Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations

EPA-452/R-23-007
March 2023

Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Health and Environmental Impacts Division
Research Triangle Park, NC

CONTACT INFORMATION

This document was prepared by staff from the Office of Air and Radiation at the U.S. Environmental Protection Agency. Questions related to this document should be addressed to the Air Economics Group in the Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina 27711 (email: OAQPSeconomics@epa.gov).

ACKNOWLEDGEMENTS

We acknowledge the contributions of staff from the EPA's National Center for Environmental Economics in the Office of Policy in preparing this analysis. We also acknowledge the contributions of staff from RTI International in preparing the compliance costs for the regulatory options analyzed in this document.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1 EXECUTIVE SUMMARY

1.1 Background

The U.S. Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O). Ethylene oxide (EtO) is one of 188 hazardous air pollutants regulated by the EPA. This document presents the regulatory impact analysis (RIA) for this proposed rule.

Commercial sterilization and fumigation operations, or "commercial sterilizers", that are impacted by this proposed rule use EtO, a flammable and colorless gas, to remove or reduce the presence of bacteria, fungi, and viruses on a variety of products to decrease risks of infection to users of these products. Affected facilities in this source category (subpart O) mostly sterilize medical devices and medical equipment, since many of these products must meet high safety standards before they can be made available to healthcare providers, patients, and other consumers. Commercial sterilizers also use EtO to sterilize some types of food products such as spices and other consumer products like cosmetics. Sterilization with EtO is primarily conducted by facilities that specialize in sterilization (*i.e.*, 'contract' sterilizers) rather than the manufacturers of the products themselves, though some manufacturers perform sterilization with EtO in-house.

This rule proposes amendments to the subpart O NESHAP requirements. The EPA is proposing to require existing and new sources in the category to reduce emissions of EtO, a hazardous air pollutant (HAP) that can cause adverse human health impacts on exposed individuals, such as cancer. The EPA is proposing decisions concerning the risk and technology review (RTR), including amendments pursuant to the technology review for certain point sources and amendments pursuant to the risk review to specifically address EtO emissions from point source and room air emissions from certain groups of facilities. The EPA is also proposing amendments to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM, adding work practice standards for periods of SSM where appropriate, and clarifying regulatory provisions for certain vent control bypasses. Lastly, the EPA is proposing to revise

monitoring and performance testing requirements and to add provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports.

1.2 Economic Basis for this Rulemaking

Regulation can be used to address market failures, which otherwise lead to a suboptimal allocation of resources within the free market. Many environmental problems are classic examples of "negative externalities", which arise when private entities do not internalize the full opportunity cost of their production, and some of this opportunity cost is borne by members of society who are neither consumers nor producers of the goods produced (*i.e.*, they are "external"). For example, the smoke from a factory may adversely affect the health of nearby residents, soil quality, and visibility. Public goods such as air quality are valued by individuals but suffer from a lack of property rights, so the value of good air quality tends to be unpriced in the markets that generate air pollution. In such cases, markets fail to allocate resources efficiently and regulatory intervention is needed to address the problem.

While recognizing that the socially optimal level of pollution is often not zero, EtO emissions impose costs on society (*e.g.*, cancer risks) that may not be reflected in the equilibrium market prices for sterilization services. If emissions from sterilizers increase risks to human health, some social costs will be borne not by the firm and its customers but rather imposed on communities near the sterilization site and other individuals exposed to their EtO emissions. Consequently, absent a regulation limiting EtO emissions and causing firms to internalize the external costs of their operations, emissions will exceed the socially optimal level.

Aside from externalities, other major forms of market failure include market power and inadequate or asymmetric information. Correcting market failures is one reason for regulation, but it is not the only reason. Other potential justifications include improving the function of government, correcting distributional inequity, or securing privacy or personal freedom.

1.3 Legal Basis for this Rulemaking

Section 112 of the Clean Air Act (CAA), which Congress modified as part of the 1990 CAA Amendments, provides the legal authority for this proposed rule. Section 112 of the CAA establishes a two-stage process to develop standards for emissions of HAP from new and existing stationary sources in various industries or sectors of the economy (*i.e.*, source

categories). Generally, the first stage involves establishing technology-based standards and the second stage involves assessing whether additional standards are needed to address any remaining risk associated with HAP emissions from the source category. This second stage is referred to as the "residual risk review." In addition to the residual risk review, the CAA requires the EPA to review standards set under CAA section 112 every 8 years and revise them as necessary, taking into account any "developments in practices, processes, or control technologies." This review is commonly referred to as the "technology review".

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources depending on the amount of HAP the source has the potential to emit.[1]

Major sources are required to meet the levels of reduction achieved in practice by the best-performing similar sources. CAA section 112(d)(2) states that the technology-based NESHAP must reflect the maximum degree of HAP emissions reduction achievable after considering cost, energy requirements, and non-air quality health and environmental impacts. These standards are commonly referred to as maximum achievable control technology (MACT) standards. MACT standards are based on emissions levels that are already being achieved by the best-controlled and lowest-emitting existing sources in a source category or subcategory. CAA section 112(d)(3) establishes a minimum stringency level for MACT standards, known as the MACT "floor." For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT) in lieu of MACT standards. In certain instances, CAA section 112(h) states that the EPA may set work practice standards in lieu of numerical emission standards.

The EPA must also consider control options that are more stringent than the MACT floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor (BTF) standards. CAA section 112(d)(2) requires the EPA to determine whether the more stringent

[1] "Major sources" are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are "area sources."

standards are achievable after considering the cost of achieving such standards, any non-air-quality health and environmental impacts, and the energy requirements of additional control.

For major sources and any area source categories subject to MACT standards, the second stage in the standard-setting process focuses on identifying and addressing any remaining (*i.e.*, "residual") risk pursuant to CAA section 112(f) and concurrently conducting a technology review pursuant to CAA section 112(d)(6). The EPA is required under CAA section 112(f)(2) to evaluate residual risk within eight years after promulgating a NESHAP to determine whether risks are acceptable and whether additional standards beyond the MACT standards are needed to provide an ample margin of safety to protect public health or prevent adverse environmental effects.[2] For area sources subject to GACT standards, there is no requirement to address residual risk, but technology reviews are required. Technology reviews assess developments in practices, processes, or control technologies and revise the standards as necessary without regard to risk, considering factors like cost and cost-effectiveness. The EPA is required to conduct a technology review every eight years after a NESHAP is promulgated. Thus, the first review after a NESHAP is promulgated is a residual risk and technology review (RTR) and the subsequent reviews are just technology reviews.

The EPA is also required to address regulatory gaps (*i.e.*, "gap-filling") when conducting NESHAP reviews, meaning it must establish missing standards for listed HAP that are known to be emitted from the source category (*Louisiana Environmental Action Network (LEAN) v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020)). Any new MACT standards related to gap-filling must be established under CAA sections 112(d)(2) and (d)(3), or, in specific circumstances, under CAA sections 112(d)(4) or (h).

1.4 Regulatory History and Recent Developments

In the first step of the EtO sterilization process, products are placed in a chamber and exposed to EtO gas at predetermined levels of temperature, humidity, pressure, and concentration of EtO. Following the dwell period, EtO is evacuated from the chamber and the

[2] If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health in consideration of all health information as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.

sterilized items are then aerated to reduce the residual EtO on them. After aeration, the sterilized items are typically moved to a shipping/warehouse area for storage until they are distributed. The sterilization process and the equipment and emission control configuration vary across facilities. The most common configuration includes a sterilization chamber, a separate aeration room, and a chamber exhaust vent. Some facilities carry out sterilization and aeration in the same chamber.

The NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations (40 CFR part 63 subpart O) was finalized in December 1994. The rule established MACT and GACT standards for EtO emissions originating from sterilization chamber vents (SCV), chamber exhaust vents[3] (CEV), and aeration room vents (ARV),[4] as well as requirements for compliance and performance testing.

The original 1994 standards were stratified based on facility wide EtO usage levels (*i.e.*, less than 1 ton per year, 1 to 10 tons per year, and 10 or greater tons per year). The NESHAP established MACT standards for SCVs, CEVs, and ARVs at facilities that use 10 or more tpy of EtO. For facilities using at least 1 tpy but less than 10 tpy of EtO, GACT standards were established for SCVs and CEVs. Facilities using less than 1 tpy of EtO had reporting and recordkeeping requirements but were not subject to any numerical emissions limits or work practice standards. In 2001, the EPA suspended certain compliance deadlines and ultimately removed the standards for CEVs due to safety concerns. The EPA completed a residual risk and technology review for the NESHAP in 2006 and concluded, at that time, that no revisions to the standards were necessary.

As explained, the EPA periodically reviews and updates NESHAPs to keep pace with technological change in regulated sectors and ensure that risks are acceptable. Since the RTR for this source category was already conducted in 2006, the EPA is only required to base the revisions in this proposal on a technology review. However, the context for this proposal is somewhat unique in that the EPA updated the Integrated Risk Information System (IRIS) value

[3] The CEV evacuates EtO-laden air from the sterilization chamber when the chamber door is opened for product unloading to reduce employee exposure to EtO.

[4] Multiple control technologies were used by EtO sterilizers at the time the NESHAP was developed. Control technologies for SCVs included: hydrolysis/Glygen absorber unit; packed bed scrubber (acid-water scrubber); thermal oxidizer/flare; catalytic oxidizer; condenser/reclaimer; and a combination packed bed scrubber and gas-solid reactor (dry bed reactor) system. Control technologies for CEVs included: packed bed scrubber; catalytic oxidizer; gas-solid reactor; and a combination packed bed scrubber and gas-solid reactor. Control technologies for ARVs included: acid-water scrubber, catalytic oxidizer, and gas-solid reactor.

associated with EtO after the 2006 RTR.[5] All else equal, the unit risk estimate for EtO is nearly 60 times higher than it was prior to the 2016 IRIS update. An update in the risk value of this magnitude is not typical for regulated HAPs. Due to these circumstances, the EPA aims not only to carry out the more routine aspects of a CAA section 112 technology review, but to reflect the substantial development in the epidemiological evidence on EtO's health effects by considering residual risk again under CAA section 112(f)(2).

At the same time, the EPA recognizes that EtO emissions are not the only public health issue to consider in this proposed rulemaking due to the important role EtO plays in the provision of safe and sterile medical devices. According to the U.S. Food and Drug Administration (FDA), more than 20 billion medical devices used in the U.S. every year are sterilized with EtO, accounting for approximately 50 percent of medical devices that require sterilization. The industry profile in chapter 2 discusses the role of EtO in providing a significant amount of healthcare products to the public and why it is often the only sterilization method than can be used for a wide variety of common medical devices.

1.5 Regulatory Options

1.5.1 Executive Order Requirements for Regulatory Impact Analysis

Several statutes and executive orders (EO) apply analytical requirements to federal rulemakings. This RIA presents several of the analyses required by these statutes and EOs, such as EO 12866 and the Regulatory Flexibility Act (RFA). Below is a summary of the requirements of EO 12866 and EO 13563 and the guidelines provided in the Office of Management and Budget (OMB) Circular A-4.[6]

This proposed rule is an economically significant regulatory action as defined by EO 12866. In accordance with EO 12866 and EO 13563 and the guidelines of OMB Circular A-4, this RIA analyzes the costs of complying with the requirements in this proposed rule for regulated facilities. The EPA did not monetize the benefits associated with the proposed requirements, but they are characterized qualitatively in chapter 4. OMB Circular A-4 requires analysis of one potential regulatory control alternative more stringent than the proposed rule and

[5] Additional information on the IRIS program is available here: https://www.epa.gov/iris.
[6] Office of Management and Budget. (2003). Circular A-4: Regulatory Analysis. Found at http://www.whitehouse.gov/omb/circulars/a004/a4.html.

one less stringent than the proposed rule. This RIA evaluates the costs and certain other impacts of a more stringent alternative and a less stringent alternative to the selected option in this proposal.

1.5.2 Process for Developing Proposed Rule

The proposed changes to the subpart O NESHAP are based on the results of the risk review and technology review, which identified the need to set standards for currently unregulated sources of HAP in the sector (*i.e.*, gap-filling), and the need for other minor updates to improve the consistency of the rule with other EPA actions and increase the clarity of the rule. The EPA is proposing numeric emission limits, operating limits, and management practices to fill regulatory gaps under CAA sections 112(d)(2), (d)(3), and (d)(5) for EtO emissions from certain emission sources and also is proposing standards under CAA section 112(f)(2) for certain emission sources in order to ensure that the standards provide an ample margin of safety to protect public health. The preamble contains a more thorough discussion of the gap-filling analysis, risk review, and technology review conducted for this proposed rule, including the range of technologies, practices, and other requirements considered and the EPA's reasoning for ultimately choosing the standards being proposed.

The EPA first determined standards to propose for previously unregulated emission sources under CAA section 112(d)(2), (d)(3), and (d)(5). The EPA is proposing to establish standards for currently unregulated "room air emissions" and several point sources. Room air emissions, or "fugitive emissions", are released from equipment used to inject EtO into sterilization chambers and remove EtO from chambers, store EtO, and from air pollution control devices. Room air emissions also include the residual EtO that comes off of sterilized products within the facility both before and after the aeration process. The EPA is also proposing to establish standards for point sources at facility usage levels that are currently unregulated, including SCVs, ARVs, and CEVs at facilities where EtO usage is less than 1 tpy; ARVs and CEVs at facilities where EtO usage is at least 1 tpy but less than 10 tpy; and CEVs at facilities where EtO usage is at least 10 tpy.

Next, taking into account the risk reductions estimated to result from the standards being proposed for previously unregulated sources described above, the EPA conducted a risk review under CAA 112(f)(2). To address unacceptable remaining risk and ensure an ample margin of

safety, the EPA is proposing health-based standards for SCVs, ARVs, and certain room area emissions. The stringency of the proposed health-based standards varies based on a facility's annual EtO usage. The usage groupings in the proposed standards are intended to address emissions from facilities identified as high risk while mitigating the compliance burden for lower risk facilities. The EPA is proposing health-based emission standards for SCVs at facilities where EtO use is at least 40 tpy, SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy, SCVs at facilities where EtO use is at least 1 tpy but less than 10, and Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy.[7] While the EPA was not required to invoke CAA 112(f)(2) in this proposed review of the subpart O NESHAP, its use was intended to target risk more efficiently than a set of standards based only on technology and gap-filling, thus balancing risk and cost considerations.

The EPA then completed a technology review for the sector, taking into account the requirements being proposed to fill regulatory gaps and address risk, pursuant to CAA section 112(d)(6). The goal of a technology review is to identify cost-effective developments in practices, process, or controls of HAP for a source category. The technology review identified improvements in control technology and emissions performance for SCVs at facilities where EtO use is at least 10 tpy, SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and ARVs at facilities where EtO use is at least 10 tpy. As part of this review, the EPA identified more stringent emission standards that could be applied to these ARVs with minimal additional economic impact. Therefore, additional technology-based standards are being proposed for ARVs at facilities where EtO use is at least 10 tpy. The EPA is also co-proposing the same requirements under (d)(6) that are being proposed under CAA 112(f)(2) for SCVs at facilities where EtO use is at least 10 tpy and SCVs at facilities where EtO use at least 1 tpy but less than 10 tpy.

The EPA is also proposing revisions related to performance testing; monitoring, reporting, and recordkeeping requirements; requirements during periods of startup, shutdown, and malfunction (SSM); and other minor technical improvements. The EPA is proposing to

[7] The EPA is proposing standards for two types of room air emissions, Group 1 and Group 2. Group 1 room air emissions come from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material. Group 2 room air emissions are released during post-aeration handling of sterilized material.

require monitoring either with an EtO continuous emissions monitoring system (CEMS) or initial and annual performance testing with continuous parameter monitoring. The proposed standards and requirements are described in greater detail in the preamble.

1.5.3 Regulatory Alternatives Analyzed in this RIA

This RIA assesses impacts of the proposed standards and two regulatory alternatives. The previous subsection describes all the standards and changes being proposed and is known as option 2 in this analysis. Option 1 is the least stringent option analyzed and option 3 is the most stringent option. Option 3 would require all affected facilities to comply with the most stringent standards that are considered in the preamble to this proposal for all emissions points (SCVs, ARVs, CEVs, and room air emissions), regardless of annual EtO usage. The health-based standards and the subcategorization of sources based on EtO usage under the proposed option 2 reduce the compliance burden for many facilities because they would not be subject to the more stringent standards applied under option 3. However, under option 2, a subset of facilities would be subject to additional standards and would incur higher compliance costs than they would under option 3. Option 2 reduces the collective compliance burden for the source category as a whole relative to option 3 even though some facilities would face stricter and more costly requirements. Under the least stringent option 1, almost all facilities in the source category would be subject to GACT standards. The three alternatives are summarized below.

Option 1: Apply GACT standards to all currently unregulated emissions at area source facilities. The current standards for regulated point sources would not be updated.

Option 2 (proposed): Apply GACT standards to all currently unregulated emissions at area source facilities. Then, based on results of the post-control risk assessment, revise established and newly proposed standards pursuant to CAA section 112(f)(2), considering economic feasibility after risk has been determined to be acceptable.

Option 3: Revise established emission limitations and propose new limitations for all currently unregulated emissions to the most stringent levels that are considered in the preamble.

1.6 Results

The impacts of regulatory actions are evaluated relative to a baseline that represents the world without the regulatory action. The cost impacts of this proposed rule were estimated over a

20-year timeframe from 2023 to 2042. The EPA chose a 20-year analytical time horizon to be consistent with the equipment lifetimes of some of the capital components that would be required to comply with the proposed rule (lifetimes are not consistent across all capital equipment). The 20-year timeframe was also chosen to capture lasting regulatory impacts while avoiding uncertainties that would be introduced if a longer timeframe (*e.g.*, 30 years) were used. Throughout this document, the EPA focuses the analysis on the proposed requirements that result in quantifiable compliance cost or emissions changes compared to the baseline. While this RIA contains some qualitative discussion of the human health risks associated with exposure to EtO emissions and a summary of the quantitative risk analysis conducted for this proposed rule, the EPA was not able to monetize the benefits associated with the emissions reductions estimated to result from this proposed rule.

The EPA identified 86 EtO sterilization facilities currently operating in the U.S., all of which will be impacted by this proposed rule and incur costs. The EPA also potentially identified, based on permits and responses to the December 2019 questionnaire and September 2021 ICR, 11 research facilities that conduct EtO sterilization, as defined under CAA 112(c)(7), which are not part of the source category. There are two commercial facilities that have announced plans to open and will be affected by the proposed rule, which brings the total number of facilities incurring costs in this RIA to 88.

1.6.1 Cost and Emissions Impacts

Table 1-1 contains a summary of the estimated cost impacts and EtO emissions reductions for the three options analyzed for this proposed rule. The EPA is proposing option 2, while option 1 and option 3 represent the less and more stringent options analyzed in this RIA, respectively. The present value (PV) of the estimated compliance costs from 2023 to 2042 for the proposed option 2 is $640 million in 2021 dollars, discounted at a 7 percent rate. The equivalent annualized value (EAV)[8] of the costs for option 2 is $74 million, using a 7 percent discount rate. Using a 3 percent discount rate, the PV and EAV of the cost impacts for option 2 are estimated to be $784 million and $53 million, respectively.

[8] The EAV represents a flow of constant annual values that, had they occurred in each year from 2023 to 2042, would yield a sum equivalent to the present value.

Table 1-1. Estimated Costs and Emissions Reductions from 2023 to 2042 (Millions 2021$ [a])

	Option 1	Option 2 (proposed)	Option 3
Capital Costs	$146	$220	$308
Total Annualized Costs[b]	$66	$68	$76
Discounted Present Value of Costs (3%)	$635	$784	$897
Equivalent Annualized Value (3%)	$43	$53	$60
Discounted Present Value of Costs (7%)	$513	$640	$746
Equivalent Annualized Value (7%)	$60	$74	$85
EtO Emissions Reductions (tpy)	15	19	20

[a] When necessary, dollar figures in this RIA have been converted to 2021$ using the annual GDP Implicit Price Deflator from the U.S. Bureau of Economic Analysis (BEA) NIPA Table 1.1.9, found at https://fred.stlouisfed.org/release/tables?rid=53&eid=41158.

[b] The total annualized costs are the sum of the annualized capital costs and other annual costs. The capital costs were annualized over the lifetime of the equipment at a 7.75 percent interest rate.

