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

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Regulatory Impact Analysis for the Final 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).

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1 EXECUTIVE SUMMARY

1.1 Background

The U.S. Environmental Protection Agency (EPA) is finalizing 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 final rule.

Commercial sterilization and fumigation operations, or "commercial sterilizers", that are impacted by this final 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. 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 finalizes amendments to the subpart O NESHAP requirements. The EPA is requiring 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 finalizing 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 fugitive sources from certain groups of facilities. The EPA is also finalizing 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 revising monitoring and

performance testing requirements and adding 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 final 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 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 EtO residuals 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 tons per year (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 rule on a technology review. However, the context for this rule is somewhat unique in that the EPA updated the Integrated Risk Information System (IRIS) value associated

[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.

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 aimed 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 final 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 14094, that latter of which was published after the proposal was released. The guidance document associated with these executive orders is the Office of Management and Budget's (OMB) Circular A-4, which has been updated since the proposal was released.[6]

This final rule is an economically significant regulatory action as defined by EO 12866 (applied at proposal) and EO 14094 (released since proposal).[7] In accordance with EO 12866 and

[5] Additional information on the IRIS program is available here: https://www.epa.gov/iris.

[6] Office of Management and Budget. (2023). Circular No. A-4. Found at https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.

[7] After the proposal was issued, Executive Order 14094 was released, and it contains some updated guidance regarding economic significance determinations. EO 14094 1(f)(1) specifies that impacts of $200 million or greater (costs, or benefits, in any single year) would indicate a rule is economically significant (compared to the $100 million threshold in EO 12866). The proposal was considered economically significant under EO 12866

EO 14094 and the guidelines of OMB Circular A-4, this RIA analyzes the costs of complying with the requirements in this final rule for regulated facilities. The EPA did not monetize the benefits associated with the requirements, but they are characterized qualitatively in chapter 4. OMB Circular A-4 requires analysis of one regulatory control alternative that is more stringent than the finalized rule and one that is less stringent than the finalized rule. This RIA evaluates the costs and certain other impacts (e.g., small entity impacts) of a more stringent alternative and a less stringent alternative to the selected set of standards being finalized in this rule. Between the proposed and final EtO rulemaking, Circular A-4 was updated and contains changes to the practices for discounting impacts that occur in the future. To maintain consistency and transparency of the impacts between the proposed and final RIA, the EPA continues to present impacts at the 3 percent and 7 percent discount rates required by Circular A-4 (2003) in this final rule RIA. If the EPA were to apply the new discount rate of 2 percent, as required by the updated Circular A-4 starting in January 2025, the present value of the costs would be higher than the present value of the costs presented at the 3 percent and 7 percent discount rates.

1.5.2 Process for Developing Final Rule

The finalized changes to the subpart O NESHAP are based on the results of the RTR, 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 finalizing numeric and percent reduction 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. The EPA is also finalizing 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. Finally, some of the standards are being finalized under CAA section 112(d)(6), or the technology review. The preamble contains a more thorough discussion of the gap-filling analysis, risk review, and technology review conducted for this rule, including the range of

and this final rule is still considered economically significant under the updated threshold in EO 14094. EO 14094 can be found at: https://www.federalregister.gov/documents/2023/04/11/2023-07760/modernizing-regulatory-review.

technologies, practices, and other requirements considered and the EPA's reasoning for ultimately choosing the standards being finalized.

The EPA first determined standards for previously unregulated emission sources under CAA section 112(d)(2), (d)(3), and (d)(5). The EPA is establishing standards for previously 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 EtO residuals that come off of sterilized products within the facility both before and after the aeration process. The EPA is also establishing standards for point sources at facility usage levels that were previously unregulated, including SCVs and ARVs at facilities where EtO usage is less than 1 tpy; and ARVs at facilities where EtO usage is at least 1 tpy but less than 10 tpy.

Next, taking into account the risk reductions estimated to result from the standards 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 finalizing health-based standards for SCVs, ARVs, CEVs, and certain room air emissions. While the EPA was not required to invoke CAA 112(f)(2) in this 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 stringency of the health-based standards varies based on a facility's annual EtO usage. The usage groupings in the standards are intended to address emissions from facilities identified as high risk while mitigating the compliance burden for lower risk facilities. The EPA is finalizing health-based emission standards for SCVs at facilities where EtO use is at least 30 tpy, SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy, SCVs at facilities where EtO use is at least 1 tpy but less than 10, ARVs at facilities where EtO use is at least 30 tpy, CEVs at area source facilities where EtO use is at least 400 tpy,[8] CEVs at area source facilities where EtO use

[8] As discussed in section IV.C.2.a.iv of the final preamble, there is one facility within the source category where revised allowable emissions from CEVs contribute to the facility's MIR exceeding 100-in-1 million, and this is an area source facility that currently uses 446 tpy of EtO. We therefore considered a more stringent CEV emission standard for area source facilities where EtO use is at least 400 tpy and found that 99.9 percent reduction would eliminate CEV emissions as a contributer to a facility's MIR exceeding 100-in-1-million for these facilities.

is at least 60 tpy but less than 400 tpy, Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy, and Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy.[9]

The EPA then completed a technology review for the sector pursuant to CAA section 112(d)(6). The goal of a technology review is to identify 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. Additional technology-based standards are being finalized for these sources, however, they do not generate additional economic impacts since all facilities are currently complying with them or are subject to at least the same emission standard pursuant to CAA section 112(f)(2). The EPA is also finalizing the same requirements under (d)(6) that are being finalized under CAA 112(f)(2) for SCVs at facilities where EtO use at least 1 tpy but less than 10 tpy.

The EPA is also finalizing 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 requiring monitoring with an EtO continuous emissions monitoring system (CEMS), with the exception of facilities where EtO use is less than 100 pounds per year, which will have the option of either using CEMS or conducting initial and annual performance testing with continuous parameter monitoring. The final standards and requirements are described in greater detail in the preamble.

Several changes were made to the final standards and to this RIA since the 2023 proposed rule. These changes are summarized below:

- The categorization of various standards based on EtO usage has changed for all emission sources. For example:

[9] The EPA is finalizing 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.

- The requirement to install a permanent total enclosure (PTE) for Group 2 room air emissions was applied to facilities with annual EtO usage of at least 20 tpy at proposal. This threshold was lowered in the final rule to include any facilities with annual EtO usage of at least 4 tpy. This change increased the total estimated costs of the finalized option relative to main option analyzed at proposal.

- The EPA finalized a requirement to implement CEMS for all facilities with annual EtO usage of 100 pounds per year or greater. This change increased the total estimated costs of the finalized option relative to main option analyzed at proposal.
- The EPA removed a requirement to conduct inspections of natural draft openings due to safety concerns. The removal of this requirement lowered the total estimated costs of the finalized option.
- The EPA changed several of the standards for CEVs and room air emissions from emissions rate standards to percent reduction standards. This change increased the estimated costs of the final rule.
- Three facilities were added to the affected facility list and one was removed based on information received since the proposal. The final list has 90 affected facilities.
- The compliance timeframe was increased to the maximum amount of time allowed by the CAA.
- For options 2 and 3, the EPA is now estimating the new validation costs to be zero, as EPA has not identified any facilities where EtO use is less than 4 tpy that are not already meeting this requirement. The proposed standards included sterilization chamber concentration limits which have been altered for the final rule.[10] This change reduced the estimated costs of the finalized option.

[10] Chamber concentration limits may necessitate new product validations, but new validations are not necessary to comply with emissions standards because emissions standards would be achieved through add-on control technology rather than through altering sterilization cycle parameters. The best management practice (BMP) being finalized for Group 2 room air emissions for area source facilities pursuant to CAA section 112(d)(5) requires area source facilities to lower the EtO concentration within each sterilization chamber to 1 ppm before

- The analytical timeframe was changed from 2023 to 2042 in the proposal RIA to 2025 to 2044 for the final RIA.
- A sensitivity analysis was added to address some potential costs that were not quantified in the RIA for the proposed rule. In response to comments about facilities possibly needing to slow operations temporarily to complete upgrades to comply with the rule, the EPA examined a scenario where the affected facilities incur additional costs in the form of lost revenues due to temporary compliance-related capacity reductions. See Appendix A for presentations of the methodology and results of this sensitivity analysis.

1.5.3 Regulatory Alternatives Analyzed in this RIA

This RIA assesses impacts of the final standards and two regulatory alternatives. The previous subsection describes all the standards and changes being finalized 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 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 final option 2 reduce the compliance burden for many facilities relative to option 3 because they would not be subject to the most stringent standards applied under option 3, which results in fewer facilities requiring PTEs. 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. Control costs and monitoring and testing costs are lower for this option than for option 2.

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the chamber can be opened. The applicability of this BMP is being limited to facilities where EtO use is less than 4 tpy pursuant to CAA section 112(f)(2). According to data collected as part of the December 2019 questionnaire and September 2021 information collection request (ICR), all facilities where EtO use is less than 4 tpy are currently meeting the BMP. Therefore, the EPA does not expect that these facilities would need to complete new validations. Emissions standards rather than chamber concentration limits are being finalized for higher EtO usage facilities, so it is expected that no facilities would need to complete new validations under the finalized option 2.

