**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

CLEANAIRE NC
933 Louise Ave.
Charlotte, North Carolina 28204;

SUSTAINABLE NEWTON
P.O. Box 146
Oxford, Georgia 30054;

VIRGINIA INTERFAITH POWER & LIGHT
P.O. Box 26059
Richmond, Virginia 23260;

NATURAL RESOURCES DEFENSE COUNCIL, INC.
40 West 20th Street, 11th Floor
New York, New York 10011;

*Plaintiffs*,

v.

DONALD TRUMP, President of the United States, in his official capacity;

U.S. ENVIRONMENTAL PROTECTION AGENCY; *and*

LEE ZELDIN, Administrator of the U.S. Environmental Protection Agency, in his official capacity;

*Defendants*.

**Case No.** 1:26-cv-233

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

1. On July 17, 2025, President Donald Trump issued a proclamation granting 40 commercial sterilizers—industrial facilities that use the cancer-causing pollutant ethylene oxide to sterilize goods including medical devices and dried food products—a two-year exemption from strengthened emission standards. Regulatory Relief for Certain Stationary Sources to

Promote American Security with Respect to Sterile Medical Equipment, 90 Fed. Reg. 34,747 (July 23, 2025) (hereinafter "Sterilizers Proclamation") (Ex. 1). Many commercial sterilizers are located in residential areas, quietly emitting a colorless but extremely toxic chemical next to homes, schools, places of worship, and other public facilities.

2. U.S. Environmental Protection Agency ("EPA") estimated that 8.5 million people living near medical sterilizers have an elevated cancer risk of 1-in-1 million, and that such facilities could pose a lifetime cancer risk as high as 6000-in-1 million. National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24,090, 24,117 (Apr. 5, 2024) (the "EtO Rule"). This is sixty times higher than EPA's own threshold for what constitutes "unacceptable risk," making sterilization facilities among the most dangerous sources regulated under the Clean Air Act. *Id.* at 24,097. The cancer risk estimates using allowable emissions—the maximum amount of ethylene oxide these facilities are permitted to emit—are even higher: 62 million people with an elevated risk of 1-in-1 million, an 8000-in-1 million lifetime cancer risk from all facilities, and a risk eighty times higher than EPA's "unacceptable risk" threshold. *Id.* at 24,095.

3. Ethylene oxide was added to EPA's carcinogen list in 2016 with an assessment warning that ethylene oxide "was 30 times more carcinogenic to people who continuously inhale it as adults and 50 times more carcinogenic to those who are exposed since birth than the agency

previously thought."[1] A 2021 ProPublica analysis concluded that ethylene oxide is the "biggest contributor to excess industrial cancer risk from air pollutants nationwide."[2]

4. To address these unacceptable health risks, including cancer risks, in 2024 EPA strengthened the hazardous air pollutant standards for the 90 commercial sterilizer facilities that use ethylene oxide in an action known as the "EtO Rule." The EtO Rule requires facilities to control building leaks, strengthen existing controls, and install continuous emissions monitoring systems, which is projected to reduce sterilizers' ethylene oxide emissions by 90% nationwide, and the number of people with a cancer risk of 1-in-1 million by approximately 92%.

5. President Trump's Sterilizers Proclamation unilaterally sweeps away these protections and gives about 45% of commercial sterilizers, from Georgia to Massachusetts and Puerto Rico to California, a free pass to continue to pollute at high levels and put communities at risk for an additional two years. By granting these exemptions, President Trump allows facilities to delay more stringent emissions controls and to forgo continuous emissions monitoring and quarterly reporting, which would provide accountability and transparency for toxic emissions leaking into neighboring communities.

[1] Kiah Collier & Maya Miller, *A Plant That Sterilizes Medical Equipment Spews Cancer-Causing Pollution on Tens of Thousands of Schoolchildren*, ProPublica (Dec. 27, 2021), https://perma.cc/Z3KH-E3ST.

[2] Lylla Younes et al., *Poison in the Air*, ProPublica (Nov. 2, 2021), https://perma.cc/TN5Z-ZCLM.

**Map 1: Exempted Sterilizers Map**, EDF, https://perma.cc/Y6Q7-ATXR.


6. The President granted these sweeping exemptions by seizing on a narrow and, until this year, never-before-used provision of the Clean Air Act. This provision allows the President to exempt a source from a hazardous air pollutant standard for up to two years only if "the technology to implement" the relevant standard is "not available" and if exempting the source "is in the national security interests of the United States." 42 U.S.C. § 7412(i)(4).

7. But in the Sterilizers Proclamation, President Trump's "determinations" are pure pretext. Although the Proclamation states that complying with the EtO Rule requires "emissions-control technologies that do not exist in a commercially viable form," several of the exempted facilities have reported that they are already utilizing emissions controls that meet the standard in the EtO Rule. 90 Fed. Reg. 34,747. And although the Proclamation cites the need to protect the

"supply [of] sterilized medical equipment," *id.*, one of the exempted facilities sterilizes *only* spices and food products, not medical equipment.

8. In the fifty-five years since Congress enacted Section 7412(i)(4), no President had exercised this exemption authority. In 2025 alone, President Trump invoked it seven times, exempting more than 180 facilities. In addition to the Sterilizers Proclamation, President Trump issued proclamations exempting nearly one-third of U.S. coal-fired power plants from mercury and other air toxics standards, 50 chemical manufacturers from ethylene oxide and other hazardous air pollutant standards, one of two copper smelters from toxic metals standards, and the entire taconite iron-ore processing and coke production industries.

9. President Trump's sweeping Sterilizers Proclamation grossly exceeds the bounds of the Section 7412(i)(4) exemption authority. It exempts about 45% of commercial sterilizers from complying with the EtO Rule in its entirety without any standard- or facility-specific analysis showing that any of the 40 specific facilities cannot meet the statutory standard. The technology needed to comply with the EtO Rule is widely available throughout the industry—and is indeed already in use at many of the facilities that received exemptions.

10. The Sterilizers Proclamation operates to suspend compliance with the EtO Rule while EPA works to repeal these critical Clean Air Act protections. Congress explicitly prohibited that sort of delay of Clean Air Act standards pending administrative reconsideration. 42 U.S.C. § 7607(d)(1)(C).

