

February 22, 2023

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Joseph Goffman  
Principal Deputy Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460

Dear Mr. Goffman:

On behalf of the National Association of Clean Air Agencies (NACAA) we would like to provide you with feedback about the community engagement and risk communication effort that EPA undertook in 2022 related to emissions of ethylene oxide (EtO) from commercial sterilizer facilities and offer recommendations for future outreach activities. NACAA is the national, non-partisan, non-profit association of air pollution control agencies in 40 states, including 117 local air agencies, the District of Columbia and five territories. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the U.S. These comments are based upon that experience. The views expressed in these comments do not represent the positions of every state and local air pollution control agency in the country.

Emissions of EtO pose a serious threat to communities around the country and NACAA believes EPA should take action to ameliorate the risks this pollutant poses, particularly in those areas that have faced disproportionate impacts from those emissions. Accordingly, we support EPA taking steps to develop hazardous air pollutant (HAP) standards to reduce emissions of EtO from commercial sterilizers and other sources, in accordance with the Clean Air Act. Additionally, NACAA agrees with EPA on the importance of providing the public with data about the risks and exposures they may face from HAP emissions and to assist communities in accessing the information they need to address their concerns. We also believe that the public is well served only if the information government entities provide is accurate and understandable.

In the spring and summer of 2022, EPA undertook a community outreach effort as part of its preparations for developing and proposing National Emission Standards for Hazardous Air Pollutants for EtO emissions from commercial sterilization facilities. This process included releasing national and site-specific information about EtO emissions and risks to the public. While we, along with EPA, favor transparency and the distribution of public information, we have deep concerns about the way EPA handled this particular project. We believe EPA's

overall intentions were good; however the process and execution were flawed. We would like to explain the problematic elements of this situation in the hope of avoiding similar circumstances in the future.

State and local air quality agencies are not simply interested stakeholders, but are EPA's co-regulators, pursuant to the Clean Air Act. These agencies have tremendous experience and expertise and are very knowledgeable about the communities and sources in their jurisdictions, in many cases having as much data as EPA does, if not more. Yet for the EPA EtO outreach program that began in the spring and summer of 2022, EPA did not treat state and local air agencies as partners, thus creating a contentious and fraught situation. The agency did not consult or seek input in advance from its state and local partners about the best way to approach the public outreach strategy. Instead, EPA merely informed state and local agencies of its planned public risk communication and outreach plans and the expeditious schedule it had set. As the state and local agencies scrambled to prepare for a public release of the EtO data, EPA was slow to share with these partners the information necessary to understand how the agency had developed some of its estimates (e.g., facility-specific analyses, assumptions and emission factors). Once EPA did share the information, it took multiple state and local agencies repeatedly raising concerns about the data (e.g., appropriateness of the assumptions, emission factors used and reproducibility) and timeline for the agency to delay the public release and, even then, not by a sufficient amount. EPA staff seemed surprised by the alarm some state and local agencies expressed, perhaps not recognizing that those agencies would, in many cases, be the first ones required to respond to the public about emissions of a harmful substance, without having been given sufficient information or time to coordinate with EPA.

Nevertheless, EPA appeared to be in a hurry to release the information publicly, including scheduling community meetings, without taking adequate time to work with state and local air agencies to ensure that they were familiar with and comfortable with the information being released. While we recognize the importance of not withholding significant information, it does not serve the public to prematurely release data before ensuring that it has been quality assured and that the message is understandable and in context, especially when the information is likely to inspire deep concern and possibly fear in the community.

We believe EPA should have developed its public outreach strategy *in consultation* with state and local officials, who could have provided invaluable insights, data and recommendations in advance for how best to provide worthwhile information to the public. As the EtO strategy played out, instead of supporting EPA, state and local agencies could have been put in the position of having to respond to the release by presenting their own (different) data to the public, thus potentially conflicting with or even repudiating EPA's information. This uncoordinated response would have been confusing and unhelpful for the affected communities, undermining their confidence and trust in all levels of government. As it turned out, it took a tremendous and hurried effort on the part of state and local agencies, working with the EPA regional offices and headquarters, to prepare as best they could for the public release of the information.

In addition to our problems with EPA's process and timeline for the EtO community outreach, we also had some concerns specific to the EtO data itself and how EPA planned to use

it. Many of those concerns were expressed to EPA previously, but we will reiterate several of them here in the hope of avoiding similar situations in the future:

- EPA did not have correct or any site-specific information from some sources, which the agency was aware of from the responses to its Section 114 information request. EPA then applied broad-based factors to individual facilities and used these to estimate fugitive emissions (sometimes assuming worst-case scenarios). Using broad factors and averages may be appropriate in developing a national rule, but it is not necessarily accurate when applied to individual facilities.
- EPA did not communicate that the information sources submitted in response to the information request letters would be used to determine the cancer risk for those facilities. Some of the facilities were under the impression the data would be used for informational purposes for formulating the new regulation.
- EPA did not adequately reach out to some of the high-risk facilities in preparing for the public outreach. For example, one state reported that all four of its sources identified as high risk already had control systems in place that are over 99 percent effective and that fugitive emissions were driven towards zero. The sources reported that no one from EPA informed them they would be identified as a high-cancer-risk source in the public data release, nor gave them the opportunity to provide updated information.
- It would have been helpful if EPA had provided a summary of the EtO ambient air monitoring data the states were reporting, what cancer risk the average concentrations represent and any messaging on how to communicate the ambient monitoring results to the public. One state noted that it monitored EtO at four monitoring stations and the average concentrations at all four represented levels well above the 100 in one million cancer risk benchmark EPA was using. (EPA acknowledged that there are issues with EtO monitoring – summa canister and laboratory method issues – and that background monitoring data is higher than expected.) It would have been helpful to receive guidance or talking points from EPA on how to characterize the EtO ambient data.

In closing, we hope the EtO public outreach process has provided some valuable lessons that will help avoid missteps in future efforts. In light of our concerns with the procedures, timeline and lack of advance coordination with state and local air agencies during the EtO public outreach effort, we urge EPA to address those issues in the future, especially by fully coordinating with state and local partners well in advance and throughout the public communication process. State and local co-regulators are eager to work cooperatively with EPA to ensure that we all provide the public with the best possible data in a timely manner, which is what they deserve and demand.

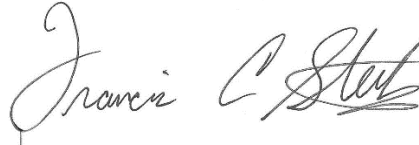
Additionally, we look forward to working cooperatively with EPA as the agency develops HAP standards to reduce emissions of EtO from commercial sterilizers and other sources, especially in those overburdened communities that have historically faced unacceptable levels and risks.

Thank you for your consideration of this input. We are happy to answer any questions and provide additional input. Please feel free to contact us or Mary Sullivan Douglas of NACAA at [mdouglas@4cleanair.org](mailto:mdouglas@4cleanair.org).

Sincerely,



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