# EPA Seeks Comment on its Proposed Changes to Ethylene Oxide Regulations

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**Overview of Ethylene Oxide Regulations**

On April 5, 2024, the US Environmental Protection Agency (EPA) published the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide (EtO). The standards sought to reduce EtO emissions from medical device sterilization and other facilities by up to 90%. As many facilities could not meet the rule's requirements before compliance deadlines, and as potential closures posed risks to public health, the Biden-Harris Administration created a presidential exemption process.

In March 2026, the Trump Administration's EPA proposed repealing the 2024 Final Rule, citing procedural and scientific concerns in addition to the medical supply chain issue[1]. The Trump Administration estimates that this proposed action would save approximately $630 million in costs over 20 years, or about $43 million annually.[2]

**Background of Ethylene Oxide Regulations**

Ethylene Oxide (EtO) is a colorless gas used to sterilize a wide range of medical devices, from basic health-care products like wound dressings to specialized devices such as heart valves, pacemakers, ventilators, surgical kits, syringes, and catheters. According to the US Food and Drug Administration (FDA), more than 20 billion medical devices require sterilization each year.

EtO is also used in other industries where heat or moisture-sensitive materials require control of microorganisms. These include surgical and medical instrument manufacturing, pharmaceutical manufacturing, spice, extract, dried and dehydrated food manufacturing, as well as packaging and labeling services.
Animal studies indicate EtO can induce tumors of the lymphohematopoietic system, brain, lung, connective tissue, uterus, and mammary glands. Some studies also indicate an increased risk of cancer of the lymphohematopoietic system and of breast cancer in EtO workers, as well as to those living near EtO manufacturing facilities.

**EPA's Request for Comments**

The EPA is now seeking comments on all aspects of this proposed action, as well as additional data that may improve its analysis. The following are among the issues for which it seeks comment:

+ Is there new information that could be used in dose-response modeling, such as epidemiological studies of cancer in humans exposed to EtO?
+ What monitoring and performance testing to demonstrate initial and continuous compliance with any new standard should be relied upon?
+ Would the proposed standards result in capacity constraints as the 2024 Final Rule in the sterilization sector?

The EPA will accept public comments on this proposal 45 days after it is published in the *Federal Register*. The EPA will then hold a virtual public hearing before adopting any revised standards.

MG+M continues to monitor this important regulatory development.  Please continue to watch this space for updatess in the EtO regulatory process.

*MG+M Law Clerk Victoria Rego is a contributing author of this article.*

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[1] For example, the Final 2024 relies on EPA's 2016 Information on the Integrated Risk Information System findings for EtO, but EPA has acknowledged disputes over certain of the dose-response models and the use of certain statistical confidence limits used in same.

[2] U.S. Environmental Protection Agency, EPA Releases Proposal for Commercial Sterilizers to Safeguard the Supply of Life-Saving Medical Tools (Mar. 13, 2026), https://www.epa.gov/newsreleases/epa-releases-proposal-commercial-sterilizers-safeguard-supply-life-saving-medical