**EOSA** **The Ethylene Oxide Sterilization Association, Inc.**
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The Honorable Lee Zeldin
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Mail Code: 1101A

Dear Administrator Zeldin:

I write on behalf of the Ethylene Oxide Sterilization Association (EOSA) to ask EPA to take near-term action regarding the *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 89 Fed. Reg. 24090 (Apr. 5, 2024), known as the "Sterilizer Rule." The Sterilizer Rule imposes extremely onerous ethylene oxide (EtO) emission standards on medical device sterilizers the most stringent of which must be met by April 2026—and is causing substantial harm to and regulatory uncertainty for EOSA's members.

EPA announced on March 12, 2025, that it will reconsider the Sterilizer Rule (alongside other NESHAPs), which is a welcome development. EOSA was also pleased to see EPA's statement that the Administration "is considering a 2-year compliance exemption via Section 112(i)(4) of the Clean Air Act for affected facilities while EPA goes through the rulemaking process." But medical device sterilizers need to decide *now* whether to expend substantial resources to acquire technology and reconfigure their facilities to try to comply with the Sterilizer Rule—or to instead cease operations. That, in turn, may disrupt the supply of critical medical devices, harming both patients and providers, or force medical providers to source those essential medical devices from abroad—increasing the offshoring of the sterilization of medical devices and inflating costs to Americans in direct contravention of the Trump administration's economic objectives.

The Sterilizer Rule was promulgated by the Biden administration under Clean Air Act ("CAA") Section 112 on April 5, 2024. The Sterilizer Rule includes standards set under Section 112(d), the CAA's hazardous pollutant "technology review" provision, and Section 112(f), the "risk review" provision, the latter of which the D.C. Circuit described as a "*one-time* 'risk review.'" *Nat'l Ass'n for Surface Finishing v. EPA*, 795 F.3d 1, 5 (D.C. Cir. 2015) (emphasis added). There are several major flaws in the Sterilizer Rule, and a litany of other issues and errors.

*First*, the Sterilizer Rule unlawfully set new standards under Section 112(f) even though EPA previously undertook the one-time risk review for this source category in 2006. 71 Fed. Reg. 17, 712, 17,716 (April 7, 2006). In doing so, EPA ignored the statutory text and context, both of which indicate that Congress intended EPA to regulate primarily through periodic technology reviews under Section 112(d) and conduct only one round of risk-based review under Section 112(f). By ignoring that Congressional mandate, EPA wrongly avoided Section 112(d)'s requirement that the agency must consider costs when setting and revising technology-based standards.

*Second*, the emission standards set in the Sterilizer Rule—particularly under Section 112(f), but also those set under Section 112(d) are extremely onerous, unsupported by the record data, and for some sterilizers will be impossible to meet. For example, EPA increased the standard for sterilization chamber vents using at least 30 tons per year ("tpy") of EtO from a 99% destruction

and removal efficiency (DRE) standard to a 99.99% DRE standard. This leaves no margin for error or equipment malfunction. Likewise, for aeration room vents ("ARVs") using at least 30 tpy of EtO, the Sterilizer Rule increased the DRE requirement from 99% to 99.9%, while wrongly rejecting commenters' request for an alternative standard. Both the SCV and ARV standards were premised on test data that EPA admitted, in the Proposed Rule, is not representative of normal operations. *See* 88 Fed. Reg. at 22,844. EPA also imposed stringent new standards on area sources; for example, EPA set a chamber exhaust vent emission standard of 99.9% DRE for facilities using at least 60 tpy of EtO. These are just a few of the stringent standards set in the Sterilizer Rule under Sections 112(f) and (d), all of which are unrealistic and unsupported by the record.

The Sterilizer Rule is also flawed because EPA arbitrarily and capriciously imposed onerous Continuous Emission Monitoring System (CEMS) mandates on facilities using at least 100 lb/year of EtO without proper notice and comment. Replacing parametric monitoring with CEMS, operating at fifteen-minutes intervals and demonstrating 90% data availability, is costly, complicated, and burdensome, while emission reduction benefits are minimal. Further, EPA failed to allow commenters to weigh in on the CEMS scheme the agency finalized, which requires application of CEMS *at each emissions inlet*, not just outlets. This CEMS scheme is thus both arbitrary and unlawful.

EOSA challenged the Sterilizer Rule in the United States Court of Appeals for the District of Columbia Circuit (No. 24-1180). In addition to raising the above major concerns, EOSA also explained that EPA wrongly set standards based on EtO *usage*, rather than based on EtO *emissions* (as the text of Section 112 requires); failed to establish technology-based standards under Section 112(d) before imposing certain of the risk-based standards; failed to consider and address comments on EPA's reliance on the flawed IRIS value for EtO; and failed to conduct rational cost/benefit analysis in deciding whether and to what extent to revise all standards. A fuller discussion of all of these issues can be found in EOSA's opening merits brief (Doc. #2080994).

