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Presidential Exemptions Offer Temporary Relief for Sterilization Facilities Amid Legal Challenges

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In recent years, ethylene oxide (EtO) has emerged as a focal point in environmental and regulatory discussions due to its dual role as a critical sterilizing agent and a human carcinogen. Widely used in commercial sterilization – particularly for medical devices that cannot be treated with steam or radiation – EtO is essential to maintaining the integrity of the health care supply chain. Approximately 50 percent of sterile medical devices in the U.S. rely on EtO for sterilization. However, the health risks associated with EtO – a human carcinogen – remain significant.

In response to these concerns, in April 2024, the U.S. Environmental Protection Agency (EPA), under the Biden administration, finalized a rule under the Clean Air Act's National Emission Standards for Hazardous Air Pollutants (NESHAP) that introduced the most stringent EtO emission controls in U.S. history. The rule's implementation has not been without controversy. The Trump administration has taken the position that the rule places severe burdens on commercial sterilization facilities and risks making sterile medical devices unavailable to patients who need them.

Presidential Action and Legal Basis

In March 2025, EPA – under Administrator Lee Zeldin – announced a regulatory overhaul initiative that included reconsideration of the 2024 EtO rule. Concurrently, on July 17, 2025, EPA opened a channel for facilities to request Presidential Exemptions from the rule, titled "Regulatory Relief for Certain Stationary Sources to Promote American Security with Respect to Sterile Medical Equipment," citing national security and technological limitations as justification criteria.

The Presidential Exemption extends compliance deadlines under the April 2024 Ethylene Oxide NESHAP for select sterilization facilities by two years. The exemption was granted under Section 112(i)(4) of the Clean Air Act, which authorizes the President to delay compliance if the required technology is not commercially viable and if doing so serves national security interests. The President is required to report each exemption to Congress, although historical precedent for such reporting is limited, so it will be of interest to see how this addressed.

Compliance Timeline and Operational Impact

The exemption has several important implications. Facilities listed in the Presidential proclamation now have their compliance deadlines extended for two years. Depending on EtO use and permit status, compliance dates have been extended to April 2028 or, in some instances, to April 2029 to meet emission reduction requirements. Additionally, the compliance date for continuous emissions monitoring and performance testing has been postponed to September 2028.

It is important to note that during the exemption period, facilities remain subject to the emission obligations that were in effect prior to the issuance of the 2024 EtO rule.

EPA Reconsideration and Rulemaking Process

The EPA has indicated its intent to reconsider the 2024 EtO rule. In a letter dated March 2025 to the Ethylene Oxide Sterilization Association, the agency outlined several areas under review. These include the authority to conduct a second residential risk review, the standards promulgated under the Clean Air Act, and the requirement for continuous emissions monitoring. A proposed rule is expected by October 2025, and a formal notice-and-comment period will follow, allowing stakeholders to engage in the rulemaking process and provide feedback. Reportedly, EPA hopes to have a revised final rule in place before April 2026.

Legal Challenges and Criticism of the Exemption

The 2024 EtO rule is currently subject to consolidated legal challenges in the D.C. Circuit Court of Appeals from both environmental health advocacy and industry groups. Additional lawsuits are anticipated, particularly targeting the Presidential Exemption, with EPA recently receiving approximately 53 requests under the Freedom of Information Act for records that pertain to exemption requests. Critics argue that the exemption lacks transparency, scientific validity, and consideration for environmental justice.

State-Level Considerations and Jurisdiction

It is important to keep in mind that states retain concurrent jurisdiction over air pollution control laws. Accordingly, it is critical to monitor how individual states respond to the federal exemption and whether they choose to recognize or challenge its applicability.

Contact Information

For more information or to discuss how these developments may impact your operations, please contact our [Environmental Group](#).