



April 14, 2025

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

Re: Comment on Proposed Rule "National Emission Standards for Hazardous Air Pollutants: Chemical Manufacturing Area Sources Technology Review", Docket ID No. EPA-HQ-OAR-2024-0303

Dear Administrator Zeldin:

On behalf of the undersigned public health organizations, we appreciate the opportunity to comment on the proposed rule titled "National Emission Standards for Hazardous Air Pollutants: Chemical Manufacturing Area Sources Technology Review." EPA's work to protect people from toxic air emissions, including ethylene oxide (EtO), is central to its mission to protect human health and the environment. The agency should finalize this rule.

Finalizing this rule fits into both EPA's mission to protect human health and the environment and the agency's first pillar of "clean air, land, and water for every American" by reducing levels of air toxics that harm families.

Reducing emissions of EtO will prevent cancer and a host of other health harms. EPA's own analyses highlight multiple health risks from EtO. At acute levels of short-term exposure, it can cause central nervous system depression and irritation of the eyes.¹ Over the long term, either from spending significant time working in commercial sterilization facilities or near one, EtO dramatically increases cancer risk, including breast cancer and cancers of the white blood cells. The National Cancer Institute finds that lymphoma and leukemia are the cancers most frequently associated with occupational exposure to EtO, with reports of stomach cancers and breast cancers as well.²

EPA's own analyses have also identified dramatic health harms associated with other emissions that would be reduced under this rule. 1,3-Butadiene is a human carcinogen and may cause

¹ U.S. Environmental Protection Agency. "Ethylene Oxide." <https://www.epa.gov/sites/default/files/2016-09/documents/ethylene-oxide.pdf>

² National Cancer Institute. "Ethylene Oxide." <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/ethylene-oxide>

additional health harms. Ethylene dichloride can cause nervous system, liver, kidney, respiratory and cardiovascular harm.³

We make the following recommendations for EPA for the final rule:

Require fenceline monitoring whenever possible. We were pleased that the proposed rule includes a fenceline monitoring program and corrective action when a specified “action level” is exceeded, along with public reporting of data. While improved monitoring and corrective action measures in monitored areas are critical, they cannot fully eliminate the cancer risk. California’s South Coast Air Quality Management District found after monitoring three commercial sterilization facilities that high concentrations of the gas were present, potentially due to fugitive emissions from aeration rooms and potentially from the sterilized items as they are prepared for shipping.⁴

This underscores not only the need to eliminate the use of EtO wherever possible, but also the need to employ and require monitoring to identify any instances where EtO is continuing to be emitted despite control measures in place. It is critical that emissions reductions be verified with monitoring to ensure the measures put in place are actually reducing emissions.

We also urge EPA to ensure that data from fenceline monitoring is not only reported frequently, but also made public frequently, so that communities near these facilities can be aware of immediate threats to their health.

Establish a New Area Source Category to address chemical manufacturing process units (CMPUs) using ethylene oxide (EtO). We were glad to see that EPA is proposing to establish a new area source category to address chemical manufacturing process units (CMPUs) using EtO. EPA is proposing to list EtO in table 1 to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Chemical Manufacturing Area Sources and to add EtO-specific requirements to the CMAS NESHAP. We support this proposal and urge it to be included in a final rule.

Add New Leak Detection and Repair (LDAR) requirements to the CMAS NESHAP for equipment leaks in organic HAP service and heat exchange systems. We were also glad to see that EPA is also proposing requiring performance testing once every five years and adding provisions for electronic reporting. EPA estimates that the proposed amendments to the CMAS NESHAP, excluding the proposed EtO emission standards, would reduce hazardous air pollutant emissions from emission sources by approximately 158 tons per year (tpy). Additionally, the proposed EtO emission standards are expected to reduce EtO emissions by approximately 4.6 tpy.

Beyond this rulemaking, we urge EPA to take the following steps to further reduce EtO exposure overall, including from its use in sterilization:

³ U.S. Environmental Protection Agency. “Regulatory Impact Analysis for the 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.” 2023.

⁴ <https://www.latimes.com/environment/story/2022-08-09/medical-sterilizing-facilities-face-growing-scrutiny>

Work with other agencies to identify alternatives to EtO. As noted above, the use of EtO leads to an inherent risk of emissions escaping and harming health; as long as this gas is used, risk to human health remains. We urge EPA to work together with the Food and Drug Administration (FDA) and any other relevant agencies to build on existing work to find alternatives for EtO quickly.

Move forward quickly to address emissions from hospital sterilizers. As noted above, the use of EtO in hospital sterilization facilities poses a grave risk to workers there. We thank EPA for its commitment to address hospital sterilizers in a future rulemaking and urge the agency to act quickly to protect healthcare workers and patients.

On behalf of the communities we serve, we urge you to protect human health from the cancer risk posed by the use of ethylene oxide in sterilization facilities and in all other uses.

Signed,

American Lung Association

Children's Environmental Health Network