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EPN Testimony on EPA's Proposal
National Emission Standards for Hazardous Air Pollutants:
Ethylene Oxide Emissions Standards for Sterilization Facilities
Residual Risk and Technology Review Reconsideration
Docket No: EPA-HQ-OAR-2019-0178
April 1, 2026

My name is Michelle Montoya and I am the Policy Director for the Environmental Protection Network. We are an organization of hundreds of former EPA employees who provide the unique technical perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

I would like to begin by acknowledging the professionalism and dedication of the EPA career staff who worked for many years on these issues. These staff devoted considerable time and effort to address and protect the American public from ethylene oxide's (EtO) toxic effects.

Unfortunately, EPA is now proposing to disregard the science and ignore its mandate under the Clean Air Act to protect public health. Consequently, we have serious concerns about the defensibility of this proposal and request that EPA reconsider this course of action.

EtO has many important uses but is largely used in commercial medical sterilization. It is also a dangerous carcinogen. Nearly 90 sterilization facilities across the country have emission requirements under the existing rule, and many operate in residential neighborhoods and near schools in unassuming buildings — creating localized exposures residents may not even realize are happening.

In this proposal, EPA has provided no mention of the real cancer risks posed to the American public by this dangerous chemical, particularly to populations living close to these facilities.

Yet EPA's own analyses have demonstrated the extremely high risks attributed to EtO emissions from commercial sterilizers.

The health protections that will be weakened if this proposal is enacted were based on EPA's Integrated Risk Information System (IRIS) assessment of EtO, a comprehensive, transparent review of the best available science on the chemical's cancer risks and the most reliable foundation for evaluating the health risks of EtO exposure. It was finalized in 2016 following a lengthy, 10-year process involving two rounds of scientific peer review. EPA has failed to produce any new science which would support a change in these findings and recommendations.

In 2018, EPA released its latest National Air Toxics Assessment (NATA) and initiated efforts to reduce EtO emissions and to engage with impacted communities. This NATA identified more than 20 neighborhoods near facilities well in excess of the agency's benchmark risk level of 100-in-1-million. More detailed subsequent analyses found dozens more communities with unacceptable, preventable risk levels - some many times higher than the initial NATA estimates.

In the 2024 final rule, EPA estimated that the maximum individual cancer risk was 6,000-in-1 million, with cancer risks above 100-in-1 million for 19,000 people, and above 1-in-1 million for 8.5 million people. The

EPA called these risks "exceptionally high" and among the highest for a residual risk assessment under section 112 of the Clean Air Act.

EPA interacted with more than 50 communities across the country following the 2018 NATA release and in advance of its 2023 proposed rulemaking. In all of these interactions, EPA expressed its concern about the toxicity of EtO, the need to achieve reductions in EtO emissions, and its intentions to use its authority to protect the health of people living near commercial sterilizers.

It is unclear what EPA's message to these same communities is now in light of the current proposed action.

EPA estimates that the foregone benefit of this proposed action will be nearly 8 tons of additional EtO being emitted annually, further increasing the cancer risk posed to neighboring communities.

A question often posed by people living near these facilities is, "Am I safe?" EPA needs to provide an honest answer about whether this proposal will ensure their safety from a public health standpoint.

EPA claims that this action will "safeguard the supply of life-saving medical tools." However, EPA notes that it "was not able to quantitatively assess potential market impacts for this proposed rule." The agency's inability to provide any real data undermines its claims about the impact of the proposed rule on the supply of medical devices.

EPA largely rests the justification for this proposal on a purely legal rationale, that EPA can only do one residual risk review, no matter how much the scientific understanding of the air toxic at issue has evolved. EPN believes this is an incorrect reading of Section 112. It is inconsistent with recognition throughout the Clean Air Act that science is always evolving and a statute whose purpose is to protect public health is properly interpreted to authorize EPA to evaluate risk when new information becomes available, especially if that information dramatically increases our understanding of the risk a pollutant like EtO poses to public health.

EPN looks forward to providing more detailed written comments on this harmful proposal.

Thank you.