NACAA
national association of clean air agencies

June 22, 2023

U.S. Environmental Protection Agency
EPA Docket Center
Docket ID Number EPA-HQ-OAR-2019-0178
Mail-Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

To Whom It May Concern:

On behalf of the National Association of Clean Air Agencies (NACAA), thank you for this opportunity to comment on the proposed National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, which was published in the *Federal Register* on April 13, 2023 (88 Fed. Reg. 22,790)[1]. 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 United States. 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.

Ethylene oxide (EtO), which is listed as a Hazardous Air Pollutant (HAP) in Section 112 of the Clean Air Act, is a substance that is carcinogenic to humans. According to EPA, "Scientific evidence in humans indicates that regular exposure to EtO over many years increases the risk of cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. Studies also show that long-term exposure to EtO increases the risk of breast cancer in women."[2] As such, it is important that EPA seek the best options for ameliorating the risks from exposure to EtO and protect the public with an ample margin of safety, as the Clean Air Act intended.

NACAA recognizes that commercial sterilization is important, especially for medical devices and equipment, and that alternatives to EtO for sterilization are not readily available in some circumstances. Since sterilization will continue, it is critical that emissions of HAPs, particularly EtO, and the associated risks

[1] https://www.govinfo.gov/content/pkg/FR-2023-04-13/pdf/2023-06676.pdf
[2] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto#what

from those releases be reduced as much as possible so the facilities can operate without endangering surrounding communities.

The need to reduce emissions is especially important considering environmental justice concerns associated with the source category, which EPA acknowledges in the proposal. The preamble states: "[m]any of these facilities are also located in communities with environmental justice (EJ) concerns." [3] It is essential that EPA continue to place environmental justice considerations at the forefront as it moves through the regulatory process and ensure it takes steps to reduce impacts to overburdened communities.

In light of these aforementioned factors, NACAA applauds EPA's intention to significantly reduce emissions of EtO and other HAPs from commercial sterilizers and agrees that EPA should further limit emissions by tightening standards and addressing previously unregulated processes and emissions.

Before discussing the specifics of the proposed rule, we must raise an issue of significant concern. There is much that is unknown or insufficiently understood about the creation, prevalence and measurement of EtO, which presents challenges in our efforts to adequately address this pollutant. It is very important that EPA accelerate the research needed to develop accurate monitoring, sampling and analytical methods for EtO. Additionally, EPA needs to improve its understanding about the formation, prevalence and role of background EtO concentrations. With respect to the latter, as one example, we note that EPA's AirToxScreen presents EtO background levels as zero.[4] However, this is highly unlikely to be the case, as shown by data in EPA's National Air Toxics Trends Sites, which are designed to be representative of community air toxics concentrations.[5] EPA must carry out research to learn more about these background concentrations and what their sources are, including unregulated source categories and photochemical reactions. The issues surrounding the characteristics of EtO and our understanding of them have ramifications for how to best reduce our exposures and risks and protect public health.

We offer the following comments on specific areas of the proposal.

Fenceline Monitoring[6]

EPA did not propose fenceline monitoring for this source category, indicating it would be technically challenging and unnecessary, but did request comment on "beyond the fenceline measurements" (i.e., ambient monitoring).[7] Fenceline monitoring or some sort of ambient monitoring would be useful to provide the nearby communities, regulatory agencies and the facilities themselves with important information about emissions levels, exposure and the efficacy of control equipment. We encourage EPA to pursue this concept, but it will be important, as stated above, for the agency to improve measurement and analysis techniques and to gain a greater understanding of the role of background emissions. While information about emissions generally serves the public well, this data is only helpful to the extent that it is reliable and accurate.

