

## Advance Notice of Proposed Rulemaking on the National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations: Fact Sheet

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### Action

- On December 5, 2019, the U.S. Environmental Protection Agency (EPA) issued an advance notice of proposed rulemaking (ANPRM) to solicit information from industry and the public regarding a potential future rulemaking to revise the standards for commercial ethylene oxide sterilization facilities.
- EPA is highlighting the agency's priority in addressing ethylene oxide emissions from sterilizers, which includes the agency's review of the Ethylene Oxide Sterilizers National Emission Standards for Hazardous Air Pollutants (NESHAP).
- As part of this effort, EPA will take three actions:
  - issuing today's ANPRM;
  - issuing a request for information to several commercial sterilization companies; and
  - beginning the nomination period for small entity representatives to advise a potential small business panel.
- The ANPRM will not impose any requirements on the regulated community; rather, it offers the public the opportunity to comment on specific topics for the agency to consider in developing a potential future proposed rule.
- This ANPRM is expected to include an assessment of the impacts of identified control strategies.
- The ANPRM gives industry and the public an opportunity to provide comments and information for EPA to consider in developing a proposed rule and assessing impacts. The agency is interested in suggested strategies for reducing emissions.
- More specifically, the ANPRM seeks information on several key topics:
  - approaches to calculate fugitive emissions;
  - capture and control of fugitive emissions;
  - work practices for reducing fugitive emissions (leak checks for ethylene oxide drums, lines and connections);
  - control of chamber exhaust vent emissions and associated safety measures;
  - new types of control devices and process equipment (*e.g.*, balancer/abator systems, aeration cells);
  - improvements to control device efficiency;
  - improvements to ethylene oxide monitoring technologies;
  - process differences between types of sterilization facilities (single-item, single-chamber, small business, etc.); and
  - accuracy of existing facility data.
- EPA recognizes the important role of ethylene oxide in sterilizing medical devices.
  - According to the Food and Drug Administration (FDA), more than 20 billion devices sold in the United States every year are sterilized with ethylene oxide, accounting for approximately 50 percent of devices that require sterilization.

- As EPA works to evaluate options for reducing air emissions from commercial sterilizer operation, the agency will continue to consult with FDA and other federal partners.
- EPA will accept comment on the ANPRM for 60 days after publication in the *Federal Register*.

### **Background**

- The NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations were finalized in December 1994. 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.
- 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.

### **EPA’s Steps to Address Ethylene Oxide Emissions**

- In 2016, EPA released its updated Integrated Risk Information System value for ethylene oxide, which indicated that cancer risks from ethylene oxide were significantly higher than previously understood.
- Since the release of the National Air Toxics Assessment in 2018, there has been considerable interest from the public in addressing emissions from these facilities as expeditiously as possible.
- EPA is committed to working with industry, and state, local and tribal air agencies as it takes the following approaches to address ethylene oxide emissions:
  - Reviewing Clean Air Act regulations for facilities that emit ethylene oxide
    - EPA has begun reviewing its air toxics emissions standards for miscellaneous organic chemical manufacturing facilities, some of which emit ethylene oxide.
    - The agency also plans to take a closer look at its rules for other types of facilities, beginning with its emissions standards for commercial sterilizers.
  - Gathering additional information on ethylene oxide emissions
    - EPA also is gathering additional information on industrial emissions of ethylene oxide, which may include data from testing at some types of facilities;
    - This information will help EPA as it evaluates opportunities to reduce ethylene oxide emissions as part of its regulations review.
    - It also will help the agency determine whether more immediate emission reduction steps are necessary in any particular locations.

### **How to Comment**

- Comments on the ANPRM should be identified by Docket ID No. EPA-HQ-OAR-2019-0178 and may be submitted by any one of the following methods:
  - Online: go to <https://www.regulations.gov/> and type the Docket ID number above in the search box. Click on the “Comment Now!” button at the top right of the page and follow the instructions for submitting your comments.

- Email: 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: U.S. Environmental Protection Agency, EPA Docket Center, Mail Code 28221T, Attention Docket ID No. EPA-HQ-OAR-2019-0178, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.
- Hand/courier delivery: EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Ave., NW, Washington, DC 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 tips on submitting comments, see <https://www.epa.gov/dockets/commenting-epadockets>.

**For Additional Information**

- A copy of the ANPRM is available on EPA's website at <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities>.