

Fact Sheet: EPA Proposes Reconsideration of Air Toxics Standards for Ethylene Oxide Commercial Sterilization Facilities

In response to legal, scientific and policy concerns, including the critical medical supply chain issue the U.S. faces due to the 2024 NESHAP rule, EPA is proposing the repeal of the burdensome Biden-era 2024 final rule for National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide (EtO) Commercial Sterilization Facilities. EtO is used to sterilize 50 percent of all medical devices in the U.S. every year—that’s 20 billion medical devices. Without EtO, it is impossible to develop a secure domestic supply chain of these critical medical devices that newborns, the elderly, and Americans undergoing surgery rely on daily to survive. If finalized as proposed, EPA’s action will ensure a strong domestic supply chain of commercial sterilized medical equipment. EPA is focused on taking actions that will save lives and protect Americans from unnecessary EtO exposure.

Summary of Action

- U.S. Environmental Protection Agency (EPA) proposed to repeal the Biden-era 2024 final rule for NESHAP for EtO Commercial Sterilization Facilities that inhibits the U.S.’s ability to have a secure domestic supply chain of sterilized medical equipment which is essential to saving lives.
- EPA is proposing that the Biden-Harris EPA never had the statutory authority under the Clean Air Act (CAA) to conduct a second risk review of the NESHAP EtO. In line with Congressional intent, EPA’s proposal would remove the standards from the Biden-era review, which justified the 2024 rule. EPA is proposing to keep the 2024 standards consistent with the CAA and that result in facilities installing emission controls consistent with the latest required technology review.
- EPA is committed to a rulemaking that will both save countless lives and advance the agency’s core mission of protecting human health and the environment, including minimizing Americans’ unnecessary exposure to EtO.

Importance to Medical Community and Americans’ Health Care

- EtO is the only safe and effective sterilization method available for many life-saving medical equipment including heart valves, pacemakers, surgical kits, gowns, drapes, ventilators, syringes, and catheters.
- Commercial sterilizers utilize EtO to sterilize 50 percent of all medical devices in the U.S. every year—or 20 billion medical devices—with no viable alternative on the market.
- EtO provides one of America’s only options for a secure domestic supply chain of sterilized essential medical equipment.

Why EPA is Reconsidering the 2024 NESHAP

- The Biden-era EtO emission standards did not follow the CAA and were based on outdated science.
- As a result of the 2024 NESHAP, the Biden-Harris Administration was forced in January 2025 to establish a Presidential exemption process from the administration’s own rule due to facilities’ inability to meet required standards before compliance deadlines, and the grave risk that the closures of these facilities posed to American lives.
- In response to legal, scientific and policy concerns, including to the critical medical supply chain issue the U.S. faces due to the 2024 NESHAP rule, the Trump EPA announced on March 12, 2025, its reconsideration of the 2024 NESHAP, and formally granted voluntary reconsideration on March 21, 2025.

Trump EPA's Commitment to Gold Standard Science

- The Biden EPA based their standards for EtO emissions off the 2016 EtO IRIS value. In the last decade, new information, including new epidemiological studies and advancements in statistical methods related to dose-response modeling, have emerged.
- EPA is seeking public comment on new information related to these sources of EtO exposure. This will guide the agency's understanding of EtO exposure and toxicity and determine whether the 2016 EtO IRIS value remains suitable for estimating risk to inform regulatory decision-making, including these proposed amendments.

Economic Analysis

- EPA estimates that this proposed action would save approximately \$630 million over 20 years, or about \$43 million annually, not including the immeasurable value of the countless lives that would be saved from lethal or significantly debilitating infections that would result without properly sterilized medical equipment.

Background

- In 1994, EPA established emission limits under the EtO Commercial Sterilization NESHAP to regulate EtO emitted from the nearly 90 commercial sterilization facilities in the U.S.
- In 2006, EPA finalized a residual risk and technology review under the CAA and made no changes.
- On April 5, 2024, EPA published a final rule after conducting a second residual risk review and technology review, outside of the agency's statutory ability under the CAA. This rule finalized unfeasible and unattainable emission standards and amendments.

How to Comment

- EPA will accept comments for 45 days after the proposal is published in the *Federal Register*. For more information please visit: <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities>.
- EPA will hold a virtual public hearing for the proposed action 15 days after publication of this proposal in the *Federal Register*.
- Comments, identified by Docket ID No. EPA-HQ-OAR-2019-0178, may be submitted via one of the following methods:
 - Go to <https://www.regulations.gov/> and follow the online instructions for submitting a comment (our preferred method).
 - Mail: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2019-0178 Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
 - Hand/Courier Delivery: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. to 4:30 p.m., Monday-Friday (except federal holidays).

More Information

- For more information on this action, please visit our Web site: <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities>.
- This action and other background information are also available online at <https://www.regulations.gov/>. Materials for this proposed action can be accessed using Docket ID No. EPA-HQ-OAR-2019-0178.