Option 2 (final): 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 new 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 create new limitations for all currently unregulated emissions to the most stringent levels that are considered in the preamble. This option would require more facilities to install PTEs than under option 2.

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 rule were estimated over a 20-year timeframe from 2025 to 2044. 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 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 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 final rule, the EPA was not able to monetize the benefits associated with the emissions reductions estimated to result from this rule.

The EPA identified 88 EtO sterilization facilities currently operating in the U.S., all of which will be impacted by this final rule and incur costs. There are two commercial facilities that have announced plans to open and will be affected by the rule, which brings the total number of facilities incurring costs in this final RIA to 90.

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 final rule. The EPA is finalizing 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 2025 to 2044 for the

final option 2 is $773 million in 2021 dollars, discounted at a 7 percent rate. The equivalent annualized value (EAV)[11] of the costs for option 2 is $88 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 $932 million and $63 million, respectively.

For option 1, the PV and EAV of the estimated costs are $446 million and $51 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 $543 million and $37 million, respectively. For the more stringent option 3, the PV and EAV of the estimated costs are $861 million and $97 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 about $1 billion and $69 million, respectively. For options 1, 2, and 3, the EPA estimated EtO emissions reductions of 13 tpy, 21 tpy, and 21 tpy, respectively.

Table 1-1. Estimated Costs and Emissions Reductions from 2025 to 2044 (Millions 2021$ [a])

	Option 1	Option 2 (final)	Option 3
Capital Costs	$158	$313	$387
Total Annualized Costs[b]	$53	$74	$89
Discounted Present Value of Costs (3%)	$543	$932	$1,025
Equivalent Annualized Value (3%)	$37	$63	$69
Discounted Present Value of Costs (7%)	$446	$773	$861
Equivalent Annualized Value (7%)	$51	$88	$97
EtO Emissions Reductions (tpy)	13	21	21

[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.

The EPA also examined a scenario where the final rule causes facilities to temporarily reduce production to complete upgrades and changes to comply with the final requirements. The analysis presented in Appendix A uses a set of assumptions to estimate potential lost revenues associated with facilities needing to temporarily reduce capacity for a year in order to complete

[11] The EAV represents a flow of constant annual values that, had they occurred in each year from 2025 to 2044, would yield a sum equivalent to the present value.

upgrades to comply with the final option 2. The results indicate that if the facilities affected by this rule need to reduce capacity by 10 percent for a year, the total annualized costs of option 2 would increase by an estimated 28 percent, from $74 million to $102 million. Alternatively, if the facilities affected by this rule need reduce capacity by 20 percent for a year, the total annualized costs of option 2 would increase by an estimated 55 percent, from $74 million to $125 million.

1.6.2 Risk, Benefits, and Environmental Justice

This final rule is expected to reduce nationwide emissions of EtO from this source category by 21 tons per year (tpy) under option 2. Option 1, the least stringent option, is estimated to reduce EtO emissions from the source category by 13 tpy. The most stringent option 3 is estimated to reduce EtO emissions from the source category by 21 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 final rule focused on populations living within 50 km of the facilities with cancer risks greater than or equal to 1-in-1 million and greater than 100-in-1 million. Of the approximately 115 million people that live within 50 kilometers (km) of the 88 facilities included in the risk assessment, 8.5 million people were estimated to have cancer risks greater than or equal to 1-in-1 million from HAP emitted from the facilities in the source category under the baseline and approximately 19,000 were estimated to have cancer risks 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 final option 2 requirements are implemented, an estimated 700,000 to 1.4 million[12] people would be exposed to cancer risks greater than or equal to 1-in-1 million 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 to 0.2 excess cancer cases per year under option 2, an 80 to 90 percent reduction compared to the baseline. Section 4.4 provides a summary of the

[12] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

risk analysis methods and findings. See section IV.C of the preamble for a detailed description of the risk analysis.

The environmental justice analysis conducted for this 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 final 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 final 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 final rule is expected to significantly reduce the number of people in all demographic groups exposed to 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 relative to the baseline. After the final option 2 is implemented, the estimated number of individuals exposed to risks greater than 100-in-1 million falls to zero. However, the few facilities with post-control risk estimates greater than or equal to 50-in-1 million are concentrated in Puerto Rico, so a high share of the remaining individuals at this risk level (which is considered acceptable) are Hispanic or Latino. While absolute risk declines significantly for Hispanic or Latino individuals after implementing the final requirements, the distribution of the remaining risk is more disproportionately concentrated among Hispanic or Latino individuals compared to the baseline.

1.6.3 Impacts on Small Entities

Chapter 5 contains the small entity impact analysis conducted for this rule. The small entity impact analysis identified potential for this final rule to have a significant economic impact on a substantial number of small entities (SISNOSE). As such, the EPA did not certify a ‘no SISNOSE’ determination for this final rule.

Out of the 90 facilities expected to incur costs to comply with the final requirements, 28 facilities, or about 31 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).[13] There are 50 ultimate parent companies that own commercial sterilization facilities affected by this final rule, as several parent companies own multiple facilities. About 44 percent (22) of the 50 parent companies are small entities. There are 13 small entities (59 percent of all affected small entities) with estimated cost-to-sales ratios of 3 percent or greater under option 2.

Appendix A estimates parent company cost-to-sales ratios when estimates of lost revenues due to temporary capacity reductions are incorporated into the total annualized cost estimates for parent companies. Based on the methods explained in Appendix A, the EPA estimates that including lost revenues in the costs of option 2 would increase the number of small entities with estimated cost-to-sales ratios of 3 percent or greater by one to two additional entities (from 13 small entities to 14 or 15 small entities).

1.6.4 Economic Impacts

EtO sterilization services are a critical input in the provision of safe medical devices. The EPA was not able to quantitatively assess potential market impacts for this final rule. However, section 5.3 qualitatively dicusses potential market impacts of this final rule, including the potential for sterilizers to raise prices of their services in response to regulation and how the medical device supply chain may be impacted. To minimize the possibility of any adverse impacts of this final rule on the availability of safe medical devices, the EPA has made a number of important changes to the proposed rule including extending the compliance deadlines to the maximum time period allowed under the CAA; modifying emission standards that the industry had identified as having a potential limiting effect on sterilization capacity; and providing additional compliance flexibilities. These changes responded to key issues raised by commenters on the proposed rulemaking.

This final rule has the potential to impose significant costs relative to sales for some owners of affected facilities, particularly those that are small entities. Nonetheless, the qualitative

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

information gathered on the industry suggests that demand for EtO sterilization services is likely to be fairly inelastic, meaning demand may be insensitive to price changes and 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, the EPA expects demand for EtO sterilization services to 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 rule down the supply chain to medical device manufacturers, hospitals, insurers, and end consumers.

If the costs of this final 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). This ability to pass on costs would support the ability of affected companies to continue to ensure a stable supply of medical devices while meeting the regulatory requirements.

The EPA also considered the possibility that limited capacity in the EtO sterilization industry could potentially disrupt the medical device supply chain if there are not enough sterilization providers available to accommodate the quantity of devices that need to be sterilized with EtO. Commenters on the rule indicated that some facilities may need to temporarily slow operations while they complete upgrades to comply with the rule, and that this could lead to an increased risk of shortages for some devices during that time. As discussed in the preamble to this final rule, many facilities have already installed or started installing one or more of the controls required to comply with the revised standards. Through EPA's engagement with the FDA throughout the rulemaking process, the EPA ascertained that this group of facilities that have already installed or are installing required controls includes many facilities that the FDA has identified as critical to the medical device supply chain. The completed and ongoing upgrades at these facilities have not thus far resulted in industry capacity issues to EPA's knowledge.

Further, the EPA has taken steps to minimize the possibility of shortages in this final rule by increasing the compliance timeframe for the final rule to the maximum allowed by the CAA. The longer compliance timeframe is expected provide enough flexibility for facilities to stagger the timing of their upgrades, and thus comply without affecting EtO sterilization capacity to a degree that causes device shortages. EPA estimates that compliance related upgrades take approximately one year, meaning that not all facilities would potentially need to slow their operations while upgrading at the same time. Upgrades are likely to be staggered because the limited number of control vendors may not be able to accommodate all facilities upgrading simultaneously, further indicating that upgrades may be staggered throughout the compliance period. Additionally, the EPA has modified the proposed best management practices (BMPs) in the final rule to minimize the possibility of impacts to the medical device supply chain. The modified BMPs remove the requirements to reduce EtO use per sterilization cycle for most facilities, which voids the need to complete new cycle validations.

1.6.5 Summary of Results

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

Table 1-2. Summary of Benefits, Costs and Net Benefits for the Regulatory Options from 2025 to 2044 (Million 2021$[a])

	Option 1				**Option 2 (Final)**				**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	$543	$37	$446	$51	$932	$63	$773	$88	$1,025	$69	$861	$97
Net Benefits	N/A		N/A		N/A		N/A		N/A		N/A	
Non-monetized Benefits	13 tpy of EtO Health effects of reduced EtO exposure				21 tpy of EtO Health effects of reduced EtO exposure				21 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 rule. This is not to imply that

there are no benefits of the rule; 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 final rule. Chapter 5 includes the small entity analysis and discusses economic impacts. Chapter 6 summarizes the net benefits and chapter 7 contains references. Appendix A contains the sensitivity analysis.

