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BLOG

EPA Announces Series of New Actions to Address Ethylene Oxide Emissions

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The U.S. Environmental Protection Agency (EPA) recently proposed three key actions to further regulate ethylene oxide (EtO) under the Clean Air Act and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's latest proposals include (1) stricter national emission standards for hazardous air pollutants (NESHAP) for commercial sterilization facilities, (2) new Clean Air Act rules for plants that make synthetic organic chemicals and plants that make a variety of polymers and resins, and (3) more stringent standards for workplaces handling EtO. We provide an overview of these proposed actions and what they may mean for your business.

An EtO Refresher

EtO is a colorless gas used to sterilize medical equipment and to make products including antifreeze, textiles, plastics, adhesives, and plastics. EPA's recent actions to further regulate EtO are rooted in the December 2016 Integrated Risk Information System (IRIS) risk assessment. As we previously reported, this assessment is the subject of controversy. The 2016 IRIS assessment for EtO characterized the chemical as a more potent "carcinogenic to humans" by the inhalation-exposure route than previously understood.[i] This resulted in increasing the inhalation unit risk estimate (URE) for EtO, which reflects a higher risk of cancer in populations exposed to EtO than the prior URE. Since the publication of the 2016 EtO IRIS value, industry and certain states have criticized the value. Meanwhile, environmental groups and communities surrounding facilities using EtO have pointed to the 2016 IRIS value as a basis for EPA to take further action to reduce EtO emissions.

Part 1: Reducing Emissions from Commercial Sterilization Facilities

Under the Clean Air Act, EPA is required to conduct a risk-and-technology review (RTR) eight years after the initial issuance of a NESHAP. If EPA finds "residual" risk or new, cost-effective control methods, it must tighten the rule. After the RTR, EPA must then conduct technology reviews every eight years. EPA has not reviewed and revised the NESHAP for commercial sterilizers since 2006. In December 2022, environmental groups sued EPA to compel the agency to complete a review of the NESHAP for commercial sterilizers. This first proposed action addresses this demand.

EPA announced its proposed revisions to the NESHAP for Commercial Sterilization Facilities on April 11, 2023.[ii] In the preamble to the rule, EPA explains that updated URE for EtO was the driver for EPA to exercise its discretionary

authority pursuant to section 112(f) of the Clean Air Act and conducting the second residual-risk review.[iii] The proposed rule regulates EtO emissions from commercial sterilizer facilities by imposing numeric emission limits, operating limits, and management practices. At a high level, EPA is proposing to:

- establish standards for the following emissions sources that are currently unregulated:
  - sterilization chamber vents, aeration room vents, and chamber exhaust vents at facilities where EtO use is less than 1 ton per year (tpy);
  - aeration room vents and chamber exhaust vents at facilities where EtO use is at least 1 tpy but less than 10 tpy;
  - chamber exhaust vents at facilities where EtO use is at least 10 tpy and room air emissions at area source facilities where EtO use is at least 10 tpy; and
  - room air emissions.
- amend and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM; and
- require that facilities either monitor with an EtO continuous emissions monitoring system (CEMS) or conduct initial and annual performance tests with continuous parameter monitoring.[iv]

EPA is proposing an expedited timeline for regulated sterilizer facilities to meet the new emission and operating requirements. If finalized as proposed, sterilizer facilities would be required to install pollution controls within 18 months of EPA issuing the final rule. Moreover, sterilization facilities would be required to begin compliance reporting within 60 days after the effective date of the final rule.

Part 2: Reducing Emissions from Chemical Manufacturers

On April 6, 2023, EPA proposed a package of Clean Air Act amendments to reduce emissions of six key air toxics, including EtO, from chemical-manufacturing facilities.[v] The proposed regulations would strengthen and update Clean Air Act rules applying to a variety of equipment and processes used to make synthetic organic chemicals, as well as processes used in polymers and resins production. According to the prepublication version of the rule, EPA is proposing the following:

