



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2020-0263; FRL-10009-83]

FIFRA Scientific Advisory Panel; Notice of Public Meetings and Request for Nominations of *Ad Hoc* Expert Reviewers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day public peer review meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) to consider and review the use of new approach methodologies (NAMs) to derive extrapolation factors and evaluate developmental neurotoxicity for human health risk assessment. Preceding the public peer review meeting, there will be a public preparatory virtual meeting, conducted via teleconference and webcast, to consider the scope and clarity of the draft charge questions for this peer review. In addition, EPA is requesting nominations of prospective candidates for service as *ad hoc* reviewers to assist the FIFRA SAP with this review. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for this review by following the instructions provided in this notice.

DATES: *Nominations:* Submit nominations of candidates to serve as *ad hoc* reviewers on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

Preparatory Virtual Meeting: The preparatory virtual meeting will be held on August 25, 2020, from 1:00 p.m. to approximately 4:00 p.m. (EDT). You must register online on or before August 25, 2020, to receive the webcast meeting link and audio teleconference information. You must

submit your written comments or request time to present oral comments for the preparatory virtual meeting on or before noon, August 21, 2020.

Peer Review Meeting: The 4-day public peer review meeting will be held September 15-18, 2020, from 9:00 a.m. to approximately 5:00 p.m. (EDT) (as needed, updated times for each day may be provided in the meeting agenda that will be posted in the docket at <http://www.regulations.gov> and the FIFRA SAP website at <http://www.epa.gov/SAP>). To make oral comments during the peer review meeting and be included on the meeting agenda, please register by noon on September 9, 2020. Any written comments submitted for the peer review meeting on or before September 9, 2020, will be provided to the FIFRA SAP for their consideration before the meeting. Comments received after September 9, 2020, and prior to the oral public comment period during the meeting will be available to the FIFRA SAP for their consideration during the meeting.

Special accommodations: Requests for special accommodations should be submitted on or before August 25, 2020, to allow EPA time to process these requests.

ADDRESSES: *Nominations:* Submit your nominations of candidates to the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

Preparatory Virtual Meeting: Registration is required to participate during the public preparatory virtual meeting. Please refer to the FIFRA SAP website at <http://www.epa.gov/sap> for information on how to register.

Peer Review Meeting: The location of the 4-day public peer review meeting will be announced on the FIFRA SAP website at <http://www.epa.gov/sap>. You may also subscribe to the following listserv for alerts regarding this and other SAP-related activities:

https://public.govdelivery.com/accounts/USAEPAOPP/subscriber/new?topic_id=USAEPAOPP

T_101. This peer review meeting may also be viewed via webcast. Please refer to the FIFRA SAP website at <http://www.epa.gov/sap> for information on how to access the webcast.

Special accommodations: For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

Comments: Submit requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

Submit written comments, identified by docket identification (ID) number EPA-HQ-OPP-2020-0263, through the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>. For additional instructions related to this meeting, see **SUPPLEMENTARY INFORMATION**.

Please note that due to the current COVID-19 public health emergency the EPA Docket Center (EPA/DC) and Reading Room were closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>. For questions about this docket, you may also contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Tamue Gibson, DFO, Office of Science

Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7642; email address: gibson.tamue@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. Where can I access information about the FIFRA SAP and this meeting?

Information about the FIFRA SAP and this meeting is available on the FIFRA SAP website at <http://www.epa.gov/scipoly/sap> and in the docket for this meeting, identified by docket ID number EPA-HQ-OPP-2020-0263, at <http://www.regulations.gov>.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through *regulations.gov* or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see Tips for Effective Comments at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. What is the purpose of the FIFRA SAP?

The FIFRA SAP serves as one of the primary scientific peer review mechanisms of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide independent scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on human health and the environment. The FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix I). The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation (NSF). The FIFRA established a Science Review Board consisting of at least 60 scientists who are available to the FIFRA SAP on an *ad hoc* basis to assist in reviews conducted by FIFRA SAP. As a scientific peer review mechanism, the FIFRA SAP provides comments, evaluations, and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of the FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. What is the purpose of this public meeting?

In 2007, the National Research Council (NRC)'s report on *Toxicity Testing in 21st Century: A Vision and a Strategy* was published which encouraged a new paradigm in toxicity testing that reduces the reliance on laboratory animals while moving towards *in vitro* and *in silico* predictive approaches that are more efficient and human relevant. EPA's Office of Pesticide Programs (OPP) has developed a strategic vision for implementing the 2007 NRC report that has multiple components involving a combination of computational and predictive modeling approaches, *in vitro* techniques, and limited, targeted *in vivo* testing.

EPA is actively engaged in numerous activities with respect to reducing laboratory animal use and implementing *in vitro* and computational approaches. As NAMs can provide human relevant information that may be challenging to obtain with whole animal testing. EPA is also interested in using *in vitro* and computational approaches for reducing the reliance on default assumptions for risk assessment, including the application of 10X uncertainty factors for inter- and intra-species extrapolation.

In recent years, EPA began collaborative work with academia, and industry to use organophosphate pesticides (OPs) as a case study for the development of NAMs for purposes of using data to inform extrapolation/uncertainty and safety factors in lieu of reliance on default factors.

The Agency is interested in using *in vitro* data to derive extrapolation factors and evaluate developmental neurotoxicity for human health risk assessment. Specifically, the Agency is seeking advice and recommendation from the FIFRA SAP on scientific issues associated with the evaluation and utility of NAMs as part of a weight of evidence evaluation of developmental neurotoxicity potential and the use of *in vitro* acetylcholinesterase inhibition data to develop interspecies and/or intraspecies data-derived extrapolation factors for organophosphate pesticides.

