



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2019-0178; FRL-10010-58-OAR]

Proposed Information Collection Request; Comment Request; Information Collection Effort for Ethylene Oxide Commercial Sterilization Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “Information Collection Effort for Ethylene Oxide Commercial Sterilization Facilities” (EPA ICR No. 2623.01, OMB Control No. 2060-NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the EPA is soliciting public comment on specific aspects of the proposed information collection as described below. This is a request for approval of a new collection. 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.

DATES: Comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OAR-2019-0178, online using <https://www.regulations.gov/> (our preferred method) or by email to *a-and-r-docket@epa.gov*. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit

comments via <https://www.regulations.gov> or email, as there is a temporary suspension of mail delivery to the EPA, and no hand deliveries are currently accepted.

The 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.

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Witosky, Sector Policies and Programs Division (E143-05), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-2865; email address: witosky.matthew@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents explaining 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 <https://www.regulations.gov/>. The telephone number for the Docket Center is (202) 566-1742. For additional information about EPA's Docket Center services and the current status, please visit us online at <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to (1) evaluate whether the proposed collection of information is necessary for the proper performance of Agency functions; (2) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on responders, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and

approval. At that time, the EPA will issue another **Federal Register** document to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide (EtO) Commercial Sterilization and Fumigation Operations were finalized in December 1994 (59 FR 62585) at 40 CFR part 63, subpart O. The NESHAP establishes emission standards for both major and area sources that use at least 1 ton of EtO in sterilization or fumigation operations in each 12-month period. The standards require existing and new major sources to control emissions to the level achievable by the maximum achievable control technology and require existing and new area sources to control emissions using generally available control technology. The current standards address EtO emissions originating at two of the three major emissions sources: the sterilization chamber vent and the aeration room vent. The third major EtO emissions source is the chamber exhaust vent (CEV), and while the 1994 NESHAP regulated emissions from CEVs, relevant standards were later removed due to safety concerns (66 FR 55577, November 2, 2001). To fulfill its requirements under sections 112(d) and 112(f) of the Clean Air Act (CAA), the EPA completed a residual risk and technology review for the NESHAP in 2006 and concluded, at that time, that no revisions to the standards were necessary (71 FR 17712, April 7, 2006).

More recently, in 2016, the EPA released its updated Integrated Risk Information System value for EtO, which indicated that cancer risks from EtO were significantly higher than previously understood. Subsequently, the National Air Toxics Assessment (NATA) released in August 2018, identified EtO emissions as a potential concern in several areas across the country. The latest NATA estimates that EtO significantly contributes to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). Further investigation revealed commercial sterilization using EtO as a source category contributing to

some of these risks, which has led the EPA to evaluate, in greater depth, potential options to reduce emissions of EtO from the source category.

Over the past year, the EPA has been gathering additional information to evaluate opportunities to reduce EtO emissions through potential rule revisions and more immediate emission reduction steps. The goal of the data gathering efforts is to better understand the emissions sources, measurement and monitoring techniques, and available control technologies and their associated efficiencies.

These data gathering efforts also included an advance notice of proposed rulemaking (ANPRM) and a CAA section 114 questionnaire requesting facility-specific data on process controls and operational practices that may reduce the amount of EtO released into the ambient air. The EPA published the ANPRM on December 12, 2019 (84 FR 67889). In the ANPRM, the EPA solicited comments on a range of issues including the modeling file and EtO annual usage, control of fugitive emissions, CEV control and safety considerations, other point source control options, and small business considerations. The public comments on the ANPRM were due on February 10, 2020, and comments received are available in the docket (<https://www.regulations.gov/>). Alongside the ANPRM, the EPA exercised its authority under section 114(a) of the CAA to initiate a questionnaire to gather information from nine companies in December 2019. The instructions and questionnaire were posted to the EPA webpage¹ where they were accessed by facilities. Facilities were required to provide electronic responses within 60 days or by February 6, 2020. Facility responses to the initial questionnaire have been collected and compiled to create a source category database. While these data gathering efforts have been successful in identifying process controls and operational practices as possible methods for reducing the amount of EtO released into the ambient air, there are still several

¹ <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities>.

important information gaps that should be filled prior to any future rulemaking activity.

In reviewing the December 2019 questionnaire results, the EPA found that each EtO commercial sterilization facility's equipment, equipment configuration, processes, and pace of technological advancement is unique. The most recent sector-level data collected by the EPA was completed over 25 years ago for the development of the original NESHAP and is now outdated. The combined data from this ICR and the December 2019 questionnaire will enable the EPA to obtain an updated, comprehensive, and consistent dataset. The combined results provide the EPA with the most information possible to achieve its objectives of reducing EtO emissions and informing potential rule revisions.

