United States Environmental Protection Agency

FACT SHEET

EPA Proposes to Strengthen Clean Air Act Standards for Ethylene Oxide from Commercial Sterilization Facilities: Fact Sheet

Action

- On April 11, 2023, the U.S. Environmental Protection Agency (EPA) proposed to significantly strengthen and update Clean Air Act standards for ethylene oxide (EtO) emitted into the air from commercial sterilizing facilities, also called commercial sterilizers. The proposed rule is estimated to cut emissions of EtO from these facilities by 80 percent when the rule is implemented.
- Commercial sterilizers that use EtO must follow the National Emission Standards for Hazardous Air Pollutants (NESHAP). EPA is proposing to update this regulation to reflect our updated understanding of risk from EtO and technologies available to reduce this risk. The Clean Air Act lists EtO as a hazardous air pollutant, also known as an "air toxic."
- Commercial sterilizers use EtO to sterilize devices that can't be sterilized using steam or radiation, such as some medical and dental equipment. According to the Food and Drug Administration, approximately 50 percent of sterile medical devices in the United States are sterilized with EtO – about 20 billion devices each year. EtO is also used to fumigate some food products such as spices.
- This Clean Air Act proposal would require air pollution control technologies, practices, and procedures which have been demonstrated to reduce EtO emissions from commercial sterilizers.
- Medical sterilization is a critical function that ensures a safe supply of medical devices for patients and hospitals. EPA is proposing an expedited timeline for facilities to meet emissions requirements in order to reduce risks to communities located near these facilities while continuing to provide important sterilization services.
    - Facilities would be required to install pollution controls within 18 months of EPA issuing the final rule.
    - In addition, facilities would be required to report performance test and evaluation results, notices of compliance status, and initial and ongoing compliance reports within 60 days after the effective date of the final rule. With each test, facilities are required to submit the results and reports to EPA within 60 days.
- This proposal would require continuous air pollution monitoring at the facility to ensure that pollution control equipment is operating effectively and require data to be submitted to EPA electronically twice a year. The continuous emissions monitors required by this proposal are the most accurate type of monitoring for EtO emissions from commercial sterilizers.
- As part of the basis for the revised standards in this proposal, EPA examined the health risk posed by commercial sterilizers to those living around the facilities. If finalized, the

proposed standards would reduce the increased lifetime cancer risk associated with EtO in all of the communities to below EPA's Clean Air Act benchmark for elevated cancer risk.

- This proposal reflects the latest data gathered from the 2021 Information Collection Request to which facilities were legally required to respond, as well as input resulting from extensive outreach to communities, facilities, and state and local agencies during 2022. As part of this outreach, EPA held meetings with over 20 communities that are located near commercial sterilization facilities and are experiencing levels of EtO exposure that could lead to elevated lifetime cancer risk.
- This proposal is part of a comprehensive series of actions to address health risks from EtO. In addition to the April 11, 2023, proposal under the Clean Air Act, EPA is taking the following steps:
    - Proposing pesticide risk reduction requirements to protect workers who use EtO in commercial sterilizers and people who live, work, and spend time in surrounding communities.
    - On April 6, 2023, EPA released a proposed rule to significantly reduce emissions of EtO from chemical manufacturing facilities.
    - EPA also is reviewing standards for other EtO-emitting source categories, including hospital sterilizers, facilities engaged in polyether polyols production, and chemical manufacturing area sources, to ensure protection of human health. In 2020, EPA completed a rulemaking to establish more protective standards for EtO from miscellaneous organic chemical manufacturing facilities.

Details about this proposal

- EPA's proposal addresses emissions at 86 facilities that are owned and operated by 46 companies. The proposal would also apply to two sterilizers that are under construction.
- This proposal would reduce the maximum individual cancer risk for a resident near a facility due to emissions from each of the commercial sterilizers to 100-in-1 million or lower. This is a reduction from maximum individual cancer risks for residents near facilities that were as high as 6,000-in-1-million.
- Following a risk and technology review conducted under the Clean Air Act, EPA is proposing to:
    - Revise and establish standards for sterilization chamber vents and aeration room vents and establish standards to specifically address ethylene oxide emissions from chamber exhaust vents and room air (i.e., fugitive) emissions.
    - Revise requirements to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM.
    - Require facilities to monitor pollution control equipment and conduct performance testing for key components of the sterilizing process. The proposal also adds provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports.