C. How can I access the FIFRA SAP documents and meeting minutes?

EPA's background paper, the supporting materials, and draft charge/questions provided to the FIFRA SAP will be available by late-June as described in Unit I.B. The Agency will provide additional background documents (e.g., the meeting agenda) as the materials become available. In addition, the FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes

will also be made available as described in Unit I.B.

III. Nominations for *Ad Hoc* Expert Reviewers

A. How do I nominate someone to be considered as an ad hoc expert reviewer to assist the FIFRA SAP in this peer review?

As part of a broader process for developing a pool of candidates for each review, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as *ad hoc* reviewers. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific topic. Nominees should be identified by name, occupation, position, address, email address, and telephone number. The Agency will consider all nominations of prospective candidates for this review that are received on or before the deadline identified in the **DATES** section. Final selection of *ad hoc* reviewers is a discretionary function of the Agency.

B. Who can I nominate to be considered as an ad hoc expert reviewer to assist the FIFRA SAP in this peer review?

Individuals nominated for this meeting should have expertise in one or more of the following areas: (i) Data derived extrapolation factors; (ii) Development and implementation of new approach methodologies; (iii) Statistics; (iv) Developmental neurotoxicity; (v) *In vitro* to *in vivo* extrapolation; and (vi) Organophosphate pesticides. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to provide expert comments on the scientific issues for this review.

C. How will EPA select ad hoc expert reviewers to assist the FIFRA SAP in this peer review?

The selection of scientists to serve on a FIFRA SAP review is based on the function of the Panel and the expertise needed to address the Agency's charge to the Panel. No interested

scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency, except EPA. Other factors considered during the selection process include availability of the potential reviewer to fully participate in the Panel's review, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on a FIFRA SAP review. Numerous qualified candidates are identified for each review; therefore, selection decisions involve carefully weighing a number of factors, including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the Panel. In order to have the collective breadth of experience needed to address the Agency's charge for this review, the Agency anticipates selecting approximately twelve *ad hoc* scientists.

FIFRA SAP members and *ad hoc* reviewers are subject to the provisions of the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, conflict of interest statutes in Title 18 of the United States Code and related regulations. In anticipation of these requirements, prospective candidates for service on the FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks, bonds, and where applicable, sources of research support. EPA will evaluate the candidate's financial disclosure form to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer

review) before the candidate is considered further for service on FIFRA SAP.

EPA plans to make a list of candidates under consideration as prospective *ad hoc* panelists for this meeting available for a 15-calendar day public comment period in July 2020. The list of the FIFRA SAP members and *ad hoc* reviewers participating at this meeting will be available as described in Unit I.B.

Those who are selected from the pool of prospective candidates will be asked to attend the preparatory and peer review meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes and final report.

IV. Public Participation

A. How may I participate in the public peer review meeting?

You may participate in the public peer review meeting by following the instructions in this unit. To ensure proper receipt of comments, nominations or other requests by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2020-0263 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages written comments for the peer review meeting be submitted using the instructions in **ADDRESSES** and Unit I.B. and C, on or before the date set in the **DATES** section. Comments received after this date and prior to the end of the oral public comment period during the meeting will still be provided to the FIFRA SAP for their consideration. Anyone submitting written comments after this date, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments during the meeting should email the DFO prior to the meeting to arrange for distribution of their comments to the FIFRA SAP.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments to the FIFRA SAP during the peer review meeting to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before the date set in the **DATES** section in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the peer review meeting and, to the extent that time permits, the Chair of the FIFRA SAP may permit the presentation of oral comments at the peer review meeting by interested persons who have not previously requested time.

The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. Oral comments before the FIFRA SAP during the peer review meeting are limited to 5 minutes unless arrangements have been made prior to the date set in the **DATES** section. In addition, each speaker should email a copy of his/her comments to the DFO prior to the meeting for distribution to the FIFRA SAP.

3. *Webcast.* This meeting may also be viewed via webcast. Please refer to the FIFRA SAP website at <http://www.epa.gov/sap> for information on how to access the webcast.

B. How may I participate in the preparatory virtual meeting?

Registration for the preparatory virtual meeting is required. To participate by listening or making a comment during this meeting, please visit: <http://www.epa.gov/sap> to register. Registration online will be confirmed by email that will include the webcast meeting link and audio teleconference information.

1. *Written comments.* Written comments for the preparatory virtual meeting should be submitted, using the instructions in **ADDRESSES** and Unit I.B. and C, on or before the date set in the **DATES** section.

2. *Oral comments.* Registration is required to participate in the preparatory virtual meeting. Please visit the FIFRA SAP website at <http://www.epa.gov/sap> to register online. Each individual or group wishing to make brief oral comments to the FIFRA SAP during the preparatory virtual meeting should submit their request when registering online or with the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before the date set in the **DATES** section. Oral comments before the FIFRA SAP during the preparatory virtual meeting are limited to approximately 5 minutes due to the time constraints of this meeting.

3. *Webcast.* The preparatory meeting will be webcast only. Please refer to the FIFRA SAP website at <http://www.epa.gov/sap> for information on how to access the webcast. Registration is required.

Authority: 5 U.S.C. App. I; 7 U.S.C. 136 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: June 8, 2020.

Hayley Hughes,

Director, Office of Science Coordination and Policy.

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