ATTACHMENT A

The Sterilizer Rule[1] - Background, Legal Flaws, and Likely Harms

Ethylene Oxide ("EtO") and its Importance to the Medical Sterilization Process

- EtO is the primary modality used to sterilize essential medical equipment.
- As EPA knows, "for many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device."[2]
- According to the FDA, about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide. These include around 95% of all surgical kits.
- The FDA warned that even temporary sterilizer facility shutdowns will cause "downstream implications for the medical device supply chain" because these facilities "typically run 24/7 . . . operating at maximum capacity."[3]

EtO Sterilizers' Regulatory History and the Rule

- In 1994, EPA issued a rule promulgating its first EtO emissions standards for sterilization facilities under section 7412(d). 94 Fed. Reg. 29,823 (Dec. 6, 1994).
- EPA completed its first Section 112(d) technology review and a Section 112(f) one-time risk review in 2006, finding "no additional control requirements are warranted." 71 Fed. Reg. 17,712 (Apr. 7, 2006).
- Nearly two decades later, EPA completed its next periodic technology review—but also revised standards based on a *second* residual risk review under Section 112(f) using the 2016 EtO IRIS value.
- Almost half of the emission standards set in the Rule—including the most stringent—were established pursuant to the Section 112(f) risk review. These include:
  - A 99.99% DRE (destruction and removal efficiency) standard for Sterilization Chamber Vents and a 99.9% DRE standard for Aeration Chamber Vents using 30+ tpy EtO.[4]
  - A 99.9% DRE standard for Chamber Exhaust Vents at area sources using 400+ tpy of EtO.
  - A 98% DRE standard for both "Group 1" room emissions at area sources using 40+ tpy EtO and "Group 2" room emissions at area sources using 20+ tpy EtO. These standards are also a change in form from the proposed mass-per-hour limit.
- The Rule eliminates the choice to comply through an alternative concentration standard.
- The Rule also requires all sources using 100+ lb/year of EtO to demonstrate compliance using Continuous Emissions Monitoring Systems (CEMS) at both inlets and outlets, thus making a costly and complex monitoring regime even more costly and complex.

---

[1] 89 Fed. Reg. 24,090 (Apr. 5, 2024).
[2] *Id.* at 24,092 (Apr. 5, 2024).
[3] FDA Center for Devices and Radiological Health, *Medical Device Benefits Statement* (Mar. 15, 2023).
[4] All new and revised standards set in the Rule are listed at 89 Fed. Reg. at 24,093–Table 1.

The Sterilizer Rule's Major Flaws

- To set the most stringent emission standards, EPA relied on CAA Section 112(f)(2)—a one-time risk review provision—to conduct a second round of risk review, instead of relying on its established authority to revise standards based on a technology review under Section 112(d).
- EPA set first-ever standards for some sources under Section 112(f)(2) even though Congress requires standards first be set via technology review under Section 112(d).
    - EPA regulated room air emissions (Group 1 and Group 2 sources) for the first time relying *solely* on section 7412(f)(2), even though Congress provided that such standards may only be promulgated "within 8 years *after promulgation of standards* for each category … of sources pursuant to subsection (d)[.]" 42 U.S.C. § 7412(f)(2)(A).
- EPA failed to reasonably assess the Rule's costs to sterilizers—and ignored economic and social costs to the medical industry and medical patients.
- EPA also did not balance the costs it considered against the Rule's claimed health benefits.
- The Rule's EtO standards are not supported by the record; they are based on performance test data EPA admitted does not reflect normal operations.
- The standards require emissions control beyond what equipment manufacturers can guarantee. There is thus no assurance for sterilizers that, if they incur the huge costs required to redesign their facilities and install new equipment, they will be able to meet the standards.
- The Rule is entirely premised on EPA's flawed 2016 IRIS value for EtO, but EPA declined to respond to comments challenging its reliance on that IRIS value in this Rule.
- The Rule unreasonably requires sterilizers to demonstrate compliance through CEMS instead of parametric monitoring, and to install CEMS on *inlets and outlets*, a regime that is costly, technically difficult, and unprecedented—and that commenters did not have a chance to address.

The Sterilizer Rule's Likely Harms

- The Rule is highly likely to disrupt the medical device supply chain, including because a significant number of sterilizers likely will close shop or move offshore rather than incur the high costs to redesign their facilities, acquire new emissions control equipment, and install CEMS.
    - EPA estimates the Rule's total annual costs will be around $88 million. 89 Fed. Reg. at 24,137. But that does not include capital costs to redesign and retrofit facilities.
    - The Small Business Association estimated that many U.S. sterilizers will need to spend *over 20% of their revenue* on compliance annually. That, in turn, will force many smaller facilities to exit the market entirely, resulting in a shortage of medical devices.
- Even facilities that choose to try to comply with the Rule will have to cease operations for long periods to install new control equipment; test that equipment; and then install and test CEMs.
- Some sterilizers are specialized to supply particular devices like catheters. If one of those facilities goes offline, temporarily or permanently, that would disrupt the domestic supply of those devices.
- If even one patient death resulted from a shortage of medical devices caused by the Rule, that would eliminate the Rule's claimed health benefits.