11. The Sterilizers Proclamation violates the Clean Air Act and exceeds the President's lawful authority. Plaintiffs ask the Court to enter appropriate relief declaring the Proclamation unlawful and invalid and enjoining EPA and its Administrator from implementing or giving effect to it.

## JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because this is a civil action arising under laws of the United States, including the Clean Air Act.

13. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because Defendants reside in this judicial district, and because a substantial part of the events giving rise to the claim occurred in this judicial district.

14. The Court has authority to enter a declaratory judgment and to provide injunctive relief pursuant to Rules 57 and 65 of the Federal Rules of Civil Procedure; the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202; the All Writs Act, 28 U.S.C. § 1651; and the Court's inherent equitable powers.

## PARTIES

*The Plaintiffs*

15. Plaintiffs are nonprofit organizations working to reduce air pollution and have members who are harmed by the exemptions' removal of protections mandated by the EtO Rule.

16. Plaintiff Natural Resources Defense Council ("NRDC") is a national nonprofit environmental membership organization with hundreds of thousands of members nationwide. NRDC's purpose is to safeguard the Earth—its people, its plants and animals, and the natural systems on which all life depends. Part of NRDC's core mission is to improve air quality and safeguard public health by combating hazardous air pollutant emissions. NRDC has many members that live, work, and recreate within six miles of facilities that received exemptions, including the Cosmed facility in Erie, Pennsylvania, the LivaNova facility in Arvada, Colorado, the Covidien facility in North Haven, Connecticut, and the Sterigenics facility in Ontario,

California. The Sterilizers Proclamation will directly harm these members by depriving them of the protections mandated by the EtO Rule.

17. Plaintiff CleanAIRE NC ("CleanAIRE") is a 501(c)(3) nonprofit organization headquartered in Charlotte, North Carolina. CleanAIRE works to protect the health of all North Carolinians through community-centered strategies to address air pollution, environmental injustice, and climate change. CleanAIRE advocates for clean air, partners with schools, healthcare systems and community organizations to educate the public on the health impacts of air pollution, conducts Health Impact Assessments, and operates air-monitoring programs to identify and address health risks from air pollution. CleanAIRE has many members who live within six miles of the Charlotte Sterigenics facility which received an exemption. The Sterilizers Proclamation will directly harm these members by depriving them of the protections mandated by the EtO Rule.

18. Plaintiff Sustainable Newton is a grassroots, community-based 501(c)(3) nonprofit organization founded by and serving residents of Newton County, Georgia. Sustainable Newton partners with residents, businesses, and government officials to implement climate solutions in Newton County. The precursor to the Sustainable Newton Environmental Hazards Committee was founded in 2019 and formed in direct response to a commercial ethylene oxide sterilizer located in Newton County. Through this committee, Sustainable Newton advocates on behalf of residents and workers for relief from environmental hazards, including ethylene oxide emissions, through increased transparency, improved air quality monitoring, and implementation of the most protective public safety measures. Sustainable Newton has several members within six miles of the Becton-Dickinson commercial sterilizer facility which received an exemption,

and these members are directly impacted by the loss of protections that the EtO Rule would have provided.

19. Plaintiff Virginia Interfaith Power & Light ("VA Interfaith Power & Light") is a 501(c)(3) nonprofit organization operating in the state of Virginia. VA Interfaith Power & Light is dedicated to collaborating with people of faith and conscience to grow healthy communities by advancing climate and environmental justice. Bringing faith communities within Virginia together to mobilize a moral response to climate change by educating leaders and advocating for just environmental policies and laws to ensure access to fresh air, clean water, and equitable energy burden for all Virginians. Virginia Interfaith Power & Light partners with faith leaders, private and state agencies, state and federal legislators, as well as frontline communities, to support their efforts to mitigate the health and economic impacts of air and water pollution, in addition to the "heat island effect." VA Interfaith Power & Light serves members and congregations located within six miles of two ethylene oxide sterilizers located in Richmond, including Sterilization Services of Virginia, which received an exemption. These congregations and members are directly affected by the loss of protections the EtO Rule would have provided. These congregations and members are directly affected by the loss of protections the EtO Rule would have provided.

*The Defendants*

20. Defendant Donald Trump is the President of the United States. He resides and conducts his duties in Washington, D.C. He is sued in his official capacity.

21. Defendant EPA is a federal agency of the United States whose mission is to protect human health and the environment, and responsibilities include issuing and enforcing

hazardous air pollutant standards, including the EtO Rule at issue here. EPA is headquartered in Washington, D.C.

22. Defendant Lee Zeldin is the EPA Administrator. He resides and conducts his duties in Washington, D.C. He is sued in his official capacity.

## LEGAL BACKGROUND

*The Clean Air Act's Program to Address Hazardous Air Pollution*

23. Clean Air Act Section 112, 42 U.S.C. § 7412, establishes the framework for EPA's regulation of "hazardous air pollutants" from stationary sources, including industrial facilities such as commercial sterilizers.

24. "Hazardous air pollutants," as defined by Clean Air Act Section 7412, are a group of 188 air pollutants determined by Congress and EPA to be particularly harmful to human health. Ethylene oxide is one such hazardous air pollutant. 42 U.S.C. § 7412(b)(1).

25. Section 7412 requires EPA to regulate hazardous air pollutants by issuing emissions standards for categories and subcategories of stationary sources of such pollutants. Emissions standards must require the maximum degree of reduction that EPA deems "achievable," taking into consideration cost as well as any non-air quality health and environmental impacts and energy requirements. *Id.* § 7412(d)(2), (3)(A)–(B).

26. After EPA establishes Section 7412 standards for a source category, the Clean Air Act requires EPA to perform recurring reviews to ensure that the standards adequately address risks to health and welfare from hazardous air pollutant emissions and that they reflect advancements in technology and practice that allow sources to achieve even greater emission reductions. This process occurs in two separate reviews, often performed together, and which are referred to as the "residual risk and technology review."

27. As part of the technology review, EPA must "review, and revise" the Section 7412 standards "as necessary (taking into account developments in practices, processes, and control technologies)." *Id.* § 7412(d)(6).

28. As part of the risk review, EPA determines whether unacceptable risk to public health remains, or is likely to remain, from hazardous air pollutant emissions even after the application of Section 7412 standards. If unacceptable risk remains, EPA must promulgate additional standards that eliminate the unacceptable risk, "provid[ing] an ample margin of safety to protect public health," and preventing "an adverse environmental effect." *Id.* § 7412(f)(2)(A).