2 INDUSTRY PROFILE

2.1 Introduction

This chapter provides an overview of the use of 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 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 sterile medical devices, and medical device manufacturers are the primary consumers of EtO sterilization services. Sterile medical devices require sterilization 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 finalized 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 Safety and Health 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. 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 EtO residuals 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 factors impacting the ease of aerating the product load (e.g., material composition or geometry), 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 sterility assurance level 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 regulation of EtO sterilization facilities under the CAA, the use of EtO in sterilization is regulated by the EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EtO sterilization is also regulated by other federal agencies including FDA and OSHA (29 CFR 1910.1047), and various state and local governments.

The EPA's OCSPP regulates the distribution, sale, and use of all pesticides (e.g. insecticides, herbicides, rodenticides, disinfectants, and sanitizers) in the U.S. OCSPP is planning to publish the EtO Final/Interim Decision under FIFRA. This action will affect the use of EtO for sterilization, and the requirements are expected to have cost impacts. However, the potential costs of OCSPP's proposed mitigations in the PID were not quantified and monetized and cost estimates will not be available for the Final/Interim Decision either.[14] It is uncertain how OSCPP's mitigation may affect commercial EtO sterilization facilities that are affected by this final NESHAP rule. Since OCSPP's Final/Interim Decision has not been finalized as of the publication date for this final NESHAP rule and there are no cost estimates available for OCSPP's mitigation, it was not possible to consider the impacts of the final OCSPP action in the regulatory baseline for this final NESHAP rule.

Sterilization procedures and associated validations for most medical devices are reviewed 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 has requirements regarding how to support a sterile specification for a product under their jurisdiction, 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).

[14] There is no statutory requirement to quantify costs of mitigation measures under FIFRA's risk-benefit standard. See 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); see also 7 U.S.C. §§ 136(bb), which define "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" (FIFRA's risk-benefit standard), and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]". In a PID, EPA sets out a proposed interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings" (40 C.F.R. §§ 155.56, 155.58(b)(1)). These findings, as is the case with a cost analysis, may be qualitative.

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, in the case of a PMA product, or submit a new 510(k) for the FDA to clear, in the case of a 510(k) product (FDA 2019c). If sterilization facilities close, the supply chain for medical devices can be impacted because completing a new validation for a single product can potentially take months before the product can then be switched to a new sterilization site. Validating a different modality of sterilization, if feasible, requires more extensive testing and documentation. For devices requiring new validations, 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 received comments on the proposed rule indicating that facilities affected by this rule may need to slow operations while completing the required 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 process of validating new cycles (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).

In this final subpart O rule, the EPA added some compliance flexibilities (e.g., longer compliance timeframe) to minimize the likelihood that EtO sterilization capacity would be impacted to a degree that causes device shortages. Additionally, several facilities affected by this rule have already installed or started installing the required controls to reduce emissions, including some facilities that were identified as critical to the medical device supply chain through EPA's engagement with the FDA throughout the rulemaking process. The completed and ongoing upgrades at these facilities are of a similar scale to those required by the rule and have not thus far resulted in industry capacity issues to EPA's knowledge.

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.[15] 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

[15] 'Consumers' would include government programs such as Medicare and Medicaid.

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 final 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 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 90 commercial EtO sterilization facilities, including the 88 active facilities currently affected by subpart O and two planned facilities that are assumed to start operating before the compliance deadline. It was assumed that these 90 facilities would continue to operate and be affected by the rule throughout the 20-year analytical timeframe from 2025 to 2044. 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 rule in the future. There are 22 affected facilities that use less than 1 tpy of EtO, 19 facilities that use more than 1 tpy but less than 10 tpy of EtO, 9 facilities that use more than 10 tpy but less than 30 tpy of EtO, and 40 facilities that use more than 30 tpy of EtO.

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 revises several of the current emissions standards for SCVs, ARVs, and CEVs.

This 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 rule, 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 finalizing 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 final amendments to the subpart O NESHAP relative to the baseline without the rule. The analysis focuses on the 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 baseline standards and estimated the emissions reductions and cost of the final 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 88 subpart O facilities currently operating 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	88
Propylene Oxide	0.7	7

3.5 Final Requirements

The EPA is finalizing emission standards to fill regulatory gaps under CAA section 112(d)(2), (3), and (5); 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; and standards pursuant to the technology review under CAA section 112(d)(6). The EPA is also finalizing 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 were previously unregulated, the EPA is setting standards under CAA sections 112(d)(2) and (3), or (d)(5): SCV and ARV at facilities where EtO use is less than 1 tpy, ARV at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEV at several usage levels, 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 finalized for the two groups of room air emissions at major sources and GACT standards are being finalized 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 finalizing health-based standards for SCVs, ARVs, CEVs, and certain room air emissions. The stringency of the health-based standards varies based on a facility's annual EtO usage. The usage groupings in the standards are intended to address emissions from facilities identified as high risk while mitigating the compliance burden for lower risk facilities. The EPA is finalizing health-based emission standards for SCVs at facilities where EtO use is at least 30 tpy, SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy, SCVs at facilities where EtO use is

at least 1 tpy but less than 10, ARVs at facilities where EtO use is at least 30 tpy, CEVs at facilities where EtO use is at least 400 tpy, CEVs at facilities where EtO use is at least 60 tpy but less than 400 tpy, Group 1 room air emissions at facilities where EtO use is at least 40 tpy, Group 2 room air emissions at facilities where EtO use is at least 20 tpy, and Group 2 room air emissions at area source facilities where EtO use is at least 30 tpy but less than 4 tpy.

Finally, the technology review identified more stringent emission standards that could be applied to 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, and ARVs at facilities where EtO use is at least 10 tpy. These standards do not generate additional economic impacts since all facilities are currently complying with them or are subject to at least the same emission standard pursuant to CAA section 112(f)(2). The EPA is also finalizing the same requirements under (d)(6) that are being finalized under CAA 112(f)(2) for SCVs at facilities where EtO use at least 1 tpy but less than 10 tpy.

Table 3-3 lists the final standards for currently unregulated sources, the standards being finalized to address unacceptable remaining risk and provide an ample margin of safety, and the standards being finalized as part of the technology review.

The EPA is also finalizing 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 requiring monitoring with an EtO CEMS, with the exception of facilities where EtO use is less than 100 pounds per year, which will have the option of either using CEMS or conducting initial and annual performance testing with continuous parameter monitoring.

Table 3-3. Final Standards (Option 2)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new	At least 30 tpy	99.99% emission reduction	112(f)(2)
		At least 10 tpy but less than 30 tpy	99.9% emission reduction	112(f)(2)
		At least 10 tpy	99.9% emission reduction	112(d)(6)
		At least 1 but less than 10 tpy	99.8% emission reduction	112(f)(2) and 112(d)(6)
		Less than 1 tpy	99% emission reduction	112(d)(5)
ARV	Existing	At least 30 tpy	99.9% emission reduction	112(f)(2)
		At least 10 tpy but less than 30 tpy	99.6% emission reduction	112(f)(2)
		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 30 tpy	99.9% emission reduction	112(f)(2)
		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 at major sources	Existing and new	N/A	99.94% emission reduction	112(d)(2) and 112(d)(3)
CEV at area sources	Existing and new	At least 60 tpy	99.9% emission reduction	112(f)(2)
		Less than 60 tpy	99% emission reduction	112(d)(5)
Group 1 room air emissions at major sources	Existing and new	N/A	97% emission reduction	112(d)(2) and 112(d)(3)
Group 1 room air emissions at area sources	Existing and new	At least 40 tpy	98% emission reduction	112(f)(2)
		Less than 40 tpy	80% emission reduction	112(d)(5)
Group 2 room air emissions at major sources	Existing and new	N/A	86% emission reduction	112(d)(2) and 112(d)(3)
Group 2 room air emissions at area sources	Existing	At least 20 tpy	98% emission reduction	112(f)(2)
		At least 4 but less than 20 tpy	80% emission reduction	112(f)(2)
		Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened	112(d)(5)
	New	At least 20 tpy	98% emission reduction	112(f)(2)
		At least 4 but less than 20 tpy	80% emission reduction	112(f)(2)
		Less than 4 tpy	80% emission reduction	112(d)(5)

The standards listed 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. Control costs and monitoring and testing costs are lower for this option than for option 2.

Option 2 (final): 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 new 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 create new limitations for all currently unregulated emissions to the most stringent levels that are considered in the preamble. This option would require more facilities to install PTEs than under option 2.

3.6 Engineering Costs

A key component of the total costs estimated for this final rule is the cost to implement the room air emissions requirements. In many cases, affected facilities would need to install a 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 standards for the SCV, ARV, and CEV. Another key cost is associated with the monitoring and testing requirements, which includes capital and annual costs associated with a CEMS or the recurring costs associated with annual performance testing, depending on the facility. There are also annual costs associated with recordkeeping and reporting, and for option 1, there are one-time new validation costs which include the costs of approval paperwork and testing.

