



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2015-0130; FRL-9923-73]**

**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 research to evaluate the potential for juvenile sensitivity to pyrethroids.

**DATES:** The meeting will be held on May 19-21, 2015, from approximately 9:00 a.m. to 5:00 p.m.

*Comments.* The Agency encourages written comments be submitted on or before May 5, 2015, and requests for oral comments be submitted on or before May 12, 2015. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after May 5, 2015, 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 April 7, 2015.

*Webcast.* This meeting may be webcast. Please refer to the FIFRA SAP website at <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:** *Meeting:* 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.

**15P-0044**

*Comments.* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0130, 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>.

*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 accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** Fred Jenkins, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3327; email address: [jenkins.fred@epa.gov](mailto:jenkins.fred@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) 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. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit CBI information to EPA through [regulations.gov](http://www.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 the commenting tips at <http://www.epa.gov/dockets/comments.html>.

### *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-2015-0130 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages written comments be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before May 5, 2015, 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 May 5, 2015, 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 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** on or before May 12, 2015, 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. Oral comments given before the FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 20 copies of his or her comments and presentation for distribution to 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: *In vitro* to *in vivo* extrapolation (IVIVE), Risk assessment, Toxicokinetics, Quantitative modeling and analyses of complex data, Pyrethroid pesticides, Age-dependent pharmacokinetics and metabolism, Enzyme maturation profiles in rodents and humans, Voltage-gated sodium channels, Ontogeny of metabolizing enzymes (e.g., carboxylesterase and P450), Clinical observations of neurotoxicology in animals (adult and neonate). 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, email address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before April 7, 2015. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before that 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 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 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR Part 2634—Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, as supplemented by EPA in 5 CFR Part 6401. In anticipation of this requirement, prospective candidates for service on 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. 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://www.epa.gov/scipoly/sap> or may be obtained from the OPP 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 (5 U.S.C. Appendix). 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 established a Science Review Board (SRB) consisting of at least 60 scientists who are available to FIFRA SAP on an ad hoc basis to assist in reviews conducted by FIFRA SAP. As a scientific 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*

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to register pesticides and the FFDCA gives the agency the authority to establish tolerances for residues resulting on food and/or feed resulting from use of a pesticide. The studies required to allow the agency to make the appropriate statutory safety findings under both of these acts are stipulated under 40 CFR Part 158. There is flexibility, however, in implementing Part 158. Additional data can be required (§158.75), alternative approaches can be accepted, and studies can be waived (§158.45). The 2007 National Research Council (NRC) report from the National Academy of Sciences (NAS) on Toxicity Testing in the 21<sup>st</sup> Century describes this new vision for toxicity testing. In response to the NRC report, EPA's Office of Pesticide Programs (OPP) developed a Strategic Direction for New Pesticide Testing and Assessment Approaches <http://www.epa.gov/pesticides/science/testing-assessment.html> which describes OPP's approach to implementing the NAS vision. One of the key components of OPP's Strategic Direction is improved approaches to more traditional toxicity tests to minimize the number of animals used while expanding the amount of information obtained. OPP also has a recent document, *Guiding Principles for Data Requirements* (<http://www.epa.gov/pesticides/regulating/data-require-guide-principle.pdf>) which describes the principles for requiring toxicology data for pesticides, specifically to "only require data that adequately inform regulatory decision making and thereby avoid unnecessary use of time and resources, data generation costs, and animal testing."

OPP is actively working on a reevaluation of the human health effects of the pyrethroids and pyrethrins under the OPP registration review program ([http://www.epa.gov/oppsrrd1/registration\\_review/index.htm](http://www.epa.gov/oppsrrd1/registration_review/index.htm)), required under FIFRA.

Until late 2009, OPP requested developmental neurotoxicity (DNT) studies for pyrethroids. However, the agency determined that the DNT studies were not providing adequate data to evaluate the potential for post-natal sensitivity to pyrethroids. In July, 2010, the FIFRA Scientific Advisory Panel (SAP) reviewed a proposed research strategy to assess the potential for juvenile sensitivity consistent with the recommendations of the NAS in its report

on Toxicity Testing in the 21<sup>st</sup> Century using a combination of *in vitro* studies, targeted *in vivo* studies, and physiologically-based pharmacokinetic (PBPK) models.

Based on feedback from the SAP and the agency, the industry research proposal was revised. Since late 2010, the Council for the Advancement of Pyrethroid Human Health Risk Assessment (CAPHRA) has worked with industry and academic scientists to develop assays and models to assess the potential for juvenile post-natal sensitivity to pyrethroids. The on-going research effort is organized around the adverse outcome pathway (AOP) for pyrethroids: Alterations with voltage-gated sodium channels (VGSC), leading to alterations in membrane excitability and firing potentials and ultimately to *in vivo* clinical syndromes. Specifically, the CAPHRA is evaluating the potency of pyrethroids to human sodium channels and transplantation of adult and juvenile rat synaptic membrane into oocytes. In addition, the CAPHRA is conducting targeted *in vivo* studies on behavioral metrics and developing PBPK models. The research, thus far, has focused on development of the overall approach using data for deltamethrin and permethrin (Type II and Type I pyrethroids, respectively). The CAPHRA research is at a point where feedback on extending this research to the other pyrethroids would be constructive. The CAPHRA proposal is to use the knowledge gained with deltamethrin and permethrin to develop more targeted datasets using read across and computational approaches (i.e., less data generation) for other pyrethroids. As such, the agency will be seeking the SAP's advice on the current state of the science with the CAPHRA research effort and proposals for next steps which include extension of data on deltamethrin and permethrin to other pyrethroids.

### 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 by approximately 4 weeks before the meeting. 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 at <http://www.regulations.gov> and the FIFRA SAP website 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 Docket at <http://www.regulations.gov>.

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

Dated: March 13, 2015.

David J. Dix,

*Director, Office of Science Coordination and Policy.*

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