- amendments to the New Source Performance Standards (NSPS) that apply to the Synthetic Organic Chemical Manufacturing Industry (SOCMI) for equipment leaks, air oxidation unit processes, distillation operations, and reactors processes;
- amendments to the NSPS for equipment leaks of volatile organic compounds in SOCMI;
- amendments to the NESHAP that apply to the SOCMI (more commonly referred to as the Hazardous Organic NESHAP or HON) and Group I and II Polymers and Resins Industries;
- strengthening the emission standards for EtO and chloroprene emissions; and
- removing general exemptions from emissions control requirements during periods of SSM.[vi]

One key provision of the rule package sure to garner attention is EPA's proposed fenceline-monitoring requirements. If finalized as proposed, facilities that make, store, use, or emit one of six key air toxics—EtO, chloroprene, benzene, 1,3-butadiene, ethylene dichloride, or vinyl chloride—would be required to conduct monitoring at their fenceline. Then, if the annual average air concentrations of any of the chemicals are higher than the applicable action level at the fenceline, owners and operators must identify the source and make repairs. The proposed action level for EtO is 0.2 micrograms per cubic meter of air. Finally, EPA would require facilities to submit quarterly data to the agency starting one year after fenceline monitoring begins. This data would be available to the public.[vii]

Part 3: Reducing Risk for Workers Exposed to EtO

The third key action is EPA's Proposed Interim Registration Review for EtO.[viii] Also announced on April 11, 2023, the Proposed Interim Registration Review seeks to implement new mitigation measures to decrease risk for workers using EtO in their jobs, as well as communities near sterilization facilities.[ix]

The FIFRA requires EPA to reevaluate pesticides every 15 years. Certain products containing EtO are considered pesticides because they are used to kill viruses and bacteria. EPA has been evaluating EtO as part of the standard registration review process and reached the Proposed Interim Decision (PID) stage. At this stage, EPA presents its findings regarding the FIFRA safety standard, proposes any modifications to the way the pesticide is used, and proposes any labeling changes.[x]

EPA's proposed interim decision for EtO includes the following updated mitigation measures:

- prohibiting certain uses of EtO where alternatives exist including use in museums, archival settings, beekeeping, some cosmetics, and musical instruments;
- lowering the amount of EtO that may be applied for medical device sterilization while still meeting FDA requirements for sterility assurance;
- requiring personal protective equipment to be worn by employees in sterilization facilities where EtO in the air is at or above 10 parts per billion (ppb) (notably, 10 ppb is the lowest level at which current technology can detect EtO in the workplace); and
- requiring engineering controls in commercial sterilization facilities and healthcare facilities. Engineering controls include, but are not limited to:
  - separating EtO sterilization spaces from other work areas;
  - using abatement device to remove EtO from the exhaust air and reduce discharge to the environment;
  - implementing an air pressure gradient so air flows from low-EtO-concentration spaces to high-EtO-concentration spaces;
  - separating HVAC systems between offices and EtO sterilization areas to ensure there is no circulation of EtO in office spaces;
  - ventilating EtO storage areas;
  - automating the transport of sterilized materials and aerated materials to remove humans and human exposure from the transport process; and
  - implementing EtO sterilization chambers where the sterilization and aeration occur within the same chamber.[xi]

In addition, the proposal includes new data collection, recordkeeping, and reporting requirements for commercial sterilization facilities. After the finalization of the Interim Registration Review Decision, the new measures will be phased in.

Key Takeaways

- In April 2023, EPA proposed a comprehensive series of actions to further regulate EtO. These actions are grounded in the 2016 IRIS assessment for EtO, which found that EtO is a far more potent carcinogen than previously understood.
- EPA is requesting public comment on the proposed actions. EPA also plans to hold public hearings and webinars.
  - Air Toxics Rules for Chemical Manufacturers: the comment deadline will be 60 days after the date of publication in the Federal Register. EPA is also holding a virtual public hearing 21 days after the date of publication in the Federal Register.
  - Air Toxics Rule for Sterilization Facilities: the comment deadline is June 12, 2023. EPA will hold virtual public hearings on May 2 and May 3.

- Proposed Interim Decision on EtO as a Pesticide: the comment deadline is June 12, 2023. EPA has requested comment on specific areas, as described in section V.G of the Proposed Interim Registration Review Decision document. EPA will also hold a public webinar to discuss proposed actions to reduce exposure to EtO from commercial sterilization facilities and healthcare facilities on May 1, 2023.

