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Notice

FIFRA Scientific Advisory Panel; Notice of Public Meeting

A Notice by the Environmental Protection Agency on 07/18/2012

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 the Pollinator Risk Assessment Framework.

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DATES:

The meeting will be held on September 11-14, 2012, from approximately 9 a.m. to 5:30 p.m.

Comments. The Agency encourages that written comments be submitted by August 28, 2012 and requests for oral comments be submitted by September 4, 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 August 28, 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 August 1, 2012.

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP's Web site, <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.

Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0543 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), Mail Code: 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>.

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), 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-2012-0543; 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 August 28, 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 August 28, 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 September 4, 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: Terrestrial Community Ecology, Entomology (honeybee), Environmental Fate and Transport, Plant Physiology/Uptake, Residue Chemistry. 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 August 1, 2012. 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 8 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 Web site at <http://www.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

This U.S. Environmental Protection Agency (EPA) FIFRA Scientific Advisory Panel (SAP) meeting will focus on a proposed tiered process for quantitatively evaluating the potential risk to pollinators (using honeybees (*Apis mellifera*) as surrogate) associated with the registered use of both systemic and non-systemic pesticides and the exposure and effects data needed to support that process. During this SAP, the EPA will provide an overview of the proposed tiered process for quantifying the potential risks of pesticides to honeybees. This overview will reflect collective efforts with Health Canada Pest Management Regulatory Agency (PMRA), and California Department of Pesticide Regulation (CalDPR). This will include an overview of the problem formulation step, where protection goals are defined, along with the conceptual model depicting potential routes of exposure and biological receptors ranging from the individual bee (larvae and adult) to the whole colony. Consistent with the risk assessment process for other taxa, the proposed process will consist of a screening-level tier based on conservative assumptions regarding exposure and laboratory-based measures of effect and extending to more refined estimates of risk based on field-based measures of exposure and effects that are more reflective of how the pesticide may act under actual use conditions. The proposed process is intended to enhance the ability of EPA, PMRA and CalDPR to reliably screen chemicals for direct and indirect effects, specifically on managed honeybee colonies, but EPA will also request advice from the SAP on the usefulness of this framework for characterizing potential effects on other, non-*Apis* pollinators. A number of sources have reported declines in certain pollinator species globally. Although a number of factors/agents have been hypothesized as potential contributors to declines in honey bee health in general, at this time, no factor has been identified as the single cause. Rather, the available science suggests that pollinator declines are a result of multiple factors which may be acting in various combinations. Research is being directed at identifying the individual and combinations of stressors that are most strongly associated with pollinator declines.

While the exact cause(s) of the general decline in pollinator species have not been determined, potential contributing factors including diseases, habitat destruction/urbanization, agricultural practices/monocultures, pesticides, nutrition, and bee management practices are among the factors being considered. Surveys of managed migratory bee colonies indicate that a broad range of pesticides have been detected in hive products (e.g., honey, stored pollen, wax). Typically, pesticides occur in combination with other pesticides. In spite of the presence of these compounds in honeybee colonies, at this time, based on the available research there has been no correlation between pollinator declines in general and the use of any pesticide or class of pesticides.

Although, the role of pesticides in pollinator declines has not been well established, global experts from different disciplines (e.g., chemistry, ecotoxicology and entomologists) and across various sectors (e.g., government, academia and industry) agree on the need to advance the science to better assess potential exposure, hazard and risk to honey bees and other pollinators from pesticides used in agriculture. The proposed process which the SAP will be asked to consider reflects a synthesis of domestic and international efforts to develop a means for quantifying the potential effects of pesticides to bees.

Consistent with the current risk assessment paradigm used by EPA, CalDPR, PMRA and other regulatory authorities globally, the proposed selection of exposure and effects data follows a tiered approach intended to address specific assessment endpoints of growth, survival and reproduction. The decision criteria for transitioning to higher tier testing will also be delineated. The collective aim of the SAP will be to delineate a process for qualitatively and quantitatively assessing risks to honeybees and by extension to other insect pollinators for which honeybees serve as surrogates. The development of a risk assessment process for honeybees and identification of the data needed to inform that process relies on a clear articulation of the problem formulation and risk management goals.

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 to late August. 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 Web site or may be obtained from the OPP Regulatory Public Docket at <http://www.regulations.gov>.

List of Subjects

- Environmental protection
- Pesticides and pests

Dated: July 10, 2012.

Frank Sanders,

Director, Office of Science Coordination and Policy.

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