For option 1, the PV and EAV of the estimated costs are $513 million and $60 million, respectively, using a 7 percent discount rate. At a 3 percent discount rate, the PV and EAV of the costs for option 1 are estimated to be $635 million and $43 million, respectively. For the more stringent option 3, the PV and EAV of the estimated costs are $746 million and $85 million, respectively, using a 7 percent discount rate. At a 3 percent discount rate, the PV and EAV of the costs for option 3 are estimated to be $897 million and $60 million, respectively. For options 1, 2, and 3, the EPA estimated EtO emissions reductions of 15 tpy, 19 tpy, and 20 tpy, respectively.

1.6.2 Risk, Benefits, and Environmental Justice

This proposed rule is expected to reduce nationwide emissions of EtO from this source category by 19 tons per year (tpy) under option 2. Option 1, the least stringent option, is estimated to reduce EtO emissions from the source category by 15 tpy. The most stringent option 3 is estimated to reduce EtO emissions from the source category by 20 tpy. As mentioned, the benefits associated with these emissions reductions are not monetized in this RIA. Nonetheless, this RIA provides quantitative risk information.

The risk analysis conducted for this proposed rule focused on populations living within 10 km of the facilities with cancer risks greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million. The analysis determined that under the baseline, 78 facilities expose 5.3 million people to cancer risk greater than or equal to 1-in-1 million, 42 facilities expose 119,000 people to cancer risk greater than or equal to 50-in-1

million, and 16 facilities expose 18,000 people to cancer risk greater than 100-in-1 million. The estimated incidence of cancer due to inhalation exposures from the source category is 0.9 excess cancer cases per year under the baseline. When the proposed option 2 requirements are implemented, an estimated 73 facilities would expose 1.1 million people to cancer risks greater than or equal to 1-in-1 million and 11 facilities would expose 1,368 people to cancer risks greater than or equal to 50-in-1 million. For the proposed option 2, the number of facilities with estimated cancer risks greater than 100-in-1 million falls to zero and the estimate of the population exposed to cancer risks greater than 100-in-1 million falls to zero people. The estimated cancer incidence due to inhalation exposures is 0.1 excess cancer cases per year under option 2, an 89 percent reduction compared to the baseline. Section 4.4 provides a brief summary of the risk analysis methods and findings. See section II.F of the preamble for a detailed description of the methods and section III.C for the risk analysis results.

The environmental justice analysis conducted for this proposed rule summarized the demographics of populations living within 10 km of commercial sterilization facilities as well as the demographics of populations living within 10 km of facilities with elevated cancer risks due to emissions from sterilization facilities under the baseline and under the proposed option 2. Under the baseline, the percentage of residents that are Hispanic or Latino is higher in census blocks near EtO sterilizers compared to the nationwide Hispanic or Latino percentage of the population. In areas characterized as having elevated cancer risk (*i.e.*, ≥50-in-1 million, >100-in-1 million) due to emissions from sterilization facilities under the baseline, the percentage of residents that are African American is high compared to the nationwide African American share of the population. These findings indicate potential for environmental justice concerns under the baseline.

Under the proposed option 2, the number of individuals exposed to elevated cancer risk declines relative to the baseline for all demographics, including large reductions for African American and Hispanic or Latino populations. Based on the estimated reductions in risk exposure, the proposed rule is expected to significantly reduce the number of people in all demographic groups exposed to risks greater than or equal to1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million relative to the baseline. However, the few facilities with higher (though still considered acceptable) post-control risk are concentrated in Puerto Rico, so a high share of the remaining individuals at higher risk (i.e., ≥50-in-1 million)

are Hispanic or Latino. While absolute risk declines significantly for Hispanic or Latino individuals after implementing the proposed requirements, the distribution of the lower remaining risk is more disproportionately concentrated among them compared to the baseline.

1.6.3 Impacts on Small Entities

Chapter 5 contains the Initial Regulatory Flexibility Analysis conducted for this proposed rule. The small entity impact analysis identified potential for this proposed rule to have a significant impact on a substantial number of small entities (SISNOSE). As such, the EPA did not certify a 'no SISNOSE' determination for this proposal.

Out of the 88 facilities expected to incur costs to comply with the proposed requirements, 24 facilities, or about 27 percent of facilities, are owned by ultimate parent companies that are classified as small entities based on the business size standards defined by the U.S. Small Business Administration (SBA).[9] There are 48 ultimate parent companies that own commercial sterilization facilities affected by this proposal, as several parent companies own multiple facilities. About 42 percent (20) of the 48 parent companies are small entities. There are 12 small entities (60 percent of all affected small entities) with estimated cost-to-sales ratios of 3 percent or greater under option 2.

1.6.4 Economic Impacts

The EPA was not able to model potential market impacts for this proposal. However, section 5.3 qualitatively dicusses potential market impacts of this proposed rule, such as the potential for sterilizers to raise prices of their services in response to regulation and how the medical device supply chain may be impacted. EtO sterilization services are a critical input in the provision of safe medical devices and there is uncertainty in how the proposal could potentially affect the medical device supply chain.

This proposed rule has the potential to impose significant costs relative to sales for some owners of affected facilities, particularly the owners that are small entities. Nonetheless, the qualitative information gathered on the industry suggests that demand for EtO sterilization services may be fairly inelastic, meaning demand may be insensitive to price changes and

[9] U.S. Small Business Administration. (2022). Table of Small Business Size Standards. Found at https://www.sba.gov/document/support-table-size-standards.

potential price increases could have minimal impact on the equilibrium quantity of products sterilized with EtO. Since demand for medical devices and healthcare services are generally considered inelastic, demand for EtO sterilization services may also be inelastic given how critical it is as an input for medical devices. Sterilization companies may be able to raise prices and pass some of the regulatory costs associated with this proposal down the supply chain to medical device manufacturers, hospitals, insurers, and end consumers. If able to pass on costs through higher prices, affected companies could potentially continue to ensure stable supply of medical devices while meeting the proposed regulatory requirements. If the costs of this proposed rule are spread out among several sectors in the medical device supply chain, overall market impacts could be minimal given the size of the medical device industry in the U.S.

Sterilization is generally a small input when considering the total costs of making and providing medical devices and healthcare services. If sterilization providers are able pass on regulatory costs by increasing the price of their services, effects on prices of devices and healthcare may be limited because price changes for inputs that are small are less likely to have large impacts on prices of end products (devices, healthcare services). While higher costs of sterilization may not present significant problems for medical device manufacturers, limited capacity in the EtO sterilization industry could still potentially disrupt the medical device supply chain if there are not enough sterilization providers available to accommodate the amount of devices that need to be sterilized with EtO. Capacity could be limited in the short run as firms adjust operations to comply with the proposed requirements. If the capacity of the industry were to potentially decline even temporarily due to the proposed rule, there could be increased risk of shortages for some devices.

1.6.5 Summary of Results

Table 1-2 summarizes the costs, benefits, and net benefits of the three regulatory options analyzed for this proposed rule.

Table 1-2. Summary of Benefits, Costs and Net Benefits for the Proposed Regulatory Options from 2023 to 2042 (Million 2021$[a])

	Option 1				Option 2 (Proposed)				Option 3			
	3 Percent		7 Percent		3 Percent		7 Percent		3 Percent		7 Percent	
	PV	EAV	PV	EAV	PV	EAV	PV	EAV	PV	EAV	PV	EAV
Total Monetized Benefits[b]	N/A		N/A		N/A		N/A		N/A		N/A	
Total Costs	$635	$43	$513	$60	$784	$53	$640	$74	$897	$60	$746	$85
Net Benefits	N/A		N/A		N/A		N/A		N/A		N/A	
Non-monetized Benefits	15 tpy of EtO Health effects of reduced EtO exposure				19 tpy of EtO Health effects of reduced EtO exposure				20 tpy of EtO Health effects of reduced EtO exposure			

[a] When necessary, dollar figures in this RIA have been converted to 2021$ using the annual GDP Implicit Price Deflator from the U.S. Bureau of Economic Analysis (BEA) NIPA Table 1.1.9, found at https://fred.stlouisfed.org/release/tables?rid=53&eid=41158.

[b] While we expect that these avoided emissions will result in reductions in adverse human health effects, we have determined that quantification of those benefits cannot be accomplished for this proposed rule. This is not to imply that there are no benefits of the proposal; rather, it is a reflection of the difficulties in modeling the health effects and monetizing the benefits of reducing HAP emissions from this source category with the data currently available.

1.7 Organization of this RIA

The remainder of this document is organized as follows. Chapter 2 provides a profile of the commercial EtO sterilization industry. Chapter 3 presents the engineering cost analysis. Chapter 4 provides information on the health risks associated with EtO exposure and summaries of the cancer risk analysis and environmental justice analysis conducted for this proposed rule. Chapter 5 includes the small entity analysis and discusses economic impacts. Chapter 6 summarizes the net benefits and chapter 7 contains references.

2 INDUSTRY PROFILE

2.1 Introduction

This chapter provides an overview of the use of ethylene oxide (EtO) in sterilization, background on the commercial EtO sterilization industry, and the steps in the EtO sterilization process. This section also provides information on the medical device industry. Although this proposed rule will not affect medical device manufacturers directly, unless the manufacturer also conducts sterilization using EtO, this industry profile would be incomplete without a characterization of the medical device sector and its relationship with commercial sterilizers. Sterilization is a key step in producing medical devices and medical device manufacturers are the primary consumers of EtO sterilization services. Medical devices are required to be sterile before they can be distributed in order to prevent disease transmission. The material in this chapter will be used to inform the discussion of potential economic impacts of the regulatory requirements being proposed for the EtO sterilization sector in section 5.3.

2.2 Ethylene Oxide Sterilization Background

Sterilization has been a key step in the medical device manufacturing process since the discovery of the role of bacteria in disease and infection. Healthcare products, or medical devices, are sterilized to reduce risks of infection from bacteria, fungi, and viruses. Terminal sterilization, the process of sterilizing a product in its final packaging, is often an essential, mandatory last step in the process of manufacturing healthcare products. Roughly 40 percent of the more than 2 million medical devices listed in the Global Universal Device Identification Database are sterilized before they reach end-users and patients (FDA 2019a).

Sterilization may be conducted ‘in-house’ by medical device manufacturers and hospitals or contracted out to commercial sterilization facilities. Reliance on contract sterilizers has grown significantly since the 1980s. A 2005 retrospective review of the Occupational Health and Safety Administration’s (OSHA) 1988 standards for occupational EtO exposure found that in-house sterilization had become far less common since the OSHA standards were promulgated (OSHA 2005). Contract sterilizers currently handle most sterilized healthcare products on the market.

This shift from in-house sterilization towards the use of contract sterilizers has been attributed to their better overall efficacy, time savings, and cost advantages in complying with regulations (GIPA 2017). Healthcare providers and manufacturers using an outside service can reduce the number of workers exposed to EtO and thus reduce their liability as employers (OSHA 2005). When a customer needs to use a variety of sterilization methods, using contract sterilizers avoids the need to invest in multiple types of sterilization technologies (OSHA 2005). Finally, many smaller medical technology companies are not familiar with the intricacies of the various regulations that affect sterilization facilities.

EtO is a gas that has been used in sterilization since the 1930s and is currently used to sterilize over 20 billion healthcare products per year in the U.S. (EOSA 2022). This represents over 50 percent of healthcare products used annually in the U.S. (FDA 2022). EtO sterilization grew rapidly in the U.S. and worldwide throughout the 20th century, particularly after the Montreal Protocol's ban on chlorofluorocarbons (CFCs) in 1985. In countries that ratified the Montreal Protocol, sterilization providers shifted from using CFCs toward EtO (OSHA 2005). The 1980s and 1990s also saw a decline in the use of blends of EtO with either CO_2 or hydrochlorofluorocarbons (HCFCs) in favor of 100 percent pure EtO (GIPA 2017). Today, hundreds of thousands of medical, pharmaceutical, hospital, and laboratory processes involve equipment sterilized with EtO (EOSA 2022). Examples of key products that rely on EtO include personal protective equipment, diagnostic testing kits, heart valves, pacemakers, surgical kits and trays, stents, dialysis sets, gowns, drapes, ventilators, syringes, bandages, and catheters (FDA 2019a).

Most of the EtO consumed in the U.S. is used for purposes other than sterilization. The majority of EtO is used as feedstock by the chemical industry or by manufacturers of products such as adhesives, plastics, detergents, polyurethane foam, fumigants, and textiles (OSHA 2002). EtO is commonly used to produce ethylene glycol, a chemical that is used to make antifreeze and polyester (ATSDR 2022). One source estimates that less than one percent of the EtO used in the U.S. is purposed for sterilization of healthcare products (EOSA 2022).

The primary customers of EtO sterilization businesses are pharmaceutical and biotechnology companies, hospitals, medical and surgical clinics, academic and research organizations, and food product manufacturers. In addition to medical and dental supplies, EtO is

used to sterilize some spices and cosmetics. The American Spice Trade Association estimated that 40 to 85 percent of spices produced in the U.S. each year are sterilized with EtO (ASTA 2009). Common spices like black pepper, oregano, and cinnamon are subject to natural contamination from pathogens like *Salmonella* and *E.coli*. EtO is the industry's preferred sterilant because it does not affect the color, texture, and flavor of spices (ASTA 2009). Spice sterilization accounts for less than 10 percent of the EtO used for commercial sterilization purposes in the U.S., with annual usage estimated at approximately 400 tons in the 2000s (ASTA 2009). Since most EtO sterilization is dedicated to medical devices, the remainder of this section and the economic impacts section in chapter 5 focuses primarily on the role EtO plays in the medical device supply chain.

EtO is the most common sterilization method for medical devices for several reasons. It is the preferred sterilant for heat and moisture sensitive products because of its effectiveness at relatively low temperatures and humidity levels (FDA 2019a). Less than 5 percent of devices, mostly those made of metal, are sterilized with steam. Products made of heat-intolerant materials like plastics or resins, products which cannot withstand moisture like wound dressings, and products with hard-to-reach crevices (e.g., catheters) rely almost entirely on EtO (FDA 2019a; CDC 2016). EtO can accommodate a wide variety of products and materials commonly found in medical devices, including plastics, resins, adhesives, metals, glass, and biologics.

Many healthcare products cannot be sterilized by any other method than EtO because they would be destroyed or rendered unusable. Medical devices require thorough sterilization but often cannot withstand alternative sterilization methods such as radiation, moist heat, dry heat, or other chemicals such as peracetic acid, chlorine dioxide, hydrogen peroxide, and nitrogen dioxide (GIPA 2017). The sterilization method is selected to meet the individual needs of a device or product according to its materials and design principles. At the same time, many medical devices and pharmaceuticals are intentionally designed to be compatible with EtO (GIPA 2017).

EtO is the preferred or exclusive sterilant for polymer resin-based products, single-use medical devices, pharmaceutical agents, procedure kits, surgical trays, synthetic gowns, and sealed combination drug devices like syringes and stents (Sterigenics 2019). Complex devices and implantable devices are especially unlikely to be able to use a sterilization method other than

EtO (EOSA 2018; GIPA 2017). The number and complexity of the components found in medical and surgical kits are increasing over time. As such, these kits are increasingly likely to contain at least one component unable to rely on sterilization methods other than EtO (GIPA 2017). Once a medical device manufacturer has determined the appropriate sterilization modality and must select a sterilization provider, important considerations include the availability and location of the sterilizer, cost, and the volume of product needing sterilization (GIPA 2017).

2.3 Overview of Sterilization Process

The EtO sterilization process generally consists of pre-conditioning the load, air removal from the sterilization chamber, EtO exposure, and nitrogen gas and air flushing, followed by aeration. The rate of the microbial kill of the process depends on key parameters including time, temperature, humidity, and EtO concentration. Since EtO is flammable, facilities must conduct safety assessments for new processes to evaluate the probability of ignition in worst case and single point failure scenarios (Sterigenics 2018).

Large sterilization chambers can accommodate loads the size of a shipping container, and loads may be comprised of different types of products that share physical and chemical characteristics. Parameters of the process are assigned to product groupings based on attributes like packaging type, density, material composition, heat tolerance, sensitivity to pressure, and chemical reaction to water vapor (Shintani 2017). The "validation" specifies these parameters. New products can be added to the cycle for a given product group so long as they are no more difficult to sterilize under the cycle conditions than the most challenging product in the group to sterilize, which is identified in the validation.

Before the EtO process, products are placed in sterile barrier packaging where they remain until reaching the end user. At the start of the process, a product load is pre-conditioned to a certain temperature and moisture level. To prepare the sterilization chamber for gas introduction, air is removed through a vacuum. When the desired pressure conditions have been achieved, EtO is introduced and the product is exposed for a period, known as the dwell time. Facilities receive EtO as a liquid and must vaporize it into a gas (Steris 2019). The EtO is then evacuated from the chamber and the load is aerated to reduce the residual EtO on the product to protect patient safety. The following is a more detailed characterization of the major phases of EtO sterilization and their timing:

1. **Preconditioning** - the product load is configured and placed in an area under pre-validated temperature and relative humidity conditions for several hours to several days (FDA 2019a). Higher temperatures and moisture levels improve the kill rate of EtO (Lambert 2013).

2. **Sterilization** - the product load is transferred from the preconditioning area to the sterilization chamber where a vacuum is used to attain desired pressure conditions and customized levels of EtO gas, nitrogen gas, and steam are applied for 8 to 16 hours to reach a certain EtO concentration level. This phase is comprised of several steps:

    a. Before EtO gas enters the chamber, vacuum is applied to remove air/oxygen and nitrogen gas is injected because EtO is flammable at concentrations above 3 percent or 30,000 parts per million (MDDI 2001). The amount of nitrogen injected must increase to evacuate the air when the pressure is higher (Steris 2019b).

    b. After air/oxygen removal, EtO is diffused in the chamber until the desired concentration is reached. During the dwell period, EtO disrupts the DNA of microbial organisms via alkylation, rendering them unable to reproduce or function properly (GIPA 2017). Steam is continuously supplied to replenish the moisture lost through the vacuum (Steris 2019).

    c. After the dwell period, most of the EtO must be removed via vacuum cycles and nitrogen washes before the chamber can be opened. More vacuum and nitrogen wash cycles are needed for batches with higher peak EtO concentrations. Air is then injected to equalize pressure in the chamber before it can be opened (Steris 2019b).

3. **Aeration** - the product load is washed with heated air for 1 to 7 days to allow EtO residues and byproducts like ethylene glycol to dissipate. The length of this phase is an important cost factor that varies based on the ease of aerating the product load, peak EtO concentration during the exposure phase, and the product's intended use. Some facilities carry out aeration in a separate chamber and others may conduct sterilization and aeration in one chamber (Shintani 2017). Air injections may be supplemented with nitrogen and/or carbon dioxide gases to speed the aeration process (GIPA 2017). The product is

market ready when EtO residues have been reduced to the acceptable level specified in the validation.

The EtO process is tailored to each product or group of products to consistently deliver the level of sterility needed. Sterilization facilities conduct extensive testing to identify the correct levels of the key parameters that determine a cycle's efficacy, including temperature, humidity, pressure, exposure time, and EtO gas concentration (GIPA 2017). EtO concentration is the most important element because it must reach a certain level for sterility to be achieved but also must be balanced with the maximum allowable EtO residuals on the product (FDA 2019a). In addition to the physical configuration of the load, a cycle's EtO concentration and exposure time depend on the nature and complexity of the products being sterilized, including their materials, porosity, surface area, density, volume, residue requirements, and sensitivity to other parameters in the process.

The microbial kill rate of EtO increases at higher temperatures. If products can withstand higher temperatures, this can reduce dwell/exposure and aeration times and reduce EtO residuals on the product. Relative humidity also impacts exposure time because water vapor increases material porosity. EtO can penetrate both the product and the cell walls of microbial organisms more easily in high moisture conditions (Dvorak 2015). Vacuums are used to displace air from the EtO chamber to prevent combustion, though some products cannot withstand low pressure conditions. A deeper vacuum and thus a lower pressure environment are associated with better efficiency during pre-exposure air removal, exposure, and post-exposure EtO removal (MDDI 1998). When more shallow vacuums are applied for pressure sensitive loads, more nitrogen washes and aeration time are needed to complete the cycle (MDDI 1998).

2.4 Other Regulatory Background

In addition to the EPA's NESHAP for the sector, EtO sterilization facilities are also regulated by the EPA's Office of Chemical Safety and Pollution Prevention, other federal agencies including FDA and OSHA (29 CFR 1910.1047), and various state and local governments.

