



This document is scheduled to be published in the Federal Register on 06/30/2016 and available online at <http://federalregister.gov/a/2016-15589>, and on FDsys.gov

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2016-0349; FRL-9948-17]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 2–day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review a set of scientific issues being considered by the Environmental Protection Agency regarding the human health and ecological risk assessments for SmartStax PRO (MON 89034 x TC1507 x MON 87411 x DAS-59122-7), a plant-incorporated protectant intended to control corn rootworm through ribonucleic acid (RNA) interference.

DATES: The meeting will be held on September 27-28, 2016, from approximately 9:00 a.m. to 5:00 p.m.

Comments. The Agency encourages written comments be submitted on or before September 13, 2016, to provide adequate time for the FIFRA SAP to review and consider the comments. The Agency encourages requests for oral comments be submitted on or before September 20, 2016. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after September 13, 2016, should contact the Designated Federal Official (DFO) listed under **FOR**

FURTHER INFORMATION CONTACT. For additional instructions, see Unit I.C. of the

SUPPLEMENTARY INFORMATION.

16P-0152

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP website at <http://www.epa.gov/sap> for information on how to access the meeting 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:

Meeting: 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-2016-0349, 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.html>.

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 accommodations, or requests to present oral comments to the DFO listed under **FOR**

FURTHER INFORMATION CONTACT.

FOR FURTHER INFORMATION CONTACT: Steven Knott, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0103; email address: knott.steven@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?

1. *Submitting CBI.* Do not submit CBI information to EPA through [regulations.gov](http://www.regulations.gov) or email. 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.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

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-2016-0349 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages written comments be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before September 13, 2016, 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 September 13, 2016, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments at the meeting should bring 15 copies for distribution to FIFRA SAP by the DFO.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments to FIFRA SAP to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before September 20, 2016, 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. Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 15 copies of his or her comments and presentation for distribution to FIFRA SAP at the meeting by the DFO.

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: Ecological risk assessment, human health risk assessment, entomology, bioinformatics, RNAi technology, biotechnology, plant breeding and genomics, and molecular biology. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to provide expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, email address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before [INSERT DATE 30 DAYS AFTER 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 that 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 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 the 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. The Agency anticipates selecting approximately eight ad hoc scientists to have the collective breadth of experience needed to address the Agency's charge for this meeting.

FIFRA SAP members are subject to the provisions of 5 CFR Part 2634--Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, as supplemented by EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidates' employment, stocks, bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms 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 the 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/sap> or may be obtained from the OPP 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 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 (5 U.S.C. Appendix). 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 (SRB) consisting of at least 60 scientists who are available to FIFRA SAP on an ad hoc basis to assist in reviews conducted by FIFRA SAP. As a scientific peer review mechanism, FIFRA SAP provides comments, evaluations, and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of the FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendations to the Agency.

B. Public Meeting

The use of RNA interference (RNAi) gene silencing technology, particularly RNAi for pesticidal purposes to control macroorganism pests, is a relatively recent innovation. Post-transcriptional silencing of gene function is a very rapid process where double-stranded RNA (dsRNA) directs sequence-specific degradation of a RNA. As EPA anticipated receiving pesticide applications based on RNAi technologies and identified the need to better understand the scientific issues concerning the assessment of the risks to human health and the environment

that RNAi technologies pose, it convened a January 28, 2014, Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP). This FIFRA SAP provided EPA with scientific advice regarding the framework for assessing RNAi pesticide products.

On October 29, 2015, EPA registered MON 87411, a corn plant-incorporated protectant (PIP) for seed increase/breeding purposes only and not for commercial release, with a time limitation of 2 years and a per-season acreage cap of 15,000 acres. In addition to *Bacillus thuringiensis* (Bt) Cry3Bb1 protein, MON 87411 expresses DvSnf7 dsRNA. Upon consumption by corn rootworm (CRW), the insect's RNAi machinery recognizes DvSnf7 dsRNA, resulting in down-regulation of the targeted DvSnf7 gene and leading to CRW mortality. Earlier this year, EPA received applications from Monsanto Company and Dow AgroSciences, LLC, requesting registration of commercial release RNAi PIPs expressing DvSnf7 dsRNA and known by the name SmartStax PRO. SmartStax PRO also expresses several Bt insecticidal Cry proteins.

EPA will present the human health risk assessment conducted for DvSnf7 dsRNA, as expressed in SmartStax PRO, and will consider the fate of ingested dsRNA and the potential for impacts on gene expression and the immune system. The action of a RNA interference construct relies upon some level of sequence homology with the target gene transcript; however, the fidelity of the sequence match may vary in some instances. EPA will discuss the role that bioinformatic analysis may play in understanding and predicting possible off-target effects within the host genome, as well as in predicting nontarget effects as part of the ecological risk assessment.

EPA will also present an ecological risk assessment for DvSnf7 dsRNA, as expressed in SmartStax PRO, and will include descriptions of environmental fate and nontarget exposure, data reviewed in support of the risk assessment, risk characterization and description, and

uncertainties. The charge to the panel will request expert opinion on completeness of the data set and uncertainties related to the risk conclusions.

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 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 at <http://www.regulations.gov> and the FIFRA SAP website at <http://www.epa.gov/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 to the FIFRA SAP website or may be obtained from the OPP Docket at <http://www.regulations.gov>.

Authority: 7 U.S.C. 136 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: June 23, 2016.

Stanley Barone,

Acting Director,

Office of Science Coordination and Policy.

[FR Doc. 2016-15589 Filed: 6/29/2016 8:45 am; Publication Date: 6/30/2016]