

Robert W. Hargrove,
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ENVIRONMENTAL PROTECTION AGENCY
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FOR FURTHER INFORMATION CONTACT
AGENCY: FIFRA Scientific Advisory Panel; Office of Pesticide Programs.

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 a set of scientific issues related to the Re-Evaluation of Human Health Effects of Atrazine: Review of Non-Cancer Effects, Drinking Water Monitoring Frequency, and Cancer Epidemiology.

DATES: The meeting will be held on July 26–29, 2011, from approximately 8:30 a.m. to 5 p.m.

Comments. The Agency encourages that written comments be submitted by July 12, 2011 and requests for oral comments be submitted by July 19, 2011. 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 12, 2011 should contact the Designated Federal Official (DFO) located 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 May 20, 2011. 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.

ADDITIONAL DATES:

District:
Fresno County, CA, Forest, High Sierra Ranger District.
Kings River Experimental Watershed

Implementation:
Sierra National Forest

Fresno County, CA, 559–297–0706 Ext. 4938.

Funding:
Agamemnon, No. 20110119


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FIFRA Scientific Advisory Panel;
Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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DATES: 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–2011–0399, by one of the following methods:


• Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays).

Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2011–0399. If your comments contain any personal information that you consider to be CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

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:
Joseph Bailey, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–2043; fax number: (202) 564–8382; e-mail address: bailey.joseph@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 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–2011–0399 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 12, 2011, 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 12, 2011 should contact the DFO listed under FOR FURTHER INFORMATION CONTACT. Anyone submitting written comments at the meeting should bring 30 copies for distribution to the FIFRA SAP.

2. Oral comments. The Agency encourages that each individual or group wishing to make brief oral comments to the FIFRA SAP submit their request to the DFO listed under FOR FURTHER INFORMATION CONTACT no later than July 19, 2011, 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: Risk assessment, environmental epidemiology, exposure assessment (particularly pesticide applicators), mammary gland development, mode of action analysis (particularly those with MOA framework experience), frameworks to evaluate human relevance, prostate development, pharmacokinetics, physiologically-based pharmacokinetic modeling, neuroendocrinology, hormone-mediated health effects, EPA axis (corticosterone), reproductive/developmental biology and environmental sampling and statistical modeling. 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 May 20, 2011. 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 lack 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 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 the sources of research support. The EPA will evaluate the candidate’s 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://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

EPA is undertaking a re-evaluation of the human health effects of atrazine. The human health re-evaluation has involved three SAP meetings in 2010 and one in 2011. The first meeting was held in February 2010 during which the Agency presented its preliminary reviews of several atrazine epidemiology studies on birth outcomes and described a project plan to evaluate atrazine epidemiology data from the Agricultural Health Study (http://aghealth.nci.nih.gov/). The second meeting in April 2010 SAP meeting focused on:

1. A preliminary review of experimental toxicology studies from laboratory mammals and in vitro studies and recent advancements in understanding atrazine’s mode of action along with:
2. Statistical and modeling approaches for evaluating monitoring frequency in community water systems (CWS). The September 2010 meeting built on the scientific analysis and SAP feedback from the April meeting. Specifically, the Agency presented scientific analyses on an empirical approach for estimating internal dosimetry, and calculation of benchmark dose estimates for purposes of deriving points of departure. In addition, EPA presented a general strategy for designing a monitoring study to characterize drinking water exposures and discussed different methods for analyzing and interpreting monitoring data collected at different sampling frequencies. The September 2010 meeting also provided proposals for updating the critical durations of exposure based on the new science, and a preliminary evaluation of potential susceptibility of the young. In addition, the September 2010 meeting included evaluation of non-cancer epidemiology studies, a weight of the evidence evaluation of the non-cancer epidemiology studies with experimental laboratory studies, and a proposal to use the non-cancer epidemiology studies qualitatively in evaluating the human relevance of experimental toxicology findings.

The July 2011 SAP meeting will build on the scientific analyses and SAP feedback from the previous three SAP meetings by proposing a conceptual framework for the evaluation of atrazine human health non-cancer effects. This proposed conceptual framework will integrate information on mode of action and adverse outcome pathways, potentially susceptible lifestages/subpopulations, drinking water exposure, internal dosimetry, and water monitoring sampling uncertainty. The Agency will solicit comment on the overall integrative approach proposed for atrazine along with technical considerations.