Sterilization procedures for most medical devices are reviewed and validated by the FDA before they can be made available on the market. Some medical devices require a 501(k)

clearance and/or Pre-Market Approval (PMA). The FDA regulates the outcome of a sterilization process, though it does not regulate commercial sterilization facilities directly aside from some reporting requirements discussed below.

To validate the efficacy of a sterilization procedure for a medical device, manufacturers work with commercial sterilization facilities and follow data intensive protocols designed to demonstrate consistent, reproducible sterility. Devices are classified into one of three regulatory classes (I, II, and III) based on risk (*e.g.*, internal vs. external use) and the level of control needed to ensure the safety and effectiveness of the device. It must be proved that the probability of viable microorganisms on a product has been reduced to an acceptable risk level, which is known as the Sterility Assurance Level (FDA 2019b). The FDA also dictates the acceptable amount of EtO residue that can remain on different types of products after sterilization, since certain levels of exposure can cause adverse health effects.

Sterilization facilities themselves are required to submit Establishment Inspection Reports (EIRs) to the FDA describing their site's features, equipment, and process monitors. The EIR also must detail how key variables are controlled in each phase of a cycle, which for EtO includes humidity, gas concentration, degassing, aeration, pressure, exposure time, and temperature (FDA 2014).

When a device manufacturer changes its sterilization facility, method, or cycle parameters, it often needs to submit a supplement to its original premarket submission for the FDA to review and approve (FDA 2019c). If sterilization facilities close, the supply chain for medical devices can be impacted because completing the revalidation for a single product can potentially take months before the product can be switched to a new sterilization site. Validating a different modality of sterilization, if feasible, requires more extensive testing and documentation. For devices requiring revalidations, manufacturers may lose revenue and incur costs related to testing, data collection, and documentation requirements. In some cases, changing the sterilization method could potentially prompt a manufacturer to undertake a design reconfiguration for the medical device (EOSA 2018).

2.4.1 Capacity Constraints

The FDA has noted that any reductions in the capacity of the commercial EtO sterilization industry can increase the likelihood of shortages for some medical devices, since most EtO sterilization facilities operate continuously at near full capacity with few breaks and most manufacturers cannot use any alternative methods to substitute for EtO (FDA 2019a). The FDA has identified supply chain risks for some EtO-dependent medical devices, such as some types of feeding tubes and catheters, due to lack of spare capacity in the EtO sterilization sector to absorb additional throughput. The FDA has also noted the potential for supply chain issues for spices if capacity declines in the commercial EtO sterilization industry. The EPA is taking comment on whether facilities affected by this proposed rule would need to close temporarily to complete upgrades.

As discussed, the ability to shift away from EtO is constrained by device compatibility factors, lacking availability and industrial scale for alternative modalities, and other costs associated with switching modalities such as higher prices, location and transportation issues, and the revalidation process (FDA 2019a). FDA outreach to manufacturers of devices that were deemed at risk for shortages indicated that all the firms' shortage mitigation plans involved either switching the EtO sterilization site to a different location or distributing other unaffected devices to replace the ones affected by the shortage, while none of the firms planned to respond by using an alternative method of sterilization (FDA 2019a). The FDA highlighted higher risks of shortages for implantable devices and products used in surgical procedures due to their sterility requirements.

In response to concerns regarding risk of shortages of some devices that rely on EtO, the FDA is working with private companies to increase innovation in alternative sterilization technologies that might in the future be able to accommodate EtO-reliant products once the technologies are proven to be effective and scalable. It should be noted, however, that there are no alternative sterilization methods for a substantial portion of medical devices and alternative modalities for highly EtO-dependent products are unlikely to be available in the near future. As mentioned, when device manufacturers change sterilization sites, methods, or process parameters (*e.g.*, peak EtO concentration), some products need approval from the FDA (FDA 2019c). There may be efforts to facilitate and speed the process for completing revalidations to reduce supply

chain risks if device manufacturers need to switch sterilization sites or if sterilizers lower the amount of EtO used in their cycles to comply with emission reduction requirements.

2.5 Overview of Medical Device Industry

The medical device industry is primarily engaged in manufacturing medical, surgical, ophthalmic, and veterinary instruments. Examples include syringes, hypodermic needles, anesthesia apparatus, blood transfusion equipment, catheters, surgical clamps, and medical thermometers. The medical device industry has grown in volume and diversity to accommodate a growing population, longer life expectancies, and increasing demand for surgical procedures and pharmaceuticals. Expenditures on medical devices in the U.S. have grown from about $86 billion in 2000 to $153 billion in 2010 and nearly reached $200 billion in 2019 (Donahoe 2021). Census Bureau data indicate that about 5 to 6 percent of total annual healthcare spending in the U.S. between 1989 and 2019 was consistently spent on medical devices (Donahoe 2021). The roughly $200 billion spent on medical devices in the U.S. in 2019 accounted for 5.2 percent of total healthcare expenditures that year.

2.5.1 Market Structure

The medical device industry is composed of a large number of relatively small companies and a small number of very large, well-diversified companies. These larger firms tend to have more market power, face less competition, and see bigger profit margins. A 2015 study found that the top 1 percent of firms by asset holdings held about 80 percent of the industry's total assets in 2012, so the industry is highly concentrated (CRS 2015).

From 2009 to 2019, prices for medical devices in the U.S. grew more slowly than both the overall Consumer Price Index and the Medical Consumer Price Index, which would tend to indicate that the industry as a whole is competitive (Donahoe 2021). Market dynamics in the medical device industry vary by product type. The market for the more simple and ubiquitous products such as surgical gloves and wound dressings is highly competitive and producers generally have low profit margins. Simple devices must be made in high volumes under secure long-term contracts with large buyers like hospital chains for producers to break even (Medpac 2017). More sophisticated medical devices such as pacemakers and implantables tend to earn higher profits but firms must overcome higher barriers to entry in those markets, including

significant research and development costs, regulatory hurdles, and patents (Medpac 2017). Small and mid-size companies tend to concentrate their efforts on the more niche devices (CRS 2015).

2.5.2 Excise Tax Case Study

A 2015 Congressional Research Service (CRS) report estimated how the supply of medical devices responded to an excise tax, finding that a tax of 2.3 percent caused a relatively small decrease in medical device output of 0.2 percent. The findings of this report may be informative for the purposes of this analysis because excise taxes and regulation both act as costs for an industry and presumably could have the same impact on market behavior so long as the regulatory costs imposed are equal to the value of the tax.

The CRS attributed the small effect of the excise tax on the supply of medical devices to insensitive demand for medical devices and the small size of the tax. The CRS concluded that the tax was unlikely to result in profit losses for the industry, including small and midsized firms, because medical device companies can pass a large share of the tax on to consumers. The CRS reached this conclusion based on evidence that the demand for medical devices does not fall much when prices rise.

The report highlighted several nuances in the medical device market that may be relevant to our characterization of potential market impacts of regulating the commercial sterilization sector. First, they note the high degree of concentration in the medical device industry. As mentioned above, a small number of large companies in the medical device industry likely hold market power, which could indicate that they may be able to resist price increases to some degree from sterilization companies looking to pass regulatory costs on to firms they contract with. Nonetheless, EtO sterilization is also fairly concentrated among a few big firms who may hold market power, so the degree to which regulated commercial sterilizers might be able to pass costs on to medical device manufacturers is uncertain and likely varies depending on the market share held by the sterilizer and by the device manufacturer they are negotiating with. Many devices cannot switch to sterilization methods other than EtO, which could also increase the ability of EtO sterilization firms to pass regulatory costs on to device manufacturers that cannot easily use a different method with lower costs.

The report also suggested that despite the high degree of concentration in the medical device industry, their ability to fully pass on the entire burden of a tax may have been limited by the presence of large intermediaries with purchasing power (*e.g.*, large hospital chains, insurers, the federal government). This dynamic in the medical device supply chain is potentially relevant in analyzing how regulatory impacts on commercial EtO sterilizers may trickle down to downstream sectors. Collectively, the different aspects of the CRS's characterization of the medical device industry indicate that there is uncertainty regarding the degree affected EtO sterilization firms may be able to pass regulatory costs down the supply chain. The share of regulatory costs passed on to intermediate or end users will depend on the mix of market power held by medical device makers and the purchasers of sterilized devices. It is plausible that costs could be spread across several parties, including the sterilizers themselves, medical device manufacturers, hospitals, insurance companies, and end consumers. For a broader discussion of the potential supply and demand responses to this regulatory action, please see section 5.3.

3 ENGINEERING COST ANALYSIS

3.1 Introduction

This section explains how the compliance costs associated with this proposed rule were estimated. The costs and emission reductions of the three options were assessed relative to a regulatory baseline that represents the status quo. The costs were estimated by multiplying facility and source counts by engineering cost estimates for the various requirements proposed in the rule. The engineering costs are also tailored to the configurations for many facilities. Assumed configurations were also applied for some facilities.

3.2 Affected Facilities

The EPA estimated costs for 88 commercial EtO sterilization facilities, including the 86 active facilities currently affected by subpart O and two planned facilities that are assumed to start operating before the proposed compliance deadline. Based on actual EtO usage data, 49 facilities use at least 10 tpy of EtO, 19 facilities use at least 1 tpy but less than 10 tpy of EtO, and 20 facilities use less than 1 tpy of EtO. Additionally, for purposes of the Group 2 room air emissions standards, there are 43 facilities that use less than 20 tpy and 45 that use at least 20 tpy of EtO. Finally, for purposes of the health-based SCV standards, there are 38 facilities that use at least 40 tpy of EtO, 11 facilities that use at least 10 tpy but less than 40 tpy of EtO, and 39 facilities that use less than 10 tpy of EtO. It was assumed that all these facilities would continue to operate and be affected by the proposed rule throughout the 20-year analytical timeframe from 2023 to 2042. Beyond the two planned facilities included in the analysis, the EPA did not estimate compliance costs for any other new sources that may become affected by this proposed rule in the future.

3.3 Emissions Points

The original subpart O NESHAP promulgated in 1994 addressed EtO emissions originating from three emission points: the sterilization chamber vent (SCV), aeration room vent (ARV), and chamber exhaust vent (CEV). The SCV evacuates EtO from the sterilization chamber following sterilization and any subsequent gas washes. The ARV evacuates EtO-laden air from the aeration chamber. The CEV evacuates EtO-laden air from the sterilization chamber

after the chamber door is opened for product unloading to reduce employee exposure to EtO. This rule establishes standards and proposes revisions to several of the current emissions standards for SCVs, ARVs, and CEVs.

This proposed rule also establishes emissions standards for room air emissions, which were not regulated under the original 1994 NESHAP or the 2006 RTR. Room air emissions, also known as fugitive emissions, come from sources and processes such as EtO storage and dispensing, handling of sterilized product, and air pollution control devices (APCDs). For purposes of this proposal, room air emissions sources include: indoor EtO storage, EtO dispensing, vacuum pump operation, pre-aeration handling of sterilized material, post-aeration handling of sterilized material, and the non-oxidizer APCD area. The EPA is proposing standards for two types of room air emissions, Group 1 and Group 2. Group 1 room air emissions come from indoor EtO storage, EtO dispensing, vacuum pump operation, and pre-aeration handling of sterilized material. Group 2 room air emissions are released during post-aeration handling of sterilized material.

3.4 Baseline

The impacts of regulatory actions are evaluated relative to a baseline that represents the world without the regulatory action. This RIA presents incremental impacts of the proposed amendments to the subpart O NESHAP relative to the baseline. The analysis focuses on the proposed requirements that result in quantifiable compliance cost or emissions changes compared to the baseline. The EPA assumed each facility achieved emissions control sufficient to meet the current standards and estimated the emissions reductions and cost of the proposed requirements relative to this baseline. Table 3-1 contains the baseline regulatory requirements in the subpart O NESHAP.

Table 3-1. Baseline Subpart O Requirements

Existing and new sources subcategory	Sterilization chamber vent (SCV)	Aeration room vent (ARV)	Chamber exhaust vent (CEV)[a]
Sources using 10 tons or more of EtO in any consecutive 12-month period	99% emission reduction	1 ppm maximum outlet concentration or 99% emission reduction	No control
Sources using 1 ton or more of EtO but less than 10 tons of EtO in any consecutive 12-month period	99% emission reduction	No control	No control
Sources using less than 1 ton of EtO in any consecutive 12-month period	Recordkeeping	Recordkeeping	Recordkeeping

[a] The CEV emission source was included in the original standard but was later eliminated in 2001.

Table 3-2 shows annual HAP emissions from the source category under the baseline. Baseline emissions of EtO from the 86 subpart O facilities are estimated to be 23 tons per year (tpy).

Table 3-2. Baseline Annual HAP Emissions from Subpart O Facilities

HAP	Emissions (tpy)	Number of Facilities
Ethylene Oxide	23	86
Propylene Oxide	0.7	7

3.5 Proposed Requirements

The EPA is proposing emission standards to fill regulatory gaps under CAA section 112(d)(2), (3), and (5) and proposing risk-based standards under CAA section 112(f)(2) to ensure that risks are acceptable and provide an ample margin of safety to protect public health. The EPA is also proposing changes to startup, shutdown, and malfunction (SSM) provisions; monitoring, recordkeeping, and reporting requirements; and performance testing requirements.

To begin, for the following emissions sources that are currently unregulated, the EPA is proposing to set standards under CAA sections 112(d)(2) and (3), or (d)(5): SCV, ARV, and CEV at facilities where EtO use is less than 1 tpy, ARV and CEV at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEV at facilities where EtO use is at least 10 tpy, and two types of room air emissions. Room air emission sources are grouped into activities that occur prior to aeration (Group 1) and activities that occur after aeration (Group 2). MACT standards are being

proposed for the two groups of room air emissions at major sources and GACT standards are being proposed for the two groups of room air emissions at area sources.

To address unacceptable remaining risk and ensure an ample margin of safety, the EPA is proposing health-based standards for SCVs, ARVs, and certain room area emissions. The stringency of the proposed health-based standards varies based on a facility's annual EtO usage. The usage groupings in the proposed standards are intended to address emissions from facilities identified as high risk while mitigating the compliance burden for lower risk facilities. The EPA is proposing health-based emission standards for SCVs at facilities where EtO use is at least 40 tpy, SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy, SCVs at facilities where EtO use is at least 1 tpy but less than 10, and Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy.

Finally, the technology review identified more stringent emission standards that could be applied to ARVs at facilities where EtO use is at least 10 tpy with minimal additional economic impact. The EPA is also co-proposing the same requirements under (d)(6) that are being proposed under CAA 112(f)(2) for SCVs at facilities where EtO use is at least 10 tpy and SCVs at facilities where EtO use at least 1 tpy but less than 10 tpy.

Table 3-3 lists the proposed standards for currently unregulated sources and the standards being proposed to address unacceptable remaining risk and provide an ample margin of safety.

Table 3-3. Proposed Standards (Option 2)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new	At least 10 tpy	99.94% emission reduction	112(f)(2) and (d)(6)
		At least 1 but less than 10 tpy	99.8% emission reduction	112(f)(2) and (d)(6)
		Less than 1 tpy	99% emission reduction	112(d)(5)
ARV	Existing	At least 10 tpy	99.6% emission reduction	112(d)(6)
		At least 1 but less than 10 tpy	99% emission reduction	112(d)(5)
		Less than 1 tpy	99% emission reduction	112(d)(5)
	New	At least 10 tpy	99.9% emission reduction	112(d)(6)
		At least 1 but less than 10 tpy	99% emission reduction	112(d)(5)
		Less than 1 tpy	99% emission reduction	
CEV	Existing and new	At least 10 tpy	3.2E-4 lb/hr	112(d)(2) and (3)
		At least 1 but less than 10 tpy	99% emission reduction	112(d)(5)
		Less than 1 tpy	99% emission reduction	112(d)(5)
Group 1 room air emissions at major sources	Existing and new	N/A	1.3E-3 lb/hr	112(d)(2) and (3)
Group 1 room air emissions at area sources	Existing and new	N/A	1.3E-3 lb/hr	112(d)(5)
Group 2 room air emissions at major sources	Existing and new	N/A	2.8E-3 lb/hr	112(d)(2) and (3)
Group 2 room air emissions at area sources	Existing	At least 20 tpy	2.8E-3 lb/hr	112(f)(2)
		Less than 20 tpy	Follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 14161:2009	112(d)(5)
	New	N/A	2.8E-3 lb/hr	112(d)(5)

The EPA is also proposing revisions related to performance testing; monitoring, reporting, and recordkeeping requirements; requirements during periods of startup, shutdown, and malfunction (SSM); and other minor technical improvements. The EPA is proposing to require monitoring either with an EtO continuous emissions monitoring system (CEMS) or initial and annual performance testing with continuous parameter monitoring.

The standards described above represent option 2. This RIA also assesses costs for the less stringent option 1 and more stringent option 3. The regulatory alternatives are summarized below.

Option 1: Apply GACT standards to all currently unregulated emissions at area source facilities. The current standards for regulated point sources would not be updated.

Option 2 (proposed): Apply GACT standards to all currently unregulated emissions at area source facilities. Then, based on results of the post-control risk assessment, revise established and newly proposed standards pursuant to CAA section 112(f)(2), considering economic feasibility after risk has been determined to be acceptable.

Option 3: Revise established emission limitations and propose new limitations for all currently unregulated emissions to the most stringent levels that are considered in the preamble.

3.6 Engineering Costs

A key component of the total costs estimated for this proposal is the cost to implement the room air emissions requirements to meet the MACT limits under option 1 and/or the health-based standards under option 2. Affected facilities must install a permanent total enclosure (PTE) and/or solid or gas reactor systems to comply with the room air emissions requirements. A second major component is the cost to install, operate, and maintain solid or gas reactor systems to meet the MACT limits and/or health-based standards for the sterilization chamber vent (SCV), aeration room vent (ARV), and chamber exhaust vent (CEV). Another key cost is associated with the monitoring and testing requirements, which includes capital and annual costs associated with a continuous emissions monitoring system (CEMS) or the recurring costs associated with performance testing, depending on the facility. Other cost items include the one-time costs to complete cycle revalidations and the annual costs associated with recordkeeping and reporting.

The engineering costs estimated for the different requirements and the number of facilities affected by those requirements across the three regulatory options are presented in Table 3-4. The ‘total annualized costs’ are the sum of the annualized capital costs and other annual costs (*e.g.*, operating and maintenance costs, recordkeeping and reporting costs). The EPA also included the total costs to complete cycle revalidations in the total annualized costs, even though these costs are only expected to be incurred once in Year 1. This was done to

simplify the presentation by providing one consistent total annualized cost estimate for each regulatory option, since the total annualized costs would be different in Year 1 than in Years 2-20 due to the one-time costs. The revalidation costs are not considered capital costs, so they should not be annualized and spread out over the time horizon. Including the Year 1 one-time costs in the total annualized cost figure yields a more conservative, or higher, estimate. Nonetheless, since the revalidation costs are relatively small, the total annualized costs for Year 1 are only slightly higher than for Years 2-20. To see how the costs vary across the years in the analytical timeframe (2023 to 2042), see Table 3-6 through Table 3-8.

Annualization of capital costs involves establishing an annual "payment" sufficient to finance the investment over the expected lifetime of the equipment or loan period. This payment is typically referred to as the "capital recovery cost." To obtain annualized capital costs, a capital recovery factor is applied to capital costs. The capital recovery factor is based on the lifetime of the capital equipment as well as the interest rate. To annualize the capital costs, the EPA assumed a 7.75 percent interest rate,[10] a 20-year lifetime for a permanent total enclosure (PTE), a 20-year lifetime for a gas or solid reactor system, and a 10-year lifetime for the CEMS capital.

The room air emissions requirements are the most costly aspect of the proposal to implement. The costs associated with the gas/solid reactors account for the largest share of the capital and annualized costs for the sector under all three regulatory options.

For most of the cost components in Table 3-4, the option 3 costs are the highest and the option 1 costs are the lowest. The recordkeeping and reporting costs as well as the monitoring and testing costs are the same across all three options. The PTE costs are generally driving the higher costs of option 3 compared to the proposed option 2. Under option 1, costs are lower than the proposed option mainly because fewer facilities would need PTE and gas/solid reactors to comply compared to the proposed option 2. However, the cycle revalidation costs are highest under option 1. This is because option 1 would require all facilities to complete cycle revalidations (as opposed to imposing an emission limit) while option 2 would only require revalidations for facilities where annual EtO use is less than 20 tpy and option 3 would not require them for any facilities.