29. Congress prescribes strict compliance schedules for Section 7412 standards. Residual risk-based emissions standards "shall become effective upon promulgation" for new sources, or 90 days after the effective date for existing sources. *Id.* § 7412(f)(3)–(4)(A). EPA may waive compliance for up to two years only if it determines "such period is necessary for the installation of controls and that steps will be taken during the period of the waiver to assure that the health of persons will be protected from imminent endangerment." *Id.* § 7412(f)(4)(B).

30. For standards revised as part of a technology review, EPA must require existing sources to comply "as expeditiously as practicable," and no later than three years after the effective date. *Id.* § 7412(i)(3)(A). EPA may grant a source up to one additional year to comply only where "such additional period is necessary for the installation of controls." *Id.* § 7412(i)(3)(B).

*Clean Air Act Procedural Requirements*

31. The Clean Air Act sets out specific rulemaking requirements for "the promulgation or revision of any . . . emission standard or limitation under section 7412(d)." *Id.* § 7607(d)(1)(C). EPA must establish a rulemaking docket, publish a notice of proposed

rulemaking in the Federal Register, and provide a statement of basis and purpose for the rule that includes the factual data on which the proposed rule is based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed rule. *Id*. § 7607(d)(3).

32. The Clean Air Act also requires EPA to allow any person to submit written comment, and to provide an opportunity for oral presentation of data, views, or arguments, on a proposed rule. *Id*. § 7607(d)(5); *see also id*. § 7607(h). In promulgating a final rule, EPA must provide a statement of basis and purpose as required at the proposal stage and must explain any major changes from the proposed to final rule. *Id*. § 7607(d)(6)(A). EPA must also provide a response to each of the significant comments, criticisms, and new data submitted during the comment period. *Id*. § 7607(d)(6)(B). EPA may not base a promulgated rule on "any information or data which has not been placed in the docket as of the date of such promulgation." *Id.* § 7607(d)(6)(C).

33. The Clean Air Act also establishes specific procedures for reconsidering a promulgated rule. The EPA Administrator can "convene a proceeding for reconsideration of the rule" but must "provide the same procedural rights as would have been afforded" in the original proceeding. *Id*. § 7607(d)(7)(B). The Act further provides that reconsideration "shall not postpone the effectiveness of the rule," except that the Administrator or a reviewing court may stay the effectiveness of the rule "for a period not to exceed three months." *Id*. Section 7607(d)(7)(B) is the sole source of authority to stay a rule after its effective date has passed. *See Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017).

*Presidential Exemption Provision*

34. Section 7412(i)(4) of the Clean Air Act authorizes the President, in narrowly prescribed circumstances, to "exempt any stationary source from compliance" with hazardous air pollutant standards promulgated under Section 7412, "for a period of not more than 2 years if the President determines [1] that the technology to implement such standard is not available and [2] that it is in the national security interests of the United States to do so." 42 U.S.C. § 7412(i)(4).

35. The President may extend the original exemption "for 1 or more additional periods, each period not to exceed 2 years." *Id*.

## FACTUAL AND PROCEDURAL BACKGROUND

*National Emission Standards for Hazardous Air Pollutants for Commercial Sterilizers*

36. The ethylene oxide commercial sterilization industry consists of facilities operating a sterilization process that uses ethylene oxide to sterilize or fumigate materials, including medical equipment, spices, and other miscellaneous products. 89 Fed. Reg. at 24,097.

37. In 1994, EPA promulgated the first hazardous air pollutant standards for the ethylene oxide commercial sterilization industry at 40 C.F.R. part 63, subpart O. National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 62,585 (Dec. 6, 1994). EPA completed a residual risk and technology review for that industry in 2006, making no changes to the 1994 standards. Ethylene Oxide Emissions Standards for Sterilization Facilities, 71 Fed. Reg. 17,712 (Apr. 7, 2006).

*The 2024 Risk and Technology Review*

38. In 2016, EPA updated its Integrated Risk Information System ("IRIS") assessment for ethylene oxide. IRIS is EPA's flagship human health assessment program, designed to

identify and characterize health hazards of chemicals from environmental exposures with the goal of protecting public health. The updated 2016 IRIS ethylene oxide assessment was published for public comment and extensively peer-reviewed by expert review panels, EPA scientists, other federal agencies, and the White House. The assessment concluded that ethylene oxide is a significantly more potent carcinogen than previously understood. Exposure to even low amounts of ethylene oxide increases the risk of lymphoid cancers, such as non-Hodgkin's lymphoma, myeloma, and lymphocytic leukemia, as well as breast cancer. Ethylene oxide exposure is also linked to respiratory, nervous system, and hormone disruption.

39. Children have greater susceptibility to the cancer risks posed by ethylene oxide exposure than adults because ethylene oxide has a mutagenic mode of action, and children's bodies and immune systems are still developing. *See* 89 Fed. Reg. at 24,149. As a result, the potency of ethylene oxide is tenfold higher for infants and children from birth up to 2 years of age, and threefold higher for 2- to 16-year-olds, than it is for adults. Therefore, young children exposed to ethylene oxide during the first years of life have very high and unacceptable cancer risks. A delay of two years to reduce ethylene oxide exposures can have adverse lifelong consequences for individuals exposed during the earliest years of life.

40. Based on this updated scientific understanding of the health risks posed by ethylene oxide, EPA assessed the emissions and risks from commercial sterilization facilities and found that ethylene oxide emissions from specific emission sources in the sterilization process are major contributors to the cancer risks associated with ethylene oxide. In its final Residual Risk Assessment, EPA estimated that cancer risks from these facilities reach as high as 6,000-in-1 million, with more than 8 million people nationwide estimated to have a cancer risk at or above 1-in-1 million due to commercial sterilizer emissions.

41. These EPA estimates are for actual, not allowable commercial sterilizer emissions. Allowable emissions are the maximum amount that commercial sterilizers are allowed to emit under Clean Air Section 112(d). 89 Fed. Reg. 24,117. Using allowable emissions, EPA estimates that cancer risks would increase to 8,000-in-1 million, with 62 million people nationwide estimated to have a cancer risk at or above 1-in-1 million, with 260,000 people nationwide estimated to have a cancer risk above 100-in-1 million. *Id.* at 24,118.

