June 27, 2023

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20004

Re: National Emission Standards for Hazardous Air Pollutants: Commercial Ethylene Oxide Sterilization Technology Review; EPA-HQ-OAR-2019-0178

The undersigned health, medical, health care and nursing organizations appreciate the opportunity to provide comment on this technology review of the NESHAP for commercial ethylene oxide sterilization facilities. We urge you to strengthen and quickly finalize this rule to better protect human health from ethylene oxide. We also urge you to accelerate work to find more alternative sterilizers to ultimately replace the use of this dangerous gas entirely.

We appreciate EPA's recent work to proactively engage the public in communities facing elevated cancer risk from ethylene oxide (EtO) in nearby commercial sterilization facilities, and the additional rulemakings EPA is undertaking to help protect both communities and workers. Stronger standards on EtO, with a future goal of eliminating its use entirely, will help achieve the necessary and historic goals outlined in the Cancer Moonshot initiative.

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 near commercial sterilization facilities or working in one, EtO dramatically increases cancer risk, including breast cancer and cancers of the white blood cells. Workers who spend their career applying EtO to medical devices in commercial sterilization facilities face a 1 in 17 cancer risk from ethylene oxide. Workers who apply EtO in healthcare facilities face a 1 in 25 risk. Workers and residents also face elevated cancer risk – 100 in one million – if they spend their careers or lives near commercial sterilization facilities.[2] The National Cancer Institute finds that lymphoma and leukemia are the

[1] U.S. Environmental Protection Agency. "Ethylene Oxide." https://www.epa.gov/sites/default/files/2016-09/documents/ethylene-oxide.pdf
[2] U.S. Environmental Protection Agency. "Ethylene Oxide (EtO) Risks and Your Health." https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-eto-risks-and-your-health#your%20health

cancers most frequently associated with occupational exposure to EtO, with reports of stomach cancers and breast cancers as well.[3]

Therefore, we appreciate that EPA is addressing this pollutant from multiple angles and urge the agency to continue to work to eliminate the risk from EtO entirely.

Within this rulemaking, we make the following recommendations for EPA:

Address off-gassing from off-site warehouses. EPA lays out the processes for EtO's use at commercial sterilization facilities in the proposed rule. In the chamber sterilization process, the items are typically placed in a chamber and treated with EtO gas, which is then evacuated. The products still have the ability to off-gas EtO, so they are aerated and then placed in a warehouse area for distribution. Similarly, if EtO is applied in the packaging of individually packaged items to be sterilized, the items similarly have the ability to off-gas. We are concerned that emissions from sterilized items could persist after the aeration process is complete, and therefore urge EPA to consider addressing emissions at the warehouses where they are stored.

Require fenceline monitoring whenever possible. The use of ethylene oxide is inherently dangerous, and while improved measures to control its cancer risk are critical, they cannot fully eliminate the 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. With leakage and off-gassing possible at every step of the process of the use of EtO for sterilization, 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.

Treat 18 months as the maximum timeline for compliance. We appreciate that given the high risk posed by EtO, EPA is requiring compliance timelines that are shorter than many similar rulemakings. We urge EPA not to extend the timeline for compliance in the final rule, and to make it shorter, if possible.

Ensure strong provisions of the proposal are finalized. Our organizations support the elimination of startup, shutdown and malfunction exemptions in the final rule. We also support EPA's choice of the more protective alternative for the specific limits throughout the proposal.

Beyond this rulemaking, we urge EPA to take the following steps to further reduce EtO exposure:

---

[3] National Cancer Institute. "Ethylene Oxide." https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/ethylene-oxide

[4] "Medical sterilizing facilities face growing scrutiny due to toxic gas concerns." 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. No one should face elevated cancer risk from products that are designed to help keep them healthy.

Signed,

Allergy & Asthma Network

Alliance of Nurses for Healthy Environments

American Lung Association

Asthma and Allergy Foundation of America

Children's Environmental Health Network

Medical Society Consortium on Climate and Health

Medical Students for a Sustainable Future

National Association of Pediatric Nurse Practitioners

Physicians for Social Responsibility Pennsylvania