[10] The 7.75 percent interest rate was obtained from https://fred.stlouisfed.org/series/PRIME on February 10, 2023.

Table 3-4. Engineering Costs and Number of Facilities Affected by Emissions Point or Cost Component across Regulatory Options (millions of 2021$)

	Option 1 (less stringent)	Option 2 (Proposed)	Option 3 (more stringent)
Permanent Total Enclosure			
Facilities Affected	24	26	47
Capital Costs	$43.8	$65.8	$142.9
Annual O&M Costs	$0.2	$0.4	$1.0
Total Annualized Costs	$4.6	$7.0	$15.3
Gas/Solid Reactors			
Facilities Affected	58	57	62
Capital Costs	$82.1	$133.9	$144.8
Annual O&M Costs	$13.6	$19.0	$20.2
Total Annualized Costs	$21.8	$32.4	$34.7
Monitoring and Testing			
Facilities Affected	87	87	87
Capital Costs	$19.9	$19.9	$19.9
Annual O&M Costs	$8.2	$8.2	$8.2
Total Annualized Costs	$11.2	$11.2	$11.2
Recordkeeping and Reporting			
Facilities Affected	88	88	88
Total One-time Costs	$6.5	$6.5	$6.5
Annual O&M Costs	$8.6	$8.6	$8.6
Total Annualized Costs	$15.2	$15.2	$15.2
Cycle Revalidations			
Facilities Affected	84	41	0
Total One-time Costs	$13.1	$2.5	$0.0
TOTAL COSTS			
Facilities Affected	88	88	88
Capital Costs	$145.8	$219.6	$307.6
Annual O&M Costs	$30.7	$36.3	$38.1
One-time Costs	$19.6	$9.0	$6.5
Total Annualized Costs	$65.8	$68.2	$76.3

Total annualized costs include annualized capital costs, annual operating and maintenance costs, and one-time costs.

Additional information about the development of the cost estimates and assumptions can be found in the *Proposal Technical Support Document: Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP*, in the docket.

3.6.1 Summary Cost Tables

Table 3-5 shows a summary of the costs of the proposed rule by option. To obtain total annualized costs, a capital recovery factor is applied to capital costs, which then are summed with other annual costs (*e.g.*, operating and maintenance costs). The capital recovery factor is based on the assumed lifetime of the capital equipment and the interest rate.

The capital cost for option 1, the least stringent option analyzed, is estimated to be $146 million in 2021 dollars. The total annualized costs for option 1 are estimated to be $66 million. The capital cost for option 2, the proposed option, is estimated to be $220 million. The total annualized costs for option 2 are estimated to be $68 million. The capital cost for option 3, the most stringent option analyzed, is estimated to be $308 million. The total annualized costs for option 3 are estimated to be $76 million.

Table 3-5. Engineering Cost Summary (millions of 2021$)

	Capital Cost	Annualized Capital Cost [a]	Annual O&M Costs	One-time Annual Costs [b]	Total Annualized Cost [c]
Option 1	$146	$16	$31	$20	$66
Option 2 (Proposed)	$220	$23	$36	$9	$68
Option 3	$308	$32	$38	$7	$76

[a] Capital costs were annualized over the lifetime of the equipment at a 5% rate. The EPA assumed a 20-year lifetime for the capital costs of PTE, a 20-year lifetime for a gas/solid reactor, and a 10-year lifetime for CEMS.

[b] These are non-capital costs incurred one time in Year 1.

[c] Total annualized costs equal the sum of annualized capital costs, annual operating and maintenance costs, and one-time annual costs.

As part of fulfilling the analytical requirements of EO 12866, the EPA presents estimates of the present value (PV) of the costs over the period 2023 to 2042. Costs are in 2021 dollars and discounted to 2023 at 3 percent and 7 percent discount rates per direction in OMB Circular A-4. The EPA also presents the equivalent annualized value (EAV) at 3 percent and 7 percent discount rates. The EAV takes the "lumpy" stream of costs *(i.e.*, different costs in different years) and converts them into a single value that, if paid each year from 2023 to 2042, would equal the original stream of values in present value terms. In other words, a sum of constant EAVs across time periods in present value terms yields the total present value (*i.e.*, the total discounted stream of costs).[11]

[11] The equivalent annualization procedure value takes the "lumpy" stream of costs *(i.e.*, different costs in different years) and converts them into a single value that, if paid each year would equal the original stream of values in present value terms. In other words, the sum of EAVs across time periods in present value terms yields the present value (*i.e.*, the total discounted stream of costs). The EPA also often presents "annualized" costs in its RIAs, which are used by engineers to determine a series of equal annual payments across years over a time period that fully finances a capital project. To obtain total annualized costs, a capital recovery factor is applied to capital costs, which then are summed with other annual costs (*e.g.*, maintenance costs). The capital recovery factor is based on the assumed lifetime of the capital equipment and the interest rate. Annualized costs can differ from equivalent annualized costs when the lifetime of the capital equipment differs from the length of

Table 3-6 through Table 3-8 show the capital costs, annual costs, and total annualized costs for each year in the analytic timeframe, in addition to the total PV and EAV of the costs over 2023 to 2042 in 2021 dollars. The PV of the costs for option 1 is estimated to be $635 million at a 3 percent discount rate. The PV of the costs for option 1 is estimated to be $513 million at a 7 percent discount rate. The EAV of the option 1 costs is estimated to be $43 million at a 3 percent discount rate and $60 million at a 7 percent discount rate. For the proposed option 2, the PV of the costs is estimated to be $784 million at a 3 percent discount rate and $640 million at a 7 percent discount rate. The EAV of the option 2 costs is estimated to be $53 million and $74 million at 3 percent and 7 percent discount rates, respectively. Finally, for option 3, the PV of the costs is estimated to be $897 million at a 3 percent discount rate and $746 million at a 7 percent discount rate. The EAV of the option 3 costs is estimated to be $60 million and $85 million at 3 percent and 7 percent discount rates, respectively.

the analytical time horizon or if the interest rate used to annualize the capital costs differs from the discount rate used to obtain the PV. Annualized compliance costs are used in comparison with parent company annual revenues to obtain cost-to-sales ratios for use in small business screening analyses.

Table 3-6. Option 1 Cost Impacts (millions of 2021$)

	Capital Costs	Annual Costs (undiscounted)		Discounted Costs (3%)	Discounted Costs (7%)
2023	$146	$50		$196	$196
2024		$31		$30	$29
2025		$31		$29	$27
2026		$31		$28	$25
2027		$31		$27	$23
2028		$31		$26	$22
2029		$31		$26	$20
2030		$31		$25	$19
2031		$31		$24	$18
2032		$31		$24	$17
2033		$31		$23	$16
2034		$31		$22	$15
2035		$31		$22	$14
2036		$31		$21	$13
2037		$31		$20	$12
2038		$31		$20	$11
2039		$31		$19	$10
2040		$31		$19	$10
2041		$31		$18	$9
2042		$31		$17	$8
			PV	$635	$513
			EAV	$43	$60

Table 3-7. Option 2 Cost Impacts (millions of 2021$) (Proposed)

	Capital Costs	Annual Costs (undiscounted)		Discounted Costs (3%)	Discounted Costs (7%)
2023	$220	$45		$265	$265
2024		$36		$35	$34
2025		$36		$34	$32
2026		$36		$33	$30
2027		$36		$32	$28
2028		$36		$31	$26
2029		$36		$30	$24
2030		$36		$29	$23
2031		$36		$29	$21
2032		$36		$28	$20
2033		$36		$27	$18
2034		$36		$26	$17
2035		$36		$25	$16
2036		$36		$25	$15
2037		$36		$24	$14
2038		$36		$23	$13
2039		$36		$23	$12
2040		$36		$22	$11
2041		$36		$21	$11
2042		$36		$21	$10
			PV	$784	$640
			EAV	$53	$74

Table 3-8. Option 3 Cost Impacts (millions of 2021$)

	Capital Costs	Annual Costs (undiscounted)		Discounted Costs (3%)	Discounted Costs (7%)
2023	$308	$45		$352	$352
2024		$38		$37	$36
2025		$38		$36	$33
2026		$38		$35	$31
2027		$38		$34	$29
2028		$38		$33	$27
2029		$38		$32	$25
2030		$38		$31	$24
2031		$38		$30	$22
2032		$38		$29	$21
2033		$38		$28	$19
2034		$38		$27	$18
2035		$38		$27	$17
2036		$38		$26	$16
2037		$38		$25	$15
2038		$38		$24	$14
2039		$38		$24	$13
2040		$38		$23	$12
2041		$38		$22	$11
2042		$38		$22	$11
			PV	$897	$746
			EAV	$60	$85

3.7 Emissions Reductions

The baseline emissions for the commercial sterilization source category are the emissions that are occurring under the current subpart O requirements for the 86 active facilities. The baseline annual emissions are 23 tpy of EtO. For options 1, 2, and 3, the EPA estimated EtO emissions reductions of 15 tpy, 19 tpy, and 20 tpy, respectively.

3.8 Characterization of Uncertainty

The cost estimates are subject to several sources of uncertainty. This analysis includes many data sources as inputs, including source counts, equipment and labor costs, and assumptions regarding the current state of the EtO sterilization industry and how individual facilities carry out their operations, the future state of the industry, and the future state of the

world (*e.g.*, regulations, technology, economic activity, and human behavior). There is also uncertainty about the specific components of the engineering costs, such as the costs of the equipment and labor required to comply with the proposal and how the costs might change over time. Facilities may comply with the proposed requirements through alternative methods that were not accounted for in the cost memo. Additionally, the EPA was not able to determine how the compliance measures might affect capacity at facilities, or whether and how long facilities would need to close to complete upgrades and thus lose revenue during that time. Each of the inputs and assumptions used are uncertain to some degree and generate uncertainty in the overall cost estimates. When the uncertainties from each stage of the analysis are compounded, even small uncertainties can have large effects on the total cost estimates.

This proposal may not impact all locations with EtO sterilizers equally, in part due to differences in state and local policies such as consent orders in locations like Illinois and Georgia.[12] In addition, the baseline may not reflect all voluntary actions firms may take to reduce EtO emissions. By not fully accounting for state and local requirements and voluntary actions in the baseline, this analysis may overestimate the costs of the proposal. This analysis assumes that compliance will start in 2023 and that upfront capital costs will be incurred in 2023, and this is likely not the case. This is a conservative assumption given the compliance schedule being proposed, which stipulates an 18-month period after the rule is finalized before compliance is necessary for many of the requirements. The cost impacts were estimated out to 2042 and more uncertainty is introduced when impacts are estimated this far into the future.

The total number of facilities subject to the action could change. The EPA only estimated costs for existing facilities, but new facilities may be constructed and become subject to the requirements. Facilities may modify or upgrade in ways that affect the number of the various emissions points impacted by this proposed rule (*e.g.*, adding a sterilization chamber or aeration room). They may alter their EtO usage and thus become subject to different requirements. Additionally, new control technology may become available in the future at lower cost, and the EPA is unable to predict exactly how industry will comply with the proposed rules in the future.

[12] For more information, see https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates.

There may be an opportunity cost associated with the installation of environmental controls (for purposes of mitigating the emission of pollutants) that is not reflected in the compliance costs included in chapter 3. If environmental investment displaces investment in productive capital, the difference between the rate of return on the marginal investment (which is discretionary in nature) displaced by the mandatory environmental investment is a measure of the opportunity cost of the environmental requirement to the regulated entity. To the extent that any opportunity costs are not included in the control costs, the compliance costs for this proposed action may be underestimated.

4 SUMMARY OF BENEFITS AND ENVIRONMENTAL JUSTICE ANALYSIS

4.1 Introduction

This section provides a qualitative discussion of the health risks associated with exposure to EtO, a summary of the nationwide risks associated with EtO emissions from the commercial sterilization source category that is subject to this proposed rule, a summary of the risk analysis for the proposed rule, and a summary of the environmental justice implications assessed for this proposed rule.

This proposed rule is expected to reduce nationwide emissions of EtO from this source category by 19 tons per year (tpy) under option 2. Option 1, the least stringent option, is estimated to reduce EtO emissions from the source category by 15 tpy. The most stringent option 3 is estimated to reduce EtO emissions from the source category by 20 tpy.

Due to methodology and data limitations, the EPA was not able to monetize the health benefits of the reductions in EtO emissions in this analysis. This does not imply that there are no benefits associated with the EtO emission reductions estimated for this proposed rule. Monetization of the benefits of reductions in cancer incidences would require several important inputs, including central estimates of cancer risks, estimates of exposure to EtO, estimates of the value of an avoided case of cancer (fatal and non-fatal, and specific to the type of cancer), and increases in secondary emissions resulting from increased electricity usage associated with emission controls and process changes. The EPA does not have estimates of the willingness-to-pay for avoided cancer cases but continues to work on developing such values for use in regulatory analysis and welcomes comment on potential methods that should be considered. Instead, this section provides a qualitative discussion of the health effects associated with EtO exposure and a summary of the cancer risks estimated for the source category under the baseline and regulatory options.

The EPA discusses capacity constraints in the commercial EtO sterilization industry and concerns about potential shortages of EtO-reliant medical devices if capacity were further constrained in previous chapters of this RIA. If the capacity of the industry were to decline further due to the compliance measures in this proposed rule, there could be increased risk of shortages for some devices and potential for impacts on patients that need those devices (*i.e.*,

negative benefits). The EPA was not able to estimate potential capacity impacts, shortages, or possible health impacts resulting from potential shortages in this analysis.

4.2 Health Effects from Exposure to Ethylene Oxide

The Department of Health and Human Services and the International Agency for Research on Cancer have classified EtO as a known human carcinogen. The EPA has concluded that EtO is carcinogenic to humans by the inhalation route of exposure. Evidence in humans indicates that exposure to EtO increases the risk of lymphoid cancer (including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and, for females, breast cancer (U.S. EPA 2016). Noncancer health endpoints affected by chronic exposure to EtO include irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. There is also some evidence linking EtO exposure to reproductive effects (U.S. EPA 2018). EtO is a mutagen, meaning it acts directly on DNA and causes chromosome damage. Children may be particularly susceptible to the harmful effects of mutagenic substances (U.S. EPA 2005).

4.3 Air Toxics Screening Assessment

Since the 2006 RTR of the EtO commercial sterilization and fumigation NESHAP, which did not update the original requirements promulgated in 1994, the EPA has gained a better understanding of the risks associated with EtO emissions. In 2016, the EPA released its updated IRIS value for EtO, which indicated that cancer risks from EtO emissions were significantly higher than characterized in the prior 1985 assessment. Subsequently, the National Air Toxics Assessment (NATA) released in August 2018, as well as its replacement, the Air Toxics Screening Assessment (or 2017 AirToxScreen) released in March 2022, identified EtO emissions as an important risk driver in several areas across the country.

Based on the 2017 AirToxScreen, EPA estimates that 123 census tracts nationwide, which contain approximately 520,000 people, have increased cancer risks greater than or equal to 100 in a million. Of these, over half of the census tracts containing approximately 310,000 people have cancer risks driven by EtO emissions from sterilizers or the chemical sector. The average national cancer risk is about 30 in a million.

4.4 Risk Analysis

This section summarizes the results of the risk analysis conducted for this proposed rule. The EPA estimated cancer risk for each census block within 50 km of every EtO sterilization facility under the baseline and under the proposed option. For each facility, the EPA calculates the Maximum Individual Risk (MIR) as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each census block. Individual cancer risk is calculated by multiplying the estimated lifetime exposure to the ambient concentration of each emitted HAP (in micrograms per cubic meter) by the corresponding unit risk estimate (URE) for each HAP. The URE is an upper-bound (*i.e.*, conservative) estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air ($\mu g/m^3$). The MIR is the highest individual lifetime cancer risk estimated for any census block within 50 km of a facility.

In addition to calculating the MIR for the census blocks around each facility, the EPA characterizes cancer risks for the source category as a whole by summing the number of individuals residing in census blocks within 50 km of the facilities whose estimated risk falls within specified ranges. The EPA also estimates annual cancer incidence by multiplying the estimated lifetime cancer risk for each census block by the number of people residing in the block, summing results for all the census blocks, and then dividing this result by a 70-year lifetime. See the preamble for further explanation of the methods used to conduct the risk assessment.[13]

The risk assessment was conducted for the 86 facilities in the commercial sterilization source category that are currently operating and 11 research and development facilities for a total of 97 facilities.[14] Table 4-1 shows the results of the chronic inhalation cancer risk analysis for

[13] In the preamble, see section II.F (How do we estimate risk posed by the source category?), section III.C (What are the results of the risk assessment and analyses?), and section III.D (What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?).

[14] The EPA analyzed risk for 11 EtO sterilization research facilities even though these facilities are not directly affected by the proposed requirements and thus will not incur costs or reduce emissions. They were included to obtain a more comprehensive and conservative estimate of risks. None of the 11 research facilities were identified as driving elevated cancer risks greater than 100-in-1 million. Thus, excluding them would only minimally change the overarching conclusions of the risk analysis. Additionally, there are two facilities planning to open (which will be affected by the proposal) that were not included in the risk analysis due to lack of data. Excluding these facilities may bias the risk estimates downward.

these facilities based on actual (as opposed to allowable) emissions under the pre-proposal baseline and under option 2. The maximum lifetime individual cancer risk (MIR) posed by the facilities assessed is estimated to be 6,000-in-1 million under the baseline, with EtO emissions from post-aeration handling of sterilized material and sterilization chamber vents identified as the major contributors to the risk. The total estimated cancer incidence is 0.9 excess cancer cases per year under the baseline. The analysis identified 16 facilities with estimated maximum cancer risk greater than 100-in-1 million under the baseline (located in: Puerto Rico-4 facilities, Tennessee-2 facilities, Virginia, Massachusetts, Colorado, Nebraska, Oklahoma, Florida, Utah, Missouri, New Jersey, and Texas), and 6 of these facilities have estimated cancer risk greater than 1,000-in-1 million (located in: Puerto Rico-2 facilities, Tennessee-2 facilities, Utah, and Missouri). The estimated population exposed to lifetime cancer risks greater than 100-in-1 million is 18,000 under the baseline, and an estimated 900 people are exposed to cancer risks between 1,000-in-1 million and the maximum of 6,000-in-1 million. The estimated population exposed to cancer risks greater than or equal to 1-in-1 million living within 50 km of a facility is approximately 8.3 million under the baseline.

Table 4-1. Inhalation Cancer Risks for EtO Sterilization Facilities Under the Baseline and Proposed Option 2

	Baseline	Proposed Option 2
Facilities		
Number of Facilities Modeled in Risk Assessment	97	97
Cancer Risks		
Maximum Individual Lifetime Cancer Risk (in 1 million)	6,000	100
Number of Facilities with Maximum Individual Lifetime Cancer Risk:		
Greater than 1,000-in-1 million	6	0
Greater than to 100-in-1 million	16	0
Population Exposure		
Number of People Exposed to Maximum Cancer Risk:		
Greater than 1,000-in-1 million	900	0
Greater than 100-in-1 million	18,000	0
Greater than or equal to 1-in-1 million	8,300,000	1,260,000
Cancer Incidence (excess cancer cases per year)	0.9	0.1

Table 4-1 also shows the risk estimates when the proposed requirements are implemented. Option 2 is estimated to reduce the cancer MIR from 6,000-in-1 million under the baseline to 100-in-1 million. The total estimated cancer incidence from the facilities assessed is

0.1 excess cancer cases per year under option 2, an 89 percent reduction from the baseline estimate. No facilities would have estimated risk greater than 100-in-1 million, compared to 16 facilities under the baseline. The estimate of the population exposed to lifetime cancer risks greater than 100-in-1 million falls from 18,000 under the baseline to zero people under option 2. Risks that exceed the 100-in-1 million threshold are generally considered unacceptable, so the proposed rule is expected to reduce risk to acceptable levels. The estimate of the population exposed to cancer risks greater than or equal to 1-in-1 million living within 50 km of a facility is 1.26 million under option 2, down from 8.3 million under the baseline.

4.4.1 Limitations

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, the EPA believes the approach, which uses conservative tools and assumptions, ensures that our decisions protect health and the environment as EPA's 2005 Guidelines for Carcinogen Risk Assessment state that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective" (the EPA's 2005 Guidelines for Carcinogen Risk Assessment, page 1-7). Section II.F.7 of the preamble for this rulemaking details the uncertainties in the emissions datasets, dispersion modeling, inhalation exposure estimates, and dose-response relationships. Another uncertainty to note is that the EPA was unable to assess risk for any EtO sterilization facilities planning to open in the future which may be affected by this proposed rule.