42. EPA further found that children that live, play or attend school or daycare near sterilization facilities are more vulnerable to ethylene oxide's cancer-causing effects due to increased susceptibility, increased exposure and longer remaining lifespans over which cancer can develop. *Id.* at 24,149.

43. Approximately 4 million children aged 0 to 17 live within six miles of a commercial sterilization facility. *Id.* Without the EtO Rule, EPA estimated that approximately 1.25 million children would face increased lifetime cancer risks greater than 1-in-1 million. *Id*.

44. EPA also conducted a technology review under Clean Air Act Section 112(d)(6) to evaluate developments in practices, processes, and control technologies for the commercial sterilization industry since the prior review in 2006. *Id.* at 24,097–98.

45. EPA finalized the EtO Rule in April 2024. *Id.* at 24,090. The EtO Rule became effective on April 5, 2024. *Id.*

*EtO Rule Strengthened Emissions Standards*

46. The EtO Rule establishes emissions control requirements for multiple emissions sources at commercial sterilization facilities. These requirements are designed to achieve ethylene oxide emissions reductions necessary to address remaining health risks with an ample margin of safety.

47. The revised standards require additional controls for previously uncontrolled or under-controlled emission points, including sterilization chamber vents ("SCVs"), aeration room vents ("ARVs"), chamber exhaust vents ("CEVs"), and certain fugitive room air emissions (classified as "Group 1" and "Group 2" room air emissions). *Id.* at 24,104–05. EPA also required all facilities with room air emissions to implement a permanent total enclosure consistent with EPA Method 204. *Id.* at 24,105. And EPA required most facilities to install a continuous emissions monitoring system ("CEMS"). *Id.* at 24,101.

48. EPA identified several proven and widely implemented control technologies—including catalytic oxidizers and gas-solid reactors—that were already in use at some commercial sterilization facilities. *See id.* at 24,120–24. EPA concluded that these controls were cost-effective in light of the magnitude of health risk reductions achieved. *See id.* at 24,125–27.

49. *Sterilization Chamber Vents*: The EtO Rule imposes standards for sterilization chamber vents that require facilities with such emission sources to achieve a specified percentage of ethylene oxide reduction depending on the volume of ethylene oxide usage at the facility. For instance, the largest facilities, where ethylene oxide usage is at least 30 tons per year, must achieve a 99.99% emission reduction. *Id.* at 24,192–93; *see also* Tbl. 1 to Subpart O of Part 63, Title 40.

| Source | Status | Ethylene Oxide Usage (tons per year) | Emission Reduction (%) |
|---|---|---|---|
| Sterilization Chamber Vent | Existing/New | ≥ 30 | 99.99 |
| | | ≥ 10 and < 30 | 99.90 |
| | | ≥ 1 and < 10 | 99.80 |
| | | < 1 | 99.00 |

50. *Aeration Room Vents*: The EtO Rule also imposes standards for aeration room vents, requiring facilities with aeration room vents to achieve a specified percentage of ethylene

oxide reduction depending on the volume of ethylene oxide usage at the facility. For instance, the largest facilities that use at least 30 tons per year of ethylene oxide must achieve a 99.90% emission reduction. 89 Fed. Reg. at 24,193; *see also* Tbl. 2 to Subpart O of Part 63, Title 40.

| Source | Status | Ethylene Oxide Usage (tons per year) | Emission Reduction (%) |
|---|---|---|---|
| Aeration Room Vent | Existing | ≥ 30 | 99.90 |
| | | ≥ 10 and < 30 | 99.60 |
| | | < 10 | 99.00 |
| | New | ≥ 10 | 99.90 |
| | | < 10 | 99.00 |

51. *Chamber Exhaust Vents*: The EtO Rule further imposes standards for chamber exhaust vents, requiring facilities with chamber exhaust vents to achieve a specified percentage of ethylene oxide reduction, depending on the volume of ethylene oxide usage at that facility. For instance, the largest area source facilities that use at least 60 tons per year of ethylene oxide must achieve a 99.90% emission reduction. 89 Fed. Reg. at 24,193–94; *see also* Tbl. 3 to Subpart O of Part 63, Title 40.

| Source | Facility Type | Status | Ethylene Oxide Usage (tons per year) | Emission Reduction (%) |
|---|---|---|---|---|
| Chamber Exhaust Vent | Major Source | Existing/New | Any | 99.94 |
| | Area Source | Existing/New | ≥ 60 | 99.90 |
| | | | < 60 | 99.00 |

52. Emissions at sterilization chamber vents, aeration chamber vents, and chamber exhaust vents may be controlled using a range of air pollution control devices ("APCDs"). These include wet scrubbers (such as acid-water scrubbers and Glygen absorber units), catalytic oxidizers, combination balancers and catalytic oxidizers, thermal oxidizers, and dry-bed scrubbers (gas-solid reactors).

53. *Room Air Emissions*: The EtO Rule also imposes standards for Group 1 and Group 2 room air emissions, based on a facility's ethylene oxide usage and whether it is a new or existing facility. 89 Fed. Reg. 24,194–95; *see also* Tbl. 4 & Tbl. 5 to Subpart O of Part 63, Title 40. Group 1 room air emissions are defined "as emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material," while Group 2 room air emissions are defined as "emissions from post-aeration handling of sterilized material." 89 Fed. Reg. 24,099. Group 1 and Group 2 room air emissions may be controlled with APCDs including acid water scrubbers, dry-bed scrubbers, combination water balancer and catalytic oxidizer, catalytic oxidizers, and cascading air systems.

| Source | Facility Type | Status | Ethylene Oxide Usage (tons per year) | Emission Reduction (%) |
|---|---|---|---|---|
| Group 1 Room Air Emissions | Major Source | Existing/New | Any | 97.00 |
| | Area Source | Existing/New | ≥ 40 | 98.00 |
| | | | < 40 | 80.00 |
| Group 2 Room Air Emissions | Major Source | Existing/New | Any | 86.00 |
| | Area Source | Existing | ≥ 20 | 98.00 |
| | | | ≥ 4 and < 20 | 80.00 |
| | | | < 4 | Reduce to 1 ppm in each chamber before opening |
| | | New | ≥ 20 | 98.00 |
| | | | < 20 | 80.0 |

