**NACAA Discussion on Proposed Rules for Commercial Sterilizers and the Hazardous Organic NESHAP**

**May 23, 2023**

EPA is seeking comment on its proposed air toxics standards for commercial sterilizers) and the Hazardous Organic NESHAP (HON). NACAA plans to submit letters on both, providing high-level comments. Comments on the HON will likely focus on the ethylene oxide (EtO) related provisions. *State and local agencies are strongly urged to submit their own comments on both proposals as well, especially if they have experience with and knowledge of these source categories and the controls and practices that work best.*

In past letters, NACAA has repeatedly expressed support for EPA’s continued use of the EtO estimates in the Integrated Risk Information System (IRIS). NACAA also has made recommendations for improving EPA’s risk assessment methodology in previous letters. The sterilizer and HON comments would restate NACAA’s support for using the IRIS estimate and reiterate our previous risk assessment recommendations.

The following are additional issues NACAA could address in comments.

**Commercial Sterilizers – Ethylene Oxide**

<https://www.govinfo.gov/content/pkg/FR-2023-04-13/pdf/2023-06676.pdf>

Fenceline Monitoring – EPA is not proposing fenceline monitoring for this source category (it is required for petroleum refineries and proposed for the HON).  They say it would be technically challenging and unnecessary.  But they are asking for comments on ambient monitoring – or other types of monitoring – for sterilizers. NACAA supported fenceline monitoring for petroleum refineries. Should we recommend fenceline monitoring for this source category?

Cumulative (Community-Based) Risk Analysis – EPA looked at facility-wide risk (e.g., all HAP-emitting operations within a contiguous area and under common control) but did not conduct a cumulative risk analysis for this proposal. For the HON proposal, EPA did a cumulative risk analysis (”community-based” risk assessment) that looked at combined inhalation risk from all local stationary sources of HAPs. EPA did not use the results in developing the HON proposal, however. Should NACAA recommend that EPA do a community-based risk analysis for the sterilizer rule (and further recommend that the agency carry out and incorporate such analyses as a regular part of rule development for future source categories)?

Emissions from Off-Site Aeration Warehouses and Storage Facilities– These facilities are not covered by the rule, although they are a source of EtO (in some cases significant). NACAA could recommend that EPA address emissions from these warehouses in this rule. Reactions?

Title V Requirements – EPA is proposing to require Title V permits for any subpart O sources – area sources. While the original rule exempted them, EPA now “determined that it is not appropriate to exempt area source EtO commercial sterilizers from the requirement to obtain a title V permit under Section 502(a).” Reactions?

Compliance Timeline – EPA is proposing an 18-month compliance deadline for existing sources, rather than the usual 3 years for MACT. Reactions?

Emission and Operating Limits and Management Practices – EPA is proposing numeric emissions limits, operating limits and management practices.  NACAA could express support for EPA’s intention to significantly reduce emissions of EtO and other HAPs and agree that EPA should further limit emissions by tightening standards and addressing previously unregulated processes and emissions. Are there major elements of EPA’s proposal that we should flag for improvement?

Continuous Compliance – EPA is proposing to “require facilities to demonstrate continuous compliance through either an annual compliance demonstration and operating limits or by using EtO CEMS [continuous emissions monitors].” Reactions?

Hazardous Organic NESHAP

<https://www.govinfo.gov/content/pkg/FR-2023-04-25/pdf/2023-07188.pdf>

NACAA will reiterate any pertinent points we make in the commercial sterilizer letter in our comments on the HON proposal (e.g., continued use of IRIS estimate for EtO, use of cumulative risk analysis in development of rule, etc.).

Fenceline Monitoring – Are there provisions in this proposed rule that could be improved? Are the action levels, corrective actions and timelines appropriate and sufficient?

Compliance Deadlines – The compliance deadlines are 2 or 3 years, depending on whether they are for the risk- or technology-based standards. Are these appropriate?

Cumulative (Community-Based) Risk Analysis – The community-based risk analysis looked at combined inhalation risk from all local stationary sources. Should EPA expand this to include other sources (e.g., mobile sources) and routes of exposure? [Similar comments on community-based risk analysis would be included in both NACAA letters.]