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 costs to complete new cycle validations and initial performance tests 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 new validation and initial testing 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. To see how the costs vary across the years in the analytical timeframe (2025 to 2044), 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,[16] a 20-year lifetime for a PTE, a 20-year lifetime for a gas or solid reactor system, and a 10-year lifetime for the capital associated with the emissions monitoring requirements.

The room air emissions requirements are the most costly aspect of the rule 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 PTE costs are generally driving the higher costs of option 3 compared to the final option 2. Under option 1, costs are lower than the final option mainly because fewer facilities would need PTE and gas/solid reactors to comply compared to the final option 2. However, the new cycle validation costs are highest under option 1. This is because option 1 would require all facilities to complete new cycle validations (it requires a chamber concentration limit as opposed to imposing an emission limit) while options 2 and 3 would not require new validations to be completed for any facilities since emissions reductions would be achieved through controls for those options.

[16] 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	Option 2 (final)	Option 3
Permanent Total Enclosure			
Facilities Affected	23	28	48
Capital Costs	$35.4	$77.5	$147.9
Annual O&M Costs	$0.2	$0.5	$1.1
Total Annualized Costs	$3.7	$8.3	$15.8
Gas/Solid Reactors			
Facilities Affected	64	83	85
Capital Costs	$102.0	$187.4	$188.4
Annual O&M Costs	$13.4	$24.7	$24.9
Total Annualized Costs	$23.6	$43.4	$43.8
Monitoring and Testing			
Facilities Affected	89	89	89
Capital Costs	$20.2	$48.1	$50.4
Annual O&M Costs	$8.3	$12.4	$12.8
Total Annualized Costs	$11.3	$19.4	$20.2
Recordkeeping and Reporting			
Facilities Affected	90	90	90
Total One-time Costs	$6.7	$6.9	$6.9
Annual O&M Costs	$2.5	$2.4	$2.4
Total Annualized Costs	$9.2	$9.3	$9.3
Cycle Validations			
Facilities Affected	87	0	0
Total One-time Costs	$5.6	$0.0	$0.0
TOTAL COSTS			
Facilities Affected	90	90	90
Capital Costs	$157.6	$312.9	$386.8
Annual O&M Costs	$24.4	$39.9	$41.2
One-time Costs	$12.3	$6.9	$6.9
Total Annualized Costs	$53.3	$74	$89.1

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 *Final 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 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 $158 million in 2021 dollars. The total annualized costs for option 1 are estimated to be $53 million. The capital cost for option 2, the final option, is estimated to be $313 million. The total annualized costs for option 2 are estimated to be $74 million. The capital cost for option 3, the most stringent option analyzed, is estimated to be $387 million. The total annualized costs for option 3 are estimated to be $89 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	$158	$17	$24	$12	$53
Option 2 (Final)	$313	$34	$40	$7	$74
Option 3	$387	$41	$41	$7	$89

[a] Capital costs were annualized over the lifetime of the equipment at a 7.75% 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 12866/14094, the EPA presents estimates of the present value (PV) of the costs over the period 2025 to 2044. Costs are in 2021 dollars and discounted to 2025 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 2025 to 2044, 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).[17]

Table 3-6 through Table 3-8 show the capital costs, annual costs, and the total PV and EAV of the costs over 2025 to 2044 in 2021 dollars. The PV of the costs for option 1 is estimated to be $543 million at a 3 percent discount rate. The PV of the costs for option 1 is estimated to be $446 million at a 7 percent discount rate. The EAV of the option 1 costs is estimated to be $37 million at a 3 percent discount rate and $51 million at a 7 percent discount rate. For the final option 2, the PV of the costs is estimated to be $932 million at a 3 percent discount rate and $773 million at a 7 percent discount rate. The EAV of the option 2 costs is estimated to be $63 million and $88 million at 3 percent and 7 percent discount rates, respectively. Finally, for option 3, the PV of the costs is estimated to be about $1 billion at a 3 percent discount rate and $861 million at a 7 percent discount rate. The EAV of the option 3 costs is estimated to be $69 million and $97 million at 3 percent and 7 percent discount rates, respectively.

[17] 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 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%)
2025	$158	$37		$194	$194
2026		$24		$24	$23
2027		$24		$23	$21
2028		$24		$22	$20
2029		$24		$22	$19
2030		$24		$21	$17
2031		$24		$20	$16
2032		$24		$20	$15
2033		$24		$19	$14
2034		$24		$19	$13
2035		$24		$18	$12
2036		$24		$18	$12
2037		$24		$17	$11
2038		$24		$17	$10
2039		$24		$16	$9
2040		$24		$16	$9
2041		$24		$15	$8
2042		$24		$15	$8
2043		$24		$14	$7
2044		$24		$14	$7
			PV	$543	$446
			EAV	$37	$51

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

	Capital Costs	Annual Costs (undiscounted)		Discounted Costs (3%)	Discounted Costs (7%)
2025	$313	$47		$360	$360
2026		$40		$39	$37
2027		$40		$38	$35
2028		$40		$37	$33
2029		$40		$35	$30
2030		$40		$34	$28
2031		$40		$33	$27
2032		$40		$32	$25
2033		$40		$32	$23
2034		$40		$31	$22
2035		$40		$30	$20
2036		$40		$29	$19
2037		$40		$28	$18
2038		$40		$27	$17
2039		$40		$26	$15
2040		$40		$26	$14
2041		$40		$25	$14
2042		$40		$24	$13
2043		$40		$23	$12
2044		$40		$23	$11
			PV	$932	$773
			EAV	$63	$88

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

	Capital Costs	Annual Costs (undiscounted)	Discounted Costs (3%)	Discounted Costs (7%)
2025	$387	$48	$435	$435
2026		$41	$40	$39
2027		$41	$39	$36
2028		$41	$38	$34
2029		$41	$37	$31
2030		$41	$36	$29
2031		$41	$35	$27
2032		$41	$34	$26
2033		$41	$33	$24
2034		$41	$32	$22
2035		$41	$31	$21
2036		$41	$30	$20
2037		$41	$29	$18
2038		$41	$28	$17
2039		$41	$27	$16
2040		$41	$26	$15
2041		$41	$26	$14
2042		$41	$25	$13
2043		$41	$24	$12
2044		$41	$23	$11
		PV	$1,025	$861
		EAV	$69	$97

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 90 active facilities. The baseline annual emissions are 23 tpy of EtO. For options 1, 2, and 3, the EPA estimated EtO emissions reductions of 13 tpy, 21 tpy, and 21 tpy, respectively.

3.8 Uncertainties

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 rule and how the costs might change over time. Facilities may comply with the requirements through alternative methods that were not accounted for in the cost memo. 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.

The EPA was also uncertain about how the compliance measures might affect capacity at facilities, or whether and how long facilities may need to close to complete upgrades and thus lose revenue during that time. To assess this uncertainty, the EPA provides a sensitivity analysis that presents estimates of forgone revenues during temporary slowdowns in operations at facilities during the compliance period in Appendix A.

This rule 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.[18] 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 rule. This analysis assumes that compliance will start in 2025 and that upfront capital costs will be incurred in 2025, and this may not be the case. Companies have two years to comply with some requirements and three years to comply with other requirements of the rule once it is published but they may begin investing in capital in 2024 or may continue up until the compliance date. The cost impacts were estimated out to 2044 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 estimated costs for existing facilities and two facilities that have announced plans to open, but other 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 rule

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

(*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 rule in the future. The EPA was also not able to predict whether some firms would choose to exit the market due to the final requirements. Some firms, such as small businesses, may not be able to obtain financing at the assumed interest rate.

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 action may be underestimated.

4 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 final rule, a summary of the risk analysis for the rule, and a summary of the environmental justice implications assessed for this rule.

This final rule is expected to reduce nationwide emissions of EtO from this source category by 21 tpy under option 2. Option 1, the least stringent option, is estimated to reduce EtO emissions from the source category by 13 tpy. The most stringent option 3 is estimated to reduce EtO emissions from the source category by 21 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 final 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. 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 due to the compliance measures in this rule, there could be increased risk of shortages for some devices and potential for impacts on patients that need those devices. The EPA was not able to estimate potential capacity impacts, shortages, or possible health impacts resulting from potential

shortages in this analysis. However, the EPA does not expect significant capacity issues that lead to device shortages and patient impacts (see explanation in section 1.6.4).

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 final rule. The EPA estimated cancer risk for each census block within 50 km of every EtO sterilization facility under the baseline and under the final 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.

The risk assessment was conducted for the 88 facilities in the commercial sterilization source category that are currently operating. Table 4-1 shows the results of the chronic inhalation cancer risk analysis for these facilities based on actual emissions under the baseline and under option 2 and Table 4-2 shows the results based on allowable emissions.

The MIR posed by the facilities assessed based on actual emissions 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. Of the approximately 115 million people that live within 50 km of the 88 facilities included in the risk assessment, 8.5 million people were estimated to have cancer risks greater than or equal to

1-in-1 million from HAP emitted from the facilities in this source category and approximately 19,000 were estimated to have cancer risks greater than 100-in-1 million.