54. *Permanent Total Enclosure*: Group 1 room air emissions at all facilities and Group 2 room air emissions at facilities using more than 4 tons per year of ethylene oxide must also be captured within a "permanent total enclosure." 89 Fed. Reg. at 24,194–95; *see also* Tbl. 4 & Tbl. 5 to Subpart O of Part 63, Title 40. A permanent total enclosure captures and contains all exhaust air from relevant room air activities—including storage, dispensing, vacuum pumps, and pre- and post-aeration handling—under negative pressure and directs all captured air to an add-

on control device. 89 Fed. Reg. at 24,104, 24,174. Room air emissions captured in a permanent total enclosure must then be routed to an add-on air pollution control device that removes ethylene oxide at the required efficiency. *Id.*

55. *Continuous Emissions Monitoring*: Commercial sterilizers using more than 100 pounds (0.05 tons) per year of ethylene oxide must install continuous emissions monitoring systems. *Id.* at 24,101; *see also* 40 C.F.R. § 63.364. Continuous emissions monitoring systems provide a direct measure of ethylene oxide concentration or ethylene oxide emission rate in the gas stream it is analyzing, allowing detection of fluctuations in ethylene oxide concentration that other methods would miss. Facilities must submit continuous emissions monitoring system data reports on a quarterly basis, with a minimum of 90% data availability, to EPA's Central Data Exchange's Compliance and Emissions Data Reporting Interface. 89 Fed. Reg. at 24,101. Once submitted, EPA "will make all information submitted through CEDRI available to the public," 40 C.F.R. § 63.366(b), (c), such as through EPA's WebFIRE data repository. *WebFIRE: WebFIRE Report Search and Retrieval*, EPA, https://perma.cc/2EDT-KKYL.

*Public Health Benefits of the EtO Rule and Cancer Risk Reductions*

56. EPA determined that the EtO Rule would reduce ethylene oxide emissions from commercial sterilizers by more than 90% and reduce the number of people with a potential cancer risk greater than or equal to 1-in-1 million from sterilization facilities by approximately 92%. 89 Fed. Reg. at 24,095, 24,137.

57. EPA found that the EtO Rule would reduce the number of children facing lifetime cancer risks from sterilization facilities of more than 1-in-1 million from 1.25 million children to 162,300 children. The number of children facing risks of greater than 100-in-1 million would drop from 4,300 children to zero children. *Id.* at 24,149.

58. EPA identified that emissions from the Sterilization Services of Virginia facility in Henrico, Virginia presented elevated cancer risks as high as 1,000-in-1 million. *Henrico, Virginia (Sterilization Services of Virginia)*, EPA, https://perma.cc/3ANB-925N.[3]

59. Emissions from the Cosmed facility in Erie, Pennsylvania presented elevated cancer risks as high as 300-in-1 million. *Erie, Pennsylvania (Cosmed Group LLC/Erie)*, EPA, https://perma.cc/7F8L-ZRSG.

60. In Linden, New Jersey, emissions from the Cosmed facility presented cancer risks as high as 2,000 in 1 million. *Linden, New Jersey (ETO Sterilization-Plant #2)*, EPA, https://perma.cc/EPY9-MEQS.

61. EPA estimated that the total capital investment costs of compliance with the EtO Rule across all U.S. commercial sterilization facilities is approximately $313 million, with a total annual cost of $74 million. 89 Fed. Reg. at 24,137. EPA analyzed business impacts and found that the average cost-to-sales ratio is about eight percent for all entities, and 0.2 percent for large entities specifically in comparison to revenues at the ultimate parent company level. *Id.* at 24,137–38.

62. Averaged across all 88 facilities, the upper-bound estimate of total capital investment costs and of total annual costs would be $3.56 million and $840,000 per facility, respectively, although EPA estimated that costs would vary depending on the individual facility's pre-existing controls. *Id.* at 24,125–26. Further, EPA stated that "the industry has demonstrated the capability to install controls on multiple facilities simultaneously without interfering with medical supply chains." *Id*. at 24,138.

[3] EPA warns that the risk information provided at this link is no longer current because, "in a number of cases, commercial sterilizers have made improvements or changes to operation that have reduced risks to residents" citing the "final amendments" to the EtO Rule. *See, e.g.*, *Henrico, Virginia (Sterilization Services of Virginia)*, EPA, https://perma.cc/3ANB-925N.

63. Based on this evidence, EPA concluded that existing commercial sterilizers could comply with the requirements of the EtO Rule within the statutory timeframes of two years (for Section 7412(f) ethylene oxide requirements) and three years (for Section 7412(d) technology-based requirements)—by April 6, 2026, and April 6, 2027, respectively. *Id*. Each of these dates represents the maximum compliance timeframe allowed under the statute.

*EPA Announces Reconsideration, Solicits Exemption Requests*

64. On March 12, 2025, in a press event billed as "the greatest day of deregulation our nation has seen," EPA announced that it would "reconsider" the EtO Rule and 31 other regulations protecting human health and the environment. News Release, EPA, EPA Launches Biggest Deregulatory Action in U.S. History (Mar. 12, 2025), *available at* https://perma.cc/EXL5-FAMQ.

65. Along with its press release, EPA published a "fact sheet" about its planned reconsideration of the EtO Rule and seven other recent rules protecting people from hazardous air pollutants. That fact sheet included an invitation to industrial facilities that "[a]ny source interested in a Presidential exemption" from any of the eight rules, "should provide their recommendations to EPA by March 31, 2025." Fact Sheet, EPA, Oil and Gas Regulations: Powering the Great American Comeback at 3, *available at* https://perma.cc/E8UM-RN3K. The fact sheet further explained, "[s]ources need only provide why technology is unavailable and why it is in the national security interests of the United States to provide the exemption." *Id*.