- The proposed actions are sure to attract legal challenges. Businesses that produce and use EtO are expected to challenge the proposed rule. The chemical industry has already challenged the 2016 IRIS assessment in lawsuits against EPA over the final miscellaneous organic chemical manufacturing (MON) rule.[xii] On the other hand, environmental groups and those living in the vicinity of commercial sterilization facilities have said that EPA should go further than what has been proposed, such as by requiring sterilization facilities to conduct fenceline monitoring.
- EPA is expected to finalize the proposed rules in 2024.

For more information on EtO regulation or the impacts of EPA's proposals on your business, please contact Jonathan D. Brightbill (Partner, White Collar, Regulatory Defense & Investigations/Environmental Litigation), Madalyn B. Feiger (Associate, Environmental), or your Winston relationship attorney.

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[i] EPA, Evaluation of Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8): In Support of Summary Information on the Integrated Risk Information System (IRIS) (Dec. 2016), available at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.

[ii] 88 Fed. Reg. 22790 (Apr. 13, 2023).

[iii] *Id.* 22794.

[iv] EPA, *EPA Proposes to Strengthen Clean Air Act Standards for Ethylene Oxide from Commercial Sterilization Facilities: Fact Sheet*, *available at* https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet%20Proposal%20to%20Address%20EtO%20Risks%20from%20Commercial%20Sterilizers.pdf.

[v] EPA, *New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry*, *prepublication version available at* https://www.epa.gov/system/files/documents/2023-04/SAN9327_HON_PR%20I%20and%20II_SOCMI%20NSPS_Proposal_Preamble_Signature_ADMIN_1.pdf.

[vi] *Id.*

[vii] EPA, *EPA's Proposal to Reduce Toxic Air Pollution from the Synthetic Organic Chemical Manufacturing Industry and the Polymers and Resins Industry: Overview*, *available at* https://www.epa.gov/system/files/documents/2023-04/PROPOSED.%20HON.PR_OVERVIEW.Fact%20Sheet.FINAL_.4.6.23_0.pdf.

[viii] EPA, Ethylene Oxide Proposed Interim Registration Review Decision, Case Number 2275 (Mar. 28, 2023), *available at* https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf.

[ix] EPA, *News Release: EPA Proposes New Standards to Protect Public Health, Reduce Exposure to Ethylene Oxide Pollution* (Apr. 11, 2023), *available at* https://www.epa.gov/newsreleases/epa-proposes-new-standards-protect-public-health-reduce-exposure-ethylene-oxide.

[x] EPA, *Fact Sheet: EPA Issues Proposed Actions to Reduce Ethylene Oxide Exposures under the Nation's Pesticide Control Law*, *available at* https://www.epa.gov/system/files/documents/2023-04/fact-sheet-proposed-actions-eto.pdf.

[xi] EPA, Risk Reduction Measures in Proposed Interim Decision, *available at* https://www.epa.gov/ingredients-used-pesticide-products/regulation-ethylene-oxide-eto-under-federal-insecticide#Risk%20Reduction%20Measures.

[xii] EPA has already used the controversial 2016 IRIS value in the MON NESHAP review. The final MON Rule, which was issued in August 2020, has been challenged in the D.C. Circuit. *See Huntsman Petrochemical LLC v. U.S. EPA*, No. 20-1414 (D.C. Cir. filed Oct. 9, 2020).

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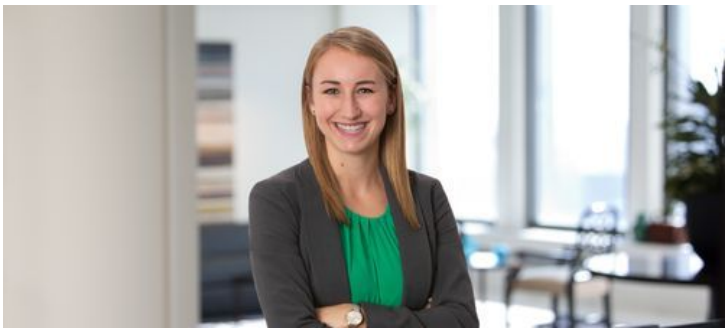

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