---

[3] 88 Fed. Reg. 22,792
[4] https://www.epa.gov/AirToxScreen/2019-airtoxscreen-assessment-results, see "Pollutant Specific Results."
[5] See https://www.epa.gov/outdoor-air-quality-data/monitor-values-report-hazardous-air-pollutants for information from National Air Toxics Trends Sites.
[6] Comment C-68
[7] 88 Fed. Reg. 22,848

If EPA opts for fenceline monitoring for this category, our assumption is that the sources will fund these efforts. If EPA pursues a different ambient-monitoring approach, we recommend that this be funded by the sources as well and that sufficient additional federal funding be provided to state and local agencies for their responsibilities under these programs.

Off-Site Aeration Emissions

In this proposal, EPA has not accounted for or addressed the emissions of EtO that occur elsewhere, after the products leave the affected facilities following the sterilization process. These include emissions that take place at off-site aeration facilities, storage warehouses, hospitals and other locations. However, these additional emissions can be substantial. For example, a company's storage warehouse in Georgia was found to be emitting nearly nine times more EtO than the nearby sterilization facility did.[8] We recommend that EPA account for and address these off-site emissions. In addition to lowering nearby exposures, to the extent these emissions contribute to background levels, such measures to reduce off-site emissions may help decrease overall EtO levels.

Title V Requirements[9]

EPA is proposing to require that area source EtO commercial sterilizers subject to subpart O obtain a Title V permit from the delegated authority, thereby removing the exemption that existed in the 2005 regulation.[10] In light of the serious health concerns related to emissions of EtO, NACAA agrees that it is appropriate to require these sources to obtain Title V permits. As EPA points out in the proposal: "The additional public participation and compliance benefits of additional informational, monitoring, reporting, certification, and enforcement requirements that exist in title V should be required for these sources. These additional requirements are important to ensure that these sources are maintaining compliance with the requirements of this rule."

Risk Assessment Methodology

Integrated Risk Information System Estimates

EPA's Integrated Risk Information System (IRIS) has been and should continue to be EPA's primary source for Unit Risk Estimates (UREs); the purpose of the database is to foster consistency in the evaluation of chemical toxicity across EPA. IRIS produces high-quality, evidence-based assessments; its information and processes for evaluating substances have undergone extensive internal and external examination and peer review. With respect to the IRIS EtO risk value specifically, it was updated in 2016 following an extremely thorough and comprehensive, peer-reviewed evaluation that took nearly two decades, beginning in December 1998.[11] It included in-depth assessments on the part of EPA and multiple rounds of extensive internal and external review and public comment, all of which were well documented. As NACAA has commented in several

---

[8] https://www.georgiahealthnews.com/2019/12/high-levels-ethylene-oxide-detected-covington-warehouse/ and https://epd.georgia.gov/bd-becton-dickinson-and-company-covington

[9] Comment C-74

[10] 88 Fed. Reg. 22,850

[11] https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730

previous letters to EPA, we strongly endorse the agency's continued reliance on the IRIS toxicity value for EtO when assessing risk.[12]

Concentrations at Census Tract Centroids

In assessing the cancer risks related to the source category, EPA used long-term concentrations affecting the census blocks within 50 kilometers of each facility.[13] This analysis dilutes the effect of sources' emissions by estimating the impact at the centroid of the census block instead of at the property line or wherever the maximum exposed individual is. Census blocks can be large geographically, depending on the population density, so the maximum point of impact can be far from the centroid. It could be elsewhere in the census block, including at or near the property line where people may live or work. EPA itself alludes to this problem in the proposal.[14] Further, even if the area near the property line is not developed, over time homes and businesses could locate closer to the facility. While it is possible that population distribution is homogenous over a census block, this assumption is not necessarily accurate in considering the predicted impacts from the location of a source. NACAA recommends EPA identify and use the truly maximum individual risk, irrespective of its location in the census block, rather than using the predicted chronic exposures at the census block centroid as surrogates for the exposure concentrations for all people living in that block.

