

### *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 (e.g., full sterility or sex-specific sterility). 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; such as those coding for markers that allow for the visual detection of the introduced genetic cassette. 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.

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, livestock, or wildlife. As such, these same species of mosquitoes may be engineered with the goal of reducing their population. For the human health 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.

Eliminating the dermal exposure route by ensuring the absence of GE proteins in the saliva of GE females would therefore eliminate the overall potential for risk from these novel proteins through that route. To that end, the 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. The outlined considerations will reduce the likelihood of developing GE mosquitoes that produce and/or secrete novel proteins into the saliva and the analytical methods will ensure that the potential for dermal exposure, and thus risk, to GE proteins is eliminated.

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.

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

The EPA is planning to release the white paper, the background documents, related supporting materials, and the charge questions to the FIFRA SAP in late August 2025 as described in Unit I.A. EPA will publish a separate document in the **Federal Register** to announce the availability of and solicit public comment on the draft documents and provide instructions for submitting comments and registering to provide oral comments. These materials will be available in the docket through <https://www.regulations.gov> (Docket ID No. EPA-HQ-OPP-2025-0756) and the FIFRA SAP website.

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

The public virtual meeting will be held via a webcast platform such as "Zoomgov.com" and audio teleconference. You must register online to receive the webcast meeting link and audio teleconference information. Please follow the registration instructions that will be announced on the FIFRA SAP website in August 2025. You may subscribe to the following listserv for alerts regarding this and other FIFRA SAP-related activities: <https://public.govdelivery.com/>

[accounts/USAEPAPPT/subscriber/new?topic\\_id=USAEPAPPT\\_101.T](https://www.regulations.gov/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101.T).

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

Dated: July 21, 2025.

Nancy B. Beck,

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

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2020-0664; FRL-12902-01-OMS]

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; NSPS for Emission Guidelines and Compliance Times for Small Municipal Waste Combustion Units Constructed on or Before August 30, 1999 (Renewal)

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Emission Guidelines and Compliance Times for Small Municipal Waste Combustion Units Constructed on or before August 30, 1999 (EPA ICR Number 1901.09, OMB Control Number 2060-0424) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through July 31, 2025. Public comments were previously requested via the **Federal Register** on August 6, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

**DATES:** Comments may be submitted on or before August 25, 2025.

**ADDRESSES:** Submit your comments, referencing Docket ID Number EPA-HQ-OAR-2020-0664, to EPA online using [www.regulations.gov](https://www.regulations.gov) (our preferred method), by email to [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless

the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Muntasir Ali, Sector Policies and Program Division, Office of Air Quality Planning and Standard, D243-05, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (919) 541-0833; email address: [ali.muntasir@epa.gov](mailto:ali.muntasir@epa.gov).

**SUPPLEMENTARY INFORMATION:** This is a proposed extension of the ICR, which is currently approved through July 31, 2025. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on August 6, 2024 during a 60-day comment period (89 FR 63933). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at [www.regulations.gov](http://www.regulations.gov) or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

**Abstract:** The Emission Guidelines and Compliance Times for Small Municipal Waste Combustion Units Constructed on or Before August 30, 1999 were originally promulgated in December 1995, but were vacated by the Federal Court during March 1997. Subsequently, the Emission Guidelines were re-proposed on August 30, 1999; and promulgated on December 6, 2000. The Emission Guidelines regulate organics (dioxin/furans), metals (cadmium, lead, mercury), particulate matter, and acid gases (hydrogen chloride, sulfur dioxide, and nitrogen oxides) for small Municipal Waste Combustion (MWC) units. Small MWC units are MWC units with capacities to

combust greater than 35 tons per day (tpd) and less than 250 tons per day (tpd) of municipal solid waste. The Emission Guidelines contain monitoring, reporting, and recordkeeping requirements that are to be included in state plans. If a State/Local Agency does not develop, adopt, and submit an approvable State plan, then facilities in that state are subject to the Federal Plan (Federal Plan Requirements for Small Municipal Waste Combustion Units Constructed On or Before August 30, 1999 (40 CFR part 62, subpart JJJ)), adopted on January 31, 2003. The Federal Plan implements the emission guidelines in jurisdictions that have not developed an approved State Plan. These regulations do not directly apply to small MWC unit owners and operators. However, MWC unit owners and operators must comply with either the State or Federal plans to implement the emission guidelines contained in this Subpart. This Information Collection Request (ICR) identifies the burden to both respondents (owners or operators of small MWC units) and the Designated Administrator (either state/local agencies or the Federal government) to implement the emission guidelines imposed by the State plans. This information is being collected to assure compliance with 40 CFR part 60, subpart BBBB.

In general, all Emission Guidelines require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to these Emission Guidelines.

**Form Numbers:** None.

**Respondents/affected entities:** Small MWC units constructed on or before August 30, 1999.

**Respondent's obligation to respond:** Mandatory (40 CFR part 60, subpart BBBB).

**Estimated number of respondents:** 14 (total).

**Frequency of response:** Initially, annually, and semiannually.

**Total estimated burden:** 55,600 hours (per year). Burden is defined at 5 CFR 1320.03(b).

**Total estimated cost:** \$5,321,000 (per year), which includes \$411,000 annualized capital or operation & maintenance costs.

**Changes in the estimates:** There is a decrease of 30,900 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to more accurate estimates of existing sources. The EPA has determined that several sources have closed since the previously-approved ICR renewal. Because there is a decrease in the number of respondents, there is also a decrease in the capital/O&M costs from the most recently approved ICR. The capital/O&M costs were increased from 2009 \$ to 2023 \$ using the CEPCI CE Index; however, the result is a net decrease in the capital/O&M costs.

**Courtney Kerwin,**

*Director, Information Engagement Division.*

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2025-0626]; FRL-12886-01-OCSPF]

### Approval of a Test Marketing Exemption for a New Chemical Under the Toxic Substances Control Act (TSCA)

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or the Agency) is providing notice of its approval of an application for test marketing exemption (TME) under the Toxic Substances Control Act (TSCA). EPA has designated this application as T-24-0001. The test marketing conditions are described in the TME application and in this document.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2025-0626, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

#### FOR FURTHER INFORMATION CONTACT:

**For technical information:** Meg Victor, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 343-9193; email address: [victor.meg@epa.gov](mailto:victor.meg@epa.gov).

**For general information:** The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620;