American College of Occupational and Environmental Medicine

April 14, 2026

Via Regulations.gov
Docket ID No.: EPA-HQ-OAR-2019-0178

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Comments on Proposed Reconsideration of NESHAP: Ethylene Oxide Emissions Standards

Dear Administrator,

The American College of Occupational and Environmental Medicine (ACOEM) appreciates the opportunity to submit comments on the U.S. Environmental Protection Agency's proposed reconsideration of the 2024 National Emission Standards for Hazardous Air Pollutants governing ethylene oxide emissions from commercial sterilization facilities.[1] ACOEM represents more than 3,200 clinicians and scientists dedicated to protecting the health of workers and communities. Our members routinely evaluate and manage health risks associated with hazardous exposures, including carcinogenic air toxics such as ethylene oxide, and are therefore uniquely positioned to provide a clinical and public health perspective on this issue.

Ethylene oxide is a well-characterized, highly potent carcinogen and systemic toxicant whose risks have been extensively documented in toxicological, epidemiologic, and mechanistic studies. The Agency for Toxic Substances and Disease Registry (ATSDR) identifies ethylene oxide as a multi-system toxicant affecting hematologic, neurologic, respiratory, reproductive, developmental, and endocrine systems, with inhalation representing the primary route of exposure in both occupational and community settings.[2] Evidence from both human and animal studies demonstrates that adverse health effects, including cancer, occur at relatively low exposure levels, and that multiple organ systems are sensitive targets of ethylene oxide toxicity.[2]

The carcinogenicity of ethylene oxide is supported by a strong, consistent body of evidence from multiple authoritative scientific organizations. The U.S. Environmental Protection Agency, through its Integrated Risk Information System (IRIS), has classified ethylene oxide as carcinogenic to humans by the inhalation route.[3] The National Toxicology Program has designated ethylene oxide as a known human carcinogen,[4] and the International Agency for Research on Cancer has classified it as a Group 1 carcinogen.[5] The mechanistic basis for these determinations lies in ethylene oxide's function as a direct-acting alkylating agent that forms DNA adducts and induces mutations and chromosomal damage.[3] This mutagenic mode of

action supports the application of a linear no-threshold model for cancer risk, meaning that no safe level of exposure can be assumed and that any incremental exposure carries a corresponding increase in cancer risk.

Epidemiologic studies further reinforce these conclusions, demonstrating increased risks of lymphohematopoietic malignancies, including leukemia and non-Hodgkin lymphoma, as well as breast cancer among exposed worker populations.[6] These findings are supported by dose-response relationships observed in large occupational cohort studies. More recent research has extended these concerns to community populations, showing elevated cancer risk among individuals residing near ethylene oxide-emitting facilities, thereby confirming that the health risks of ethylene oxide are not confined to occupational settings but also affect surrounding communities.[7]

Ethylene oxide continues to play an important role in the sterilization of medical equipment, with approximately half of all U.S. medical devices sterilized using this chemical, and commercial sterilization facilities distributed across the country.[8] However, this widespread use results in both occupational and ambient air exposures, placing sterilization workers, healthcare personnel, industrial workers, and residents near these facilities at risk. Given the high carcinogenic potency of ethylene oxide, even low-level chronic exposures contribute meaningfully to cumulative lifetime cancer risk.[3]

The 2024 NESHAP rule represented a scientifically grounded and necessary regulatory response to this evolving body of evidence. The rule incorporated enhanced emission-control technologies and monitoring requirements to significantly reduce emissions and associated health risks. EPA projected that these measures would reduce ethylene oxide emissions from the regulated source category by approximately 80 to 90 percent, thereby substantially reducing cancer risk among both workers and nearby residents.[8] In contrast, the proposed reconsideration would rescind key protective measures, resulting in increased emissions and corresponding increases in health risk. EPA has acknowledged that the health impacts associated with increased ethylene oxide emissions have not been fully monetized and that their inclusion would reduce or eliminate the projected economic benefits of the rollback.[8]

The current reconsideration does not challenge the scientific basis of the 2024 rule. Rather, it rests on a legal argument that EPA lacked statutory authority to conduct a discretionary residual risk review beyond an initial statutory timeframe.[1] This argument is grounded in a narrow interpretation of Clean Air Act Section 112(f)(2) and asserts that EPA's authority to evaluate and address residual risk is limited to a one-time review conducted within a specified period following the promulgation of technology-based standards.

From both a legal and public health perspective, this interpretation is inconsistent with the structure and purpose of the Clean Air Act. The statute establishes a comprehensive and iterative regulatory framework that includes not only technology-based standards under Section 112(d) and residual risk review under Section 112(f), but also an explicit requirement under Section 112(d)(6) that EPA review and revise standards as necessary to reflect

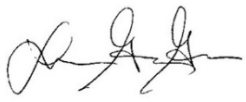
developments in practices, processes, and control technologies.[9] This statutory language demonstrates that Congress intended EPA's authority to be ongoing and adaptive, allowing the Agency to respond to new scientific evidence and evolving understanding of risk.

Limiting EPA's authority to a single, time-bound review would produce outcomes that are fundamentally inconsistent with the statute's public health mission. Under such an interpretation, EPA would be precluded from acting on newly identified hazards or updated risk assessments if those findings emerged outside an arbitrary statutory window, effectively locking regulatory standards in place based on outdated science. As noted in the underlying analysis, this would mean that even if new evidence demonstrated substantially greater carcinogenic risk, EPA would be unable to act to protect workers and communities. Such a result is incompatible with both the Clean Air Act's protective purpose and longstanding principles of administrative law.

From the perspective of occupational and environmental medicine, the obligation to act on evolving scientific evidence is fundamental. Exposure limits and regulatory standards must be continuously updated to reflect advances in toxicology, epidemiology, and risk assessment. Failure to incorporate new knowledge into regulatory decision-making results in preventable disease and mortality, particularly for populations with sustained or cumulative exposure. Ethylene oxide represents a clear case in which mechanistic evidence, epidemiologic findings, and environmental exposure data converge to demonstrate significant and ongoing risk, thereby warranting strong and sustained regulatory controls.

In conclusion, ethylene oxide is a highly potent carcinogen with well-established risks that have become increasingly clear over time. The 2024 NESHAP rule reflects the best available science and represents a necessary and appropriate measure to protect public health. The Clean Air Act was designed to enable EPA to respond to such evolving knowledge, and any interpretation that limits this authority undermines both the statute and its fundamental purpose. For these reasons, ACOEM strongly urges EPA to withdraw the proposed reconsideration and to retain and fully implement the 2024 NESHAP standards. EPA should reaffirm its statutory authority to update standards based on evolving scientific evidence and continue to prioritize protecting workers and communities from hazardous air pollutants, such as ethylene oxide. Regulatory standards should align with contemporary principles of carcinogenic risk assessment, including the recognition that no safe exposure threshold exists for genotoxic carcinogens such as ethylene oxide.

Respectfully submitted,



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