Facility-Wide and Community-Based Risk Analysis

For this proposal, EPA has rightly recognized the importance of considering the impact of emissions from all HAP-emitting operations in a facility to determine the facility-wide risks, rather than focusing solely on the source category that is the subject of the regulation.[15] We note, however, that EPA did not expand its analysis to include air toxics-related cancer risks from all large facilities in communities in the vicinity, including sources that would not be covered by the rule, as the agency did for the synthetic organic chemical manufacturers (also known as the HON) proposal.[16, 17]

Since the public's exposure is not limited to one chemical or source category at a time, we support EPA expanding its analysis of the impacts of emissions to include other operations and pollutants, as it did for the HON proposal. This is a step in the right direction, which in the future should be expanded to include other types of sources (e.g., mobile sources) and other routes of exposure beyond inhalation as well. We also suggest these expanded community-based risk analyses become standard practice when developing air toxics regulations. As with other elements of this proposal, however, these provisions emphasize the urgency of EPA improving its understanding of the characteristics and accurate measurement of EtO, as stated earlier.

---

[12] https://www.4cleanair.org/wp-content/uploads/Documents/hydrochloric_acid_RTR_comments.pdf
https://www.4cleanair.org/wp-content/uploads/Documents/MON-NACAA_Comments_2-6-20.pdf
https://www.4cleanair.org/wp-content/uploads/Documents/NACAAToxicsTransitionIssues-05252021.pdf
https://www.4cleanair.org/wp-content/uploads/MON-Reaffirmation-Comments-March-2022.pdf

[13] 88 Fed. Reg. 22,802

[14] 88 Fed. Reg. 22,805

[15] 88 Fed. Reg. 22,804

[16] 88 Fed. Reg. 22,799

[17] 88 Fed. Reg. 25,102

Acute Exposure

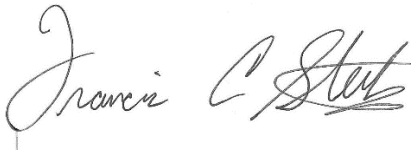
NACAA's past comments have raised concerns with EPA's use of Acute Exposure Guideline Levels (AEGLs) or Emergency Response Planning Guidelines (ERPGs) values to address acute exposures in the residual risk assessments. It appears EPA is still using them for those purposes in this proposal.[18] These limits were developed for accident release emergency planning and are not appropriate for assessing daily human exposure scenarios. In the December 2002 EPA document, "A Review of the Reference Dose and Reference Concentration Processes," the agency stated that the primary purpose of the AEGL program is to develop guidelines for once-in-a-lifetime short-term exposures to airborne concentrations of acutely toxic chemicals. They are not meant to evaluate the acute impacts from routine emissions that occur over the life of a facility. Unlike the reference concentrations (RfCs) for chronic exposures, the AEGLs and ERPGs do not include adequate safety and uncertainty factors and cannot be relied upon to protect the public from the adverse effects of exposure to toxic air pollutants. The use of AEGLs or ERPGs in residual risk assessments is not appropriate and does not ensure that public health is adequately protected from the acute impacts of HAP exposure. EPA has included the use of the California Reference Exposure Levels (RELs) to address acute exposures in residual risk assessments[19] and EPA should use the RELs for these assessments.

Allowable Emissions

EPA should consider potential or allowable emissions, rather than actual emissions, as much as possible in evaluating residual risk when developing regulations. Since facility emissions could increase over time for a variety of reasons, and with them the associated impacts, the use of potential or allowable emissions is more appropriate. An analysis based on actual emissions from a single point in time could underestimate the residual risk from a source category. Further, the HAP thresholds are based on maximum potential-to-emit, as opposed to actual emissions, and air agencies issue permits based on potential emissions. Limiting the scope of a risk evaluation to actual emissions would be inconsistent with the applicability section of Part 63 rules. The agency should use allowable emissions as much as possible in the future, including in assessing acute health risks.

Thank you for this opportunity to comment on the proposal. Please contact us if we can provide additional information.

Sincerely,



Latrice Babin, PhD
Harris County, Texas
Co-Chair
NACAA Air Toxics Committee

Francis C. Steitz
New Jersey
Co-Chair
NACAA Air Toxics Committee

[18] 88 Fed. Reg. 22,803
[19] 88 Fed. Reg. 22,802