

STERI-TECH, INC.

Contract Sterilization & Disposable Apparel Mfg. Co. Box 1145, Salinas, P. R. 00751

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To: U.S. Environmental Protection Agency
From: Giovanni R. Sánchez Cruz / STI Technical Services Manager
Date: 05/30/25
Re: Sterilizer Rule (89 FR 24090): Steri-Tech Inc

I am writing on behalf of Steri-Tech Inc in Salinas, Puerto Rico to request that the President issue a two-year exemption according to his authority under Clean Air Act (CAA) Section 112(i)(4) for all emission standards and associated requirements created or revised in EPA's April 4, 2024 *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 89 FR 24090 (April 5, 2024) (Sterilizer Rule).

Steri-Tech requests that the President issue a two-year exemption as quickly as reasonable but designate it as taking effect on the compliance deadlines for the standards in the Sterilizer Rule. Specifically:

- For standards set or revised under CAA Section 112(f) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 6, 2026 (the compliance deadline for those standards);
- For standards set or revised under CAA Section 112(d) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 5, 2027 (the compliance deadlines for those standards).

As explained in the attached letter submitted to EPA on March 17 on behalf of the Ethylene Oxide Sterilization Association (EOSA), the technology necessary to implement the standards is not available because manufacturers cannot guarantee that existing emissions control equipment will enable sources to meet the new standards; there is not a sufficient supply of the necessary technology; and there are not enough experienced installation professional and technical experts to install and test that equipment within the current compliance timeframes.

As also explained in EOSA's March 17 letter, it is in the national security interests of the United States to issue the requested exemption because if some facilities choose to cease operations rather than attempt compliance (which is likely), that will disrupt the supply of sterilized medical devices, raise the cost of those devices, and/or force medical suppliers or providers to source sterilized medical devices from abroad.

Please don't hesitate to let me know if any additional information is needed. Steri-Tech Inc appreciates EPA's attention to this important matter and urges EPA to recommend that the President issue the requested exemption as quickly as reasonable.

Regards,


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