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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2016-0385; FRL-9949-22]

Federal Insecticide, Fungicide, and Rodenticide Act Scientific 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 a set of scientific issues being evaluated by the Environmental Protection Agency (EPA) regarding EPA's evaluation of the carcinogenic potential of glyphosate, a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings.

DATES: The meeting will be held on October 18-21, 2016, from approximately 9 a.m. to 5 p.m.

Comments. The Agency encourages written comments be submitted on or before October 4, 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 October 11, 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 October 4, 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-0167

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 FROM 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-2016-0385, 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 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.

1. *Written comments.* To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2016-0385 in the subject line on the first page of your request. The Agency encourages written comments be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before October 4, 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 October 4, 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 October 11, 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: Carcinogenicity (mammalian), cancer biostatistics, rodent cancer bioassays, epidemiology (cancer/occupational), genotoxicity/genetic toxicology/mutagenicity (related to human cancer risk), risk assessment, weight of evidence analysis, and mode of action/human relevance/adverse outcome pathway frameworks. 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 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 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 (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 (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

Glyphosate is a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings. Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-agricultural sites, such as greenhouses, aquatic areas, and residential areas. Use of glyphosate in the United States and globally has increased overtime, particularly with the introduction of glyphosate-resistant crops; however, usage has stabilized in recent years due to the increased number of weed species becoming resistant to glyphosate. Glyphosate is currently undergoing Registration Review, which is a program where all registered pesticides are reviewed at least every 15 years as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act.

Recently, several international agencies have evaluated the carcinogenic potential of glyphosate. In March 2015, the International Agency for Research on Cancer (IARC), a subdivision of the World Health Organization (WHO), determined that glyphosate was a probable carcinogen (group 2A). Later, in November 2015, the European Food Safety Authority (EFSA) determined that glyphosate was unlikely to pose a carcinogenic hazard to humans. In May 2016, the Joint Food and Agriculture Organization (FAO)/WHO Meeting on Pesticide Residues (JMPR), another subdivision of the WHO, concluded that glyphosate was unlikely to pose a carcinogenic risk to humans from exposure through the diet.

Recently, EPA collected and analyzed a substantial amount of data informing the carcinogenic potential of glyphosate and utilized its draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment" to assess the potential carcinogenic hazard. The draft framework provides the foundation for evaluating multiple lines of scientific evidence and includes two key components: Problem formulation and use of the mode of action/adverse outcome pathway (MOA/AOP) frameworks. A comprehensive analysis of data on glyphosate from submitted guideline studies and the open literature was performed. This includes epidemiological, animal carcinogenicity, genotoxicity, metabolism, and mechanistic studies. Guideline studies were collected for consideration from the toxicological databases for glyphosate and glyphosate salts. A fit-for-purpose systematic review was executed to obtain relevant and appropriate open literature studies with the potential to inform the human carcinogenic potential of glyphosate. Furthermore, the list of studies obtained from the toxicological databases and systematic review was cross-referenced

with recent internal reviews, review articles from the open literature, and international agency evaluations (*i.e.*, IARC, EFSA, JMPR).

Available data from epidemiological, animal carcinogenicity, and genotoxicity studies were reviewed and evaluated for study quality and results to inform the human carcinogenic potential of glyphosate. Additionally, as described in the draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment," the multiple lines of evidence were integrated in a weight-of-evidence analysis using the modified Bradford Hill Criteria considering concepts, such as strength, consistency, dose response, temporal concordance, and biological plausibility. The agency will solicit advice from the SAP on the evaluation and interpretation of the available data for each line of evidence and the weight-of-evidence analysis, as well as how the available data inform cancer classification descriptors according to the agency's 2005 Guidelines for Carcinogen Risk Assessment.

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-September. 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: July 19, 2016.

Stanley Barone, Acting

Director, Office of Science Coordination and Policy.

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