Assistant Administrator for Chemical Safety and Pollution Prevention, signed the following document:

Action: Notice.

Title: Pesticides; Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides; Notice of Availability and Public Meeting

FRL #: 9993-03 (19P-0081)

Docket ID #: EPA-HQ-OPP-2019-0185

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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-2019-0185; FRL-9993-03]**

**Pesticides; Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides; Notice of Availability and Public Meeting**

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is seeking comment on a draft revised method for conducting national level threatened and endangered (listed) species biological evaluations (BEs) for pesticides. EPA is also announcing a public meeting on June 10, 2019, where EPA will present the draft revised method and provide an additional opportunity for the public to provide feedback.

**DATES:** *Meeting:* The public meeting will be held from 9:00 a.m. to 12:00 noon, Eastern Standard Time, on June 10, 2019, and you must register to participate in the meeting using the instructions in Unit III. on or before May 30, 2019.

*Accommodations requests:* To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

*Comments:* Comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** *Meeting:* The meeting will be held in the Lobby-level Conference Center of EPA's Potomac Yard South Bldg. (One Potomac Yard), 2777 South Crystal Drive, Arlington, VA 22202-4501. EPA's Potomac Yard South Bldg. is approximately 1 mile from the Crystal

City Metro Station. Register to participate in the meeting using the instructions in Unit III.

*Comments:* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2019-0185, 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:** Tracy Perry, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0128; email address: [perry.tracy@epa.gov](mailto:perry.tracy@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

This 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. Given the broad interest, the Agency has not attempted to identify or describe all the specific entities that may be affected by this action.

*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>.

*C. How Can I Get Copies of this Document and Other Related Information?*

A copy of the EPA Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides is available in the docket. The docket, identified by docket ID number EPA-HQ-OPP-2019-0185, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-

1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

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

### *A. Authority*

The Endangered Species Act (ESA), 16 U.S.C. 1531 *et seq.*, requires federal agencies, such as EPA, to ensure that their actions are not likely to jeopardize the continued existence of species listed as threatened or endangered under the ESA or destroy or adversely modify the designated critical habitat of such species. The registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, constitutes an EPA "action" under the ESA. If EPA determines a pesticide may affect a listed species or its designated critical habitat, EPA must initiate consultation with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service (collectively referred to as the Services), as appropriate. EPA initiates formal consultation with the Services through the conduct and transmittal of a biological evaluation (BE) with its findings.

### *B. Background*

On January 18, 2017, EPA released its first nationwide BEs for pesticides conducted using a pilot interagency method developed by EPA and the Services, with collaboration from the U.S. Department of Agriculture (USDA). The pilot method was developed following the recommendations of the April 2013 National Academy of Sciences' (NAS) report, *Assessing Risks to Endangered and Threatened Species from Pesticides*. When developing the pilot process, EPA and the Services intended to revisit and refine the method to address limitations identified through evaluation of the pilot chemicals (i.e., chlorpyrifos, diazinon and malathion). A full description of the pilot method and the NAS report recommendations are available at:

*<https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and>.*

EPA believes that the pilot method had the following major limitations: (1) The method did not meaningfully distinguish species that are likely to be exposed to and affected by the assessed pesticides from those that are not likely; (2) The level of effort was too high for EPA to sustain for all pesticides; and (3) The amount of documentation produced was too great for the public to review and comment upon in a reasonable timeframe. Consistent with the pilot process, EPA has developed and is proposing a revised method for the nationwide evaluation of pesticide risks to listed species that is based on the experience gained through the pilot BEs and on information received in public comments on the draft pilot BEs and through several stakeholder meetings. EPA's draft revised method, which continues to follow NAS's recommendations, is designed to be: (1) Efficient, relying upon automation as much as possible; (2) Protective without being overly conservative; (3) Transparent; and (4) Scientifically defensible, relying on the best available data.

### *C. Summary of Major Aspects of Draft Revised Method*

The following is a summary of the major aspects for which the EPA is seeking comment on the draft revised method for assessing risk to listed species.

First, to more accurately represent where and to what extent a pesticide is likely to be applied, EPA is proposing an approach for incorporating pesticide-specific usage data into the listed species consultation process. The pilot BEs relied on use assumptions from pesticide product labels to represent where the pilot chemicals were likely to be applied (e.g., applied to all labelled crops at maximum application rates simultaneously). The revised method proposes to incorporate usage data (e.g., survey data, including actual application rates) in the determination

of where a pesticide is likely to be applied.

Second, based on the accuracy of the spatial data utilized and the conservative assumptions related to the action area and potential drift, EPA is interpreting a <1% overlap of listed species' ranges with potential use sites as unreliable and not representative of real exposure potential.

Third, EPA's revised method proposes the use of probabilistic methods to determine the likelihood of a species to be adversely affected by a pesticide. The goal of the probabilistic analysis is to more fully capture and characterize the variability in the range of potential exposures and toxicological effects to listed species and to better inform the biological opinion.

The fourth major area of revision is to apply a weight-of-evidence framework to distinguish those listed species that are likely to be adversely affected (LAA) from those that are not likely to be adversely affected (NLAA), based on criteria (e.g., dietary preferences, migration patterns, extent of range potentially exposed) associated with the likelihood that an individual will be exposed and affected.

#### *D. Public Comments Sought*

EPA is seeking comment on the draft revised method for assessing risk to listed species, and is specifically interested in comments regarding the degree to which the following aspects of its draft revised method are reasonable and represent advances in the pilot methodologies for assessing risk to listed species: 1) The proposed methodology for incorporating usage data in Steps 1 and 2 of the BE; 2) The proposed interpretation that a <1% overlap of listed species' ranges with potential use sites is unreliable, based on the accuracy of the underlying data, and does not represent real-world exposure; 3) The proposed approach for introducing components of probabilistic analyses into the BE; and 4) The proposed weight-of-evidence framework.

### **III. Public Meeting**

EPA will host a public meeting, along with representatives from the Services and USDA, to present the draft revised method and to provide an additional opportunity for the public to provide feedback. This meeting is an opportunity for stakeholders and agencies to continue their dialogue on the technical aspects of implementing the NAS recommendations, building on public meetings held in November 2013, April and October 2014, April 2015, and June 2016, and furthers the agencies' goal of developing a sustainable methodology and process for assessing pesticide impacts on listed species that is efficient, inclusive, and transparent.

*Date:* The meeting will be held on Monday, June 10, 2019 from 9:00 am. to 12:00 noon, E.S.T. Additional meeting details, including an agenda, teleconference and webinar information, will be available shortly in the docket.

*Accommodations requests:* To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting to give EPA as much time as possible to accommodate your request.

*Requests to participate:* You must register by Thursday, May 30, 2019 to attend either in person or via teleconference/webinar. Public comments may be made during the oral comment session of the meeting. Requests to participate in the meeting and to make oral comments must be submitted to the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

Dated: \_\_\_\_\_.

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**Alexandra Dapolito Dunn,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*