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The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
EPA Docket Center (EPA/DC), Mail Code 28221T
Attention Docket ID No. EPA-HQ-OAR-2019-0178
1200 Pennsylvania Avenue, NW,
Washington, DC 20460

RE: EPA Proposal for New Standards to Protect Public Health, Reduce Exposure to Ethylene Oxide Pollution, Docket ID No. EPA-HQ-OAR-2019-0178

Dear Administrator Regan,

On behalf of the American College of Occupational and Environmental Medicine (ACOEM), I am writing in support of the EPA's proposed amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Commercial Sterilization Facilities (1). These amendments will result in a nationwide reduction of ethylene oxide (EtO) air emissions from sterilization facilities and chemical plants, which poses cancer risks to the surrounding community, and will implement stronger protection measures for EtO-exposed workers. EtO is used to manufacture other chemicals, such as plastics and antifreeze, and to sterilize medical equipment and spices. In April 2023, EPA issued three proposals to decrease risk to communities and workers: 1) reduce EtO emissions from chemical plants, 2) reduce EtO emissions from commercial sterilizers, and 3) reduce risk to workers in sterilization industries. These proposals will cut source emissions by 19 tons per year, reducing cancer risk among both facility workers and the surrounding communities.

Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting employee health through preventive medicine, clinical care, research, and education. The College represents over 4,000 physicians and other health care professionals devoted to preventing and managing occupational injuries and exposures. Within ACOEM, an Environmental Health Special Interest Section is dedicated to environmental health, focusing on the exposure and injury hazards Americans face.

Many of our members practice in medical centers across the US and see workers and community members exposed to EtO. We are concerned about the long-term cancer risks of EtO exposure among those who work, live, go to school, or attend daycare in communities surrounding commercial sterilization facilities. The recent risk assessment by EPA, released in 2023, showed an increased lifetime cancer risk for long-term inhalational exposure (35 years X 8 hours/day) in workers who directly handle EtO in sterilization facilities and in healthcare settings (1,2). EPA risk assessments also showed an elevated cancer risk for those living near commercial sterilizers and exposed 24 hours a day for 70 years (2,3). In 2016 EPA found an increased risk of lymphohematopoietic cancers (such as non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and female breast cancer in sterilization workers (4). Both the National

Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC) classify EtO as a known human carcinogen (5,6).

Considered one of the best-studied cohorts of EtO-exposed workers is the National Institute for Occupational Safety and Health (NIOSH) mortality studies of 18,235 sterilization plant workers followed from 1987 to 1998 (7, 8, 9). Although the authors did not find an overall increased risk of cancer mortality, they noted that “positive exposure-response trends were found for males for lymphoid cancer mortality, and for females for breast cancer mortality”, particularly in workers with the longest exposure latency and highest cumulative exposures. A recent 2019 systematic literature review and meta-analysis showed an increased risk of lymphohematopoietic cancers (primarily in older studies) in EtO production and sterilization workers but no increased risk of breast cancer (10).

Regarding community risk, a 2020 study of EtO biomarkers found increased levels in people living closer to EtO-emitting facilities compared to those living farther away. The authors concluded that living near EtO-emitting facilities may put people at greater risk of cancer or other EtO-associated health outcomes (11). A recent large cohort study examined the association between nonoccupational EtO exposure in the community and distance from EtO emitting facilities and breast cancer risk among postmenopausal women. There was an increased risk for breast carcinoma in situ within 10 km of facilities among the highly exposed. Increasing distances from facilities weakened this association. No clear association was seen with non-Hodgkin lymphoma (12).

Clearly, further research is needed, particularly for community risks. However, we cannot ignore the risks to workers and communities that EtO may pose. It is imperative that we protect public health by bringing emission levels down by 86% for the cancer risk to fall below the EPA’s Clean Air Act benchmark. Additionally, ACOEM supports securing stronger worker protections, whose important efforts supply sterilized medical equipment for our US healthcare system to function. We look forward to seeing the finalization of the two proposals to protect Americans from EtO cancer risks.

On behalf of ACOEM, we thank you for your leadership on this critical issue. Please do not hesitate to contact Dane Farrell (Dane@cascadeassociates.net), ACOEM’s Government Affairs Representative, with any questions.

Sincerely,



Kenji Saito, MD, JD, FACOEM
President

American College of Occupational and Environmental Medicine (ACOEM)

References

1. EPA. Actions to Protect Workers and Communities from Ethylene Oxide (EtO) Risk. <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/actions-protect-workers-and-communities-ethylene-oxide-eto>
2. EPA. Ethylene Oxide (EtO). Addendum to “Draft Human Health and Ecological Risk Assessment in Support of Registration Review”- Inhalation Exposure Risk Assessment in Support of Registration Review. 2023. <https://www.epa.gov/system/files/documents/2023-04/eto-draft-human-health-ra-add.pdf>
3. EPA. Community Engagement on Ethylene Oxide (EtO). Past outreach efforts to residents with elevated risk. <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/community-engagement-ethylene-oxide-eto>
4. EPA. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8), 2016. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf
https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf
5. National Toxicology Program. Ethylene Oxide. Report on Carcinogens. 15th edition. <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/ethyleneoxide.pdf>
6. IARC. IARC Monograph on the Evaluation of Carcinogenic Risks to Humans. 1,3-Butadiene, Ethylene Oxide, and Vinyl Halides. Volume 97. 2008. <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/1-3-Butadiene-Ethylene-Oxide-And-Vinyl-Halides-Vinyl-Fluoride-Vinyl-Chloride-And-Vinyl-Bromide--2008>
7. Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, Nowlin S. 1991. Mortality among workers exposed to ethylene oxide. *N Engl J Med* 324(20): 1402-1407.
8. Steenland K, Whelan E, Deddens J, et al. Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States). *Cancer Causes Control*. 2003;14(6):531-539.
9. Steenland K, Stayner L, Deddens J. Mortality analyses in a cohort of 18 235 ethylene oxide exposed workers: follow up extended from 1987 to 1998. *Occup Environ Med*. 2004;61(1): 2-7.
10. Marsh, GM, Keeton KA, Riodan AS, Best EA, Benson SM. Ethylene oxide and risk of lymphohematopoietic cancer and breast cancer: a systematic literature review and meta-analysis. *International Archives of Occupational and Environmental Health*. 2019; 92:919-939.
11. Szwec E, Friedman L, Buchanan S. Levels of Ethylene Oxide Biomarker in an Exposed Residential Community. *International Journal of Environmental Research and Public Health Communication*. 2020: 1-7.
12. Jones R, Fisher J, Medgyesi D, et al. Ethylene Oxide Emissions and Incident Breast Cancer and Non-Hodgkin Lymphoma in a US Cohort. *Journal of the National Cancer Institute*, 2023, 115(4), 405-412.