66. Following up on its invitation to industrial facilities to request exemptions, on or about March 24, 2025, EPA posted a new webpage announcing it had established "an electronic mailbox"—airaction@epa.gov—"to allow the regulated community to request a Presidential Exemption under section 112(i)(4)." *Clean Air Section 112 Presidential Exemption Information*,

EPA, https://perma.cc/WKL5-44FC. EPA asked that requests be submitted "by March 31, 2025," a week after the webpage was posted. *Id.*

67. EPA did not solicit any input from the public or provide any opportunity for public comment.

68. Facility owners and operators across multiple source categories sent exemption requests to that email inbox. Many exemption requests from commercial sterilizers were identical submissions devoid of facility-specific information, copying and pasting a letter submitted by the Ethylene Oxide Sterilization Association ("EOSA"). The letter submitted by EOSA, and attached to many of the facilities' exemption requests, urged the President to grant a blanket two-year compliance exemption for all facilities subject to the EtO Rule based on alleged technological unavailability and national security considerations.

*The Sterilizers Proclamation*

69. On July 17, 2025, President Trump issued a proclamation purporting to exempt a list of commercial sterilizers "from compliance with the EtO Rule for a period of 2 years beyond the EtO Rule's relevant compliance dates." 90 Fed. Reg. at 34,747.

70. The Sterilizers Proclamation cited to "authority vested in [the President] by the Constitution and the laws of the United States, including section 112(i)(4) of the Clean Air Act, 42 U.S.C. 7412(i)(4)." *Id.*

71. The Sterilizers Proclamation stated that it "applies to all compliance deadlines established under the EtO Rule applicable to the stationary sources listed in Annex I, with each such deadline extended by 2 years from the date originally required for such deadline." *Id.*

72. The Sterilizers Proclamation included what it referred to as two "determinations." *Id.*

73. First, the Sterilizers Proclamation purported to "determine" that "[t]he technology to implement the EtO Rule is not available," claiming that "[s]uch technology does not exist in a commercially viable form sufficient to allow implementation of and compliance with the EtO Rule by the compliance dates set forth in the EtO Rule." *Id.* at 34,747–48.

74. Second, the Sterilizers Proclamation purported to determine that "[i]t is in the national security interests of the United States to issue this Exemption for the reasons stated in paragraphs 1 and 3 of this proclamation." *Id.* at 34,748. Paragraph 1 asserted that "[t]he continued utilization of ethylene oxide by commercial sterilization facilities is essential to ensuring that our Nation provides its sick and injured with the best outcomes possible—an objective that is at the forefront of the Federal Government's responsibility to the American people." *Id.* at 34,747. Paragraph 3 asserted that "[b]y requiring compliance with standards premised on the application of emissions-control technologies that do not exist in a commercially viable form, the EtO Rule risks making critical sterile medical devices unavailable to care for patients in our civilian and military medical systems." *Id.*

75. The Sterilizers Proclamation and "Annex I" were published in the Federal Register on July 23, 2025. *Id.* at 34,749–51.

76. The Sterilizers Proclamation included no facility-, standard-, or technology-specific determinations. Instead, it broadly and conclusorily asserts that the technology to implement the EtO Rule (in its entirety) is not available and that granting exemptions is in the national security interests of the United States.

*Technology to Implement the EtO Rule's Requirements Is Widely Available and Already in Use*

77. Technology to implement the standards in the EtO rule is available. The Sterilizers Proclamation's unsupported determinations to the contrary are contradicted by the public record, including EPA's own factual findings in the EtO Rule.

78. Controls necessary to meet the standards for sterilization chamber vents, aeration room vents, and chamber exhaust vents are commercially available from manufacturers and are well-established in the commercial sterilization industry. *See* 89 Fed. Reg. at 24,138.

79. Controls necessary to meet the Group 1 and Group 2 room air emission standards are commercially available from manufacturers and are well-established in the commercial sterilization industry. *See id.* at 24,138.

80. Ethylene oxide continuous emissions monitors are readily available for purchase and use by commercial sterilization facilities. *Id.* at 24,132. These devices are technically feasible for use in the commercial sterilization industry and are already in use and demonstrated in the field. *Id*.

81. Permanent total enclosure relies on existing technologies that are commercially available from manufacturers and are well-established in the commercial sterilization industry. *See id.* at 24,138. Permanent total enclosures are already in use in the industry and have been demonstrated feasible for commercial sterilization facilities. *See id.* at 24,132.

82. In 2024, EPA estimated that 7 out of a total of 88 commercial sterilizer facilities "already met the emission standards and will not need to install additional emission controls" to comply with the EtO rule. *Id.* at 24,138.

83. EPA also concluded that many facilities already achieved compliance with one or more of the final EtO Rule standards, as summarized in the Table below. *See id.* at 24,138.

84. For instance, EPA found that 66 of 88 facilities appeared to already be in compliance with revised sterilization chamber vent standards. *Id.*

85. EPA found that 26 of 55 facilities with aeration room vent emissions points appeared to already be in compliance with revised aeration room vent standards. *Id.*

86. EPA found that 20 of 40 facilities with chamber exhaust vents appeared to already be in compliance with revised chamber exhaust vent standards. *Id.*

**Table 1 - 89 Fed. Reg. at 24,138, Tbl. 22**

TABLE 22—APPARENT COMPLIANCE STATUS WITH FINAL RULE AND COMPLIANCE TIMEFRAMES

| Emission source | Facility EtO use | Number of facilities with this affected source | Number of facilities appearing to achieve final standard [1] | Compliance timeframe |
|---|---|---|---|---|
| SCV | At least 30 tpy | 38 | 19 | Two years. |
| | At least 10 but less than 30 tpy. | 9 | 9 | Two years. |
| | At least 1 but less than 10 tpy. | 18 | 16 | Two years. |
| | Less than 1 tpy | 23 | 22 | Three years. |
| ARV | At least 30 tpy | 36 | 12 | Two years. |
| | At least 10 but less than 30 tpy. | 5 | 5 | Three years. |
| | At least 1 but less than 10 tpy. | 10 | 7 | Three years. |
| | Less than 1 tpy | 4 | 2 | Three years. |
| CEVs at major source facilities | N/A | 0 | N/A | Three years. |
| CEVs at area source facilities | At least 60 tpy | 25 | 12 | Two years. |
| | Less than 60 tpy | 15 | 8 | Three years. |
| Group 1 room air emissions at major sources | N/A | 0 | N/A | Three years. |
| Group 1 room air emissions at area sources | At least 40 tpy | 36 | 16 | Two years. |
| | Less than 40 tpy | 38 | 7 | Three years. |
| Group 2 room air emissions at major sources | N/A | 1 | 0 | Three years. |
| Group 2 room air emissions at area sources | At least 20 tpy | 44 | 17 | Two years. |
| | At least 4 but less than 20 tpy. | 13 | 1 | Two years. |
| | Less than 4 tpy | 27 | 27 | Three years. |

[1] The phrase "appearing to achieve" is used (as opposed to "achieving") to account for uncertainties in the data. A notable example is the SCVs where, for a given facility, the emission reduction on the first evacuation may not high enough to ensure that the standard is being met across all evacuations. Another uncertainty is the fraction of EtO going to each emission stream. In some instances, there is facility-specific information available, and in others, there is no information available and default fractions are applied as a result.

