



Ethylene Oxide

Federal Air Regulations Update

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With Guest Speaker

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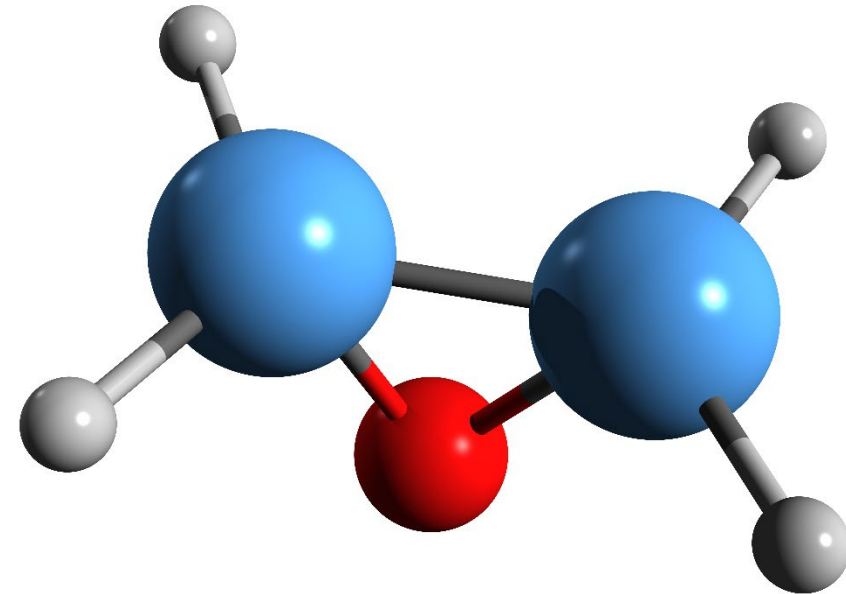
Logistics

- ❑ How can I ask questions?
 - Please enter your questions in the Questions box.
 - There will be a Q&A at the end.
- ❑ Will I get a certificate of completion?
 - Yes, all attendees will automatically be sent a certificate of completion later this afternoon.
- ❑ Will I get a copy of the slides?
 - Yes, we will post a recording of the webinar and a copy of the slides on our website. A link will be emailed to all registrants tomorrow.



Agenda

- ❑ Ethylene oxide (EtO) regulation in recent history;
 - Key Drivers;
 - Important Rules;
 - Challenges to U.S. EPA procedure and statutory authority.
- ❑ Current changes to EtO regulation
 - Sterilizers
 - PEPO
 - CMAS
- ❑ Future of EtO regulation



Historical Perspectives

- ❑ 2016 Integrated Risk Information System (IRIS) value update for EtO.
- ❑ 2018 Update to the National Air Toxics Assessment.
- ❑ 2020 Miscellaneous Organic Chemical Manufacturing (MON) Rule.
- ❑ 2024 - Three unique rulemakings:
 - EO Emissions Standards for Sterilization Facilities; SOCM (HON) and Group I & II Polymers and Resins; and
 - Polyether Polyols.
- ❑ 2025 Chemical Manufacturing Area Source Rule



Historical Perspectives (Cont.)



- ❑ Various challenges to the EtO IRIS value:
 - Data Quality Act petition;
 - Independent analyses by state agencies; and
 - *Huntsman Petrochemical v. EPA* (D.C. Cir. 2024)
- ❑ Challenges to U.S. EPA's authority to conduct second risk reviews.



Evolving Changes to EtO Regulations



2026 Sterilizers Proposal

- ❑ U.S. EPA proposed to remove the risk-based EtO standards on “lack of authority” basis.
 - EtO emission reduction requirements for sterilization chamber vents, aeration room vents, chamber exhaust vents (area sources), and “group 1” and “group 2” room air vents (area sources).
 - Proposing to revert to standards to MACT, GACT, technology-based standards.
 - Some proposed standards are less stringent, others are not.
- ❑ U.S. EPA also proposed to remove the requirement to use a permanent total enclosure (PTE) for room air emissions.



2026 PEPO and CMAS Final Rule

- ❑ For PEPO U.S. EPA finalized technology review-based EtO standards “as necessary” instead of risk-based standards.
 - Control thresholds were raised for process vents, equipment leaks, wastewater, storage vessels, and heat exchangers
 - Some control requirements were made less stringent; others remained the same.
 - No fenceline monitoring for EtO
- ❑ U.S. EPA deferred setting EtO standards for CMAS.



Looking to the Future

- ❑ U.S. EPA is currently reconsidering the HON rule.
- ❑ Combine PEPO reconsideration with the HON?
- ❑ Deferred action on CMAS?
- ❑ Future of the EO IRIS value?
- ❑ Potential to revisit MON?



Questions or Comments?

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