Table 4-1. Inhalation Cancer Risks based on Actual Emissions for EtO Sterilization Facilities Under the Baseline and Final Option 2

	Baseline	Final Option 2
Facilities		
Number of Facilities Modeled in Risk Assessment	88	88
Cancer Risks		
Maximum Individual Lifetime Cancer Risk (in 1 million)	6,000	100
Population Exposure		
Number of People Exposed to Maximum Cancer Risk:		
Greater than 100-in-1 million	19,000	0
Greater than or equal to 1-in-1 million	8,500,000	700,000 to 1.4 million[1]
Cancer Incidence (excess cancer cases per year)	0.9	0.1-0.2[1]

[1] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

Based on allowable emission estimates under the baseline (Table 4-2), the MIR could be as high as 8,000-in-1 million. The total estimated cancer incidence is 8 excess cancer cases per year. Approximately 62 million people were estimated to have cancer risks greater than or equal to 1-in-1 million from allowable emissions and approximately 260,000 were estimated to have cancer risks greater than 100-in-1 million.

After the final option 2 requirements are implemented, the EPA estimated that the baseline cancer MIR of 6,000-in-1 million for actual emissions and 8,000-in-1 million for allowable emissions would both be reduced to 100-in-1 million. The estimated cancer incidence declines to 0.2 excess cancer cases per year (and could be as low as 0.1 excess cancer cases per year when accounting for some facilities that are currently performing better than the standards) compared to the baseline estimate of 0.9 excess cancer cases per year for actual emissions and 8 excess cancer cases per year for allowable emissions (*i.e.*, the incremental effect is 0.7 avoided excess cancer cases for actual emissions and 7.8 avoided excess cancer cases for allowable emissions). The EPA estimates that zero people would have cancer risks greater than 100-in-1 million under option 2 for both actual and allowable emissions, down from 19,000 people for actual emissions and 260,000 people for allowable emissions. In addition, the number of people estimated to have a cancer risk greater than or equal to 1-in-1 million would be reduced to 1.4 million (and could be as low as 700,000 when accounting for some facilities that are currently

performing better than the standards), down from 8.5 million people for actual emissions and 62 million people for allowable emissions under the baseline. Risks that exceed the 100-in-1 million threshold are generally considered unacceptable, so the EPA expects the final rule to reduce risk to acceptable levels.

Table 4-2. Inhalation Cancer Risks based on Allowable Emissions for EtO Sterilization Facilities Under the Baseline and Final Option 2

	Baseline	Final Option 2
Facilities		
Number of Facilities Modeled in Risk Assessment	88	88
Cancer Risks		
Maximum Individual Lifetime Cancer Risk (in 1 million)	8,000	100
Population Exposure		
Number of People Exposed to Maximum Cancer Risk:		
Greater than 100-in-1 million	260,000	0
Greater than or equal to 1-in-1 million	62,000,000	700,000 to 1.4 million[1]
Cancer Incidence (excess cancer cases per year)	8	0.1-0.2[1]

[1] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

4.4.1 Limitations

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this rule. 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). Inherent to risk assessments, there are 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 rule.

4.5 Environmental Justice Analysis

For this 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 final 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 final rule.

4.5.1 Background

Environmental Justice is defined as the just treatment and meaningful involvement of all people regardless of income, race, color, national origin, Tribal affiliation, or disability, in agency decision-making and other Federal activities that affect human health and the environment so that people: (i) are fully protected from disproportionate and adverse human health and environmental effects (including risks) and hazards, including those related to climate change, the cumulative impacts of environmental and other burdens, and the legacy of racism or other structural or systemic barriers; and (ii) have equitable access to a healthy, sustainable, and resilient environment in which to live, play, work, learn, grow, worship, and engage in cultural and subsistence practices. [19] 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.

4.5.2 Methods

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

[19] For additional reference see OMB Circular A-4 (whitehouse.gov)

disproportionately represented in areas near higher risk EtO sterilization facilities under baseline conditions and after the final 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 that 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 EPA focuses on the 10 km radius for the demographic analysis in this RIA because it encompasses all the facility MIR locations and captures 100 percent of the population with risks greater than 100-in-1 million. The results of the proximity analysis for populations living within 50 km are included in the technical report included in the docket.

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 rule. 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 final control 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 17.3 million people live within 10 km of the 88 EtO sterilization facilities analyzed.[20] 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 75 facilities; 124,000 people to risk greater than or equal to 50-in-1 million around 38 facilities; and 19,000 people to risk greater than 100-in-1 million around 16 facilities.

The baseline proximity analysis indicates that the percent of the population that is Hispanic or Latino living within 10 km of any of the 88 EtO sterilization facilities is higher than the national average (36 percent versus 19 percent). This is driven largely by 7 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 percentage of the population living within 10 km of commercial sterilization facilities is somewhat higher than the national averages for the following demographics: African American, Other and Multiracial, below poverty level, over 25 without a high school diploma, and linguistically isolated.[21] 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.

[20] The two planned facilities that are expected to be impacted by this rule are not included in the EJ analysis.
[21] 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 4-2. 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	17,300,000	5,300,000
Number of Facilities	-	88	75
		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%	36%	39%
Other and Multiracial	8%	11%	7%
		Income	
Below Poverty Level	13%	15%	16%
Above Poverty Level	87%	85%	84%
		Education	
Over 25 and without a High School Diploma	12%	16%	18%
Over 25 and with a High School Diploma	88%	84%	82%
		Linguistic Isolation	
Linguistically Isolated	5%	10%	11%

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	17,300,000	124,000
Number of Facilities	-	88	38
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	31%
African American	12%	13%	43%
Native American	0.7%	0.3%	0.1%
Hispanic or Latino (white and nonwhite)	19%	36%	22%
Other and Multiracial	8%	11%	3%
		Income	
Below Poverty Level	13%	15%	22%
Above Poverty Level	87%	85%	78%
		Education	
Over 25 and without a High School Diploma	12%	16%	17%
Over 25 and with a High School Diploma	88%	84%	83%
		Linguistic Isolation	
Linguistically Isolated	5%	10%	9%

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	17,300,000	19,000
Number of Facilities	-	88	16
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	40%
African American	12%	13%	31%
Native American	0.7%	0.3%	0.1%
Hispanic or Latino (white and nonwhite)	19%	36%	26%
Other and Multiracial	8%	11%	3%
		Income	
Below Poverty Level	13%	15%	25%
Above Poverty Level	87%	85%	75%
		Education	
Over 25 and without a High School Diploma	12%	16%	18%
Over 25 and with a High School Diploma	88%	84%	82%
		Linguistic Isolation	
Linguistically Isolated	5%	10%	16%

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 (39 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 (43 percent African American in areas with risk greater than or equal to 50-in-1 million and 31 percent in areas with risk above 100-in-1 million, versus 12 percent nationwide) and those living below the poverty level (25 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 (43 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 (31 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 88 facilities is 13 percent (only marginally higher than the 12 percent national average), while the baseline risk-based analysis shows much higher percentages (43 percent African American in areas with baseline cancer risk greater than or equal to 50-in-1 million). The percent of the population below the poverty level is also higher in the baseline risk-based analysis for areas with greater than 100-in-1-million risk levels (25 percent) than the proximity analysis (15 percent). The contrast between the proximity and baseline risk results for African Americans and the population living below the poverty level indicates that these groups 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 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 and income below the poverty level 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 rule would affect the distribution of risks (i.e., the proportions of the demographics represented at each risk level) and the absolute risks (i.e., the number of people at each risk level by demographic group) compared to the baseline, the EPA conducted a post-control risk-based demographic analysis for the controls being finalized under 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 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 before and after implementing the final standards. The results

indicate that the 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 700,000, reduce the number of individuals within 10 km of a facility with risk greater than or equal to 50-in-1 million from 124,000 to 170 people, and reduce the number of individuals within 10 km of a facility with risk greater than 100-in-1 million from 19,000 to zero 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*
Total Population	328,000,000	5,300,000	700,000
Number of Facilities		75	67
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	40%
African American	12%	15%	18%
Native American	0.7%	0.3%	0.2%
Hispanic or Latino (white and nonwhite)	19%	39%	34%
Other and Multiracial	8%	7%	8%
		Income	
Below Poverty Level	13%	16%	15%
Above Poverty Level	87%	84%	85%
		Education	
Over 25 and without a High School Diploma	12%	18%	15%
Over 25 and with a High School Diploma	88%	82%	85%
		Linguistic Isolation	
Linguistically Isolated	5%	11%	11%

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*
Total Population	328,000,000	124,000	170
Number of Facilities		42	11
		Race and Ethnicity	
White (non-Hispanic)	60%	31%	12%
African American	12%	43%	11%
Native American	0.7%	0.1%	0.3%
Hispanic or Latino (white and nonwhite)	19%	22%	76%
Other and Multiracial	8%	3%	0.4%
		Income	
Below Poverty Level	13%	22%	30%
Above Poverty Level	87%	78%	70%
		Education	
Over 25 and without a High School Diploma	12%	17%	31%
Over 25 and with a High School Diploma	88%	83%	69%
		Linguistic Isolation	
Linguistically Isolated	5%	9%	47%

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	19,000	0
Number of Facilities		16	0
		Race and Ethnicity	
White (non-Hispanic)	60%	40%	-
African American	12%	31%	-
Native American	0.7%	0.1%	-
Hispanic or Latino (white and nonwhite)	19%	26%	-
Other and Multiracial	8%	3%	-
		Income	
Below Poverty Level	13%	25%	-
Above Poverty Level	87%	75%	-
		Education	
Over 25 and without a High School Diploma	12%	18%	-
Over 25 and with a High School Diploma	88%	82%	-
		Linguistic Isolation	
Linguistically Isolated	5%	16%	-

Compared to the baseline, the final controls reduce the absolute number of individuals in all the demographic groups that live within 10 km of a facility 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. The baseline and post-control demographics percentages 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). However, for populations in census blocks within 10 km of facilities with estimated cancer risks greater than or equal to 50-in-1 million, the post-control demographics percentages (i.e., the distribution of the demographics) differ from the baseline percentages for these demographics: African American, Hispanic or Latino, living below the poverty line, without a HS diploma, and linguistically isolated.

