

EPA Planning to Implement Strict Ethylene Oxide (EtO) Emissions

June 13, 2023

On December 14, 2022, Plaintiffs California Communities Against Toxics (CCAT), Clean Power Lake County, Rio Grande International Study Center, Sierra Club, and Union of Concerned Scientists filed a complaint in the U.S. District Court for the District of Columbia alleging that the Environmental Protection Agency (EPA) had failed to perform its nondiscretionary duty to “review, and revise as necessary” the National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide Emissions Standards for Sterilization Facilities at least every eight years.

On May 31, 2023, the EPA provided notice of a proposed consent decree in the case, *California Communities Against Toxics (CCAT), et al. v. Regan*, No. 1:22-cv-03724 (DDC), which revolves around the issue of ethylene oxide (EtO), a flammable and colorless gas used primarily to manufacture other chemicals and as a sterilizing agent for medical equipment. The proposed consent decree would establish a deadline for EPA to sign a final rule for this action.

Plaintiffs allege that in 2006, EPA conducted a risk assessment of this source category pursuant to CAA section 112(f)(2) and a technology review of its NESHAP pursuant to section 112(d)(6), neither of which resulted in revisions to the Sterilization Facilities NESHAP. [71 FR 17712](#) (April 7, 2006). EPA has not completed a section 112(d)(6) review of this NESHAP since then. EPA recently published a proposed rule that includes revisions to the Sterilization Facilities NESHAP pursuant to CAA section 112(d)(6) of the Act. [88 FR 22790](#) (April 13, 2023).

Plaintiffs, along with other environmental and public health advocacy groups, further allege that EPA failed to regulate and enforce adequate safeguards regarding the emissions of EtO. The groups claim that the EPA’s lack of action has endangered communities by exposing them to significant health risks associated with EtO, which is classified as a human carcinogen.

The Proposed Consent Decree

The [proposed consent decree](#) is the result of negotiations between the parties trying to resolve the lawsuit. If approved by the court, the decree will set forth the agreed-upon steps the EPA must take to address the concerns raised in the lawsuit.

The proposed consent decree would establish a deadline for the EPA to sign a final rule for this action. These steps may include but are not limited to the development and implementation of new regulations and standards, more stringent monitoring and reporting requirements, or additional enforcement actions against facilities that do not comply with the updated guidelines. The proposed consent decree, if finalized, would

require that the EPA sign a final rule on its review and “necessary revisions” of the Sterilization Facility NESHAP pursuant to section 112(d)(6) by March 1, 2024.

Impact of the Consent Decree Across the Country

This proposed consent decree would update standards with respect to EtO emissions by sterilization facilities. The implementation and finalization of the rule will have a significant economic impact on the industry, many members of which may not be able to afford the costs or costs that will be passed onto consumers by health care providers and health insurance companies.

Next Steps – What Can I Do?

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of the consent decree, the Agency will accept written comments. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Manufacturers should consider retaining counsel to submit public comment by the June 30, 2023, deadline.

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