Therefore, the EPA is now contemplating exercising its authority under section 114(a) of the CAA to broaden its data collection efforts through this new ICR to include all facilities subject to 40 CFR part 63, subpart O. The data collected through this new ICR, as well as the initial questionnaire, would enable the EPA to have a complete understanding of all emissions, emissions sources, processes, and control technologies in use at EtO sterilization facilities nationwide, providing the most robust foundation for a potential future rulemaking. Based on the EPA's knowledge of EtO sterilization facilities, an estimated 108 facilities have been identified within the EtO commercial sterilization source category. If OMB approves this new ICR, respondents not included in the initial questionnaire would be required to complete the questionnaire under the authority of section 114 of the CAA. The EPA anticipates issuing the CAA section 114 letters by December 2020. These letters would require owners or operators to complete and submit the questionnaire within 90 days from the date they receive the letter from the EPA. The ICR process, including the instructions and questionnaire, would be identical to the questionnaire that was initiated in December 2019. The instructions for the questionnaire are an Adobe portable document format (PDF), and the questionnaire is a Microsoft Excel workbook

that is available in the docket. The questionnaire contains 14 worksheets. Each worksheet has one or more tables designed to collect specific information as detailed in Table 1.

TABLE 1. QUESTIONNAIRE DATA COLLECTION FORM DESIGN

Tab Name	Description of Data
Introduction	Introduction and instructions for completing and submitting the questionnaire
Terms	Definitions or explanations of technical terms
Facility Details	Information about facility registrations, ownership, general characteristics, facility-level data
Room Area	Characteristics, inventory of components, and control of individual room areas where EtO is used or emitted
EtO & EG Storage	Questions regarding EtO storage in drums and containers, and ethylene glycol (EG) tanks
Sterilizer Chambers	Operation, monitoring, and control characteristics of sterilizer chambers, including chamber exhaust vents
Aeration	Details of aeration equipment
APCD Summary	Information about all air pollution control devices operated by the facility
APCD Details	Details regarding air pollution control devices such as scrubbers, catalytic oxidizers, thermal oxidizers, and others
EtO Monitoring	Information about workspace monitoring, personal monitoring, room monitoring conducted by facility
Miscellaneous	Questions regarding facility's wastewater treatment and other items of EtO commercial sterilization operation
Additional Info	Extra space to provide any additional information requested within the questionnaire
Documents	Designated fields for reporter to attach documents requested throughout the questionnaire (<i>e.g.</i> , facility diagram; process flow diagrams; air permit; permit application documents; startup, shutdown, malfunction plan; EtO calculations and supporting information; performance tests; engineering tests; parametric monitoring; standard operating procedures; EtO monitoring results; documentation of studies done on quantifying EtO residuals in your products; and other process and instrumentation diagrams)
Certification	Reporter's information and certification for completing and submitting the questionnaire

As described in the instructions and the questionnaire, facilities may claim certain data as CBI in their response. There is a cell in each worksheet to indicate whether the worksheet contains CBI and if so, each cell containing data being claimed as CBI should be shaded red. It

should be noted that CAA section 114(c) exempts emissions data from claims of confidentiality, and emissions data provided may be made available to the public. Emissions data should not be marked confidential. A definition of what the EPA considers emissions data is provided in 40 CFR 2.301(a)(2)(i). Facilities claiming CBI must submit both a non-confidential and confidential version of their response. All non-confidential responses to the ICR would be submitted to the EPA via email or on a thumb drive, CD-ROM, or DVD through the U.S. mail. All confidential responses to the ICR would be submitted on a thumb drive, CD-ROM, or DVD to the EPA through the U.S. mail. Non-confidential information collected from this ICR will be made available to the public. Any information designated as confidential by an ICR respondent that the EPA subsequently determines to constitute CBI or a trade secret under the EPA's CBI regulations at 40 CFR part 2, subpart B, will be protected pursuant to those regulations and, for trade secrets, under 18 U.S.C. 1905. If no claim of confidentiality accompanies the information when it is received by the EPA, it may be made available to the public by the EPA without further notice pursuant to the EPA regulations at 40 CFR 2.203.

Form numbers: None.

Respondents/affected entities: Facilities subject to 40 CFR part 63, subpart O.

Respondent's obligation to respond: Responses to the ICR are mandatory under the authority of section 114 of the CAA.

Estimated number of respondents: 66 (total).

Frequency of response: Once.

Total estimated burden: The estimated cumulative respondent burden is 6,201 hours. The estimated cumulative Agency burden to administer this ICR is 1,727 hours. Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: The estimated cumulative costs to respondents is \$569,967, including \$995

operation and maintenance costs for media and postage for submitting questionnaires containing CBI. The estimated cumulative Agency costs is \$100,049 including \$1,440 operation and maintenance costs for data storage.

Dated: June 5, 2020.

Penny Lassiter,

Director, Sector Policies and Programs Division.

[FR Doc. 2020-12728 Filed: 6/11/2020 8:45 am; Publication Date: 6/12/2020]