87. EPA further estimated that only 28 of the 88 commercial sterilization facilities would need to implement permanent total enclosure requirements and install additional abatement devices. *Id.*

88. The Sterilizers Proclamation purports to exempt from the EtO Rule even facilities that already possess and operate control technologies needed to meet the applicable standards.

89. For example, two Sterigenics facilities in Los Angeles, California, located on Gifford Avenue and E. 50th Street received exemptions under the Sterilizers Proclamation. 90 Fed. Reg. at 34,749.

90. Under the EtO Rule, the Sterigenics Gifford Avenue and E. 50th Street facilities are subject to a 99.99% emission reduction standard for sterilization chamber vents.

91. In response to an EPA information request, the Sterigenics Gifford Avenue facility reported annual air emissions data indicating that it was already achieving a 99.99% or greater emission reduction at its sterilization chamber vent in 2019. That emission reduction is sufficient to comply with the EtO Rule.

92. In April 2024, the Sterigenics E. 50th Street facility was granted a permit to construct a new air pollution control system designed to meet a control efficiency of 99.99% or greater emission reduction, which likewise would also comply with the EtO Rule.

93. In January 2023, both the Sterigenics Gifford Avenue and E. 50th Street facilities were issued permits to construct permanent total enclosures.

94. The facilities subsequently notified the South Coast Air Quality Management District that permanent total enclosures for both buildings have been constructed. *Id.*

95. The permanent total enclosures constructed at both facilities satisfy the requirements of the EtO Rule.

96. Another exempted Sterigenics facility located at 2971 Olympic Industrial Drive in Atlanta, Georgia, is required to meet the following emission reductions: 99.99% for its sterilization chamber vent; 99.90% for its aeration room vent; 99.90% for its chamber evacuation vent; and 98.00% for its Group 1 and 2 room air emissions.

97. Stack testing conducted in 2022 shows that the facility was already complying with, and exceeding, the EtO Rule emission reduction standards. Measured emission reductions were 99.99997% for at least three sterilization chamber vents; 99.96% for aeration room vent; 99.95% for chamber evacuation vent; and 98.24% for Group 1 and 2 room air emissions.

98. The Atlanta Sterigenics facility has also installed a continuous emissions monitoring system which passed an annual relative accuracy test audit report since installation.

99. By 2020, the Atlanta Sterigenics facility had installed a permanent total enclosure and passed a permanent total enclosure test.

100. Other exempted facilities similarly possess requisite control technologies or have demonstrated the ability to achieve compliance with the EtO Rule. For example, EPA's docket shows that at least 24 facilities that received exemptions as a result of the Sterilizers. Proclamation would comply with one or more of the standards established in the EtO Rule.

101. For example, the Trinity Sterile facility in Salisbury, Maryland, was already achieving 99.99% emission reduction at both its sterilization chamber vent and aeration room vent.

102. The Cook Incorporated facility in Ellettsville, Indiana, reported data in response to an EPA information request that indicated that, in 2020, it was already achieving 99.99% emission reduction at its sterilization chamber vents, 99.90% emission reduction at its aeration room vents; and 99.99% emission reduction at two chamber exhaust vents. These destruction removal efficiencies are sufficient to comply with the EtO Rule.

103. Sterilization Services of Georgia, in Atlanta, Georgia, has consistently met or exceeded a sterilization chamber vent emission reduction of 99.99% since 2022; is exceeding a chamber exhaust vent emission reduction of 99.90% (tested at 99.997% in 2023); is exceeding a

Group 1 room air emissions emission reduction of 98.00% (tested at 98.90% in 2023); and passed a permanent total enclosure test in 2021 and 2022.

104. The Sterilizers Proclamation purports to exempt from continuous emissions monitoring facilities that already possess and operate continuous emissions monitoring technologies.

105. For example, multiple exempted facilities in Georgia and Florida installed continuous emissions monitoring systems between 2023 and 2025, including air pollution control devices. And at least all of the exempted facilities in Georgia also passed required annual emissions audits.

106. The Sterilizers Proclamation even purports to grant an exemption, issued for the stated purpose of "promot[ing] American security with respect to sterile medical equipment," to a facility that does not sterilize medical equipment, but instead sterilizes spices, food, and pet foods. 90 Fed. Reg. 34,747.

107. The Cosmed Linden facility in Linden, New Jersey received an exemption. 90 Fed. Reg. 34,750.

108. The Cosmed Linden facility does not sterilize medical equipment. It sterilizes agricultural commodities such as spices and nuts. *Linden, New Jersey (ETO Sterilization-Plant #2)*, EPA, https://perma.cc/EPY9-MEQS.

109. The Sterilizers Proclamation's indiscriminate exemptions apply without any consideration of whether the facilities have the technology and operational capability to implement the EtO Rule's standards.

*The Court's Equitable Authority to Review Ultra Vires Executive Action*

110. The Sterilizers Proclamation exceeds the President's statutory authority because, by granting sweeping exemptions to one quarter of regulated sources without making facility-, standard-, or technology-specific determinations, the Proclamation exceeds the bounds of the President's Section 7412(i)(4) authority.

111. The Proclamation unlawfully alters the compliance dates established by the EtO Rule, thereby exceeding the scope of authority conferred under Section 7412(i)(4). Section 7412(i)(4) authorizes only narrow exemptions under specific statutorily defined circumstances; it does not give the President authority to amend EPA standards or their compliance deadlines. Amendments to such standards may only be made by EPA and only after notice and comment rulemaking.

112. This Circuit has held that presidential actions are subject to judicial review to ensure conformity with statutory requirements where "the authorizing statute or another statute places discernible limits on the President's discretion." *Mountain States Legal Found. v. Bush*, 306 F.3d 1132, 1136 (D.C. Cir. 2002) (citing, *inter alia*, *Chamber of Com. v. Reich*, 74 F.3d 1322, 1331 (D.C. Cir. 1996)).

