BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0182; FRL-9382-3]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review proposed Endocrine Disruptor Screening Program (EDSP) Tier 2 Ecotoxicity Tests.

DATES: The meeting will be held on June 25-28, 2013, from 9 a.m. to approximately 5:30 p.m.

Comments. The Agency encourages that written comments be submitted by June 11, 2013 and requests for oral comments be submitted by June 18, 2013. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after June 11, 2013 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-2013-0182, 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*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets/contacts.html*.

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: Sharlene Matten, DFO, 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; email 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) 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?

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-2013-0182 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 June 11, 2013, 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 June 11, 2013 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 June 18, 2013, 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 25 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:

- Ecotoxicology (fish, avian, and/or amphibian toxicology);
- Comparative Endocrinology and Endocrine Toxicology;
- Histopathology;
- Biostatistics;
- Population Modeling;
- Regulatory toxicology/risk assessment;
- Invertebrate Toxicology and Endocrinology;
- Reproductive physiology;
- Developmental biology/toxicology;
- Thyroid physiology;
- Toxicological pathology;
- Morphometrics;
- Quantitative ecology/biostatistics; and
- Systems biology.

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 12-15 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

Section 408(p) of the Federal Food Drug and Cosmetic Act (FFDCA) requires the EPA to:

> Develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate (21 U.S.C. 346a(p)).

Subsequent to passage of the Food Quality Protection Act in 1996, which amended FFDCA and FIFRA, and amendments to the Safe Drinking Water Act the same year, the EPA formed the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), a Federal advisory committee of scientists and stakeholders that was charged by the EPA to provide recommendations on how to implement its EDSP. The EDSP is described in detail at the following website: *http://www.epa.gov/scipoly/oscpendo/*. Based on the recommendations from the EDSTAC (EDSTAC 1998), the EPA made a number of key decisions using the Administrator's discretionary authority to include not only the estrogen hormonal

pathway, but the androgen and thyroid pathways of the endocrine system in humans as well as in wildlife.

The EDSTAC also recommended the Agency adopt a two-tiered screening and testing program. Tier 1 is an integrated battery of relatively short-term *in vitro* and *in vivo* assays designed to detect the potential of a chemical to interact with the endocrine system, principally the estrogen, androgen, and thyroid hormonal pathways. Test chemicals determined to have the potential to interact with the endocrine system, based on a weight-of-evidence analysis of the results of Tier 1 screening and inclusive of other scientifically relevant information, would be considered for Tier 2 testing. Tier 2 tests consist of more comprehensive, long-term tests during various life stages and multiple generations enhanced with endocrine-specific endpoints across multiple taxonomic groups, including mammals, birds, fish, amphibians, and invertebrates. The purpose of Tier 2 testing is to identify any potential adverse outcome and provide quantitative concentration-response information that may be used for risk assessment.

The EDSP is mandated under FFDCA to use "validated" assays to screen and test for endocrine disrupting chemicals. The focus of this SAP review is on the validation status, based on Organization for Economic Co-Operation and Development (OECD) and Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) validation principles, for the proposed EDSP Tier 2 ecotoxicity tests including:

1. Japanese quail two-generation toxicity test.
2. Larval amphibian growth and development assay.
3. Medaka multigeneration test.

4. Mysid two-generation toxicity test.

The EDSP Tier 2 ecotoxicity tests have been developed and validated based on selected chemicals known to interact with the estrogen, androgen and/or thyroid hormonal pathways of the endocrine system. In general, the performance of respective Tier 2 ecotoxicity tests to determine the magnitude and duration of endocrine mediated effects and quantitatively assess concentration-response relationships will be the focus of this SAP. The SAP will be asked to comment on the reproducibility of results and factors that may impact interpretation of whether or not the proposed Tier 2 tests are sufficient to provide a more comprehensive assessment of the potential of a test chemical to cause - endocrine mediated adverse effects in the subject taxa.

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 approximately 15 days prior to 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 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.

Dated: March 22, 2013.

Steven M. Knott, Acting

Director, Office of Science Coordination and Policy.

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