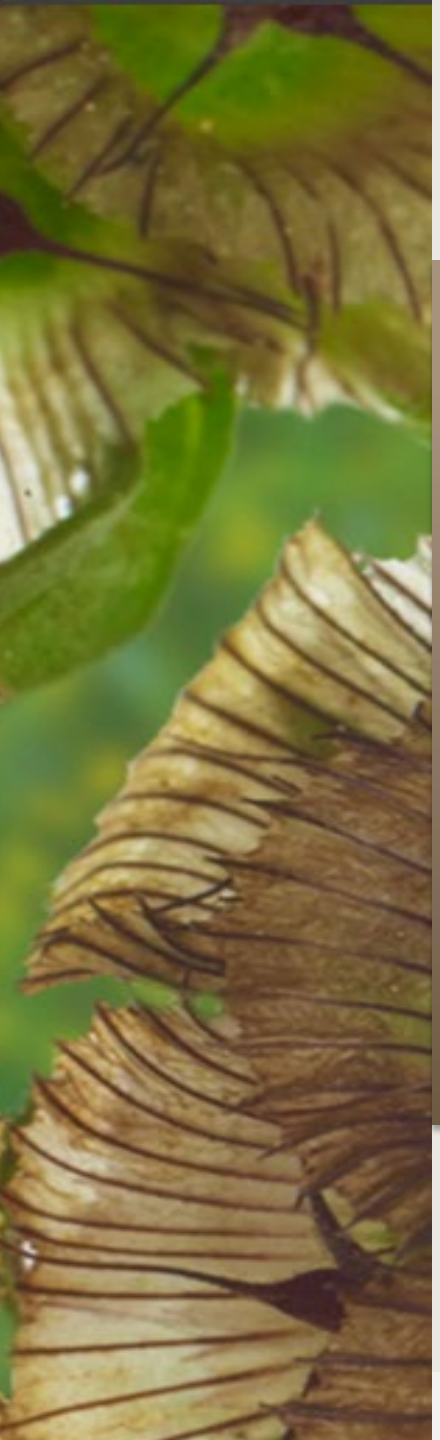

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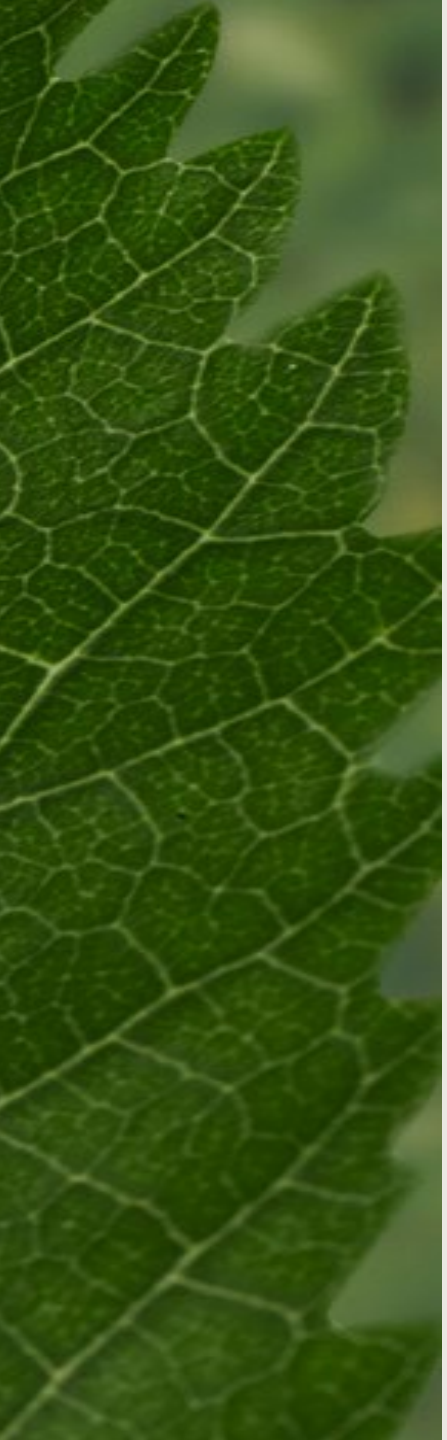
THE ETHYLENE OXIDE STERILIZATION ASSOCIATION, INC. (EOSA)

Potential Impacts of Upcoming Ethylene Oxide (EtO) National Emission Standards for Hazardous Air Pollutants (NESHAP) Proposed Rulemaking

