
Frank Sanders,
Director, Office of Science Coordination and Policy.

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ENVIRONMENTAL PROTECTION AGENCY

FIFRA Scientific Advisory Panel;
Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 1-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 Comparative Adult and Juvenile Sensitivity Toxicity Protocols for Pyrethroids.

DATES: The meeting will be held on July 23, 2010, from 8:30 a.m. to approximately 5 p.m.

Comments. The Agency encourages that written comments be submitted by July 8, 2010 and requests for oral comments be submitted by July 15, 2010. 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 8, 2010 should contact the Designated Federal Official (DFO) listed under FOR FURTHER INFORMATION CONTACT to obtain special accommodations. For additional instructions, see Unit I.C. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Sharlene R. 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; e-mail 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), 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–2010–0378 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 8, 2010, 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 8, 2010 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 15, 2010, 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: pyrethroid pesticides, rodent and human metabolic enzymes and their related ontogeny, in vitro pharmacokinetic studies, particularly when used in risk assessment; voltage-gated sodium channels, ontogeny and specificity; mode of action and risk assessment, and tissue dosimetry. 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 14, 2010. 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 or nonmembership by 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://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 (OCSSPP) 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

The Office of Pesticide Programs (OPP) is actively working on a reevaluation of the human health effects of the pyrethroids and pyrethrins under the OPP registration review program http://www.epa.gov/oppsrdr1/ reevaluation/pyrethroids-pyrethrins.html required under FIFRA. As directed by FQPA, the Agency is to make special considerations for pre- and post-natal exposures concerning the susceptibility of infants and children. Guideline studies submitted to the Agency for pesticide registration address a variety of routes, toxicity endpoints, and durations. These studies, however, generally do not provide direct measures of relative sensitivity between adult and juvenile laboratory animals. Moreover, the guideline studies often do not adequately quantify pyrethroid toxicity due to their rapid pharmacokinetic time course and mode-of-action (i.e., sodium channel disruption leading to alterations in membrane excitability and firing potentials, ultimately resulting in signs of neurotoxic behavior). In a February 16, 2010 letter to the public, EPA asked interested parties to voluntarily submit study protocols to better understand the juvenile sensitivity for synthetic pyrethroids and naturally-occurring pyrethrins (see pyrethroid docket, EPA–HQ–OPP–2008–0331).

Pyrethroids exert toxicity by interfering with the voltage-gated sodium channels in the nervous system. Ideally, an in vivo measure of sodium channel disruption could be evaluated in laboratory animals to assess the initiating event in the toxicity pathway of this class. However, a rapid and practical in vitro metric is not likely to be available within the Agency’s registration review schedule for the 20+ pyrethroids that are currently registered. The Agency believes that a well-designed set of in vivo and in vitro studies, and possibly in silico studies, would provide the Agency with the necessary scientific information to conduct a risk assessment. The Agency has identified some key scientific issues which are important in considering comparative age sensitivity for this class of pesticides such as: 1) the ontogeny of hydrolytic and oxidative metabolic enzymes; 2) the ontogeny and differentiation of sodium channels; 3) dose-dependent (high vs. low) effects; and 4) rodent to human concordance and species sensitivity.

Proposals submitted by May 21, 2010 will be reviewed by the Agency and presented to the FIFRA SAP for their independent evaluation. The Agency is asking the SAP to comment on the relevance and reliability, as well as the strengths and limitations of the proposal studies in addressing age-specific sensitivity to pyrethroids. Based on the recommendations of the SAP and comments from the public, the Agency will develop a scientifically-based study design for use in pyrethroid risk characterization.

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/scipoly/index.html. 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 Regulatory Public Docket at http://www.regulations.gov.

List of Subjects

Environmental protection, Pesticides and pests.


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ENVIRONMENTAL PROTECTION AGENCY

[FRL–9143–8]

Proposed Administrative Settlement Agreement Under Section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act for the Chemical Leaman Tank Lines, Inc. Superfund Site Located in Logan Township, Gloucester County, NJ

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed administrative settlement and opportunity for public comment.

SUMMARY: The United States Environmental Protection Agency (“EPA”) is proposing to enter into an administrative settlement agreement (“Settlement Agreement”) with Quality Distribution, Inc. (the “Settling Party”) pursuant to Section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA”), 42 U.S.C. 9622. The Settlement Agreement provides for Settling Party payment of certain response costs incurred by EPA at the Chemical Leaman Tank Lines, Inc. Superfund Site (“Site”) located in Logan Township, Gloucester County, New Jersey.

In accordance with Section 122(i) of CERCLA, 42 U.S.C. 9622(i), this notice is being published to inform the public of the proposed Settlement Agreement and of the opportunity to comment. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the proposed Settlement Agreement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that