BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2014-0331; FRL-9910-22]

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 New High Throughput Methods to Estimate Chemical Exposure.

DATES: The meeting will be held on July 29 to August 1, 2014, from approximately 9:00 a.m. to 5:00 p.m.

Comments. The Agency encourages that written comments be submitted by July 15, 2014 and requests for oral comments be submitted by July 22, 2014. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after July 15, 2014 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 14 days from date of publication in the* Federal Register].

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-2014-0331, 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.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

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.

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: 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; fax number: (202) 564-8382; 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 (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?

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-2014-0331 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 July 15, 2014, 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 July 15, 2014 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 July 22, 2014, 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: Computational exposure modeling, Mathematical modeling of environmental and biological systems and their interactions, Toxicokinetics, Pharmacokinetics, Environmental fate and transport, Modeling of chemical concentrations in water sources, Bioinformatics, Biomathematics, Statistics, Environment and health risk/impact assessment, including vulnerable and/or susceptible populations, Ecological risk assessment, Human exposure assessment, Ecological exposure assessment, Pharma, Monitoring of environmental contaminants- surface water and groundwater. Note: In support of the US 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 actions being proposed by the agency 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 "New High Throughput Methods to Estimate Chemical Exposure". The EPA encourages all grass-root organizations and residents to submit public comments on this issue which 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 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 11 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://www.epa.gov/scipoly/sap* or may be obtained from the OPP Docket or 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 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

EPA has made many recent advances in high throughput bioactivity testing. However, concurrent advances in rapid, quantitative prediction of human and ecological exposures have been lacking, despite the clear importance of both measures for a risk-based approach to prioritizing and screening chemicals. A recent report by the National Research Council of the National Academies, Exposure Science in the 21st Century: a Vision and a Strategy (NRC 2012) laid out a number of applications in chemical evaluation of both toxicity and risk in critical need of quantitative exposure predictions, including screening and prioritization of chemicals for targeted toxicity testing, focused exposure assessments or monitoring studies, and quantification of population vulnerability. Despite these significant needs, for the majority of chemicals (e.g. non-pesticide environmental compounds) there are no or limited estimates of exposure. For example, exposure estimates exist for only 7% of the ToxCast Phase II chemical list. In addition, the data required for generating exposure estimates for large numbers of chemicals is severely lacking (*Egeghy et al*. 2012).

This SAP will review the use of EPA's ExpoCast model to rapidly estimate potential chemical exposures for prioritization and screening purposes. The focus will be on bounded chemical exposure values for people and the environment for the Endocrine Disruptor Screening Program (EDSP) Universe of Chemicals. In addition to exposure, the SAP will review methods to extrapolate an *in vivo* dose from *in vitro* dose data. This will involve presenting pharmacokinetic (PK) data for chemicals that have been run through a battery of high throughput endocrine screening assays and the methodology to use that PK information to estimate an *in vivo* dose. This exposure and RTK information along with high throughput *in vitro* bioactivity data will allow the EPA to assign a risk ranking to chemicals and prioritize them accordingly.

ExpoCast is an EPA initiative to develop the necessary approaches and tools for rapidly prioritizing and screening thousands of chemicals based on the potential for human exposure. This focus for ExpoCast is distinct from many existing exposure tools that support regulatory risk assessment. Traditional exposure tools are lower throughput, requiring considerable data to make predictions of sufficient precision for a full risk assessment. ExpoCast efforts have focused on empirically assessing the uncertainty in forecasts made with limited available data, finding that in some cases even highly uncertain forecasts may be useful for prioritization and screening.

In order to relate high throughput bioactivity data and rapid exposure predictions, an *in vitro-in vivo* extrapolation (IVIVE) via PK is needed. This IVIVE relates the *in vitro* compound concentrations (μM) found to be bioactive to the *in vivo* doses needed to produce serum concentrations equal to the *in vitro* concentrations. Without the time and resources necessary to generate *in vivo* PK data for the thousands of chemicals in the EDSP universe, high throughput pharmacokinetics (HTPK) can serve as a useful surrogate. HTPK methods were developed for

pharmaceuticals to estimate therapeutic doses for clinical studies. HTPK technologies have been effective for pharmaceutical compounds and predicted concentrations are typically on the order of the measured *in vivo* concentrations. For non-therapeutic compounds in humans, PK data is not available and so it is essential to carefully characterize the predictive ability of the HTPK models and define the domain of applicability.

High throughput exposure prediction and high throughput PK, when taken together with *in vitro* bioactivity profiling as a surrogate for hazard, will allow for a risk-based, rapid prioritization and screening of chemicals in the EDSP universe and beyond.

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 July 9, 2014. 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 Docket or at *http://www.regulations.gov*.

List of Subjects

Environmental protection, Pesticides and pests, Environmental justice.

Dated: May 20, 2014.

David J. Dix,

Director, Office of Science Coordination and Policy.

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