February 3, 2023

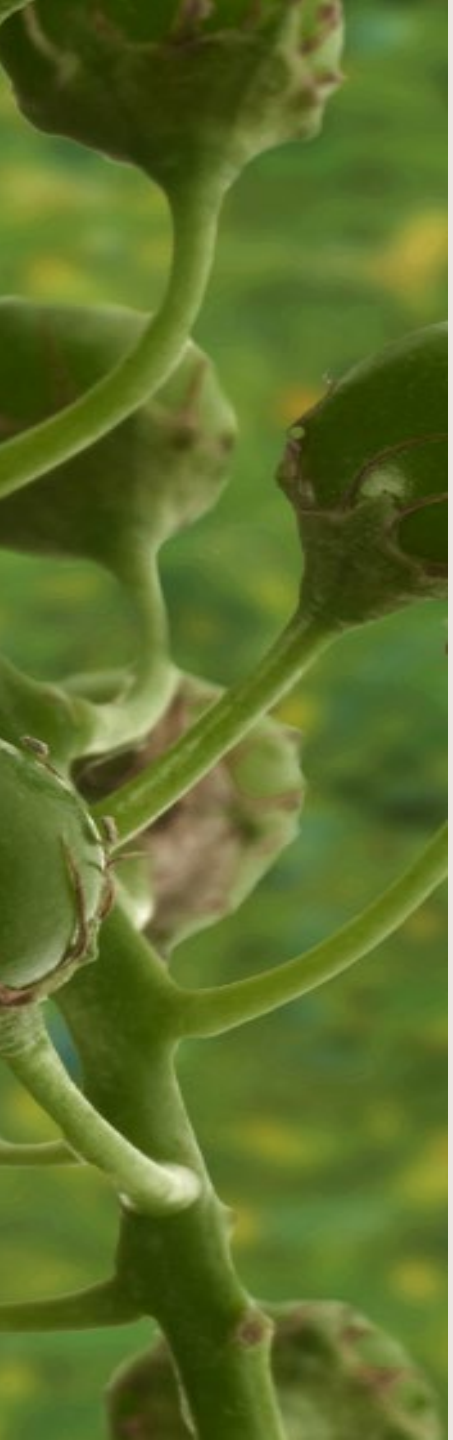


Background

- Sterilization with EtO is critical and essential for public health, and for a safe, effective healthcare system
- Billions of medical products are sterilized each year that are essential for avoiding significant adverse effects on patient health
- Approximately 50% of medical products sterilized are sterilized using EtO, and currently there are no alternative methods that can replace it
- EtO is widely used due to its unique properties and efficacy, which has been proven over decades of use
- Alternatives to industrial EtO sterilization are limited in material compatibility, penetration, and scalability. Use of other proven industrial sterilization methods, such as radiation and steam, are not compatible with the majority of products currently sterilized by EtO. Novel methods, such as VHP, ClO_2, NO_2 and others, are very limited in terms of applicability. Even if viable alternatives could be developed in the future, it will take years, if not decades, to develop and acquire FDA approval
- The development of new life-saving, life-sustaining, and life-enhancing products, which could include new materials, new devices, combination devices, etc., can often only be accomplished using EtO as the sterilization modality

Background

- The industry has been actively and voluntarily pursuing ways to reduce EtO worker exposure and emissions, and will continue these efforts
- The sterilization capacity in the U.S. and globally is at or near its limit, and especially in the U.S., there have only been limited investments in new capacity due to uncertainty of the regulatory environment
- Small sterilization businesses in particular are tremendously burdened by the significant investment in new technology and uncertainty of regulation, placing further at risk the viability of those small businesses
- Significant concerns exist around the current limitations of technology (*e.g.*, ability to meet emissions control standards or even measure EtO concentration at extremely low levels required by potential new regulation), and the limited equipment supply base and resultant availability of this equipment
- Vast differences in device, packaging, cycle design, equipment, and facilities preclude a "one size fits all" approach to regulation
- There will be negative impact to the supply of medical devices if more sterilization facilities close due to unwarranted regulatory requirements and/or local activism



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Key Concerns

- Patient care: Sterility assurance is critical and cannot be compromised
- Supply continuity: Adequate capacity and assurance of supply of sterilized medical products will be put at significant risk if proposed regulations are not carefully considered
- National security: Operation and control of processes that are critical to healthcare within the United States; shutdown of additional sterilizers would reduce domestic capabilities
- Technology: A technology-neutral approach should be applied to avoid overreliance on a limited number of equipment suppliers and/or technologies. The limitations of proposed technology should be well understood and implementable in an industrial setting
- Prescriptive vs. performance-based regulations: Given the many variations in device/packaging, cycle design, equipment design, facility design, and geography, a performance-based standard that allows for flexibility can promote innovation and lead to more rapid implementation
- Cycle design: Any validation method should be able to be used provided it meets the applicable emission and worker exposure requirements. Cycle validation methodology (*e.g.*, half cycle, cycle calculation, or BI/bioburden approach) and EtO concentration do not correlate with emissions and worker exposure. Any cycle validation methodology, including those mentioned above, can be used to meet performance-based requirements

