Sterigenics' Statement and Frequently Asked Questions on EPA's Recent Proposed Reconsideration for 2024 Commercial Sterilizer Rule

March 16, 2026

On March 13, 2026, the U.S. Environmental Protection Agency ("EPA") announced a proposal to reconsider portions of the 2024 ethylene oxide NESHAP rule for commercial sterilizers. Sterigenics views this as an important step in EPA's ongoing review of the appropriate scientific and regulatory framework for evaluating EtO risk at low concentrations, including whether the 2016 IRIS value remains the right tool for current rulemaking decisions. We support regulation grounded in transparent, peer-reviewed science that protects public health and preserves access to sterile medical products and a resilient healthcare supply chain.

Sterigenics remains fully committed to our mission of Safeguarding Global Health® and shares the EPA's commitment to safeguarding communities while maintaining the safe and reliable supply of sterile medical equipment to the healthcare industry. Sterigenics has and will continue to invest in state-of-the-art facility enhancements across our EtO facilities.

As we have consistently demonstrated throughout our history, we strive to operate in compliance with applicable federal, state, and local rules and regulations and cooperate with our regulators to ensure the safety of our employees, the communities in which we operate, and patients around the world.

Frequently Asked Questions

Q: What is EPA proposing?

EPA is proposing to revisit the 2024 ethylene oxide NESHAP rule for commercial sterilizers. The proposal would rescind the 2024 NESHAP standards under Clean Air Act section 112(f)(2), revise certain aeration-room requirements, and change some compliance demonstration provisions. EPA said the proposal was driven by legal, scientific, and policy concerns, including supply-chain concerns. In addition, EPA is reexamining the scientific basis for using the 2016 IRIS value to quantify low-concentration risk and is acknowledging significant uncertainty around that value, and it asked for comment on alternative values, ranges, or other ways of assessing risk.

Q: Is anything final yet?

No. This is a proposal. EPA says comments are due 45 days after Federal Register publication, and EPA plans a virtual public hearing 15 days after publication.

Q: Does this change Sterigenics' compliance obligations today?

No. This is still a proposal, not final, and EPA is proposing to retain the existing compliance dates for the standards that would remain in place.

Q: Why is EPA reconsidering the 2024 rule?

EPA says it is reconsidering the rule for a mix of legal, scientific, and practical reasons. EPA also says the proposal is intended to help protect the medical-device supply chain, noting that more than 20 billion medical devices used in the U.S. each year are sterilized with ETO and cannot be sterilized with any alternative method.

Q: Why is supply chain such a big part of EPA's rationale?

EPA says commercial sterilizers process more than 20 billion medical devices used in the U.S. each year, representing about 50 percent of devices that require sterilization. EPA's fact sheet states that ETO is the only safe and effective sterilization method available for many critical products and that the proposal is intended to support a secure domestic supply chain.

Q: What does the proposal say about IRIS?

EPA is reexamining the scientific basis for using the 2016 IRIS regulatory value, specifically as it relates to low-concentration exposure. EPA noted that "significant uncertainties regarding the magnitude of EtO's carcinogenic potency, particularly at low concentrations, would be an additional reason for rescinding" the 2024 rule. EPA noted uncertainties "regarding the quantity and relative contribution of endogenous, tobacco smoke, and background ETO levels from non-industrial sources," as well as "new scientific evidence" that emerged since 2016. EPA also noted that the combination of use of a different model and different statistical limit "could have resulted in an EtO IRIS value that was up to five times lower (i.e., ETO is five times safer than the 2016 EtO IRIS value stated.)"

EPA is asking for comments on whether a different value, range, or approach would be more appropriate.

Q: What is IRIS in simple terms?

IRIS is EPA's human-health risk assessment program for chemicals. It identifies and characterizes health hazards of chemicals found in the environment according to EPA risk assessment policies for EPA and others to use in risk assessments and rulemaking. IRIS is a risk assessment system; it does not identify whether a substance actually causes harm to anyone at the concentrations that IRIS models.

Cautionary Note Regarding Forward-Looking Statements

This document contains forward-looking statements that reflect management's expectations about future events and the company's operating plans and performance and speaks only as of the date hereof. These forward-looking statements are subject to various risks and uncertainties. For information on certain factors that could cause actual events or results to differ materially from our expectations, please refer to the company's filings with the SEC, such as its annual and quarterly reports. The company undertakes no obligation to publicly update or revise these forward-looking statements, except as otherwise required by law.