To illustrate the conceptual framework, a case study will be provided that demonstrates an approach for estimating non-cancer risk to atrazine based on an internal dose metric for temporally, spatially, and demographically explicit information. The Agency will use feedback received from the SAP at the July 2011 meeting as it completes the scientific analysis for determining whether or not adjustments may be necessary in the sampling frequency of CWS monitoring. The evaluation of non-cancer effects will include studies available up through April 29, 2010.

In the 2003 Interim Reregistration Eligibility Decision (RED) for atrazine, the Agency noted that it would convene another SAP meeting concerning atrazine and its possible association with carcinogenic effects, particularly as new information from the National Cancer Institute’s (NCI) Agricultural Health Study (AHS) is made available. The Agency believes it is appropriate at this time to re-evaluate the cancer epidemiology literature on atrazine in a SAP meeting; EPA notes that the evidence of atrazine carcinogenicity based upon experimental animal data were evaluated by the SAP in April 2010. As such, at the July 2011 meeting, the Agency will provide a preliminary review of cancer epidemiology studies and a draft weight of the evidence (WOE) analysis on cancer that integrates mode of action, experimental toxicology information, and epidemiology. This draft WOE analysis will follow the Draft Framework for Incorporating Epidemiologic and Human Incident Data in Health Risk Assessment, which was reviewed by the SAP in February 2010. The Agency will include epidemiological studies on the cancer effects of atrazine available up through April 29, 2010. The Agricultural Health Study is anticipated to be published in spring 2011 and will be part of this review given that this study is considered to be a pivotal line of evidence.

At the February 2010 SAP, the Agency presented a proposed plan for a collaborative project with investigators from the AHS to evaluate approaches for estimating exposure to pesticide applicators. At the July 2011 meeting, the Agency will discuss the status of the collaborative project (which includes a case study involving atrazine) and solicit comment from the Panel on the overall direction of the project and the methods development aspects of this effort. This project is part of a larger effort by OPP to improve the incorporation of epidemiology in human health risk assessment. The feedback from the SAP may not be used for atrazine risk assessment per se but
will inform EPA’s continued efforts to improve risk assessment approaches and methodologies.

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 late June. 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/scipaly/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 (202) 564–2067 or fax (202) 565–2098. General information concerning the EPA Science Advisory Board can be found on the EPA Web site at http://www.epa.gov/sab.

SUPPLEMENTARY INFORMATION: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. Pursuant to FACA and EPA policy, notice is hereby given that the SAB will hold a public teleconference to conduct a quality review of a draft report entitled “SAB Review of EPA’s Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments.” The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: The SAB was asked to review and provide advice to EPA on a draft report, entitled “EPA’s Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments.” To conduct this review, the SAB Staff Office requested public nominations of experts (73 FR 61114) and formed the ad hoc SAB Dioxin Review Panel. The Panel held face-to-face public meetings on July 13–15, 2010 (75 FR 28805) and October 27–29, 2010 (75 FR 57779), and follow-up public teleconference meetings on March 1 and March 2, 2011 (76 FR 6784) to review EPA’s draft document. The SAB will conduct a quality review of the Panel’s draft report, “SAB Review of EPA’s Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments.” Background information about this SAB advisory activity can be found on the SAB Web site at http://yosemite.epa.gov/sab/sabproduct.nsf/ fedgstr_activities/Dioxin%20Reass%20-%202011OpenDocument.

Availability of Meeting Materials: The agenda and other materials in support of the teleconference will be placed on the SAB Web site at http://www.epa.gov/sab in advance of the teleconference.

Procedures for Providing Public Input: Public comment for consideration by EPA’s federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for SAB panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the Designated Federal Officer directly. Oral Statements: Individuals or groups requesting an oral presentation will be limited to five minutes. Those interested in being placed on the public speakers list for the June 6, 2011, teleconference should contact Ms. Sanzone at the contact information provided above no later than May 27, 2011. Written Statements: Written statements should be supplied to the DFO via e-mail at the contact information noted above by May 27, 2011, for the teleconference so that the information may be made available to the Panel members for their consideration. Written statements should be supplied in one of the following electronic formats: Adobe Acrobat PDF, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Ms. Sanzone at (202) 564–2067 or sanzone.stephanie@epa.gov. To request accommodation of a disability, please