



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2025-0756; FRL-12903-02-OCSP]

### **FIFRA Scientific Advisory Panel (SAP); Determining the Absence of Novel Proteins in the Saliva of Genetically Engineered Mosquitoes for Mosquito Control; Notice of Availability, and Request for Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or “Agency”) is announcing the availability of and soliciting public comment on materials that are being submitted to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) for peer review on “Determining the Absence of Novel Proteins in the Saliva of Genetically Engineered Mosquitoes for Mosquito Control.” The white paper, charge questions, background documents, and related supporting materials are available for public review and comment. The FIFRA SAP will consider and review the documents at a 3-day virtual public meeting that was previously announced in the *Federal Register* of July 24, 2025. The virtual public meeting will be held on November 3-5, 2025, via a webcast platform such as “Zoomgov.com” and audio teleconference.

**DATES:** The following is a chronological listing of the dates for the specific activities that are described in more detail under **SUPPLEMENTARY INFORMATION**.

[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] – Deadline to submit written comments on the peer review documents (white paper, charge questions, background documents, and related supported materials).

October 24, 2025 – Deadline to submit a request for special accommodations to allow sufficient time for EPA to process the request before the meeting.

October 27, 2025 (12:00 p.m. ET) – Deadline to register to be listed on the meeting agenda to make oral comments during the virtual meeting.

October 30, 2025 – Deadline to submit a written version of oral comments that will be made during the virtual meeting.

November 3-5, 2025 – FIFRA SAP public virtual meeting.

November 5, 2025 –Deadline for those not making oral comments to register to receive the links to observe the meeting.

**ADDRESSES:**

*To comment:* Submit written comments, identified by docket identification (ID) number EPA-HQ-OPP-2025-0756, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Copyrighted material will not be posted without explicit permission from the copyright holder. Members of the public should also be aware that personal information included in any written comments may be posted on the internet at <https://www.regulations.gov>. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

*To register for the meeting:* For information on how to register and access the virtual public meeting, please refer to the FIFRA SAP website at <https://www.epa.gov/sap>. EPA intends to announce registration instructions on the FIFRA SAP website by October 2025. You may also subscribe to the following listserv for alerts regarding this and other FIFRA SAP-related activities at [https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic\\_id=USAEPAPPT\\_101.T](https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101.T).

*To request special accommodations:* For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** The DFO, Alie Muneer, Mission Support

Division, Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-6369 or the main office number: (202) 564-8450; email address: *muneer.alie@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. What action is the Agency taking?*

EPA is announcing the availability of and soliciting public comment on the white paper, entitled “Determining the Absence of Novel Proteins in the Saliva of Genetically Engineered Mosquitoes for Mosquito Control,” charge questions, background documents, and related supporting materials, which are available in the docket. EPA will be soliciting comments from the FIFRA SAP on the Agency's draft memorandum for developers of GE mosquitoes and case studies with the intent to provide additional acceptable methodologies. If appropriate, based on the recommendations from the FIFRA SAP, EPA will update and release the final memorandum to provide support to developers of these technologies on how EPA will utilize the data in its human health risk assessment.

This document provides instructions for accessing the materials provided to the FIFRA SAP, submitting written comments, and registering to provide oral comments and attend the virtual meeting.

#### *B. What is the Agency's authority for taking this action?*

The FIFRA SAP is a federal advisory committee established in 1975 under FIFRA, 7 U.S.C. 136 *et seq.*, to provide independent scientific advice to EPA on health and safety issues related to pesticides. The FIFRA SAP operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. 10, and supports activities under FIFRA, the Federal Food, Drug, and Cosmetic Act (FFDCA) and other applicable statutes.

#### *C. Does this action apply to me?*

This action is directed to the public in general. This action may be of interest to persons

who are or may be required to conduct testing of chemical substances under the 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.

*D. What should I consider as I submit my comments to EPA?*

*1. Submitting Confidential Business Information (CBI).*

Do not submit CBI or other sensitive information electronically to EPA through <https://www.regulations.gov> or email. To include information in your comment that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** for instructions before submitting CBI or other sensitive information.

*2. Tips for preparing your comments.*

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>. See also the instructions in Unit III.