4.5 Environmental Justice Analysis

For this proposed rulemaking, the EPA conducted a proximity-based and risk-based environmental justice (EJ) analysis to assess the distribution of risk associated with exposure to EtO emissions from the commercial sterilization source category. The EJ analysis characterizes risk under baseline conditions and under the proposed requirements. This section offers a summary of the EJ analysis—a more detailed discussion of the methods and results is available in the preamble for this proposed rule.

4.5.1 Background

EO 12898 (59 FR 7629; February 16, 1994) and EO 14008 (86 FR 7619; January 27, 2021) establish federal executive policy on environmental justice. EO 12898's main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the U.S.

The EPA defines environmental justice as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.[15] In general, the determination of whether a disproportionate impact exists is ultimately a policy judgment which, while informed by analysis, is the responsibility of the decision-maker. The environmental justice analysis assesses differences in anticipated impacts across population groups of concern for both the baseline and regulatory options, using the best available information (both quantitative and qualitative) to inform the decision-maker and the public. The baseline analysis describes the current (pre-control) distribution of risk and exposures, identifying potential disparities while the policy analysis describes the distribution of risk and exposures after a control strategy or policy requirement has been applied (post-control), identifying how potential disparities change in response to the rulemaking.

A regulatory action may involve potential environmental justice concerns by: (1) creating new disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; (2) exacerbating existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; or (3) presenting opportunities to address existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples through the action under development.

4.5.2 Methods

The EPA quantitatively evaluated the proximity of EtO sterilization facilities to potentially disadvantaged populations, and evaluated whether certain demographics are

[15] For more information, see https://www.epa.gov/environmentaljustice.

disproportionately represented in areas near higher risk EtO sterilization facilities under baseline conditions and after the proposed requirements are implemented.

EtO is considered a "local" pollutant, meaning emissions carry greater risk for individuals who live or spend significant time near the emissions sources. Demographic proximity analyses characterize the distance of vulnerable populations to environmental hazards as a proxy for exposure and the potential for adverse health impacts that may occur at a local scale due to economic activity at a given location.

The EPA conducted a proximity-based analysis for populations living within 10 km of all EtO sterilization facilities, as well as a risk-based analysis for populations living within 10 km of EtO sterilization facilities which have estimated facility-wide cancer risks greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million. The EPA provides the percent of the population in various demographics for these areas, including by poverty level, race, ethnicity, linguistic isolation, and educational attainment.

The analysis identified all census blocks within a 10 km radius of the location of each facility, and then linked each block with census-based demographic data. The total population within a specific radius around each facility is the sum of the population for every census block within that specified radius, based on each block's population provided by the 2010 decennial Census. Statistics on block group level race, ethnicity, education level, poverty status, and linguistic isolation were obtained from the Census' American Community Survey (ACS) 5-year averages for 2015-2019.

The risk-based environmental justice analysis provides the demographics for populations living within 10 km of sterilization facilities with estimated cancer risk greater than 100-in-1 million, greater than or equal to 50-in-1 million, and greater than or equal to 1-in-1 million under a baseline emissions scenario and under a post-control scenario to see how risks for various populations change due to the proposal. The analysis evaluates whether the distribution of baseline risk is similar to what might be expected based on national average demographics and whether the distribution of risks changes after implementing the proposed requirements.

4.5.3 Results

4.5.3.1 Baseline

Tables 4-2, 4-3, and 4-4 show the total population and the population percentages for each demographic group for the following: the nationwide population, the total population living within 10 km of EtO sterilization facilities, and the population living within 10 km of EtO sterilization facilities with cancer risks greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million. A total of 19.4 million people live within 10 km of the 97[16] EtO sterilization facilities analyzed. The analysis indicates that under the baseline, emissions from the facilities expose a total of 5.3 million people to cancer risk greater than or equal to 1-in-1 million around 78 facilities; 119,000 people to risk greater than or equal to 50-in-1 million around 42 facilities; and 18,000 people to risk greater than 100-in-1 million around 16 facilities.

[16] The EJ analysis included research facilities that will not be directly affected by or incur costs due to this proposed rule. While most of this RIA focuses on the 88 facilities that will incur incremental costs due to the proposed requirements, the 97 EtO sterilization facilities assessed in the EJ analysis includes 11 research facilities and the 86 active subpart O facilities. The two planned facilities that are expected to be impacted by this proposal are not included in the EJ analysis. The inclusion of the research facilities is not expected to materially impact the main conclusions of the EJ analysis.

Table 4-2. Baseline Demographic Summary: Proximity and Cancer Risk Greater than or Equal to 1-in-1 million for Populations Living Within 10 km of Facilities

Demographic Group	Nationwide	Total Population within 10 km of EtO facilities	Population with Risk ≥1-in-1 million within 10 km of EtO facilities
Total Population	328,000,000	19,400,000	5,300,000
Number of Facilities	-	97	78
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	40%
African American	12%	13%	15%
Native American	0.7%	0.3%	0.3%
Hispanic or Latino (white and nonwhite)	19%	34%	38%
Other and Multiracial	8%	13%	7%
		Income	
Below Poverty Level	13%	14%	16%
Above Poverty Level	87%	86%	84%
		Education	
Over 25 and without a High School Diploma	12%	15%	18%
Over 25 and with a High School Diploma	88%	85%	82%
		Linguistic Isolation	
Linguistically Isolated	5%	10%	11%

The results of the baseline proximity analysis indicate that the percent of the population that is Hispanic or Latino living within 10 km of any of the 97 EtO sterilization facilities is higher than the national average (34 percent versus 19 percent). This is driven largely by seven facilities in Puerto Rico, where 99 percent of the 658,000 people living in census blocks within 10 km of facilities are Hispanic or Latino. The proportions of other demographic groups living within 10 km of sterilization facilities are relatively similar to the national averages, although some differences exist. The percentage of the population living within 10 km of commercial sterilization facilities is higher than the national averages for the following demographics: Other and Multiracial, over 25 without a high school diploma, and linguistically isolated.[17] However, the higher percentage characterized as linguistically isolated compared to the national average is largely driven by the facilities in Puerto Rico, where an average of 67 percent of the population is linguistically isolated.

[17] Linguistic isolation is defined as "a household in which all members age 14 years and over speak a non-English language and also speak English less than "very well" (have difficulty with English)".

Table 4-3. Baseline Demographic Summary: Proximity and Cancer Risk Greater than or Equal to 50-in-1 million for Populations Living Within 10 km of Facilities

Demographic Group	Nationwide	Total Population within 10 km of EtO facilities	Population with Risk ≥50-in-1 million within 10 km of EtO facilities
Total Population	328,000,000	19,400,000	119,000
Number of Facilities	-	97	42
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	33%
African American	12%	13%	45%
Native American	0.7%	0.3%	0.1%
Hispanic or Latino (white and nonwhite)	19%	34%	19%
Other and Multiracial	8%	13%	3%
		Income	
Below Poverty Level	13%	14%	22%
Above Poverty Level	87%	86%	78%
		Education	
Over 25 and without a High School Diploma	12%	15%	17%
Over 25 and with a High School Diploma	88%	85%	83%
		Linguistic Isolation	
Linguistically Isolated	5%	10%	7%

Table 4-4. Baseline Demographic Summary: Proximity and Cancer Risk Greater than 100-in-1 million for Populations Living Within 10 km of Facilities

Demographic Group	Nationwide	Total Population within 10 km of EtO facilities	Population with Risk >100-in-1 million within 10 km of EtO facilities
Total Population	328,000,000	19,400,000	18,000
Number of Facilities	-	97	16
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	45%
African American	12%	13%	34%
Native American	0.7%	0.3%	0.1%
Hispanic or Latino (white and nonwhite)	19%	34%	18%
Other and Multiracial	8%	13%	3%
		Income	
Below Poverty Level	13%	14%	23%
Above Poverty Level	87%	86%	77%
		Education	
Over 25 and without a High School Diploma	12%	16%	16%
Over 25 and with a High School Diploma	88%	85%	84%
		Linguistic Isolation	
Linguistically Isolated	5%	10%	10%

The baseline risk-based analysis summarizes the demographics of populations living within 10 km of facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 4-2), greater than or equal to 50-in-1 million (Table 4-3), and greater than 100-in-1 million (Table 4-4). The demographics of the population with estimated cancer risks greater than or equal to 1-in-1 million under the baseline are very similar to the total population within 10 km

of all facilities. The percent of the population that is Hispanic or Latino (38 percent versus 19 percent nationally) and linguistically isolated (11 percent versus 5 percent nationally) are higher than the nationwide averages but similar to the percentages for the total population within 10 km of all facilities. In contrast, the demographic groups disproportionately represented in areas with higher baseline cancer risk are African Americans (45 percent African American in areas with risk greater than or equal to 50-in-1 million and 34 percent in areas with risk above 100-in-1 million, versus 12 percent nationwide) and those living below the poverty level (23 percent in areas with risk above 100-in-1 million versus 13 percent nationally). The much higher percent of African Americans with baseline cancer risk greater than or equal to 50-in-1 million (45 percent) compared to the national average percent African American (12 percent) is driven mostly by seven facilities that have African American population percentages living within 10 km that are two to eight times greater than the national average. Similarly, the high percent of African Americans with baseline cancer risk greater than 100-in-1 million (34 percent compared to 12 percent nationally) is driven mostly by three facilities that have African American percentages living within 10 km that are 2.5 to eight times greater than the national average.

The proximity analysis indicates that the share of the population that is African American living within 10 km of all 97 facilities is 13 percent (only marginally higher than the 12 percent national average), while the baseline risk-based analysis shows much higher percentages (45 percent African American in areas with baseline cancer risk greater than or equal to 50-in-1 million). The contrast between the proximity and baseline risk results for African Americans indicates that they are not over-represented in areas around all the sterilization facilities, but they are over-represented in areas near the higher risk facilities. In other words, the higher risk facilities appear to be concentrated in areas with higher shares of African American residents (and to a lesser degree where the percent living in poverty is higher), even though the average to lower risk facilities do not show this siting pattern.

In summary, the baseline proximity analysis indicates that the percentage of residents that are Hispanic or Latino living near commercial sterilization facilities is higher than would be expected compared to the nation as a whole. The baseline risk-based demographic analysis, which focuses on locations with cancer risk greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million, suggests that African Americans

are disproportionately represented in areas with higher risk sterilization facilities. These results indicate potential for EJ concerns under baseline conditions.

4.5.3.2 Post-Control

To evaluate how this proposal would affect the distribution of risks compared to the baseline, the EPA conducted a post-control risk-based demographic analysis for option 2. Tables 4-5, 4-6, and 4-7 show the results of the analysis for populations living within 10 km of a facility and with cancer risks greater than or equal 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million after implementing the proposed standards. The results indicate the proposed standards would reduce the number of individuals within 10 km of a facility with cancer risk greater than or equal to 1-in-1 million from 5.3 million to 1.15 million, reduce the number of individuals within 10 km of a facility with risk greater than or equal to 50-in-1 million from 119,000 to 1,400 people, and reduce the number of individuals within 10 km of a facility with risk greater than 100-in-1 million from 18,000 to 0 people.

Table 4-5. Post-Control Demographic Summary: Cancer Risk Greater than or Equal to 1-in-1 Million for Populations Living Within 10 km of Facilities

Demographic Group	Nationwide	Population with Risk ≥1-in-1 million within 10 km of EtO facilities	
		Baseline	*Post-Control*[1]
Total Population	328,000,000	5,300,000	1,150,000
Number of Facilities		78	73
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	38%
African American	12%	15%	18%
Native American	0.7%	0.3%	0.4%
Hispanic or Latino (white and nonwhite)	19%	38%	37%
Other and Multiracial	8%	7%	7%
		Income	
Below Poverty Level	13%	16%	16%
Above Poverty Level	87%	84%	84%
		Education	
Over 25 and without a High School Diploma	12%	18%	16%
Over 25 and with a High School Diploma	88%	82%	84%
		Linguistic Isolation	
Linguistically Isolated	5%	11%	9%

[1] The proposed Group 1 room air emission standards were not included in the risk assessment, so number of facilities and total population exposed post-control may be lower.

Table 4-6. Post-Control Demographic Summary: Cancer Risk Greater than or Equal to 50-in-1 Million for Populations Living Within 10 km of Facilities

Demographic Group	Nationwide	Population with Risk ≥50-in-1 million within 10 km of EtO facilities	
		Baseline	*Post Control*[1]
Total Population	328,000,000	119,000	1,400
Number of Facilities		42	11
		Race and Ethnicity	
White (non-Hispanic)	60%	33%	15%
African American	12%	45%	10%
Native American	0.7%	0.1%	0.3%
Hispanic or Latino (white and nonwhite)	19%	19%	72%
Other and Multiracial	8%	3%	3%
		Income	
Below Poverty Level	13%	22%	26%
Above Poverty Level	87%	78%	74%
		Education	
Over 25 and without a High School Diploma	12%	17%	20%
Over 25 and with a High School Diploma	88%	83%	80%
		Linguistic Isolation	
Linguistically Isolated	5%	7%	21%

[1] The proposed Group 1 room air emission standards were not included in the risk assessment, so number of facilities and total population exposed post-control may be lower.

Table 4-7. Post-Control Demographic Summary: Cancer Risk Greater than 100-in-1 Million for Populations Living Within 10 km of Facilities

Demographic Group	Nationwide	Population with Risk >100-in-1 million within 10 km of EtO facilities	
		Baseline	*Post Control*
Total Population	328,000,000	18,000	0
Number of Facilities		16	0
		Race and Ethnicity	
White (non-Hispanic)	60%	45%	-
African American	12%	34%	-
Native American	0.7%	0.1%	-
Hispanic or Latino (white and nonwhite)	19%	18%	-
Other and Multiracial	8%	3%	-
		Income	
Below Poverty Level	13%	23%	-
Above Poverty Level	87%	77%	-
		Education	
Over 25 and without a High School Diploma	12%	16%	-
Over 25 and with a High School Diploma	88%	84%	-
		Linguistic Isolation	
Linguistically Isolated	5%	10%	-

The baseline and post-control demographics are similar for populations in census blocks within 10 km of facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 4-5). Under the proposed option, there are no facilities or individuals with estimated risks

greater than 100-in-1 million (Table 4-7), so there are no disproportionately represented demographics at this risk level post-control. Therefore, the proposed requirements are expected to mitigate the potential EJ concerns that were present under the baseline at the greater than 100-in-1 million risk level. Risks that exceed the 100-in-1 million threshold are generally considered unacceptable, so the proposed rule is expected to reduce risk to acceptable levels for all demographics.

After implementing the proposed standards, the percentage and number of African Americans with cancer risks greater than equal to 50-in-1 million are significantly reduced and they are no longer disproportionately represented in areas with higher risk facilities, as was the case under the baseline. The percent of the population that is African American in areas with cancer risk greater than or equal to 50-in-1 million fell from 45 percent under the baseline to 10 percent after implementing the proposed controls (Table 4-6). However, the post-control percentage of residents that are Hispanic or Latino in areas with cancer risks greater than or equal to 50-in-1 million increased to 72 percent (compared to 19 percent under the baseline), driven mostly by three facilities in Puerto Rico with this post-control risk level. Nonetheless, the number of Hispanic or Latino individuals exposed to risks greater than or equal to 50-in-1 million fell to 1,000 people, an 80 percent decline relative to the baseline. Similarly, the percentage of the population below the poverty level and linguistically isolated in areas with risk greater than or equal to 50-in-1 million increased from the baseline, though the number of individuals in these demographics with risk greater than or equal to 50-in-1 million decreased significantly post-control. It is important to note that while the distribution of the post-control risks that are greater than or equal to 50-in-1 million is more disproportionately concentrated among these demographics, this risk level is still generally considered acceptable.

Based on the estimated declines in the number of individuals exposed to elevated cancer risks, the proposed rule is expected to mitigate potential EJ concerns relative to the baseline. The post-control risk-based demographics indicate that the proposed option 2 would significantly reduce the number of people in all demographic groups, including vulnerable populations, exposed to cancer risks greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million. The proposal reduces the number of people with risks greater than 100-in-1 million from 18,000 to 0, so there are no over-represented demographics post-control and the EJ concerns that were present under the baseline at this risk level appear to

dissipate. However, the proportion of the population exposed to higher risks after implementing the proposed requirements increases for several demographics (Hispanic or Latino, living below the poverty level, and linguistically isolated). The percentage of the population that is Hispanic or Latino with cancer risk greater than or equal to 50-in-1 million increased compared to the baseline because many of the facilities with this level of remaining risk are in Puerto Rico.

4.5.4 Limitations

This analysis is subject to several limitations and uncertainties. First, there may be flaws in the underlying demographic data. Second, this analysis is subject to many of the same sources of uncertainty as the risk analysis summarized in section 4.4.1, such as the uncertainties associated with the baseline emissions estimates, post-control emissions reductions, and the risk modeling parameters and assumptions. The analysis also does not account for the variation in exposure risk for different individuals or the variability in risk over space in areas within 10 km of EtO sterilization facilities. The analysis does not account for potential differences in underlying susceptibility, vulnerability, or risk factors across different population demographics in proximity to sterilization facilities affected by this proposed rule. Finally, the analysis assumes that demographic characteristics of the nation and in areas near sterilization facilities will not change in the future, but the EPA is unable to predict how demographics might shift after the source category has complied with a final rule. Disparities may exist that were not identified in this analysis.

5 ECONOMIC IMPACTS

5.1 Introduction

This proposed rule is a significant action under section (3)(f)(1) of Executive Order 12866. The presentation of the compliance cost estimates in chapter 3 does not speak directly to potential economic and distributional impacts of the proposed rule, which may be important consequences to consider. This chapter contains the small entity analysis conducted for this proposal and qualitative discussions of potential market and employment impacts.

5.2 Initial Regulatory Flexibility Analysis

This section presents the Initial Regulatory Flexibility Analysis (IRFA) for this proposed rule. This section describes the methods used to perform the small entity screening conducted for this proposal and the results of the screening. A small entity screening is used to determine whether a regulatory action may have a significant economic impact on a substantial number of small entities (SISNOSE). Thresholds for what constitutes 'significant' for economic impacts and 'substantial' for the number of small entities are outlined in guidance prepared for the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

The EPA did not certify a 'no SISNOSE' determination for this proposal as the small entity screening analysis identified potential for significant cost impacts on a substantial share of the small entities affected by this proposed rule. When a 'no SISNOSE' determination cannot be certified, the agency responsible for issuing the regulation in question must complete an IRFA. This section describes the IRFA conducted for this proposed rule, including summaries of the EPA's small entity outreach and other efforts to reduce impacts on small businesses.

5.2.1 Regulatory Flexibility Act Background

The Regulatory Flexibility Act (RFA; 5 U.S.C.§ 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act (Public Law No. 104-121), provides that whenever an agency is required to publish a general notice of proposed rulemaking, it must prepare and make available an initial regulatory flexibility analysis (IRFA), unless it certifies that

the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities (5 U.S.C. § 605[b]). Small entities include small businesses, small organizations, and small governmental jurisdictions. An IRFA describes the economic impact of the proposed rule on small entities and any significant alternatives to the proposed rule that would accomplish the objectives of the rule while minimizing significant economic impacts on small entities. Pursuant to section 603 of the RFA, the EPA prepared an IRFA that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact.

5.2.2 Reasons Why Action is Being Considered

This industry is regulated by the EPA because pollutants emitted from EtO sterilization and fumigation facilities are considered to cause or contribute significantly to air pollution that may reasonably be anticipated to endanger public health. This action is being proposed to comply with CAA section 112 requirements, which direct the EPA to complete periodic reviews of NESHAPs following initial promulgation. The proposed requirements are being considered to address unacceptable health risks linked to emissions from subpart O facilities and to provide an ample margin of safety to protect public health.

