MARKET DISRUPTION BRIEF

EtO sterilization (October 28)

The U.S. Environmental Protection Agency (EPA) has released the final rule to reduce emissions of ethylene oxide (EtO) at commercial sterilization facilities.

Latest Update

On October 30 there is a webinar titled, Medical Device Sterilization Town Hall: Sterilization Short Topics and Open Q&A. Hosted by the FDA. You can find more information here.

Current conditions

On March 14, 2024, the EPA issued a final rule regarding ethylene oxide (EtO) emission standards for commercial sterilization facilities. Vizient has been closely monitoring this situation as it develops; below is the brief we have maintained on this topic. We are actively reviewing the rule to determine potential impacts and will update this brief accordingly. Additional information can be found in these links shared by the EPA:

- Fact Sheet: Overview of the Final Air Toxics Rule
- Video Presentation: Final Rule Overview
- Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations

Background

In April 2023, the U.S. Environmental Protection Agency (EPA) proposed changes that may impacts how Commercial Sterilization Facilities use EtO when to sterilizing heat- and moisture-sensitive equipment, devices and goods to increase protections for workers and community members. These changes will apply to commercial sterilization facilities. Future proposed regulations regarding healthcare sterilization facilities are anticipated, per EPA, however, the specific timing of these proposed regulations is unclear. Sterilizing with EtO is efficient and thorough where other sterilization methods may destroy a product. Currently, no available, practicable alternatives are equally effective against contaminants as EtO.

According to the EPA, the changes are expected to reduce the risk of cancer. Also, the EPA indicates that the changes are expected to reduce the documented increased risk of cancer for employees and those living in communities near sterilization facilities

EtO has been used in medical sterilization for many decades. The EPA's EtO emissions standards that have guided its use and handling have been refined over time just like other industrial or manufacturing standards. The final rule provides several new requirements for commercial sterilization facilities that aim to reduce EtO emissions by over 90 percent.

In addition, as part of the FDA's approach to reduce the use of EtO, they announced that it considers vaporized hydrogen peroxide (VHP) as an established method of sterilization for medical devices. Find FDA medical device webinars and town halls, including Medical Device Sterilization Town Halls, here.

About EtO

A flammable, colorless gas, EtO is used to sterilize equipment, goods and plastic devices that can't be sterilized with steam or radiation. About 50% of U.S. sterile medical devices – about 20 billion devices per year – are sterilized with EtO, according to the Food and Drug Administration. Devices sterilized include general health care products (e.g., wound dressings) to more specialized devices to treat specific body areas (e.g., stents). Many devices cannot be sterilized any other way.

Based on available data, the EPA does not consider EtO levels in the outdoor air to cause acute effects. Short-term inhalation can cause headache, dizziness, nausea, fatigue, respiratory irritations and possibly gastrointestinal issues. Long-term, regular exposure to EtO has been shown to increase the risk of certain cancers.

To learn more, please contact:
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Final Rule's impact to commercial sterilization facilities

- Review and comply with the final changes to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilizers (e.g., this may require facilities to install certain technologies, practices and procedures to reduce EtO emissions; comply with newly established standards for emissions that were previously unregulated, like building leaks and chamber exhaust vents, ensure compliance with emissions standards during periods of startup, shutdown and malfunction, meeting new monitoring, reporting and testing requirements)
- Meet key compliance timeframes:

Facility EtO Use	Compliance Timeframe*	Number of Facilities
Over 60 tons per year	Two Years*	28
1-60 tons per year	Two to three years	29
Less than 1 ton per year	Three years	21

*Note: EPA, reiterated that if more time is needed to comply with any standard in the final rule, that current law allows the President to exempt any stationary source from compliance with any standard for a period of up to two years under certain circumstances

Supply chain effects

When the EtO changes were proposed, stakeholders raised concerns that shortages of medical equipment and devices may ensue. In the final rule, EPA indicates that it "does not anticipate that the implementation of these standards will have any adverse impacts on the medical supply chain." As needed, Vizient will advocate to EPA if shortages or other supply chain disruptions related to the final rule occur.

Pre-ruling Supplier responses

Vizient has contacted suppliers who have offered a variety of responses to the proposed EtO changes prior to the final ruling.

- Some of the suppliers already use advanced technology for a safer environment and are assessing what additional changes will be needed to continue using EtO for sterilization under the new rules.
- Many suppliers are in the review process to determine any required changes. They expressed concern that new changes could shut down sterilization facilities, affecting patient care.
- Others are focused on developing contingency plans that rely on a diverse, multi-state network of EtO sterilizers in case one supplier is out of compliance.
- A few also report they have no products affected, while some have products produced in other countries that have their own EtO policies not affected by the EPA requirements.

We are actively engaged with our Supplier partners for impact statements now that the rule is final and compliance timelines are clear. We will provide on-going updates.

Q&A

Q: Are there alternatives to EtO?

A: For many of the devices, equipment and supplies used to deliver care, currently no available, practicable alternatives are equally effective against contaminants as EtO, which is used to sterilize approximately 50 percent of all medical supplies. Sterilization of heat- and moisture-sensitive equipment and goods requires the use of EtO as it is efficient and thorough where other sterilization methods may destroy a product.

Per AdvaMed:

- Gamma and e-beam radiation can cause plastics to become brittle or even disintegrate.
- Steam melts plastics and can damage heat- and moisture-sensitive products.
- Hydrogen peroxide and gas plasma cannot be used for large-scale sterilization and do not penetrate the interior chambers of a product.

Q: Is EtO used in other countries around the world?

A: Because of its effectiveness, EtO sterilization facilities can be found all over the world, including facilities in Europe, the UK and Asia.

Q: Is EtO used in other industries, and will those be targeted, too?

A: Yes. Relative to the other uses of EtO, only a small amount is used in the production and sterilization of medical goods and equipment. Most EtO is used as an “ingredient” to produce other chemicals that are then used to manufacture items like clothing fabric, shampoo, beverage containers and cosmetics.

Additionally, EtO is added to certain foods, such as nuts, spices, dry fruits and cereals, to keep them safe from insects and microorganisms, including enterohemorrhagic E. coli and Salmonella spp.

Also, EPA is in the process of reviewing the current NESHAP for Hospital Sterilizers but has yet to release a proposed rule.

Q: When were the EPA standards last updated?

A: The EPA updated EtO National Emission Standards for Hazardous Air Pollutants for commercial sterilization facilities in a final rule announced on March 14, 2024. More information regarding this regulation’s history is available here.

Additional Resources

EtO risk explained, EtO emissions and medical device shortages, EPA proposes new rule, EPA fact sheet, EPA fact sheet 2

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