After implementing the final standards, the percentage and number of African Americans with cancer risks greater than equal to 50-in-1 million are significantly reduced and African Americans 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 43 percent under the baseline to 11 percent after implementing the required controls (Table 4-6). While the number of individuals exposed to risks greater than or equal to 50-in-1 million was significantly decreased post-control to 170 individuals, the percentage of residents that remained at that level of risk were disproportionately Hispanic or Latino individuals as the percent increased to 76 percent (compared to 22 percent under the baseline), driven mostly by three facilities at this remaining risk level in Puerto Rico. Similarly, the percentage of the population below the poverty level, without a HS diploma, and linguistically isolated in areas with risk greater than or equal to 50-in-1 million increased relative to the baseline percentages, 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.

After implementing the final control option, the total population exposed to cancer risks greater than 100-in-1 million is estimated to be zero (Table 4-7). Risks that exceed the 100-in-1 million threshold are generally considered unacceptable, so EPA expects the final rule to reduce risk to acceptable levels for all demographics. Thus, from an absolute exposure perspective, this rule is expected to reduce potential for EJ concerns surrounding EtO emissions from the source category.

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 final 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 final rule is a significant action under section (3)(f)(1) of EO 12866.[22] The presentation of the compliance cost estimates in chapter 3 does not speak directly to potential economic and distributional impacts of the rule, which may be important consequences to consider. This chapter contains a discussion of the small entity analysis conducted for this rule and qualitative discussions of potential market and employment impacts.

5.2 Small Entity Screening Analysis

This section describes the methods used to perform the small entity screening analysis, as well as the results of the screening analysis for this rule. A small entity screening analysis 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 final rule as the small entity screening analysis identified the potential for significant cost impacts on a substantial share of the small entities affected by this final rule.

5.2.1 Description and Estimate of Affected Small Entities

The RFA describes small entities as "small businesses," "small governments," and "small organizations" (5 USC 601). The amendments being finalized 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,

[22] After the proposal was issued, Executive Order 14094 was released, and it contains some updated guidance regarding economic significance determinations. Executive Order 14094 1(f)(1) specifies that impacts of $200 million or greater (costs, or benefits, in any single year) would indicate that a rule is economically significant (compared to a $100 million threshold in Executive Order 12866). This final rule is still considered economically significant under the updated threshold in Executive Order 14094.

rather than the facility. 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 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.[23] 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 revenues, number of employees, and North American Industrial Classification System (NAICS) code using the Dun & Bradstreet Hoover's online database.[24] U.S. Small Business Administration (SBA) size standards are defined for each NAICS code based on either annual revenues or number of 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 number of employees) to the size 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

[23] https://echo.epa.gov
[24] Dun & Bradstreet, Inc. (2022). D&B Hoovers. Retrieved from https://app.dnbhoovers.com/.

known as the "sales test" and is consistent with guidance published by SBA's Office of Advocacy.[25]

The EPA identified 88 EtO sterilization facilities currently operating in the U.S. that will be impacted by this final rule and incur costs. The EPA knows of two planned facilities that are expected to start operating before the compliance deadline, so the total number of affected facilities is 90.

There are 50 ultimate parent companies that own the 90 commercial sterilization facilities affected by this final rule, as several parent companies own multiple facilities. About 44 percent (22) of the 50 parent companies are small entities. Out of the 90 facilities expected to incur costs to comply with the rule, 28 facilities, or about 31 percent of facilities, are owned by ultimate parent companies that are small entities based on the business size standards defined by the SBA.[26]

See Table 5-1 for average entity-level annualized cost estimates for the final option 2 and annual sales by entity size. The average annualized cost of the final option 2 is about $1.2 million for small entities and about $1.9 million for large entities. Average annual sales for the 22 small entities is $39 million while the 28 large businesses have average annual sales of $15.8 billion.

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	22	44%	28	31%	$1.2	39
Large	28	56%	62	69%	$1.9	15,804
All	50		90		$1.6	8,867

[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 final 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 (34

[25] 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/.

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

out of 50, or 68 percent) have medical equipment- or health service-related NAICS codes. The industry with the highest number of companies and facilities affected by this 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 5-2. 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	16.5		4	13
325412	Pharmaceutical Preparation Manufacturing		1,300	2	3
339113	Surgical Appliance and Supplies Manufacturing		800	2	2
621999	All Other Miscellaneous Ambulatory Health Care Services	20.5		2	7
311942	Spice and Extract Manufacturing		650	1	3
315220	Cut and Sew Apparel Contractors		750	1	1
325520	Adhesive Manufacturing		550	1	1
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing		1,000	1	1
333244	Sawmill, Woodworking, and Paper Machinery Manufacturing		550	1	3
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing		1,250	1	1
424210	Drugs and Druggists' Sundries Merchant Wholesalers		250	1	1
525910	Open-End Investment Funds	40		1	1
541380	Testing Laboratories and Services	19		1	1
541611	Administrative Management and General Management Consulting Services	24.5		1	1
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)		1,000	1	1
551112	Offices of Other Holding Companies	45.5		1	1
611210	Junior Colleges	32.5		1	1
621511	Medical Laboratories	41.5		1	1
622110	General Medical and Surgical Hospitals	47		1	1
811219	Electronic and Precision Equipment Repair and Maintenance	34		1	1
812990	All Other Personal Services	15		1	8

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

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	0.3	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
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
Chemence Inc.	325520	14	50	Yes	1
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	Yes	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

Mt. San Antonio Community College	611210	100	2,678	No	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
Sonova Holding AG	334510	3,918	16,733	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	Yes	1
Trinity Sterile, Inc.	339112	59	117	Yes	1

5.2.2 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.[27] 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

[27] 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.

compliance costs less than 1 percent of sales are not expected to experience significant economic impacts due to the rule. Small entities with costs between 1 and 3 percent, or greater than 3 percent, may potentially experience significant economic impacts according to SBA guidance.

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 22 small entities represent 44 percent of total affected entities. For the least stringent option (option 1), the average annualized cost per entity for small entities is about $0.7 million in 2021 dollars, compared to $1.4 million for large entities. On average, small entities are estimated to experience a 13 percent cost-to-sales ratio for option 1, compared to an average of 0.1 percent for large entities and about 6 percent for all entities. The highest cost-sales-ratio estimated is 84 percent.

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	22	44%	$0.7	13.1%	3.8%	0.1%	84.3%
Large	28	56%	$1.4	0.1%	0.0%	0.0%	0.9%
All	50	100%	$1.1	5.8%	0.2%	0.0%	84.3%

The average, median, and maximum cost-to-sales ratios are higher for the final option 2 (Table 5-5). The average annualized cost of option 2 per entity for small entities is about $1.2 million in 2021 dollars, compared to $1.9 million for large entities. On average, small entities are estimated to experience an 18 percent cost-to-sales ratio for option 2, compared to an average of 0.2 percent for large entities and 8 percent for all entities. The highest cost-to-sales-ratio estimated for an entity is 69 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 $1.3 million in 2021 dollars, compared to $2.2 million for large entities. On average, small entities are estimated to experience a 23 percent cost-to-sales ratio for option 3, compared to an average of 0.2 percent for large entities and about 10 percent for all entities. The highest cost-to-sales-ratio under option 3 is estimated to be 161 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	22	44%	$1.2	18.0%	4.7%	0.1%	68.7%
Large	28	56%	$1.9	0.2%	0.0%	0.0%	1.3%
All	50	100%	$1.6	8.0%	0.2%	0.0%	68.7%

Large entities incur most of the total costs estimated for the final 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 final 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 $39 million for small entities (Table 5-1). For option 2, the average cost-to-sales ratio for small entities is over 100 times higher than the average 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	22	44%	$1.3	22.8%	5.5%	0.2%	161.1%
Large	28	56%	$2.2	0.2%	0.0%	0.0%	1.3%
All	50	100%	$1.8	10.1%	0.3%	0.0%	161.1%

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 final option 2, 21 out of 22 parent companies identified as small entities (95 percent) are estimated to incur annualized costs greater than 1 percent of annual revenues. Thirteen out of 22 small entities (59 percent) are estimated to incur annualized costs greater than 3 percent of annual revenues. The 13 small entities with 3 percent or greater cost-to-sales ratios under option 2 collectively own 19 facilities.