## **II. Background**

*A. What is the purpose of the FIFRA SAP?*

The FIFRA SAP serves as one of the primary scientific peer review mechanisms of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide independent scientific advice, information, and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on human health and the environment. The 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. 10). The 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 the FIFRA SAP on an *ad hoc* basis to assist in reviews conducted by the FIFRA SAP. As a scientific peer review mechanism, the

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. Why did EPA develop these documents?*

Genetic engineering can be used to develop modified mosquitoes for mosquito control purposes. A hallmark of GE mosquitoes is their species-specific mode-of-action, as they rely on the mating of modified male mosquitoes with wild-type females that are present in the treatment area. GE male mosquitoes express reproductive incompatibilities that are designed to reduce the number of offspring emerging from these matings. When released in quantities and at frequencies sufficient to outcompete the wild-type males, fewer mosquitoes of that species emerge in the treatment area, reducing its population size over time. GE mosquitoes may be engineered to carry one or more genes that code for a pesticidal trait as well as other genes that are integral to its function. To date, EPA has granted one Experimental Use Permit for a GE *Ae. aegypti* product, called OX5034, for which the company is now seeking a commercial registration. Similar GE mosquito products are currently in various stages of development.

While for novel types of pesticides, such as a GE mosquito, EPA determines on a case-by-case basis the data and information needed to support the risk assessments, the base data are anchored in the established tiered biochemical data requirements at 40 CFR part 158. This information is then supplemented with product-specific information, such as the biology of the particular GE mosquito and any novel exposure potentials.

In the United States, various species of mosquitoes are known to transmit diseases that are of concern to humans. As such, these same species of mosquitoes may be engineered with the goal of reducing their population. For the human health risk assessment, determining the likelihood of the presence of GE females in the environment is important as female mosquitoes (but not males) bite humans and therefore may pose a unique intradermal route of pesticide

exposure. Generally, the number of GE females in the environment is expected to be very low, however some GE females may either be incidentally released and/or emerge in the environment from matings.

EPA performs human health risk assessments and by definition risk is a function of both hazard and exposure. Determination on whether a protein is present in the saliva of female mosquitoes informs the likelihood of exposure, and thus overall risk, of humans to these proteins through the intradermal route. To that end, EPA has developed a draft memorandum that outlines genetic design considerations to minimize the likelihood for an engineered protein to be present in the saliva of GE females and to provide recommendations on specific tests to empirically determine protein absence in the saliva.

EPA will be soliciting advice from the SAP on specific aspects of the Agency's draft memorandum for developers of GE mosquitoes and case studies with the intent to provide additional acceptable methodologies. If appropriate, based on the recommendations from the FIFRA SAP, EPA will update and release the final memorandum to provide support to developers of these technologies on how EPA will utilize the data in its human health risk assessment.

### **III. Virtual Public Meeting of the FIFRA SAP**

#### *A. How can I access the documents submitted for review to the FIFRA SAP?*

These documents, including the white paper, charge questions, draft memorandum, background documents, and related supporting materials, mentioned in Unit II.B provided to the FIFRA SAP are available in the docket at <https://www.regulations.gov> (docket ID No. EPA-HQ-OPP-2025-0756) and the FIFRA SAP website at <https://www.epa.gov/sap>. In addition, as additional background materials become available and are provided to the FIFRA SAP, EPA will include those additional background documents (e.g., *FIFRA SAP* members and consultants participating in the meeting and the meeting agenda) in the docket and accessible through the FIFRA SAP website.

After the public meeting, the FIFRA SAP will prepare meeting minutes and a final report document summarizing its recommendations to the EPA. This document will also be posted in the docket and made available at *regulations.gov* and the FIFRA SAP website.

*B. How can I provide comments for the FIFRA SAP's consideration?*

To ensure proper receipt of comments, it is imperative that you identify docket ID No. EPA-HQ-OPP-2025-0756 in the subject line on the first page of your comments and follow the instructions in this unit.

*1. Written comments.*

The Agency encourages written comments for this meeting be submitted by the deadlines set in the **DATES** section of this document and as described in the **ADDRESSES** section of this document.

*2. Oral comments.*

To request time to present oral comments during the virtual public meeting, you must register online by the deadlines set in the **DATES** section of this document. Oral comments during the virtual public meetings are limited to five minutes unless arrangements have been made with the DFO, within the constraints of the meeting agenda, prior to noon (12:00 p.m. ET), October 27, 2025. In addition, each speaker should submit a written copy of their oral comments and any supporting materials (e.g., presentation slides) to the DFO prior to the meeting for distribution to the FIFRA SAP by the deadline set in the **DATES** section of this document.

*C. How can I participate in the virtual public meeting?*

To participate in the virtual public meeting, you must register online to receive the webcast and streaming service meeting links and audio teleconference information for the meeting. Online registration will be available approximately one month prior to the meeting and will remain open through the end of the meeting. To make oral comments during the meeting, follow the instructions in this document.

**Authority:** 5 U.S.C. 10; 7 U.S.C. 136 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: August 15, 2025.

**Nancy B. Beck,**

*Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2025-15950 Filed: 8/20/2025 8:45 am; Publication Date: 8/21/2025]