As noted above, EPA has announced it will reconsider the Sterilizer Rule. EPA also recently moved to hold the litigation over the Sterilizer Rule in abeyance for 60 days "to allow new Agency leadership to review" the Sterilizer Rule and "to decide what action, if any, is necessary." *Cal. Cmtys. Against Toxics v. EPA*, No. 24-1178 (D.C. Cir. filed Feb. 18, 2025) (Doc. 2101209). EOSA appreciates EPA's recognition of the need to reconsider the Sterilizer Rule. But while EPA does so, EOSA's members continue to face the Sterilizer Rule's fast-approaching compliance deadlines: April 6, 2026, for standards set under Section 112(f) and April 5, 2027, for standards set under Section 112(d). These deadlines (particularly the former, which applies to the most stringent standards) require sterilizers to decide now whether to commit significant financial and operational resources—including to purchase new control technologies, redesign facilities, and restructure operations—to try to comply with the Sterilizer Rule, which is not possible for all facilities.

Lending further urgency to EPA's reconsideration of the Sterilizer Rule and the standards and deadlines set therein, the D.C. Circuit denied EPA's abeyance motion and the case has been set for argument on April 15, 2025. EOSA therefore urges EPA to act quickly to relieve sterilizers of the Sterilizer Rule's obligations, preventing unnecessary expenditures and irrevocable decisions that some sterilizers will likely be forced to make absent near-term relief.

To address the urgent compliance challenges posed by the Sterilizer Rule, EOSA identifies two potential pathways for relief. Ideally, EPA should pursue both to ensure that sterilizers can continue to operate in the near term, even while EPA reconsiders the Sterilizer Rule more broadly.

**Path 1: Presidential Waiver under Section 112(i)(4)**

As suggested by EPA, the President should exercise his authority under CAA § 112(i)(4) to grant a two-year compliance exemption commencing on the Sterilizer Rule's compliance deadlines: April 6, 2026, for risk-based standards and April 5, 2027, for technology-based standards. The President may grant such an exemption for all sources regulated by the Sterilizer Rule in one action,[1] based upon findings that (1) "it is in the national security interests … to do so" and (2) "the technology to implement such standard is not available." 42 U.S.C. § 7412(i)(4).

The first requirement—national security interests—is satisfied due to the critical role that sterilization facilities play in maintaining the U.S. medical device supply chain. Compliance with the Sterilizer Rule's deadlines, particularly the two-year deadline for compliance with the risk-based standards set under Section 112(f), will significantly reduce sterilization capacity. This, in turn, will lead to severe shortages of life-critical medical devices such as catheters, surgical kits, syringes, bandages, IV equipment, and needles, disrupting essential healthcare services. EOSA cautioned in its Comments on the Proposed Sterilizer Rule that the loss of capacity while facility reconstruction and modifications are underway will cause "a large reduction in medical device sterilization capacity and a severe shortage of sterilized medical devices." EOSA Comments 59, EPA-HQ-OAR-2019-0178-0618. Medical industry stakeholders similarly noted that modifying sterilization equipment is "no trivial matter":

> These complex facilities, no two of which share the same design or process, typically must go at least partially offline to make modifications to the equipment. Even routine maintenance or periodic upgrades require significant planning to minimize downtime across the monthly or annual supply cycle.

Advanced Medical Technology Association Comments 9–10, EPA-HQ-OAR-2019-0178-0601.

Without relief, sterilizers may be unable to meet demand for sterilized medical devices, leading to shortages that force medical providers to seek alternative sources abroad and increase the United States' dependence on foreign suppliers for essential medical devices. This growing reliance on foreign sterilization capacity and imported medical equipment poses an immediate national security risk, as any disruption—whether from geopolitical conflicts, trade restrictions, or economic coercion—could severely limit the United States' ability to maintain an independent and resilient healthcare system, jeopardizing timely access to life-saving medical equipment.

[1] Nothing in Section 112(i)(4) bars the President from issuing an exemption that applies to all regulated sources—and the President should do so here to ensure that all sterilization facilities are relieved from the obligation to comply with the Sterilizer Rule.

The second requirement technology unavailability is also met. It will be impossible for all regulated sources to obtain and install necessary control technology by April 2026 due to the limited number of equipment manufacturers and workforce shortages.

EOSA has explained that many of the Sterilizer Rule's requirements "require significant facility reconstruction and major equipment procurement and installation" that could take years—particularly if all sterilizers must redesign their facilities and install equipment to meet the new standards at the same time. EOSA Comments 58 59. And "[t]he availability of the equipment, materials, and contractor services necessary to modify emission control systems is severely limited." Sterigenics Comments 28, EPA-HQ-OAR-2019-0178-0632. Between supply chain constraints, the time-intensive process of facility redesign to accommodate new equipment, and the extensive testing and validation required before any system can become operational, the necessary control technology is functionally unavailable within the required timeframes.

Further, even if it were possible for all facilities to secure the needed equipment and make the necessary design and structural changes within the current compliance periods, the limited number of experienced installation professionals and technical experts who support this industry makes timely compliance by all regulated sources logistically infeasible. *See* AdvaMed Comments at 10. There is simply no way that all regulated sources will be able to obtain both the necessary equipment *and* the skilled technicians needed to successfully install, test, and bring that equipment online within the same two-year period, as required under the Sterilizer Rule.