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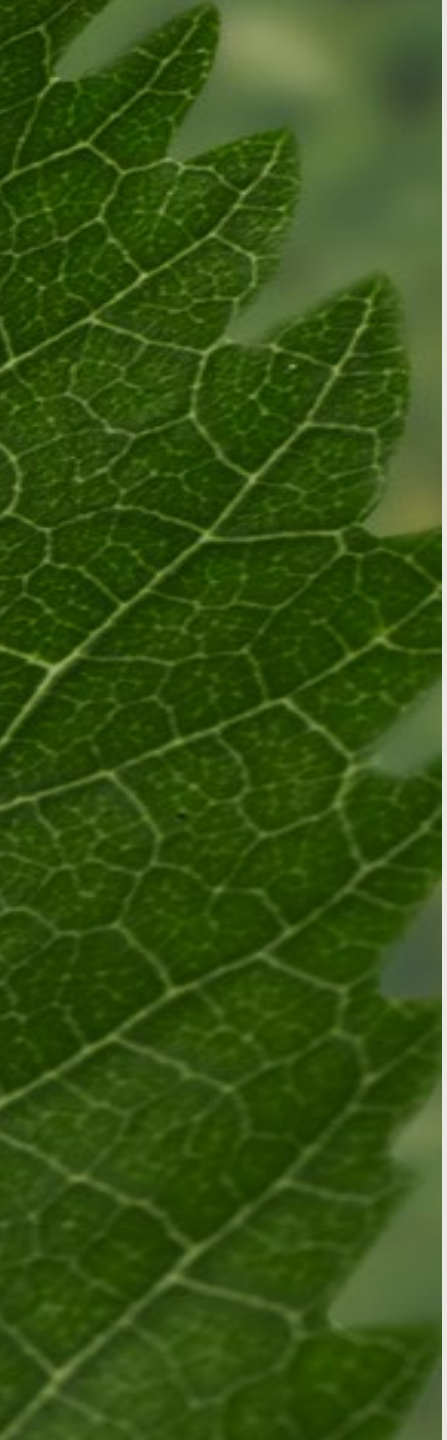
Key Concerns

- The significant adverse consequences of the proposed regulatory actions must be weighed against the benefits of those proposed measures, given the enormity of those adverse consequences and their immediate significant impact on public health
- Conflicting/adverse regulatory outcomes must be considered due to conflicts/overlaps among NESHAP, FIFRA, and other regulations. As is typical in these situations, regulations under one statute can negatively affect conditions that another statute regulates, potentially causing significant unintended adverse impacts on employee safety and the environment. A holistic approach is essential to avoid these unintended adverse impacts
- Significant adverse economic, business, and job implications, including, potentially, facility closures and/or business and jobs moving offshore
- There is a large range of risk values that have been developed by credible regulatory bodies (EPA, TCEQ), and the disparity between these two assessments (>2,000 fold) warrants a formal review of the EtO IRIS assessment. According to IRIS, normal background concentrations of EtO (from automobile exhaust, decay of plant matter, etc.), as well as endogenous EtO from normal biological functions, cause unacceptable bystander risk. Also, according to IRIS, occupational exposures put workers at an extraordinarily high risk (1 in 10 cancer risk to occupational workers, according to IRIS), which was not observed in the original NIOSH study cohort, or any other study



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Asks

- Implementation of achievable performance-based standards that would not further restrict capacity and would allow for flexibility in implementation timing
- Technology-neutral approach to emission control and engineering controls with adequate implementation timeline
- Holistic evaluation of regulations to avoid one rule being in direct conflict, or counterproductive to another, which could cause significant adverse unintended consequences
- Risk/benefit analysis, that appropriately considers the potential adverse impacts on patients, public health and safety, and the entire healthcare system
- Inclusion of background and endogenous levels in risk assessment, risk communication, and rulemaking
- Flexibility in cycle design and validation approach that meets emission and worker exposure requirements
- Use an existing credible alternative assessment such as TCEQ and/or have the IRIS assessment reviewed by an independent scientific body outside of EPA, prior to implementing the final rulemaking. Credible alternative assessments have been done, the outcomes of which are much more plausible, and scientifically accurate, and take the ambient and endogenous EtO levels into account, as well as provide more reliable and accurate predictions of cancer case incidence vs. epidemiological study data