

Advocacy Comments on EPA's Proposals to Limit Ethylene Oxide Emissions from Commercial Sterilizers

On April 13, 2023, the Environmental Protection Agency (EPA) published two proposed actions that would restrict use of Ethylene Oxide (EtO) for sterilization: a proposed rule entitled National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review and a notice of availability for Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide.

Advocacy is concerned that these actions would lead to a significant number of small entities leaving the market for commercial sterilization, harming small medical device manufacturers, and causing significant supply chain disruptions and harm to patients needing sterilized medical devices. EPA has the discretion under the Clean Air Act to consider the costs and consequences of these actions and should reconsider these policies to minimize the impact on small entities and reduce the likelihood they will leave the market.

In the final agency actions, EPA should do the following:

- Give small commercial sterilizers the maximum amount of time the Clean Air Act allows to comply.
- Adopt the Best Management Practices alternatives for area sources.
- Allow small commercial sterilizers that are area sources to continue operating without Title V permits.
- Exclude the proposed engineering controls from the final Interim Decision.

A complete copy of [Advocacy's letter to EPA](#) is available. For more information, please contact Dave Rostker, Assistant Chief Counsel, at david.rostker@sba.gov.