- EPA estimates that the capital costs for the proposed rule would be $220 million (2021$). EPA estimates the rule would reduce emissions of EtO by 80%, or 19 tons per year. The annualized costs are projected to be $68 million.
- EPA will accept comment on this proposal for 60 days after publication in the *Federal Register* and will offer a multi-day virtual public hearing. Details about the public hearing will be posted on EPA's website.

Ethylene Oxide

- Ethylene oxide is a flammable, colorless gas used to make other chemicals that are used in making a range of products, including antifreeze, textiles, plastics, detergents, and adhesives. Ethylene oxide also is used to sterilize medical equipment and spices.
- Commercial sterilization is one of the main source categories (along with chemical manufacturing and hospital sterilizers) that emits ethylene oxide.
- EtO can cause cancer in humans. Scientific evidence in humans indicates that exposure to EtO for many years increases the risk of cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. Studies also show that long-term exposure to EtO increases the risk of breast cancer in women.
- Because children's bodies are growing, they are expected to be more susceptible to the toxic effects caused by EtO. This is because EtO is mutagenic, meaning it can damage DNA. As children grow, they tend to be more susceptible to the harmful effects caused by chemicals, including chemicals that are mutagenic. For anyone, including children, risks would decrease with decreased exposure.
- EtO primarily enters the environment in air. EtO released into the air will break down within several months.

Background

- Originally issued in 1994, the NESHAP for ethylene oxide commercial sterilizers established emission limits for three parts of the facility. The NESHAP established emission standards for both large and small commercial sterilizers that use at least 1 ton of ethylene oxide in sterilization or fumigation operations in any 12-month period.
- The 1994 standards required 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.
- In 2001, EPA revised the NESHAP to remove chamber exhaust vent control requirements due to safety concerns associated with the existing requirements.
- In 2006, EPA finalized the risk and technology review and concluded there were no changes to the original NESHAP at that time.
- In 2016, EPA released its updated Integrated Risk Information System (IRIS) unit risk estimate for ethylene oxide, which indicated that cancer risks from ethylene oxide were significantly higher than previously understood.

- Subsequently, EPA released its National Air Toxics Assessment (NATA) in August 2018. Based on 2014 emissions data, NATA identified ethylene oxide emissions as an important risk driver in several areas across the country.
- Further investigation revealed that the Ethylene Oxide Commercial Sterilization source category contributes to some of these risks. This led the EPA to conduct a detailed evaluation of potential options to reduce emissions of ethylene oxide from commercial sterilizers.
- EPA assessed developments in practices, processes, and control technologies through communication with state agencies (including regional, state, and local regulators), Small Business Environmental Assistance Program personnel, industry representatives, and trade association representatives.
- In 2019, EPA began gathering additional information to evaluate opportunities to reduce ethylene oxide emissions through potential rule revisions and more immediate emission reduction steps.
    - In December 2019, EPA issued an advance notice of proposed rulemaking soliciting information and requesting comment on a potential future rulemaking.
- In September 2021, EPA sent a Clean Air Act section 114 information collection request (ICR) to all commercial sterilizers. The ICR required sterilizers to provide a broad range of information on emissions from ethylene oxide sterilization operations to assess the impacts of various control technologies. Data from the ICR responses improved EPA's understanding of facility processes and emissions.
- In August 2022, EPA announced updated risk information for residents of communities near the 86 commercial sterilizers currently operating in the U.S. The Agency conducted outreach to those communities with commercial sterilizers that posed the highest risk to residents. Outreach included community meetings, webinars, and sharing information on EPA's website.
    - The influx of data the agency received from the ICR and outreach has been evaluated and incorporated into this proposed rulemaking.

How to Comment

- Comments on the proposed rule should be identified by Docket ID: EPA-HQ-OAR-2019-0178 and may be submitted by one of the following methods:
    - Online: Go to www.regulations.gov and follow the instructions for submitting your comments.
    - E-mail: Send comments by email to a-and-r-docket@epa.gov, Attention Docket ID No. EPA-HQ-OAR-2019-0178. Please include the docket number in the subject line of your email message.
    - Fax: You may fax your comments to: (202) 566-9744, Attention Docket ID. No. EPA-HQ-OAR-2019-0178.
    - Mail: Environmental Protection Agency, EPA Docket Center (EPA/DC), Mail Code 28221T, Attention Docket ID No. EPA-HQ-OAR-2019-0178, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

- Hand delivery/courier delivery: EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Ave., NW, Washington, D.C. 20004, Attention Docket ID No. EPA-HQ-OAR-2019-0178. Please note that hand/courier deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

For more information, please visit https://epa.gov/ethylene-oxide