Under the less stringent option 1, 19 out of 22 parent companies identified as small entities (86 percent) are estimated to incur annualized costs greater than 1 percent of annual revenues. Thirteen out of 22 small entities (59 percent) are estimated to incur annualized costs

greater than 3 percent of annual revenues. The 13 small entities with 3 percent or greater cost-to-sales ratios under option 1 collectively own 17 facilities.

Under the more stringent option 3, 21 out of 22 parent companies identified as small entities (95 percent) are estimated to incur annualized costs greater than 1 percent of annual revenues. Sixteen out of 22 small entities (73 percent) are estimated to incur annualized costs greater than 3 percent of annual revenues. Those 16 small entities with 3 percent or greater cost-to-sales ratios under option 3 collectively own 22 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=50, Facilities=90)				
Option 1	$158	$53	19 (38%)	13 (26%)
Option 2	$313	$74	23 (46%)	13 (26%)
Option 3	$387	$89	23 (46%)	16 (32%)
Small Entities (n=22, Facilities=28)				
Option 1	$36	$15	19 (86%)	13 (59%)
Option 2	$104	$27	21 (95%)	13 (59%)
Option 3	$121	$29	21 (95%)	16 (73%)

The results of this small entity screening indicate potential for a significant share (over half) of the small entities affected by this final rule to incur high costs relative to their revenues. Large entities affected by the rule have much lower cost-to-sales ratios. For all three options, all the entities with cost-to-sales ratios above 3 percent are small entities. Across the options, there are five to eight small entities and zero to two large entities with cost-to-sales ratios equal to or 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=50)							
Option 1	$158	$53	31 (62%)	6 (12%)	3 (6%)	2 (4%)	8 (16%)
Option 2	$313	$74	27 (54%)	10 (20%)	2 (4%)	2 (4%)	9 (18%)
Option 3	$387	$89	27 (54%)	7 (14%)	4 (8%)	2 (4%)	10 (20%)
Small Entities (n=22)							
Option 1	$36	$15	3 (14%)	6 (27%)	3 (14%)	2 (9%)	8 (36%)
Option 2	$104	$27	1 (5%)	8 (36%)	2 (9%)	2 (9%)	9 (41%)
Option 3	$121	$29	1 (5%)	5 (23%)	4 (18%)	2 (9%)	10 (45%)

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=90)							
Option 1	$158	$53	65 (72%)	8 (9%)	5 (6%)	3 (3%)	9 (10%)
Option 2	$313	$74	53 (59%)	18 (20%)	4 (4%)	4 (4%)	11 (12%)
Option 3	$387	$89	53 (59%)	15 (17%)	6 (7%)	4 (4%)	12 (13%)
Facilities owned by Small Entities (n=28)							
Option 1	$36	$15	3 (11%)	8 (29%)	5 (18%)	3 (11%)	9 (32%)
Option 2	$104	$27	1 (4%)	8 (29%)	4 (14%)	4 (14%)	11 (39%)
Option 3	$121	$29	1 (4%)	5 (18%)	6 (21%)	4 (14%)	12 (43%)

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, raise prices to recoup regulatory costs, 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 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.

5.2.3 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 **Error! Reference source not found.**.

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.

5.3 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 final rule. Sterilization services are inputs to the supply chain that delivers healthcare services to institutions and individuals. In general, the potential impacts of this final rule on the market for medical devices depend on a number of factors that are themselves subject to uncertainty. 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 is.

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 quantity of devices that need to be sterilized with EtO. Comments on the proposed rule indicated that individual facilities or firms may need to reduce capacity in the short run to install controls or adjust their operations to the requirements. The EPA increased the compliance timeframe for the final rule to the maximum allowed by the CAA to provide opportunity to stagger the timing of upgrades and thus avoid facilities simultaneously reducing capacity. In addition, the EPA made changes to the form of certain standards in order to avoid the need for new cycle validations or reductions in throughput. These flexibilities are intended to minimize the potential for impacts on the availability of medical devices.

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 5.2.1, the small entities affected by this final 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 rule compared to small firms when comparing their costs relative to revenues though they could exit the sterilization market to focus on more profitable business segments. 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 reported 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

Because demand for medical devices and healthcare services is 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 patients 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.

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.

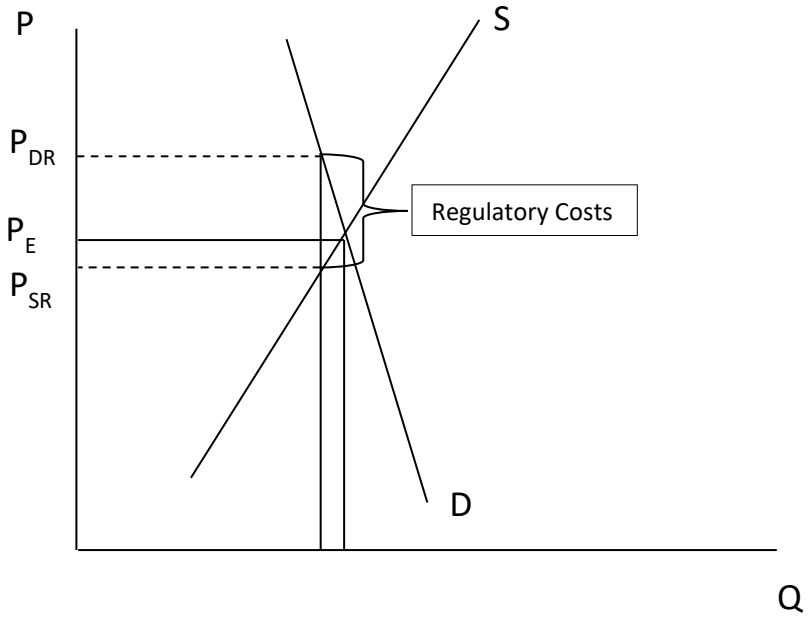

Figure 5-1. Illustrative Example of Potential Impacts with Inelastic Supply and Demand

This illustrative example should not be considered a formal estimate of the market impacts of this 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 5.3.3, the final 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 final 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 final rule, the net benefits are negative.

Table 6-1. Summary of Benefits, Costs and Net Benefits for the Final Regulatory Options from 2025 to 2044 (Million 2021$ [a])

	Option 1				Option 2 (Final)				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	$543	$37	$446	$51	$932	$63	$773	$88	$1,025	$69	$861	$97
Net Benefits	N/A		N/A		N/A		N/A		N/A		N/A	
Non-monetized Benefits	13 tpy of EtO Health effects of reduced EtO exposure				21 tpy of EtO Health effects of reduced EtO exposure				21 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 rule. This is not to imply that there are no benefits of the rule; 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 rule and how the costs might change over time. The EPA estimated costs for existing facilities and two planned facilities, but other new facilities may be constructed in the future 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 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 final rule 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.[28]

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 rule. There is uncertainty associated with the inputs and assumptions used in the dispersion modeling, the inhalation exposure estimates, and the dose-response relationships.

Finally, there is uncertainty regarding potential market impacts. These impacts were discussed qualitatively, but the degree to which the rule may affect EtO sterilization industry capacity, prices in the sterilization and medical device markets, and medical device availability is uncertain. EPA does not expect supply disruptions, but if disruptions were to occur in particular device markets, there could be delays in treatment or increased costs to obtain those devices.

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

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APPENDIX A. SENSITIVITY ANALYSIS

The EPA performed a sensitivity analysis of the costs estimated for this final rule in response to comments on the proposed rule that suggested costs were underestimated. Commenters noted that affected sterilization facilities would not be able to continue operating at baseline levels while completing upgrades needed to comply with the rule. According to the EPA Air Pollution Control Cost Manual, lost revenues should be considered a cost of a regulatory action when facilities need to close outside of their typical annual maintenance period in order to perform upgrades and make changes to comply with a rule. According to the EPA Air Pollution Control Cost Manual,[29] "If the shut-downs do not occur in a well planned and routine manner, any additional foregone production of goods and products would need to be included as a private cost attributable to the retrofit cost." This sensitivity analysis is included in this RIA for the final rule to assess the potential impacts of accounting for lost revenues associated with temporary capacity losses.

To estimate lost revenues, the EPA would ideally have data on facility level annual revenues from EtO sterilization operations and be able to calculate the percentage of annual production that facilities would need to forgo to complete compliance measures. Since the EPA does not have facility level annual revenues earned from EtO sterilization and does not know what percent of annual production would be lost during the compliance period, this sensitivity analysis instead relies on a number of assumptions to estimate lost revenues.

Based on comments received on the proposed rule, this analysis assumes that affected facilities will need a year to complete facility re-designs and install PTEs and/or other controls, during which time their capacity will be reduced by 10[30] to 20 percent.[31] This analysis presents lost revenue estimates for both a 10 percent and a 20 percent capacity reduction at all facilities for one year, even though the compliance timeframe is two to three years and potential capacity

[29] EPA Air Pollution Control Cost Manual – Chapter 2. Found at: https://www.epa.gov/sites/default/files/2017-12/documents/epaccmcostestimationmethodchapter_7thedition_2017.pdf.

[30] Commenter provided the following statement: "For example, a 10% reduction in capacity across the 83 commercial sterilizers in the U.S. implies that an additional 8 sterilization facilities will be required to maintain existing throughput" (see Docket Item No. EPA–HQ–OAR–2019–0178–0618).

