

Congress of the United States
Washington, DC 20515

July 1, 2021

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW, Mail Stop 1301A
Washington, DC 20460

Re: Bipartisan EtO Task Force Meeting Request

Dear Administrator Regan:

Congratulations on your confirmation as Administrator of the U.S. Environmental Protection Agency (EPA). We write as members of the bipartisan Congressional Ethylene Oxide (EtO) Task Force and represent communities around the country impacted by EtO emissions. We look forward to serving as a resource to the EPA and working together to ensure federal regulations protect our constituents from EtO emissions. We would like to request a meeting with you to discuss EPA's ongoing EtO work and the principles we outline below.

As you may know, EtO is an industrial chemical used as a sterilant and as an intermediary in a variety of industrial manufacturing processes. In 2016, the EPA formally recognized EtO as a known carcinogen and, as a result, included the chemical in the National Air Toxics Assessment. Subsequently, the EPA identified communities around the country—including our districts—that faced potentially dangerous levels of EtO emissions. As you might imagine, this action has raised considerable concern among our constituents.

Since 2018, the EPA has had an inconsistent approach to how it assisted communities facing EtO emissions. In 2018, the EPA funded and coordinated ambient air monitoring in Willowbrook, IL, a critical effort that informed the local community, prompted strict state-level regulations, and identified the true extent of emissions in the area. However, among the dozens of communities facing potentially dangerous emissions, Willowbrook was the only one to receive this level of attention. We have been calling on the EPA to exercise the same due diligence in the communities we represent, and to keep public health at the forefront of the agency's EtO rulemaking. As a task force, we have developed the following five principles that we believe should guide the EPA's work on EtO.

First, we firmly believe that any prospective EtO regulations must be guided first and foremost by the need to protect public health. The EPA has a responsibility to assure communities affected by industrial EtO use that the air they breathe is safe. A risk and technology review would be insufficient to fully address the public health concerns of EtO emissions, which is why we agree with the EPA's Office of Inspector General (OIG) report that EPA must start with a residual risk review for EtO as part of its sterilization rulemaking process.

Second, looking at the actions by EPA to address EtO in Willowbrook, it's clear ambient air monitoring is absolutely critical in identifying the extent of community exposure to EtO. It was only after EPA's air monitoring regime that we fully understood how significant a role that fugitive emissions played in community exposure. The prior administration proposed only using computer modeling during its rulemaking, which have overlooked the critical lessons learned in Willowbrook about fugitive emissions.

We believe that only through ambient air monitoring can we truly know the extent of EtO emissions in a community—including a more comprehensive understanding of the national background levels of EtO. We have urged appropriators to include funding for the EPA to conduct ambient air monitoring for EtO-affected communities, and we strongly encourage you to make ambient air monitoring part of the EPA's sterilization rulemaking process.

Third, in line with the recommendations made by the EPA OIG, we ask that you make community engagement a central part of the EPA's work on EtO. Many of these communities, including those that we represent, feel left behind by the EPA's past work on EtO—especially in light of the disparate response between Willowbrook and other areas. As the EPA continues its work to more stringently regulate EtO, we ask that you view us as a resource and potential partner for connecting with our constituents. It is essential that EtO-impacted communities feel heard throughout the EPA's rulemaking and that they are given an opportunity to voice their concerns directly to the agency.

Fourth, we are concerned with industry efforts to dilute or undermine the findings of the Integrated Risk Information System (IRIS) assessment on EtO. We recognize that the EPA's work must be driven by the most up-to-date science and we welcome further study that builds upon the conclusions of the IRIS value. But we caution the EPA from reassessing the IRIS value for EtO without additional, federally-collected data.

Finally, we ask that the forthcoming sterilization rule reflect the diversity of businesses within the medical device sterilization supply chain. We appreciate industry concern about any one-size-fits-all approach, and we look forward to engaging with the EPA on the conclusions of its Small Business Advocacy Review Panel. We firmly believe the federal government should be a resource so that all businesses can meet the same strong standard, and do not believe we should sacrifice public health through an emission standard that has exceptions for certain actors.

Thank you for your work on this and other environmental issues. We look forward to working together to ensure all communities are protected from the danger of EtO emissions and would appreciate the opportunity to discuss these issues with you in person.

Sincerely,



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Co-Chair, EtO Task Force



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