5.2.3 Statement of Objectives and Legal Basis for Proposed Rule

The EPA is required under CAA section 112(d) to establish emission standards for each category or subcategory of major and area sources of HAPs listed for regulation in section 112(b). These standards are applicable to new or existing sources of HAPs and require the maximum degree of emission reduction. The EPA is required to review these standards set under CAA section 112 every eight years following their promulgation and revise them as necessary, taking into account any "developments in practices, processes, or control technologies." This review is known as the technology review. It has been over 25 years since the initial NESHAP for this source category was promulgated in 1994 and roughly 15 years since the last technology review. As such, this proposal is overdue. This proposal also establishes standards for currently unregulated sources of EtO emissions at subpart O facilities under CAA section 112(d), such as fugitive emissions. The decision in *Louisiana Environmental Action Network v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020) concluded that the EPA is required to address regulatory gaps (*i.e.*, "gap-

filling") when conducting NESHAP reviews. Finally, the EPA determined that a risk review was warranted (despite not being required) due to the updated unit risk estimate associated with EtO, which is significantly higher than it was during the last review of this NESHAP in 2006. Therefore, the EPA is proposing requirements under CAA section 112(f) to address unacceptable health risk attributed to emissions from subpart O facilities and to provide an ample margin of safety to protect public health.

5.2.4 Description and Estimate of Affected Small Entities

The Regulatory Flexibility Act (RFA) describes small entities as "small businesses," "small governments," and "small organizations" (5 USC 601). The proposed amendments being considered by the EPA in this action are expected to affect a variety of businesses, including small businesses, but would not affect any small governments or small organizations. The "business" is defined as the owner company, rather than the facility. In an IRFA, the EPA evaluates affected entities at the highest level of business ownership, or the ultimate parent company level. The analysis uses the size of the ultimate parent company to determine the resources it has available to comply with the rule.

The EPA used several sources of information to develop the list of commercial sterilization facilities that may be impacted by this proposed rule. The EPA began with the facility list used during the previous RTR and supplemented that with facilities in the 2017 National Emissions Inventory (NEI), as well as facilities identified using the Office of Enforcement and Compliance Assurance's Enforcement and Compliance History Online tool.[18] The EPA reviewed available federal, state, and local data to determine whether any of these facilities had closed or ceased using EtO for sterilization purposes. EPA regional offices were asked to identify any commercial sterilization facilities that were missed. Additionally, the December 2019 Section 114 questionnaire and the September 2021 Information Collection Request (ICR) asked parent companies to provide information on any commercial sterilization facilities they owned that had not already been identified.

To conduct a small entity screening, the EPA first identifies the ultimate parent companies that own affected facilities, and obtains those companies' most recent annual

[18] https://echo.epa.gov

revenues, number of employees, and North American Industrial Classification System (NAICS) code using the Dun & Bradstreet Hoover's online database.[19] SBA size standards are defined for each NAICS code based on either annual revenues or employees. To determine whether an entity is small, the EPA identifies the size standard corresponding to the NAICS code of the ultimate parent company and compares the company's annual revenues (or employees) to the standards. To assess potential impacts on small entities, the EPA calculates cost-to-sales ratios, which compare facility-level annualized compliance costs aggregated to the ultimate parent company level to annual sales revenues of the ultimate parent company. This metric for evaluating impacts is known as the "sales test" and is consistent with guidance published by the SBA's Office of Advocacy.[20]

The EPA identified 97 EtO sterilization facilities currently operating in the U.S., 86 of which will be impacted by this proposed rule and incur costs. There are 11 active facilities that will not be affected by the proposed rule because they are purposed solely for conducting research. The EPA knows of two planned facilities that are expected to start operating before the proposed compliance deadline, so the total number of affected facilities is 88.

There are 48 ultimate parent companies that own the 88 commercial sterilization facilities affected by this proposal, as several parent companies own multiple facilities. About 42 percent (20) of the 48 parent companies are small entities. Out of the 88 facilities expected to incur costs to comply with the proposal, 24 facilities, or about 27 percent of facilities, are owned by ultimate parent companies that are small entities based on the business size standards defined by the U.S. Small Business Administration (SBA).[21]

See Table 5-1 for average entity-level annualized cost estimates for the proposed option 2 and annual sales by entity size. The average annualized cost of the proposed option 2 is about $1 million for small entities and about $1.7 million for large entities. Average annual sales for the 20 small entities is $41 million while the 28 large businesses have average annual sales of $15.7 billion.

[19] Dun & Bradstreet, Inc. (2022). D&B Hoovers. Retrieved from https://app.dnbhoovers.com/.

[20] U.S. SBA, Office of Advocacy. (2017). A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act. Retrieved from https://advocacy.sba.gov/2017/08/31/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/.

[21] U.S. Small Business Administration. (2022). Table of Small Business Size Standards. Found at https://www.sba.gov/document/support-table-size-standards.

Table 5-1. Mean Option 2 Costs and Sales (2021$) by Entity Size

Entity Size	Number of Affected Entities	Percent of Affected Entities	Number of Affected Facilities	Percent of Affected Facilities	Mean Annualized Cost (millions)[a]	Mean Annual Sales (millions)
Small	20	42%	24	27%	$1.0	$41
Large	28	58%	64	73%	$1.7	$15,665
All	48	100%	88	100%	$1.4	$9,155

[a] Annualized costs are summed across facilities owned by an entity.

Table 5-2 shows the NAICS codes for the ultimate parent companies that own facilities affected by this proposed rule. The table also contains the SBA size standards for the affected NAICS codes. The table shows a wide variety of industries, although most of the companies affected (31 out of 48, or 65 percent) have medical equipment- or health service-related NAICS codes. The industry with the highest number of companies and facilities affected by this proposed rule is NAICS 339112, 'Surgical and Medical Instrument Manufacturing', with 17 affected parent companies and 24 affected facilities. The second most common NAICS code is 423450, 'Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers', with 6 affected parent companies and 13 affected facilities.

Table 5-3 lists the entities affected by this proposed rule and includes their NAICS code, number of facilities owned, and whether they are a small entity.

Table 5-2. Affected NAICS Codes and SBA Small Entity Size Standards

2019 NAICS Code	NAICS Description	Small Entity Standard: Receipts (million $)	Small Entity Standard: Employees	Parent Companies Affected	Facilities Affected
339112	Surgical and Medical Instrument Manufacturing		1,000	17	24
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers		200	6	13
561990	All Other Support Services	12		4	13
339113	Surgical Appliance and Supplies Manufacturing		750	2	2
621999	All Other Miscellaneous Ambulatory Health Care Services	16.5		2	7
325412	Pharmaceutical Preparation Manufacturing		1,250	2	3
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)		1,000	2	2
333244	Printing Machinery and Equipment Manufacturing		750	1	3
541380	Testing Laboratories	16.5		1	1
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing		1,000	1	1
622110	General Medical and Surgical Hospitals	41.5		1	1
621511	Medical Laboratories	35		1	1
315220	Men's and Boys' Cut and Sew Apparel Manufacturing		750	1	1
311942	Spice and Extract Manufacturing		500	1	3
812990	All Other Personal Services	8		1	8
424210	Drugs and Druggists' Sundries Merchant Wholesalers		250	1	1
811219	Other Electronic and Precision Equipment Repair and Maintenance	22		1	1
541611	Administrative Management and General Management Consulting Services	16.5		1	1
551112	Offices of Other Holding Companies	22		1	1
525910	Open-End Investment Funds	35		1	1

Table 5-3. Affected Parent Companies

Ultimate Parent Company	NAICS Code	Annual Revenues (millions)	Employees	Small Business	Affected Facilities
3M Company	339112	32,180	95,000	No	1
Abbott Laboratories	325412	34,610	109,000	No	2
Alcon AG	525910	6,830	23,655	No	1
Andersen Scientific Inc	811219	0.26	2	Yes	1
Applied Medical Corporation	339112	700	4,319	No	1
Arthrex, Inc.	339112	620	1,200	No	1
Aso Corporation	339113	47	240	Yes	1
B. Braun of America Inc.	339112	960	4,099	No	1
Baxter International Inc.	339112	11,670	50,000	No	1
Becton, Dickinson and Company	339112	17,120	72,063	No	5
Blue Line Sterilization Services LLC	561990	1.4	6	Yes	1

Ultimate Parent Company	NAICS Code	Annual Revenues (millions)	Employees	Small Business	Affected Facilities
Bon Secours Mercy Health, Inc.	622110	9,970	19,000	No	1
Boston Scientific Corporation	339112	9,910	38,000	No	3
Boulder BioMed, LLC	423450	2.6	12	Yes	1
Cardinal Health, Inc.	424210	152,920	30,000	No	1
Chatham Corporation	333244	69	400	Yes	3
Cook Group Incorporated	339112	1,610	12,000	No	1
Cosmed Group, Inc.	561990	11	94	Yes	2
Deroyal Industries, Inc.	339112	412	2,000	No	1
DF World of Spices GmbH	551112	580	3,268	No	1
Dynatec Scientific Laboratories	541380	3.7	35	Yes	1
Edwards Lifesciences Corp	339113	4,390	13,000	No	1
Elite Spice, Inc.	311942	110	600	No	3
Eto Sterilization Inc.	332994	2.5	11	Yes	1
Johnson & Johnson	325412	82,580	136,400	No	1
Jorgensen Laboratories, Inc.	423450	14	35	Yes	1
Lemco Enterprises, Inc.	561990	1.0	9	Yes	1
Life Science Outsourcing, Inc.	339112	20	80	Yes	1
Lifenet Health	339112	376	500	Yes	1
Livanova PLC	339112	930	1,325	No	1
Medline Industries, LP	339112	7,750	25,000	No	1
Medtronic Public Limited Company	621999	30,120	102,662	No	5
Midwest Sterilization Corporation	621999	13	100	Yes	2
North American Science Associates, LLC	541715	102	533	Yes	1
Owens & Minor, Inc.	423450	8,480	18,800	No	8
Parter Medical Products, Inc.	423450	39	160	Yes	1
Professional Contract Sterilization, Inc.	339112	2.9	10	Yes	1
Puerto Rico Hospital Supply, Inc.	423450	51	150	Yes	1
Robert Busse & Co., Inc.	423450	93	280	No	1
Sotera Health LLC	561990	446	1,950	No	9
Steris Public Limited Company	812990	3,030	12,359	No	8
Steritec Inc.	621511	3.5	13	Yes	1
Steri-Tech, Inc.	315220	1.7	38	Yes	1
Stryker Corporation	339112	14,350	43,042	No	1
Terumo Corporation	339112	5,790	26,482	No	2
The Jackson Laboratory	541715	441	2,100	No	1
Torque Medical Holdings, LLC	541611	18	91	No	1
Trinity Sterile, Inc.	339112	59	117	Yes	1

5.2.5 Compliance Cost Impact Estimates

The EPA uses a "sales test" as the impact methodology in small entity analyses for rulemakings as opposed to a "profits test", in which annualized compliance costs are calculated as a share of profits. This is consistent with EPA guidance on the Small Business Regulatory Enforcement Fairness Act and guidance from the SBA's Office of Advocacy, which suggests that cost as a percentage of total revenues is a suitable metric for evaluating cost impacts on small entities relative to large entities.[22] This is because revenues or sales data are commonly available for entities impacted by regulators and profits data are often private or misrepresent true profits earned by firms after accounting and tax considerations.

The EPA calculated cost-to-sales ratios (CSRs) by first estimating the total annualized compliance cost for each affected entity using a 7.75 percent interest rate to annualize capital costs over the lifetime of the equipment and summing the annualized capital costs with other annual costs such as operating and maintenance costs. The EPA summed the annualized compliance costs for each facility owned by an affected entity and divided the costs by the company's annual sales to obtain the cost-to-sales ratio. Small entities incurring annualized compliance costs less than 1 percent of sales are not expected to experience significant economic impacts due to the proposed rule. Small entities with costs between 1 and 3 percent, or greater than 3 percent, may potentially experience significant economic impacts.

Tables 5-4 through 5-6 show the number of entities, and the mean annualized costs per entity, mean cost-to-sales ratio, median cost-to-sales ratio, minimum cost-to-sales ratio, and maximum cost-to-sales ratio by entity size for the three regulatory options. The 20 small entities represent 42 percent of total affected entities. For the least stringent option (option 1), the average annualized cost per entity for small entities is about $0.9 million in 2021 dollars, compared to $1.7 million for large entities. On average, small entities are estimated to experience a 16 percent cost-to-sales ratio for option 1, compared to an average of 0.2 percent for large entities and about 7 percent for all entities. The highest cost-sales-ratio estimated is 68 percent.

[22] U.S. SBA, Office of Advocacy. (2012). A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, Implementing the President's Small Business Agenda and Executive Order 13272, May 2012. Found at https://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf.

Table 5-4. Summary of Option 1 Costs per Entity and Cost-to-Sales Ratios by Entity Size

Entity Size	Number of Affected Entities	Percent of Affected Entities	Mean Annualized Cost per Entity (mill 2021$)	Mean CSR	Median CSR	Min CSR	Max CSR
Small	20	42%	$0.9	16%	8.1%	0%	68%
Large	28	58%	$1.7	0.2%	0%	0%	1.8%
All	48	100%	$1.4	6.9%	0.4%	0%	68%

The average, median, and maximum cost-to-sales ratios are higher for the proposed option 2 (Table 5-5). The average annualized cost of option 2 per entity for small entities is about $1 million in 2021 dollars, compared to $1.7 million for large entities. On average, small entities are estimated to experience a 19 percent cost-to-sales ratio for option 2, compared to an average of 0.3 percent for large entities and about 8 percent for all entities. The highest cost-sales-ratio estimated for an entity is 68 percent. Option 3 has the highest average cost-to-sales ratios (Table 5-6). The average annualized cost of option 3 per entity for small entities is about $1 million in 2021 dollars, compared to $2 million for large entities. On average, small entities are estimated to experience a 21 percent cost-to-sales ratio for option 3, compared to an average of 0.4 percent for large entities and about 9 percent for all entities. The highest cost-sales-ratio under option 3 is estimated to be 114 percent.

Table 5-5. Summary of Option 2 Costs per Entity and Cost-to-Sales Ratios by Entity Size

Entity Size	Number of Affected Entities	Percent of Affected Entities	Mean Annualized Cost per Entity (mill 2021$)	Mean CSR	Median CSR	Min CSR	Max CSR
Small	20	42%	$1.0	19%	7.3%	0%	68%
Large	28	58%	$1.7	0.3%	0%	0%	3.9%
All	48	100%	$1.4	7.9%	0.3%	0%	68%

Large entities incur most of the total costs estimated for the proposed option and they incur higher total annualized costs per entity on average than small entities. However, when estimated costs are examined relative to revenues, large entities are much less impacted by the proposed rule than small entities. For all three regulatory options, the average cost-to-sales ratio for small entities is significantly higher than for large entities. This is driven by differences in revenues—average entity-level annual revenues are over $15 billion for large entities and about

$41 million for small entities (Table 5-1). For option 2, the average cost-to-sales ratio for small entities is about 60 times higher than for large entities.

Table 5-6. Summary of Option 3 Costs per Entity and Cost-to-Sales Ratios by Entity Size

Entity Size	Number of Affected Entities	Percent of Affected Entities	Mean Annualized Cost per Entity (mill 2021$)	Mean CSR	Median CSR	Min CSR	Max CSR
Small	20	42%	$1.0	21%	7.5%	0.1%	114%
Large	28	58%	$2.0	0.4%	0%	0%	4.1%
All	48	100%	$1.6	8.9%	0.4%	0%	114%

See Table 5-7 for a summary of the number and percent of businesses (and small businesses) that meet or exceed the 1 and 3 percent cost-to-sales ratio thresholds for each of the three regulatory options. Under the proposed option 2, 17 out of 20 parent companies identified as small entities (85 percent) are estimated to incur annualized costs greater than 1 percent of annual revenues. Twelve out of 20 small entities (60 percent) are estimated to incur annualized costs greater than 3 percent of annual revenues. The 12 small entities with 3 percent or greater cost-to-sales ratios under option 2 collectively own 16 facilities.

Under the less stringent option 1, 17 out of 20 parent companies identified as small entities (85 percent) are estimated to incur annualized costs greater than 1 percent of annual revenues. Twelve out of 20 small entities (60 percent) are estimated to incur annualized costs greater than 3 percent of annual revenues. The 12 small entities with 3 percent or greater cost-to-sales ratios under option 1 collectively own 16 facilities.

Table 5-7. Cost-to-Sales Ratio Summary for Options 1, 2, and 3

	Capital Cost (Million 2021$)	Annualized Cost	Entities with 1% or greater Cost-to-Sales	Entities with 3% or greater Cost-to-Sales
All Entities (n=48, Facilities=88)				
Option 1	$146	$66	19 (40%)	12 (25%)
Option 2	$220	$68	20 (42%)	13 (27%)
Option 3	$308	$76	21 (44%)	13 (27%)
Small Entities (n=20, Facilities=24)				
Option 1	$44	$17	17 (85%)	12 (60%)
Option 2	$71	$20	17 (85%)	12 (60%)
Option 3	$84	$21	18 (90%)	12 (60%)

Under the more stringent option 3, 18 out of 20 parent companies identified as small entities (90 percent) are estimated to incur annualized costs greater than 1 percent of annual revenues. Twelve out of 20 small entities (60 percent) are estimated to incur annualized costs greater than 3 percent of annual revenues. Those 12 small entities with 3 percent or greater cost-to-sales ratios under option 3 collectively own 16 facilities.

The results of this small entity screening indicate potential for a significant share of the small entities affected by this proposed rule to incur high costs relative to their revenues. Large entities affected by the proposed rule have much lower cost-to-sales ratios. For option 1, all the entities with cost-to-sales ratios above 3 percent are small entities. Under option 2 and option 3, there are 12 small entities and one large entity with cost-to-sales ratios above 3 percent. Across the options, there are five to six small entities and two large entities with cost-to-sales ratios above 1 percent but lower than 3 percent. See Table 5-8 through Table 5-9 for further breakdown of the number and percent of entities (and facilities) affected at various cost-to-sales thresholds.

Table 5-8. Number and Percent of Entities at Various Cost-to-Sales Levels

	Capital Cost	Annualized Cost	Cost-to-Sales Ratios				
			Less than 1%	1% to 3%	3% to 5%	5% to 10%	Greater than 10%
All Entities (n=48)							
Option 1	$146	$66	29 (60%)	7 (15%)	2 (4%)	0 (0%)	10 (21%)
Option 2	$220	$68	28 (58%)	7 (15%)	3 (6%)	0 (0%)	10 (21%)
Option 3	$308	$76	27 (56%)	8 (17%)	3 (6%)	0 (0%)	10 (21%)
Small Entities (n=20)							
Option 1	$44	$17	3 (15%)	5 (25%)	2 (10%)	0 (0%)	10 (50%)
Option 2	$71	$20	3 (15%)	5 (25%)	2 (10%)	0 (0%)	10 (50%)
Option 3	$84	$21	2 (10%)	6 (30%)	2 (10%)	0 (0%)	10 (50%)

Table 5-9. Number and Percent of Facilities Affected at Various Cost-to-Sales Levels

	Capital Cost	Annualized Cost	Cost-to-Sales Ratios				
			Less than 1%	1% to 3%	3% to 5%	5% to 10%	Greater than 10%
Facilities owned by All Entities (n=88)							
Option 1	$146	$66	57 (65%)	15 (17%)	4 (5%)	0 (0%)	12 (14%)
Option 2	$220	$68	54 (61%)	15 (17%)	7 (8%)	0 (0%)	12 (14%)
Option 3	$308	$76	53 (60%)	16 (18%)	7 (8%)	0 (0%)	12 (14%)
Facilities owned by Small Entities (n=24)							
Option 1	$44	$17	3 (13%)	5 (21%)	4 (17%)	0 (0%)	12 (50%)
Option 2	$71	$20	3 (13%)	5 (21%)	4 (17%)	0 (0%)	12 (50%)
Option 3	$84	$21	2 (8%)	6 (25%)	4 (17%)	0 (0%)	12 (50%)

Regulatory costs can disproportionately impact small entities for several reasons, even when larger firms incur higher absolute costs. In addition to potentially holding more market power, larger companies may be better positioned financially than small businesses to invest in proven compliance mechanisms, obtain financing for upgrades, or conduct research and development needed to innovate and identify more efficient compliance methods. Small firms have fewer units of production to spread compliance costs over. In some situations, larger firms may also have the advantage of being closer to meeting a more stringent new standard under baseline conditions.

While the EPA cannot anticipate outcomes for any particular facility or parent company, the number of firms and the size distribution of affected firms in the EtO sterilization sector could be affected by this proposed rule. Impacted facilities will vary in cost structure, company

size in terms of revenue and employees, access to financing opportunities, and the type and range of products they sterilize.