[31] Commenter provided the following statement: "During… upgrades, EtO sterilization capacity was reduced by more than 20 percent as emissions control equipment was installed and tested." (see Docket Item No. EPA–HQ–OAR–2019–0178–0566).

reductions are likely to be staggered throughout the compliance period. It is assumed that facilities will be able to operate and sterilize products back at baseline levels after one year. In absence of facility-level EtO sterilization revenue data, the EPA used Census data to estimate average annual revenues at facilities affected by this rule.

The EPA used data from the 2021 Annual Survey of Manufactures (ASM), conducted by the U.S. Census Bureau, to obtain number of establishment and annual receipts for NAICS 339112 (Surgical and medical instrument manufacturing) and 339113 (Surgical appliance and supplies manufacturing).[32] Using this data, the EPA calculated average annual receipts per establishment in the two industries combined in 2021. This value was assumed to be a proxy for average annual revenues earned by facilities affected by this rule.

There are many more establishments in these NAICS codes than there are EtO sterilization facilities affected by this rule (over 1,200 establishments in NAICS 339112 and over 1,800 establishments in NAICS 339113 for 2021, versus 90 sterilization facilities affected by this rule). However, the EPA is assuming that the average revenues for establishments in these NAICS codes can serve as a proxy for average annual revenues earned by EtO sterilization facilities. The most common NAICS code among the 50 parent companies that own facilities affected by this rule is NAICS 339112. The EPA multiplied the average annual revenue per establishment estimate for 2021 in the two NAICS codes by the number of facilities affected by this rule (90) to estimate total annual revenues earned by the source category.

The average annual receipt estimate may not serve as an accurate proxy for EtO sterilization revenues. However, due to lack of more detailed data and with the following caveats, the EPA assumes that the value for annual revenue in 2021 is a suitable estimate to apply in the compliance years for this rule (roughly 2024 and 2025). First, most establishments in NAICS 339112 and 339113 manufacture medical equipment and do not conduct EtO sterilization. Some of the affected facilities sterilize spices, and thus may not be well represented by NAICS 339112 and 339113. Because some sterilization facilities conduct multiple types of sterilization including steam, gamma radiation, etc, the establishment level revenues may overestimate the revenues derived from the production line affected by this rule. Next, the set of facilities affected by this rule is heterogeneous in several ways, with some large facilities likely

[32] For information on the ASM see https://www.census.gov/programs-surveys/asm/data.html.

earning relatively high annual revenues and other smaller facilities earning relatively low annual revenues compared to the assumed average revenue estimate. Additionally, the assumption of a capacity loss of 10 or 20 percent may not be suitable for all facilities, such as the seven affected facilities that have currently met the emissions standards and do not require PTEs or any other controls. Some facilities affected by this rule may not need to reduce capacity at all to comply with the rule, while other facilities may need to reduce capacity more than 10 to 20 percent or may need longer than a year to finish upgrades.

This analysis estimates total lost revenue for one year and annualized lost revenue due to temporary capacity reductions. The share of annualized lost revenues to total annualized costs for option 2 is calculated for both a 10 percent and 20 percent capacity reduction. We examine how including the annualized lost revenues in the option 2 costs would affect the economic impacts on affected businesses (or entities) compared to the cost impacts presented in chapter 5 for option 2. By estimating annualized lost revenues, it is implicitly assumed that companies will be able to spread the impact of their temporary loss in revenues across the analytical time frame, similar to the EPA's assumption about how capital costs can be financed.

Using data from the 2021 ASM, the EPA estimated an average revenue per facility in 2021 of about $24.6 million. Multiplying this by 90 EtO sterilization facilities yields a source category total annual revenue estimate of about $2.2 billion. Thus, a 10 percent capacity reduction for a year would be associated with a revenue loss of $221 million, or about $22 million on an annualized basis (assuming a 20-year timeframe and 7.75 percent interest rate). Adding this lost revenue to the total annualized cost estimate for option 2 of about $74 million, the potential annualized lost revenue associated with a 10 percent capacity reduction for a year increases total annualized cost by about 28 percent. Alternatively, assuming a 20 percent capacity reduction for a year, the potential revenue loss is $443 million, or about $44 million on an annualized basis, increasing the total annualized cost estimate for option 2 by about 55 percent.

Next, the EPA examined the potential economic impacts of these higher costs using the methods used in the smally entity impact analysis in section 5.2. Parent company level cost-to-sales ratios were calculated using annualized costs that include the annualized lost revenue estimates to determine how much the ratios increase for the 50 affected parent companies and

specifically, for the 22 small entities. If lost revenues result in more companies having cost-to-sales ratios that exceed a certain threshold (i.e., 3 percent per EPA guidance on the RFA[33]), then this sensitivity analysis indicates the potential for greater economic impacts than was identified in the main analysis.

The EPA increased each individual parent company's total annualized cost estimate for option 2 by 28 percent and 55 percent to account for potential revenue losses associated with 10 and 20 percent capacity reductions, respectively, and then re-calculated the company-level cost-to-sales ratios. The total annualized costs at the parent company level are increased by these percentages and then compared to parent company annual revenues, as was described and presented in section 5.2. Instead of increasing each company's costs by a lump sum dollar amount, such as adding 1/50th of the source category annualized revenue loss estimate presented above, the EPA believes this method better accounts for the heterogeneity in the requirements faced by the 50 companies. In other words, one might expect that a company with relatively high estimated compliance costs for option 2 would need to implement more extensive controls and may need to reduce capacity more than a company that has a relatively low compliance costs for option 2. The combined revenue losses for the source category are the same either way, but the chosen method better accounts for the different needs across the affected facilities by allowing revenue loss estimates to vary as a percentage of company-level costs rather than adding a uniform lump sum to all companies' costs.

If each company incurred 28 percent higher total annualized costs (i.e., their total annualized costs include the revenue losses associated with a 10 percent capacity reduction for a year, annualized over the analytical timeframe), one additional company, a small entity, would exceed a 3 percent cost-to-sales ratio in addition to the 13 companies estimated to exceed this threshold as discussed in section 5.2.2. If each company incurred 55 percent higher total annualized costs (i.e., due to a 20 percent capacity reduction for a year), two additional companies, both of which are small entities, would exceed a 3 percent cost-to-sales ratio in addition to the 13 companies estimated to exceed this threshold presented in section 5.2.2. Thus, under a scenario where all affected companies incur revenue losses associated with a 20 percent capacity reduction, there are 15 companies, all of which are small entities, with estimated cost-

[33] U.S. EPA. (2006). Final Guidance for EPA Rulewriters: Regulatory Flexibility Act. https://www.epa.gov/sites/default/files/2015-06/documents/guidance-regflexact.pdf.

to-sales ratios that exceed 3 percent. As presented in Chapter 5, about 59 percent of the 22 small entities exceed a 3 percent cost-to-sales ratio under option 2 whereas this sensitivity analysis indicates that potentially 68 percent of the small entities could exceed this ratio. None of the larger businesses exceed a 3 percent cost-to-sales ratio under option 2 in the main analysis or in this sensitivity analysis.

In absence of better quantitative information to estimate lost revenues with more certainty, the EPA concluded that the method used in this analysis was the best available option to assess the potential cost impacts of facilities needing to temporarily reduce capacity to adjust operations to comply with the final rule. This analysis was prepared as a sensitivity analysis separate from the main analysis in response to comments on the proposed rule that suggested the costs were underestimated. Uncertainties in this analysis could be partially addressed by using actual annual sales revenues for each of the 90 facilities affected by the rule. Nevertheless, the sensitivity analysis indicates that accounting for lost revenues slightly increases the number of small entities with high cost-to-sales ratios (from 13 small entities potentially to 15 small entities). While the small business impacts are concerning, accounting for lost revenues does not appear to materially affect the main conclusions of the small entity analysis in chapter 5, which already highlights the potential for adverse impacts on small entities.

Based on the results of this sensitivity analysis, the EPA is not updating the potential market impacts discussed in section 5.3. The EPA does not expect that accounting for potential lost revenues in the costs would introduce significantly higher economic impacts on the owners of facilities affected by this rule based on the analysis of cost-to-sales ratios. This analysis of lost revenues does not directly speak to potential medical device supply chain risks associated with temporary operational slowdowns if many facilities reduce capacity simultaneously. If many affected facilities reduce the quantity of products they sterilize to complete upgrades at the same time, more capacity would be lost temporarily, which could potentially temporarily impact the supply of the medical devices. To mitigate this risk, the EPA is finalizing the longest compliance timeframe possible to provide affected facilities the opportunity to stagger the timing of their upgrades to reduce potential for medical device shortages. Although this sensitivity analysis assumed all capacity reductions would occur in one year, the finalized compliance timeframe offers flexibility to stagger the timing of upgrades at affected facilities over two to three years. Several facilities have already begun installing the required controls without reports of industry

capacity issues. The EPA also modified the proposed BMPs in the final rule to reduce the possibility of impacts to the medical device supply chain. The final BMPs remove the requirements to reduce EtO use per sterilization cycle for most facilities, which voids the need to complete time-consuming new cycle validations.

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