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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2016-0062; FRL-9942-63]

### 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 Chlorpyrifos: Analysis of Biomonitoring Data.

**DATES:** The meeting will be held on April 19-21, 2016, from approximately 9 a.m. to 5 p.m.

*Comments.* The Agency encourages written comments be submitted on or before April 5, 2016, and requests for oral comments be submitted on or before April 12, 2016. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after April 5, 2016, 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 [*insert date 15 days from date of publication in the Federal Register*].

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

**16P-0034**

*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.

*Comments.* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2016-0062, 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*.

**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 (FDCA) 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 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-2016-0062 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 April 5, 2016, 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 April 5, 2016, 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 April 12, 2016, 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 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 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: Human biomonitoring data and interpretation of such data; epidemiology (particularly reproductive/developmental, and environmental), exposure assessment of pesticides (residential and agricultural worker); route-specific pharmacokinetics (dermal, oral); physiologically-based pharmacokinetic modeling (PBPK); cholinergic and non-cholinergic mechanisms; cholinesterase inhibition; developmental neurotoxicity; human health risk assessment; organophosphate pesticides; and pharmacokinetics. [Note: In support of the U.S. Environmental Protection Agency's (EPA) priority of "Making a Visible Difference in Communities" across the country, the Agency is committed to helping minority, low-income, tribal and other vulnerable populations improve their health and environment. In an effort to ensure that the Agency's proposed actions are taking into consideration input from potential communities with environmental justice concerns, the EPA is offering an opportunity to provide input on the FIFRA SAP meeting to address scientific issues associated with "Chlorpyrifos: Analysis of Biomonitoring Data." The EPA encourages all grass-roots organizations and residents to submit public comments on this issue that is being addressed during the FIFRA Scientific Advisory Panel meeting. The Agency also encourages community environmental justice advocates to give a voice to their communities by nominating candidates for consideration to serve on this panel.] Nominees should be scientists who have sufficient professional qualifications, including training and experience, to provide 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 *[insert date 15 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 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 the 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. The Agency anticipates selecting approximately 8 ad hoc scientists to have the collective breadth of experience needed to address the Agency's charge for this meeting.

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 the

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 the 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 the 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*

Chlorpyrifos (0,0-diethyl-0-3,5,6-trichloro -2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide. The FIFRA SAP previously reviewed the human health effects of chlorpyrifos in 2008 and 2012, and the chlorpyrifos physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) model in 2011. At the 2008 and 2012 SAP meetings, the Agency presented information on a variety of science issues such as inhibition of the enzyme acetylcholinesterase (AChE) in the nervous system, epidemiology studies in infants and children which suggest that chlorpyrifos and other OPs impact neurodevelopment, and a growing body of literature with laboratory animals (rats and mice) indicating that gestational and/or early postnatal exposure to chlorpyrifos may cause persistent effects into adulthood. Like other OPs, chlorpyrifos binds to and phosphorylates the enzyme acetylcholinesterase (AChE) in both the central (brain) and peripheral nervous systems. This can lead to accumulation of acetylcholine and ultimately, at sufficiently high doses, to clinical signs of toxicity. As recommended by the FIFRA SAP in 2008 and 2012, the Agency used inhibition of AChE as the critical effect to derive points of departure for the 2014 human health risk assessment. However, the 2014 human health risk assessment identified uncertainty in the degree to which points of departure derived from AChE inhibition are protective for neurodevelopmental effects in humans.

In 2008 and 2012, the FIFRA SAP cautioned the Agency against using the biomonitoring data from epidemiology studies, particularly those from Columbia University in this case, to directly derive points of departure due to uncertainties associated with a lack of knowledge about timing of indoor chlorpyrifos applications and a single measure of exposure (cord blood) which were collected by the Columbia researchers. The concern is that single measures of exposure may not reflect the entire pregnancy or temporal exposure uncertainty coupled with



unknown windows of susceptibility. The 2012 SAP recommended that the Agency consider use of a PBPK model to further characterize the dose estimates in the epidemiology studies.

Based on human health risks identified in the 2014 human health risk assessment, the Agency published a 2015 proposed tolerance revocation for chlorpyrifos; in that proposal the Agency noted that the evaluation of the available biomonitoring was continuing. While EPA would have preferred to complete that analysis prior to commencing rulemaking, the timing for the proposal was directed by the U.S. Court of Appeals for the 9<sup>th</sup> Circuit, which ordered EPA to respond to an administrative petition to revoke all chlorpyrifos tolerances by October 31, 2015. In any case, at this point in time, the Agency's analysis of biomonitoring data from cord blood collected as part of the Columbia University epidemiology studies has progressed to a point where peer review would be useful. Specifically, the Agency has done additional characterization of the pharmacokinetic profile of simulated exposures from oral and dermal exposures using the PBPK model. Based on this evaluation, the Agency now believes the cord blood data are sufficiently robust for deriving points of departure. The Agency will solicit comment from the SAP on the evaluation of biomonitoring data using the PBPK model, proposed points of departure and extrapolation/uncertainty factors, and examples of a proposed approach to use the PBPK model to simulate internal doses from current exposure patterns from drinking water, food and worker exposure.

### *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 mid-March. 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 to 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: February 26, 2016.

David J. Dix,

*Director, Office of Science Coordination and Policy.*

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