5.2.6 Caveats and Limitations

The cost-to-sales ratios estimated in this analysis may be overstated or understated depending on the accuracy of the information in the underlying data on parent company ownership and parent company revenues in addition to the accuracy of the facility-level engineering costs. The uncertainties associated with the cost estimates are discussed in section 3.8.

While a "sales test" can provide some insight as to the economic impact of an action such as this one, it assumes that the impacts of a regulation are solely incident on a directly affected firm (therefore, no impact to consumers of the affected product), or solely incident on consumers of output directly affected by this action (therefore, no impact to companies that are producers of the affected product). Thus, an analysis such as this one is best viewed as providing insight on a polar example of economic impacts: maximum impact to directly affected companies. A "sales test" analysis does not consider shifts in supply and demand curves to reflect intermediate economic outcomes.

5.2.7 Reporting, Recordkeeping, and Other Compliance Requirements

The EPA is proposing amendments that affect reporting, recordkeeping, and other compliance requirements in subpart O. The requirements are mandatory for all operators of facilities subject to the standards. Section 114 of the CAA (42 U.S.C. 7414) authorizes the EPA to establish recordkeeping and reporting requirements. The EPA and delegated permitting authorities use the information in operators' reports and records to ensure compliance with the standards and identify facilities, records, or processes that may need inspection.

This proposed rule changes the notification, performance testing, and reporting and recordkeeping requirements for several emission sources at affected commercial sterilization facilities (*e.g.*, SCV, ARV, CEV, and room air emissions). The proposed amendments also require electronic reporting, remove the SSM exemption, and impose other revisions that affect reporting and recordkeeping.

This proposed rule requires industry respondents to provide one-time and periodic notifications, including initial notification, notification of performance tests, and notification of compliance status. Respondents are also required to submit electronic reports documenting compliance and performance test results, including details on any compliance issues. Notifications and responses are required on a quarterly, semiannual, annual, or one-time basis depending on the facility and type of response. Operators are required to keep documentation of the supporting information included in these notifications and reports.

The industry recordkeeping and reporting burden of this proposed rule is associated with reviewing the proposed requirements, gathering relevant information, conducting initial performance tests and periodic performance tests if necessary, installing and maintaining emissions monitors, developing systems to process and maintain information, writing and submitting notifications and reports, and training personnel in compliance and use of the information systems. The average annual recordkeeping and reporting burden (averaged over the first three years after the compliance date) for the 87 responding facilities subject to subpart O is estimated to be approximately $11.5 million in cost[23] ($2019) and approximately 87,000 in labor hours per year on average for the first three years. The annual public reporting and recordkeeping burden is estimated to average approximately 20,000 hours per year for the first three years. Burden is defined at 5 CFR 1320.3(b).

Due to technical aspects of EtO sterilization operations and the types of control equipment required by the proposal, the recordkeeping and reporting requirements are the same for both small and large entities. The EPA considers these to be the minimum requirements needed to ensure compliance and, therefore, cannot reduce them further for small entities.

5.2.8 Related Federal Rules

EtO sterilization is also regulated by the EPA under the NESHAP for Hospital Sterilizers. The NESHAP for the hospital sterilizers was developed under the Urban Air Toxics Strategy[24] and covers EtO used to sterilize medical equipment at all hospitals nationwide. The Hospital Sterilizers NESHAP was finalized in December 2007 (72 FR 73611). Hospital sterilizers are not

[23] The reporting and recordkeeping cost burden estimate includes capital, labor, and other operating and maintenance costs.
[24] 64 FR 387065

covered under the commercial EtO sterilization source category (Subpart O). In addition, the EPA's Office of Pesticide Programs within the Office of Chemical Safety and Pollution Prevention (OCSPP) regulates the distribution, sale and use of all pesticides (insecticides, herbicides, rodenticides, disinfectants, and sanitizers) in the U.S. and establishes maximum levels for pesticide residues in food. EtO has antimicrobial uses, for medical device sterilization, and is also a conventional pesticide used to treat spices.

Aside from the EPA, several other Federal agencies regulate commercial sterilization facilities:

- The Food and Drug Administration (FDA) validates sterilization processes for medical devices. FDA regulations in 21 CFR (Food and Drugs) refer to voluntary consensus standards that describe how to develop the validation cycles for EtO, gamma, and e-beam sterilization for medical devices. The standards that FDA refers to include ISO 11135:2014, ISO 10993-7:2008(R)2012, ISO 11137, and ISO 13485:2016. Furthermore, the FDA defines quality management system requirements for medical devices and the acceptable EtO residual levels for sterilized products. Spice fumigation is regulated under the Food Safety Modernization Act at 21 CFR Part 117.
- The Occupational Health and Safety Administration (OSHA) sets permissible worker exposure limits to EtO within sterilization facilities at 29 CFR §1910.1047.
- The Department of Transportation regulates the drums used to transport EtO at 49 CFR §173.323.

5.2.9 Regulatory Flexibility Alternatives

Pursuant to sections 603 and 609(b) of the RFA, the EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review (SBAR) Panel to obtain recommendations from small entity representatives (SERs) that would potentially be subject to the proposed rule.

The SBAR Panel reviewed the information provided by the EPA to the SERs and the SERs' oral and written comments from the pre-panel outreach and panel outreach. The Panel's review identified several significant alternatives for consideration by the Administrator of the EPA which accomplish the stated objectives of the CAA and minimize any significant economic

impact of the proposed rule on small entities. The significant issues and alternatives identified by the Panel are summarized below. A copy of the full SBAR Panel Report is available in the docket.

Format of the Standards. As described in the preamble, the EPA is proposing emission reduction requirements for SCVs and ARVs at all facilities, as well as CEVs at facilities where EtO use is less than 10 tpy. The Panel recommended that EPA review the technical and economic feasibility of the emission reduction requirements under consideration. The EPA determined that the proposed emission reduction requirements are technically and economically feasible. The EPA is soliciting comment on all proposed standards.

The EPA is also proposing emission rate standards for CEVs at facilities where EtO use is at least 10 tpy, as well as room air emissions for all facilities. For emission reduction requirements, the EPA is soliciting comment on whether to adopt equivalent emission rate standards and, if so, how those equivalent emission rates should be calculated. The Panel recommended that the EPA consider an outlet EtO concentration that correlates with the increased emission reduction standards. The Panel also recommended that the EPA consider regulatory alternatives based on process changes that lower EtO concentration in downstream, post-sterilization, and post-aeration areas. The EPA has considered concentration standards but is unable to justify them due to the potential for dilution of the emission stream as a means of compliance (*i.e.*, no emission reduction). The only way to mitigate this problem is to also set a limit on the volumetric flow rate of the emission stream. As explained in section III of the preamble, if both the volumetric flow rate and EtO concentration are restricted, there are at least two potential outcomes. One outcome is that a facility could keep the volume of the enclosure constant but restrict the number of air changes per hour. This could potentially result in an increase in EtO concentration within the enclosure. In order to maintain personnel safety, significant upgrades and changes may need to be made, which could require significant costs. Another possible outcome is that the facility could keep the number of air changes per hour constant but restrict the volume of the enclosure. Both of these outcomes could result in a reduced capacity to sterilize medical products, which could further impact the facilities and the supply chains that rely on them. The EPA is only proposing limits on both the volumetric flow rate and EtO concentration for two facilities because it is necessary to reduce risk to acceptable levels and because the EPA is unable to justify a lower emission rate standard due to limitations

of current EtO measurement technology. However, the EPA is taking comment on this approach (Comment C-33 in the preamble).

Room Air Emissions. The Panel recommended that the EPA review the post-aeration room areas for shipping and warehouse and clearly define the activities, per the EPA's obligation to set standards for unregulated emissions at major sources (LEAN v. EPA, 955 F.3d 1088 (D.C. Cir. 2020)). As described in the preamble to the proposal,[25] the EPA is proposing to define emissions from post-aeration handling of sterilized material as "Group 2 room air emissions".

As described in the preamble, the EPA is proposing to require facilities to operate areas with room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51 where those emissions are subject to an emission limit. The EPA believes this is necessary to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard. The Panel recommended that the EPA confirm the status of facilities with respect to whether they have implemented or are implementing capture and control for room air emissions. The Panel also recommended that the EPA continue to observe those facilities that either implemented or are in the process of implementing Method 204 to identify any potential issues with compliance, as well as potential remedies to those issues. The EPA has identified at least four facilities that have demonstrated compliance with Method 204, indicating that this is technically feasible for the source category. The EPA continues to monitor these facilities but has not observed any issues significant enough to indicate that implementation of Method 204 is infeasible.

As part of the September 2021 ICR, the EPA requested information on stand-alone warehouses. These are facilities where sterilized product may be sent after it leaves the sterilization facility. The Panel recommended that the EPA clearly explain future intended actions related to reduction of EtO emissions at offsite shipping and warehouse facilities. The EPA is not proposing requirements for these facilities as part of this action. However, the EPA plans to evaluate the data received and determine what requirements these facilities should be subject to, if any.

Subcategorization. The Panel recommended that the EPA explore potential subcategories that would minimize cost burden to small businesses while also minimizing risk to

[25] See preamble section III.A

nearby populations as appropriate. As described in the preamble to this proposal, the EPA is proposing to establish different requirements for Group 2 room air emissions at existing area source facilities depending on annual EtO use. For existing area source facilities where EtO use is at least 20 tpy (as well as major source facilities), the EPA is proposing to limit Group 2 room air emissions to 2.8E-3 lb/hr. To ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, the EPA is proposing to require each of these facilities to operate areas with Group 2 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. For Group 2 room air emissions at existing area source facilities where EtO use is less than 20 tpy, the EPA is proposing to require these facilities to follow either the Cycle Calculation Approach or the Bioburden / Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 14161:2009. The EPA had considered, but was unable to justify, applying the emission rate limit to all existing Group 2 room air emissions at area source facilities. This is because the cost to sales ratio would exceed five percent for six companies, all of which are small entities. However, for Group 2 room air emissions at existing area source facilities where EtO use is at least 20 tpy, the EPA believes that the emission rate limit is necessary to reduce risk to acceptable levels.

The Panel also recommended that the EPA investigate whether subcategories based on class, size, or type could be developed based on observed differences in downstream room air concentration. However, the EPA has not found any correlation between room air concentration and either the risk that a facility poses or whether it is owned by a small entity. Therefore, the EPA did not find that subcategorization based on room air concentration would reduce impacts on small businesses.

Compliance Timeframe. As discussed in the preamble to this proposal,[26] the EPA is proposing an 18-month compliance timeframe for all existing source standards. The Panel recommended that the EPA highlight the availability of a 1-year extension of the compliance date if the source demonstrates to the state permitting authority or the EPA determines that an extension is necessary for the installation of controls (Section 112(i)(3(B) of the CAA). In addition, the Panel recommended that, should a 1-year extension under 112(i)(3) be granted, the

[26] See preamble section III.H

EPA also take comment on how to complement other available statutory compliance flexibilities that may be necessary to maintain adequate sterilization capacity to protect public health. The EPA acknowledges that there are several factors that either support or undermine the justification for an expedited compliance timeframe for existing sources. In order to implement the capture and emission reduction systems necessary to comply with the proposed requirements, facilities will need to cease operations for a certain period of time in order to implement these systems. However, an expedited compliance timeframe could result in more facilities needing to cease operations simultaneously. This means that increased coordination would be needed to ensure that the supply of medical devices is not adversely impacted. The EPA also recognizes the health risks that this source category currently poses and that the risks of EtO exposure have been made known for some time. In addition, a significant portion of the industry is already operating the types of capture and control systems that we anticipate will be needed to comply with the proposed standards. The EPA is soliciting comment on this compliance timeframe (Comment C-77 in the preamble).

The Panel also recommended that the EPA consult with the FDA to understand the impact to the supply of medical equipment that could occur if all EtO sterilization facilities are concurrently making significant upgrades to their air pollution control techniques and will potentially have simultaneous periods of shutdown. As discussed in preamble, the EPA has had discussions with FDA regarding the potential impacts of this proposal on commercial sterilization facilities. These discussions highlighted concerns regarding the potential impact on the availability of certain medical devices, including those that are (1) experiencing or at risk of experiencing a shortage, (2) in high demand as a result of the COVID-19 pandemic, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility.

Other Items. The Panel recommended that the EPA consider GACT standards for area sources to the maximum extent possible and take comment on GACT standards for area sources. As described in the preamble to this proposal,[27] the EPA is proposing GACT standards for all unregulated emissions from area source facilities. The EPA believes that this is appropriate because (1) a significant portion of the area source facilities are owned by small entities, (2) companies could experience significant economic burden if MACT standards are imposed, (3)

[27] See preamble section III.D

the EPA is trying to minimize disruptions to the supply of medical devices, and (4) the EPA is proposing revisions to certain standards based on an assessment of the post-control risks under CAA section 112(f)(2).

The Panel recommended that the EPA explore regulatory alternatives that will incentivize lower EtO usage. As previously mentioned, the EPA is proposing emission rate standards for CEVs at facilities where EtO use is at least 10 tpy, as well as room air emissions for all facilities. For emission reduction requirements, the EPA is soliciting comment on whether to adopt equivalent emission rate standards and, if so, how those equivalent emission rates should be calculated. In addition, for existing Group 2 room air emissions at area source facilities where EtO use is less than 20 tpy, the EPA is proposing a BMP that would these facilities to follow either the Cycle Calculation Approach or the Bioburden / Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 14161:2009. The EPA believes that emission rate standards incentivize lower EtO usage because a facility would be less likely to need significant modifications in order to demonstrate compliance, considering current EtO measurement technology. In addition, the approaches listed in the BMP use approximately 50 percent less EtO than less conservative approaches, such as the Half Cycle Approach.

As discussed in the preamble to this proposal,[28] the EPA is proposing a compliance alternative for combined emission streams. Specifically, the EPA is proposing that if any of the composite streams is subject to an emission reduction standard, then the emission reduction standard for the combined stream is equal to the most stringent emission reduction standard for the composite streams. In addition, if any of the composite streams are subject to an emission rate standard, then the emission rate standard for the combined stream is equal to the sum of the emission rate standards for the composite streams. The EPA is soliciting comment on this proposed compliance alternative (Comment C-75 in the preamble). The Panel recommended that the EPA propose a compliance alternative for operators to route a portion of or all EtO exhaust streams to a common stack and monitor for direct EtO emissions, with specific EtO emission concentration limits. The Panel further recommended that the EPA:

[28] See preamble section III.G.3.d

- Specifically solicit comments on what provisions of the current rule and proposed rule should be covered by this alternative and how reporting and recordkeeping could be streamlined,
- Solicit comment on the appropriate way to set an EtO emission concentration limit, and whether the concentration limit should be set as a site-specific limit based on the particular circumstances of a facility, and
- Solicit comment on the technical and economic factors that would drive a firm to adopt this alternative.

In developing this proposed rule, the EPA has observed that many companies have implemented a wide variety of emission stream combinations. Therefore, this compliance alternative was designed to be independent of the emission stream types (*e.g.*, SCV, room air) that are included in a combined emission stream. The EPA believes that this compliance alternative will streamline performance testing, which would further streamline recordkeeping and reporting requirements. As previously discussed, the EPA has considered concentration standards but is unable to justify them.

The Panel recommended that the EPA take comment on proximity requirements for new sources as described in the final report. The Panel also recommended that the EPA request comment on whether a proximity restriction could or should substitute for emission control requirements for new or existing sources elsewhere in the proposal. As described in the preamble, the proposed emission standards for new sources are at least as stringent as those being proposed for existing sources. Therefore, the EPA does not believe it is necessary to solicit comment on proximity requirements.

The Panel recommended that the EPA consider changes that a facility has made to comply with OSHA standards when proposing updates to the rule. As part of both the December 2019 Questionnaire and the September 2021 ICR, the EPA collected data on facility characteristics that would need to be properly managed to comply with OSHA standards, including room air changes per hour, temperature, and EtO concentration (from both personnel badges and gas chromatograph monitoring).

The EPA will prepare a Small Entity Compliance Guide to help small entities comply with this rule when it is finalized. As required by section 604 of the RFA, the EPA will prepare a final regulatory flexibility analysis (FRFA) for this action as part of the final rule. The FRFA will address the issues raised by public comments on the IRFA.

5.3 Market Impacts

This section discusses potential supply and demand responses to the regulatory costs imposed on facilities in the EtO sterilization industry affected by this proposed rule. Sterilization services are inputs to the supply chain that delivers healthcare services to institutions and individuals. There is uncertainty in how the proposed rule could potentially affect the medical device supply chain. This discussion of potential economic impacts is guided by the general assumption that the supply chain can be loosely characterized starting with the commercial EtO sterilizers, whose services are used as inputs by medical device manufacturers, whose devices are generally purchased by hospitals and other healthcare providers, whose services are then sold to end consumers and paid for in varying shares by the patients themselves, the federal government, and insurers.

The price and quantity effects of any regulatory costs as well as how the cost burden is potentially divided between the directly regulated sector, intermediate goods and services in the supply chain that use the regulated good as an input, and end consumers are driven by supply and demand in these respective markets and represented in the slopes of those supply and demand curves. Economists use elasticities, or the percentage change in quantity supplied (or demanded) divided by the percentage change in price, to measure the responsiveness of producers and consumers to price changes.

All else equal, commercial EtO sterilizers would likely offer to sterilize more products when the price of their services rises. The price elasticity of supply measures how much the supply of EtO sterilization capacity responds to changes in the price of EtO sterilization services. If sterilizers have significant flexibility to increase (decrease) the amount of product they sterilize when the price of their services rises (falls), the supply of EtO sterilization is considered elastic. In contrast, if the amount of product sterilized with EtO only changes by small amounts when the price rises, the supply of EtO sterilization is considered relatively inelastic. In the case of a price increase, supply changes may be more constrained in the short run if firms need time

to adjust operations and increase production capacity. On the demand side, customers would generally be expected to purchase fewer products sterilized with EtO when the price to sterilize those products rises. Several factors influence how sensitive consumers are to price changes. If consumers can easily switch from one good or service to another because there are many close substitutes, demand tends to be more elastic. The more elastic the supply and inelastic the demand, the smaller the effect of a price change on the market equilibrium quantity. Nonetheless, economic theory suggests that consumers will bear a higher share of welfare losses when supply is more responsive to price changes than demand.

Regulatory costs can be represented as an upward shift in the supply curve for the regulated industry, but further information is needed to determine the degree to which that shift results in a higher equilibrium price and/or lower equilibrium quantity as well as who bears the impacts (*e.g.*, the regulated industry, its customers, indirectly affected markets). Any regulatory-induced price impacts on sterilization services, or indirect price impacts on medical devices and healthcare services, will depend on several factors beyond the elasticity of demand and supply in these markets, including elasticities of substitution, and whether market power and/or purchasing power is present in these various stages of the supply chain.

Sterilization is generally a small input when considering the total costs of making and providing medical devices and healthcare services. If sterilization providers are able pass on regulatory costs by increasing the price of their services, effects on prices of devices and healthcare may be limited because price changes for inputs that are small are less likely to have large impacts on prices of end products (devices, healthcare services). While higher costs of sterilization may not present significant problems for medical device manufacturers, limited capacity in the EtO sterilization industry could still potentially disrupt the medical device supply chain if there are not enough sterilization providers available to accommodate the amount of devices that need to be sterilized with EtO. Capacity could be limited in the short run as firms adjust operations to comply with the proposed requirements and complete product revalidations.

5.3.1 Supply Response to Regulation

To date, there have been no previous studies describing how the EtO sterilization industry reacts to regulation. However, given what is known about the industry, there is reason to believe that supply is inelastic and a portion of the regulatory costs could potentially be passed forward

in the price of sterilized products. The EtO sterilization industry is a mix of small and large companies and facilities that sterilize a wide of range of medical devices. Larger companies and facilities, as well as companies and facilities of any size that sterilize more sophisticated devices such as pacemakers, may exert more market power and be able to pass on regulatory costs to some degree. On the other hand, smaller companies and facilities or companies and facilities of any size that sterilize more common medical devices such as syringes may be characterized as competitive and price takers, which means one firm cannot influence the price of sterilization services. As a result, these companies and facilities may not be able pass on as much of their regulatory costs to intermediate or end users. As the cost to conduct sterilization increases due to regulation, profits for these companies and facilities would decrease, which may induce some to exit the market.