Finally, control device manufacturers cannot guarantee that their equipment will operate to meet the Sterilizer Rule's stringent performance deadlines. *See* Sterigenics Comments at 28. This further highlights the technological infeasibility of meeting the current compliance deadlines as well as the irrationality and infeasibility of the standards themselves. This is a particularly compelling basis for the President to find that "the technology to implement such standard is not available," 42 U.S.C. § 7412(i)(4), and grant a two-year waiver.

Even the Biden Administration recognized the compliance challenges posed by the Sterilizer Rule. In its *Memorandum on the Orderly Implementation of the Air Toxics Standards for Ethylene Oxide Commercial Sterilizers* (Jan. 16, 2025), the Administration acknowledged that waivers or exemptions may be necessary to "achiev[ing] the … Rule's critical health protections as soon as practicable, while safeguarding the supply of safe medical products from disruption that would compromise the health and welfare of the American people."

EPA should therefore urge President Trump to exercise his authority under Section 112(i)(4) and quickly issue a two-year compliance exemption for all sources regulated under the Sterilizer Rule, effective when each set of standards set therein would otherwise apply. The exemptions then may be extended for one or more additional periods, if necessary.

**Path 2: EPA Rulemaking to Stay or Extend Deadlines**

Also or alternatively, EPA should take a near-term discrete administrative action to rescind the Rule 112(f) risk-based standards, or at least stay the compliance deadlines, based on a finding that the standards are likely unlawful and EPA's stated commitment to reconsider the Sterilizer Rule.

Because Section 112(f) allows EPA to grant no more than two years for compliance with risk-based standards (although, as discussed above, the President may issue a further two-year exemption—and should do so here), EPA should take near-term, discrete administrative action to rescind at least the risk-based standards set in the Sterilizer Rule based on a finding that its reliance on Section 112(f) to revise EtO emission standards was unlawful. EPA has a solid basis for taking that initial step now: under the Biden Administration, EPA ignored the statutory text and context, both of which confirm that the risk-review is (as the D.C. Circuit previously stated), a "one-time" event, and therefore EPA's conduct of a second risk review was unlawful.

Alternatively, EPA could take a discrete administrative action to stay the Sterilizer Rule's compliance deadlines (ideally for all standards, but at least the Section 112(f) risk-based standards) pending completion of reconsideration and a new notice-and-comment rulemaking process to rescind, replace, or revise the Sterilizer Rule. Such action would relieve sterilizers of near-term compliance obligations and reduce the risk that many sterilizers will cease operations and thereby disrupt the supply of medical devices even while EPA is reconsidering the Sterilizer Rule.

Because the Sterilizer Rule is the result of a notice-and-comment rulemaking process, rescinding or revising the Sterilizer Rule or even just staying the compliance deadlines likely also requires rulemaking to minimize the chance that a reviewing court vacates such action. But EPA could invoke the Administrative Procedure Act's "good cause" exception to notice and comment because the key legal issue whether EPA can conduct a second round of risk review for a source category has already been subject to a notice-and-comment process, and it is a pure statutory construction question on which EPA can correct course now. Further notice-and-comment on that issue is thus "unnecessary," and it is also "impracticable" and "contrary to the public interest" given the urgency of the issue and the impact on the medical device supply chain. *See* 5 U.S.C. 553(b)(B). Or, EPA could issue an interim final rule rescinding at least the Section 112(f) standards and thereby obviating the nearest-term compliance deadlines. This option would allow further notice and comment, but still provide immediate relief for sterilizers facing the difficult choice whether to try to comply with the Sterilizer Rule despite the near-impossibility of doing so or cease operations and disrupt the domestic medical supply chain.

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EOSA appreciates EPA's commitment to reconsidering the Sterilizer Rule and addressing the concerns of regulated facilities. EOSA also appreciates the Agency's willingness to consider near-term actions, such as a Presidential exemption and/or discrete administrative action to address the Section 112(f) standards and associated compliance deadlines. As many facilities confront immediate investment decisions, regulatory clarity is essential. EOSA urges EPA to take timely action to ensure that sterilization facilities remain operational while advancing long-term regulatory solutions that balance public health objectives with industry feasibility.

Thank you for your consideration. Please feel free to contact me at mzhuang@bc-cm.com if you have any questions regarding this request.

EOSA



Sincerely,

Meibao Zhuang
Senior Manager
Ethylene Oxide Sterilization Association

*Cc:*

Abbie Tardif, Principal Deputy Assistant Administrator for the Office of Air and Radiation

Alex Dominguez, Deputy Assistant Administrator for Mobile Sources, Office of Air and Radiation

Peter Tsirigotis, Director, EPA Office of Air Quality Planning and Standards

Penny Lassiter, Director, Sector Policies and Programs Division, EPA Office of Air Quality Planning and Standards