

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0898; FRL-9326-7]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 3-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review Common Effects Assessment Methodology developed in the Office of Pesticide Programs and Office of Water.

DATES: The meeting will be held on January 31, 2012 to February 2, 2012, from 9 a.m. to approximately 5:30 p.m.

Comments. The Agency encourages that written comments be submitted by January 17, 2012 and requests for oral comments be submitted by January 24, 2012. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after January 17, 2012 should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before November 30, 2011.

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP's website, http://www.epa.gov/scipoly/SAP for information on how to access the webcast. Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

Comments. Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0898, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special

arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2011-0898. 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. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at http://www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

Nominations, requests to present oral comments, and requests for special accommodations. Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special seating accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Sharlene R. Matten, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0130; fax number: (202) 564-8382; e-mail address: *matten.sharlene@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, however, 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), FIFRA, and the Food Quality

Protection Act of 1996 (FQPA). 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. If you have any questions regarding the applicability of this action to a particular entity, consult the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

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

When submitting comments, remember to:

- 1. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- 2. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- 3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- 4. Describe any assumptions and provide any technical information and/or data that you used.
- 5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
 - 6. Provide specific examples to illustrate your concerns and suggest alternatives.
- 7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- 8. Make sure to submit your comments by the comment period deadline identified.
- C. How May I Participate in this Meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2011-0898 in the subject line on the first page of your request.

- 1. Written comments. The Agency encourages that written comments be submitted, using the instructions in ADDRESSES, no later than January 17, 2012, to provide FIFRA SAP the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after January 17, 2012 should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT.** Anyone submitting written comments at the meeting should bring 30 copies for distribution to FIFRA SAP.
- 2. *Oral comments*. The Agency encourages that each individual or group wishing to make brief oral comments to FIFRA SAP submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than January 24, 2012, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the 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 (e.g., overhead projector, 35 mm projector, chalkboard). Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of his or her comments and presentation slides for distribution to the FIFRA SAP at the meeting.

- 3. Seating at the meeting. Seating at the meeting will be open and on a first-come basis.
- 4. Request for nominations to serve as ad hoc members of FIFRA SAP for this meeting. As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: Aquatic toxicity estimation tools, aquatic plant toxicity, aquatic animal toxicity, statistics, species sensitivity distributions, and application of toxicity data to development of aquatic life criteria. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before [insert date 14 days from date of publication in the **Federal Register**]. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before this date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP 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 the EPA. Other factors considered during the selection process include availability of the potential panel member to fully participate in the panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack 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 FIFRA SAP. Numerous qualified candidates are identified for each panel. 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 meeting, the Agency anticipates selecting approximately 10 to 12 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, 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 and bonds, and where applicable, sources of research support. The EPA will evaluate the candidates financial disclosure form to assess whether there are financial conflicts of interest, appearance of a lack 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. Those who are selected from the pool of prospective candidates will be asked to attend the public 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. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP website at http://epa.gov/scipoly/sap or may be obtained from the OPP Regulatory Public Docket at http://www.regulations.gov.

II. Background

A. Purpose of FIFRA SAP

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. 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. FIFRA, as amended by FQPA, established a Science Review Board consisting of at least 60 scientists who are available to the SAP on an ad hoc basis to assist in reviews conducted by the SAP. As a peer review mechanism, FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

Both the U.S. Environmental Protection Agency (USEPA), Office of Pesticide Programs (OPP) and the Office of Water (OW) assess the effects of pesticides on aquatic ecosystems using approaches that afford a high degree of protection for aquatic life. EPA's stakeholders have identified differences in the approaches that the OW and the OPP use to evaluate possible effects from pesticides on fish, other aquatic organisms, and aquatic plants. While there are differences in the effects characterization approaches used by EPA under the Clean Water Act (CWA) and FIFRA, both were developed with high quality data using rigorously peer-reviewed assessment methodologies. In characterizing pesticide effects, both programs consider acute effects as well as chronic and sub-lethal effects on growth, survival, and reproduction in their risk assessments.

EPA is now exploring how to build on the substantial high quality science already developed by both programs to develop additional toxicity estimation tools and approaches to support a consistent and common set of effects characterization methods using best available information. EPA's goal in this effort is to develop tools, methods, and approaches that:

- Continue to be based upon sound science and utilize available data,
- Are legally defensible under our statutory mandates,
- Are based upon methodologies that are as consistent and practical as possible,
- Are implementable at the Federal and State levels,
- Are developed as quickly and efficiently as possible, and

Reflect stakeholder input and comments.

In order to characterize potential adverse effects of chemicals in the aquatic environment, EPA uses available toxicity data from studies involving individual test species, which serve as surrogates for untested species. These data are collected for individual organisms exposed to chemicals (e.g., pesticides) and are then frequently extended to represent effects to populations of the same species, populations of similar genera/taxa, or to aquatic ecosystems. The focus of the current efforts is to examine how limited test results can best be used to characterize adverse effects on aquatic animals and plants. To that end, EPA is exploring two general types of methods that may be used to extrapolate from toxicity test results to taxa-specific and community-based measures of effects relevant to the regulatory needs of OPP and OW, as well as the ability of predictive tools to augment in data limited situations. These methods include sensitivity distributions and assessment factors (AFs) both of which may be used to account for uncertainty, particularly in situations where toxicity data are limited. A portion of this work will address the derivation of an "Aquatic Life Screening Value" (ALSV) that is related to the fifth percentile in a sensitivity distribution. ALSVs may be used to screen concentrations of pesticides and effluents in ambient waters and may be used by States and Tribes in the development of water quality standards. Other portions of this work will address other percentiles in sensitivity distributions that can be used to evaluate concentrations of pesticides in ambient water in other ways.

EPA is requesting the SAP provide advice on several proposed tools and methods to characterize the toxicity and effects of chemical stressors on aquatic animals and plants.

- 1. Use of Predictive Toxicology Tools in Characterizing Effects of Chemical Stressors to Aquatic Animals;
- 2. Use of Assessment Factors (AF) in Characterizing Acute Effects of Chemical Stressors on Aquatic Animals ;
- 3. Use of Species Sensitivity Distributions (SSD) in Characterizing Acute Effects of Chemical Stressors on Aquatic Animals;
- 4. Evaluation of Chronic Toxicity Data and the Estimation of Acute to Chronic Ratios (ACR) in Characterizing Chronic Effects of Stressors on Aquatic Animals;
- 5. Methods for Characterizing Effects of Chemical Stressors to Aquatic Plants; and
- 6. Approaches for Characterizing Effects of Chemicals with Limited Data. *C. FIFRA SAP Documents and Meeting Minutes*

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and ad hoc members for this meeting), and the meeting agenda will be available in early January 2012. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, at http://www.regulations.gov and the FIFRA SAP homepage at http://www.epa.gov/scipoly/sap.

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be posted on the FIFRA SAP website or may be obtained from the OPP Regulatory Public Docket at http://www.regulations.gov.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: November 3, 2011.

Frank Sanders,

Director, Office of Science Coordination and Policy.

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