As discussed in section 5.2.5, the small entities affected by this proposed rule are expected to incur much higher costs relative to their revenues, potentially leading to a higher risk of market exit for small firms. Large entities account for a higher share of industry output of sterilized devices and are estimated to incur much lower impacts from the proposed rule compared to small firms when comparing their costs relative to revenues. Consequently, potential effects on industry capacity may be more limited under a scenario where firm exit is limited to small companies, though the industry would become more concentrated.

Given the capacity constraints in the commercial EtO sterilization industry and the costs associated with switching sterilization sites for a device (see Chapter 2), device manufacturers may have limited opportunity to shop around and find sterilizers offering lower prices should their usual provider raise prices due to regulatory costs. However, in the healthcare market there are some large medical device manufacturing firms and large buyers of sterilized medical supplies and equipment such as hospitals, the federal government, and insurance companies that can exert market power. Buyers with market power can potentially resist cost passthrough. For example, large medical device firms may hold bargaining power and be able to resist cost passthrough (*i.e.*, higher sterilization prices) from the commercial EtO sterilizers. Alternatively, they may accept higher sterilization prices and then try to pass those increased costs on to *their* customers. It is also possible that the ability of device makers to pass on higher sterilization costs may be limited by purchasing power of large intermediaries like insurers, the government, and large hospital networks. High-volume, long-term contracts between sterilizers and device

manufacturers, or between device manufacturers and hospitals, may limit cost passthrough or serve as partial barriers that prevent any one sector in the supply chain from incurring all of the increased costs from additional regulations of the EtO sterilization industry.

5.3.2 Demand Response to Regulation

Since demand for medical devices and healthcare services are generally considered inelastic, demand for EtO sterilization services may also be inelastic given how critical it is as an input. Ellis et al. 2017 estimate demand elasticities for healthcare services between 2008 and 2014, estimating an elasticity of -0.44 for healthcare services overall. This is relatively close to other estimates in the literature such as Scoggins and Weinberg's (2017) range of -0.31 to -0.15 and the RAND Health Insurance Experiment estimate of -0.2 (Aron-Dine et al. 2013). A 2006 review of econometric studies found the elasticity of demand for healthcare to be around -0.2 in many cases (Liu and Collet 2006). A demand elasticity of -0.2 suggests that a 10 percent increase in the price of healthcare will lead to an approximately 2 percent reduction in the quantity of healthcare demanded. There is relatively less empirical work on the elasticity of supply in the healthcare industry.

Medical devices are generally not final goods but inputs into delivering health care to consumers. For example, a consumer does not typically purchase a pacemaker from the manufacturer, but instead, purchases the procedure that implants the device in the chest, which includes services such as the time of a surgeon or specialist and the medical devices necessary to perform the procedure, (*e.g.*, catheter, wires, surgical blades). Because sterilization is a necessity and sterilization using EtO has high market share and limited substitutes, the price of EtO sterilization services may increase. Given the relative low elasticity of demand for sterilized health products, cost increases may be passed from sterilizers to medical device manufacturers to hospitals and end-use consumers. However, any price effects transmitted to end-use consumers are likely to be small. Sterilization is a small input when considering the total costs of making and providing medical devices and healthcare services, and price changes for small inputs are less likely to have large impacts on prices of end products. However, potential price changes experienced by end-use consumers of healthcare services would likely vary by service category and their insurance coverage.

The demand for a good that is an input into the provision of a final consumer service depends, in part, on the degree to which that input can be substituted for other inputs. Demand is less elastic for products with fewer substitutes. The qualitative discussion in section 2.2 on the limited availability of substitute sterilization technologies (*i.e.*, the substitution elasticity between EtO and other sterilization methods is likely to be very small) suggests that demand for EtO sterilization may be relatively inelastic. Quantity demanded is less responsive to changes in price when demand is inelastic. In addition, the substitution elasticity between medical devices sterilized with EtO and other medical devices not sterilized with EtO is also likely to be very small based on the information presented in section 2.2 highlighting the share of devices reliant on EtO sterilization and the prevalence of healthcare products that are made of materials that can only tolerate sterilization using EtO.

5.3.3 Illustrative Example

Figure 5-1 illustrates the case of increased regulatory costs where both supply and demand are relatively inelastic, but demand is more inelastic than supply. In Figure 5-1, Q_E represents the pre-regulation quantity of sterilized products demanded and supplied at price P_E. After a rule is promulgated, Q_R represents the post-regulation quantity of sterilized products that would be purchased when costs from the regulation are incurred. As shown in Figure 5-1, the consumers of sterilized products pay a higher proportion of the increased cost ($P_{DR} - P_E$) than the commercial EtO sterilizers ($P_E - P_{SR}$). In this case, consumers are absorbing more of the increased costs from a regulation. While illustrative, there are reasons to expect that consumers (*e.g.*, device makers, intermediaries, end-user patients) may pay a high share of the increased costs. Many consumers are insured, and even though premiums could eventually increase, the cost of sterilized devices used for medical care or in procedures that are deemed necessary should be covered by insurance. Insurers may pass on a small increase in price (*i.e.*, co-pay). Even if consumers absorb a high share of the regulatory costs, the EPA does not expect large increases in prices of devices and healthcare since sterilization is represents a small share of the total costs involved in producing medical devices and providing healthcare services.

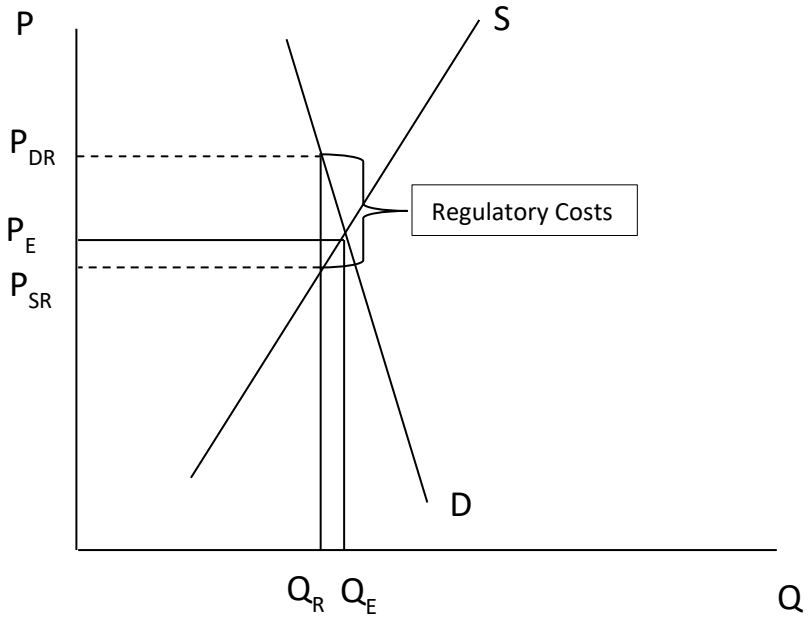

Figure 5-1. Illustrative Example of Potential Impacts with Inelastic Supply and Demand

National engineering compliance cost estimates are often used to approximate the social cost of a rule. However, in cases where the engineering costs of compliance are used to estimate social cost, the burden of the regulation is typically measured as falling solely on the affected producers, who experience a profit loss exactly equal to these compliance cost estimates. Thus, the entire economic welfare loss is a change in producer surplus with no assumed change in consumer surplus because no changes in price and consumption are estimated. This is typically referred to as a "full-cost absorption" scenario in which all factors of production are assumed to be fixed and firms are unable to adjust their output levels when faced with additional costs. In contrast, this illustrative example builds on the engineering cost analysis, draws on sterilization and healthcare industry information, and incorporates economic theory related to producer and consumer behavior to characterize potential changes in market conditions under simplified hypothetical circumstances.

This illustrative example should not be considered a formal estimate of the market impacts of this proposed rule. The EPA is missing many of the parameters (*e.g.*, prices, quantities, elasticities) needed to truly investigate potential market impacts, and the values and

parameters that have some basis in the literature are not specific to the EtO sterilization market or the products sterilized with EtO.

5.4 Employment Impacts

This section presents a qualitative overview of the various ways that environmental regulation can affect employment. Regulation can affect employment via its effect on output by changing the marginal cost of production, and by affecting the relative proportions of labor and capital used by regulated firms (*i.e.*, the labor intensity of production). Standard neoclassical theory alone does not point to a definitive net effect of regulation on labor demand at regulated firms. Employment impacts of environmental regulations are generally composed of a mix of potential declines and gains in different areas of the economy (*e.g.*, the directly regulated sector, upstream and downstream sectors, and the pollution abatement sector) over time.

Labor markets respond to regulation in complex ways and regulatory employment impacts can vary across occupations, regions, and industries. The response depends on the elasticities of demand and supply for labor and for the goods or services produced by the regulated industry, as well as in response to other labor market conditions (*e.g.*, wage stickiness, long-term unemployment). Isolating regulatory impacts on employment is a challenge, as they are difficult to disentangle from impacts caused by a wide variety of ongoing, concurrent economic changes. The EPA continues to explore the relevant theoretical and empirical literature and to seek public comments in order to ensure that the way the EPA characterizes the employment effects of its regulations is reasonable and informative.

Environmental regulation "typically affects the distribution of employment among industries rather than the general employment level" (Arrow et al. 1996). Even if impacts are small after long-run market adjustments to full employment, many regulatory actions have transitional effects in the short run (OMB 2015). These movements of workers in and out of jobs in response to environmental regulation are potentially important and of interest to policymakers. Transitional job losses have consequences for workers that operate in declining industries or occupations, have limited capacity to migrate, or reside in communities or regions with high unemployment rates.

As indicated by the market impacts discussion in section 5.3, the proposed requirements may cause shifts in the prices and supply of sterilization services, although any shifts are expected to be small. The demand for EtO sterilization services is likely to be inelastic. As a result, demand for labor among commercial EtO sterilizers and associated industries is unlikely to change to a large degree but might experience adjustments as there may be compliance-related labor needed for the manufacture, installation, operation, and maintenance of equipment associated with permanent total enclosures and continuous emissions monitoring systems, as examples. In addition, there may be changes in employment due to effects on output from directly regulated sterilization companies and sectors that use their services. If the cost of conducting EtO sterilization increases sufficiently as a result of this action, then net revenues of directly regulated firms and indirectly affected medical device manufacturing firms may fall and employment at these firms may potentially decline. However, as explained, the EPA expects any potential market and employment impacts to be relatively small.

6 NET BENEFITS

The net benefits of the proposed amendments to the subpart O NESHAP for EtO commercial sterilization and fumigation facilities are shown in Table 6-1. Since the EPA estimated costs but was unable to monetize the health benefits of this proposed rule, the net benefits are negative.

Table 6-1. Summary of Benefits, Costs and Net Benefits for the Proposed Regulatory Options from 2023 to 2042 (Million 2021$ [a])

	Option 1				Option 2 (Proposed)				Option 3			
	3 Percent		7 Percent		3 Percent		7 Percent		3 Percent		7 Percent	
	PV	EAV	PV	EAV	PV	EAV	PV	EAV	PV	EAV	PV	EAV
Total Monetized Benefits[b]	N/A		N/A		N/A		N/A		N/A		N/A	
Total Costs	$635	$43	$513	$60	$784	$53	$640	$74	$897	$60	$746	$85
Net Benefits	N/A		N/A		N/A		N/A		N/A		N/A	
Non-monetized Benefits	15 tpy of EtO Health effects of reduced EtO exposure				19 tpy of EtO Health effects of reduced EtO exposure				20 tpy of EtO Health effects of reduced EtO exposure			

[a] When necessary, dollar figures in this RIA have been converted to 2021$ using the annual GDP Implicit Price Deflator from the U.S. Bureau of Economic Analysis (BEA) NIPA Table 1.1.9, found at https://fred.stlouisfed.org/release/tables?rid=53&eid=41158.

[b] While we expect that these avoided emissions will result in reductions in adverse human health effects, we have determined that quantification of those benefits cannot be accomplished for this proposed rule. This is not to imply that there are no benefits of the proposal; rather, it is a reflection of the difficulties in modeling the health effects and monetizing the benefits of reducing HAP emissions from this source category with the data currently available.

6.1 Uncertainties

The results of this analysis are subject to many sources of uncertainty. This analysis includes many data sources as inputs, including source counts, equipment and labor costs, and assumptions regarding the current state of the EtO sterilization industry and how individual facilities carry out their operations, the future state of the industry, and the future state of the world (*e.g.*, regulations, technology, economic activity, and human behavior). There is also uncertainty about the specific components of the engineering costs, such as the costs of the equipment and labor required to comply with the proposal and how the costs might change over time. The EPA only estimated costs for existing facilities, but new facilities may be constructed

and become subject to the requirements. Facilities may modify or upgrade in ways that affect the number of the various emissions points impacted by this proposed rule (*e.g.*, adding a sterilization chamber or aeration room). They may alter their EtO usage and thus become subject to different requirements. Additionally, new control technology may become available in the future at lower cost.

This proposal may not impact all locations with EtO sterilizers equally, in part due to differences in state and local policies such as consent orders in locations like Illinois and Georgia.[29] Additionally, these discussions and analyses are subject to various types of uncertainty regarding input parameters and assumptions.

The risk results and environmental justice analysis are subject to several sources of uncertainty. First, there is uncertainty in the baseline emissions dataset and the modeling conducted to estimate the emissions reductions due to the proposal. There is also uncertainty associated with the inputs and assumptions used in the dispersion modeling, the inhalation exposure estimates, and the dose-response relationships.

[29] For more information, see https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates.

7 REFERENCES

Agency for Toxic Substances and Disease Registry (ATSDR). (2022). Toxicological Profile for Ethylene Oxide. U.S. Public Health Service, U.S. Department of Health and Human Services. Found at https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf.

American Spice Trade Association. (2009). Ethylene Oxide White Paper. Found at https://www.astaspice.org/download/1419.

Aron-Dine, A., Einav, L., & Finkelstein, A. (2013). The RAND health insurance experiment, three decades later. *Journal of Economic Perspectives*, *27*(1), 197-222.

Arrow, K. J., Cropper, M. L., Eads, G. C., Hahn, R. W., Lave, L. B., Noll, R. G., ... & Stavins, R. (1996). Benefit-cost analysis in environmental, health, and safety regulation. *Washington, DC: American Enterprise Institute*, 1-17.

Centers for Disease Control and Prevention. (2016). Low-Temperature Sterilization Technologies: Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). Found at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/low-temp.html.

Congressional Research Service. (2015). The Medical Device Excise Tax: Economic Analysis. Found at https://crsreports.congress.gov/product/pdf/R/R43342.

Donahoe, G. (2021). Estimates of Medical Device Spending in the United States. Found at https://www.advamed.org/wp-content/uploads/2021/12/Estimates-Medical-Device-Spending-United-States-Report-2021.pdf.

Dvorak, P. (2015). Validating sterilization process by ethylene oxide. *Medical Design & Outsourcing*. Found at https://www.medicaldesignandoutsourcing.com/validating-sterilization-processes-by-ethylene-oxide/.

Ellis, R. P., Martins, B., & Zhu, W. (2017). Health care demand elasticities by type of service. *Journal of health economics*, *55*, 232-243.

Ethylene Oxide Sterilization Association (EOSA). 2018. The Benefits of Ethylene Oxide Sterilization. Found at https://www.eosa.org/sites/default/files/2018-08/The%20Benefits%20of%20Ethylene%20Oxide%20Sterilization.pdf.

Ethylene Oxide Sterilization Association (EOSA). (2022). Comments on Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical (MON) Manufacturing Residual Risk and Technology

Review for Ethylene Oxide (EtO) (Docket Number EPA-HQ-OAR-2018-0746). Found at https://insideepa.com/sites/insideepa.com/files/documents/2022/mar/epa2022_0539j.pdf.

Food and Drug Administration. (2014). Sterilization Process Controls. Found at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/sterilization-process-controls.

Food and Drug Administration. (2019a). FDA Executive Summary Prepared for the November 6-7, 2019 Meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee on Reduction of Ethylene Oxide Sterilization Emissions for Medical Devices and Potential for Utilizing Other Sterilization Modalities. Found at https://www.fda.gov/media/132186/download.

Food and Drug Administration. (2019b). Ethylene Oxide Sterilization for Medical Devices. Found at https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices.

Food and Drug Administration. (2019c). Center for Devices and Radiological Health Ethylene Oxide Sterilization Master File Pilot Program. Found at https://www.federalregister.gov/documents/2019/11/26/2019-25631/center-for-devices-and-radiological-health-ethylene-oxide-sterilization-master-file-pilot-program.

Food and Drug Administration. (2022). Sterilization for Medical Devices. Found at https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#ethylene.

Gamma Industry Processing Alliance (GIPA). (2017). A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products. Found at http://gipalliance.net/wp-content/uploads/2013/01/GIPA-WP-GIPA-iia-Sterilization-Modalities-FINAL-Version-2017-October-308772.pdf.

International Trade Administration. (2016). 2016 Top Markets Report – Medical Devices. Found at https://legacy.trade.gov/topmarkets/pdf/Medical_Devices_Top_Markets_Report.pdf.

Lambert, B., & Martin, J. (2013). Sterilization of implants and devices. *Biomaterials Science*: 1339-1353. Found at https://www.sciencedirect.com/science/article/pii/B978008087780800125X.

Liu, S., & Chollet, D. (2006). Price and income elasticity of the demand for health insurance and health care services: a critical review of the literature.

Medical Device and Diagnostic Industry. (1998). EtO sterilization: Principles of process design. Found at https://www.mddionline.com/eto-sterilization-principles-process-design.

Medical Device and Diagnostic Industry. (2001). Optimizing EtO sterilization. Found at https://www.mddionline.com/optimizing-eto-sterilization.

Medpac. (2017). Chapter 7: An overview of the medical device industry. Report to the Congress: Medicare and the Health Care Delivery System. Found at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch7.pdf.

Occupational Safety and Health Administration. (2002). OSHA fact sheet on ethylene oxide. Found at https://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf.

Occupational Safety and Health Administration. (2005). Regulatory review of the Occupational Safety and Health Administration's ethylene oxide standard [29 CFR 1910.1047]. Found at https://www.osha.gov/dea/lookback/ethylene_oxide_lookback.pdf.

Office of Management and Budget. (2015). 2015 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act.

Schmalensee, R., & Stavins, R. N. (2011). A guide to economic and policy analysis of EPA's Transport Rule. Found at https://www.analysisgroup.com/globalassets/insights/publishing/2011_stavinsschmalansee_transportrulereport.pdf.

Scoggins, J. F., & Weinberg, D. A. (2017). Healthcare Coinsurance Elasticity Coefficient Estimation Using Monthly Cross-sectional, Time-series Claims Data. *Health economics*, *26*(6), 795-801.

Shintani, H. (2017). Ethylene oxide gas sterilization of medical devices. *Biocontrol Science*. Vol. 22; No.1: 1－16. Found at https://www.gasdetection.com/wp-content/uploads/ethylene_oxide_gas_sterilization_of_medical_devices.pdf.

Sterigenics. (2018). Stored Energy Device Safety Assessment for Ethylene Oxide Sterilization. Found at https://sterigenics.com/wp-content/uploads/2018/09/EO_Battery_Battery_Assesment_Brochure_WEB.pdf.

Sterigenics. (2019). Ethylene Oxide Sterilization. Found at https://sterigenics.com/technologies/ethylene-oxide/.

Steris. (2019). Anatomy of an ethylene oxide sterilizer. Found at https://www.steris-ast.com/tech-tip/anatomy-ethylene-oxide-sterilizer/.

Steris. (2019b). Anatomy of an ethylene oxide sterilization process. Found at https://www.steris-ast.com/tech-tip/anatomy-ethylene-oxide-sterilization-process/.

U.S. EPA. (2005). Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. Found at https://www.epa.gov/sites/default/files/2013-09/documents/childrens_supplement_final.pdf.

U.S. EPA. (2016). Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System

(IRIS). National Center for Environmental Assessment, Office of Research and Development. Washington, DC. EPA/635/R-16/350Fa. Found at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.

U.S. EPA. (2018). Ethylene Oxide. Health Effects Notebook for Hazardous Air Pollutants. Found at https://www.epa.gov/sites/default/files/2016-09/documents/ethylene-oxide.pdf.

United States Environmental Protection Agency	Office of Air Quality Planning and Standards Health and Environmental Impacts Division Research Triangle Park, NC	Publication No. EPA-452/R-23-007 March 2023