113. The statutory provision at issue here, Section 7412(i)(4), provides such discernible limits on the President's discretion by requiring a determination that, for specific facilities, "technology to implement" a standard "is not available" *and* that the exemption "is in the national security interests of the United States." 42 U.S.C. § 7412(i)(4).

114. The Court therefore has authority to review the Sterilizers Proclamation to determine whether the President's exercise of statutory authority complied with the statutory conditions on that authority.

115. Indisputable facts demonstrate that the President was applying an unreasonable construction of the statutory conditions under which he may exercise the Section 7412(i)(4) exemption authority.

116. Because a necessary factual predicate required by the Clean Air Act—that the technology to implement "is not available"—is not present, the Sterilizers Proclamation unlawfully exercises authority not conveyed by Section 7412(i)(4).

117. The Court has the power to declare the Sterilizers Proclamation unlawful and ultra vires. *Am. Forest Res. Council v. United States*, 77 F.4th 787, 796 (D.C. Cir. 2023); *Mass. Lobstermen's Ass'n v. Ross*, 945 F.3d 535, 540 (D.C. Cir. 2019); *Chamber of Com. v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996).

**STANDING**

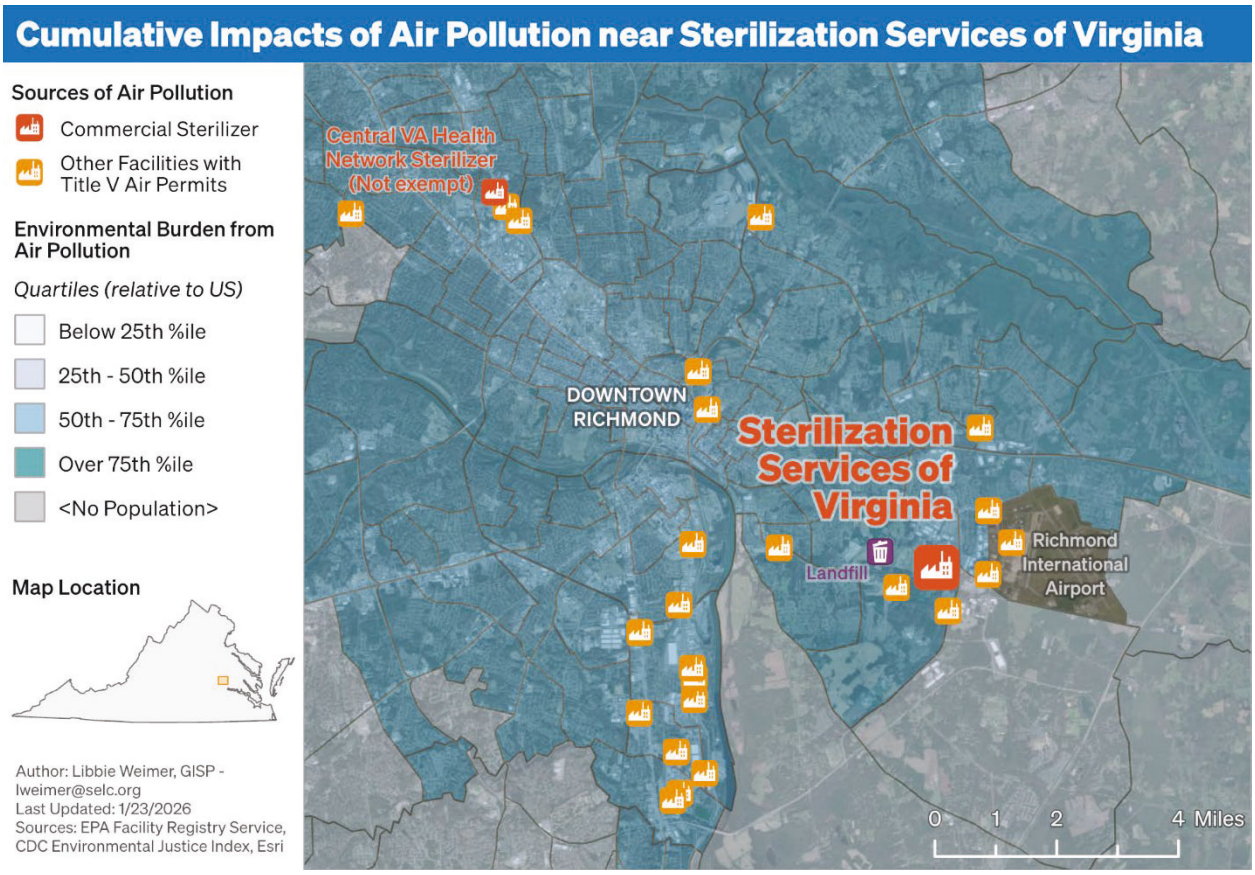
118. Plaintiffs and their members live, work, and recreate in areas where they are exposed to increased air pollution and ethylene oxide emitted from the exempted facilities. Exposure to ethylene oxide emitted by exempted commercial sterilizer facilities causes adverse health effects, including elevated cancer risks.

119. EPA has determined that ethylene oxide is far more carcinogenic than previously understood and that long-term exposure, even at very low concentrations, can significantly increase lifetime cancer risk particularly for people living, working, or recreating near commercial sterilizers. EPA's risk assessments show that ethylene oxide emissions can drive cancer risks at the census-tract level far above levels EPA considers acceptable, disproportionately burdening nearby residential communities, schools, and childcare centers.

120. In Richmond, Virginia, there are two sterilizers less than ten miles apart, including the exempted Sterilization Services of Virginia. The following map depicts the location of both

sterilization facilities in the Richmond metropolitan area, other facilities with Title V Air Permits, a landfill, and the Richmond International Airport. The map shows that these pollution sources are located in areas identified as experiencing environmental burdens above the 75th percentile.

**Map 2: Sterilization Services of Virginia**




121. Ethylene oxide emissions from Sterilization Services of Virginia contribute to elevated cancer risks, with a maximum excess cancer risk level of 1,000 additional cases per 1 million people. In 2022 alone, the facility reported releasing 13,821 pounds of ethylene oxide.

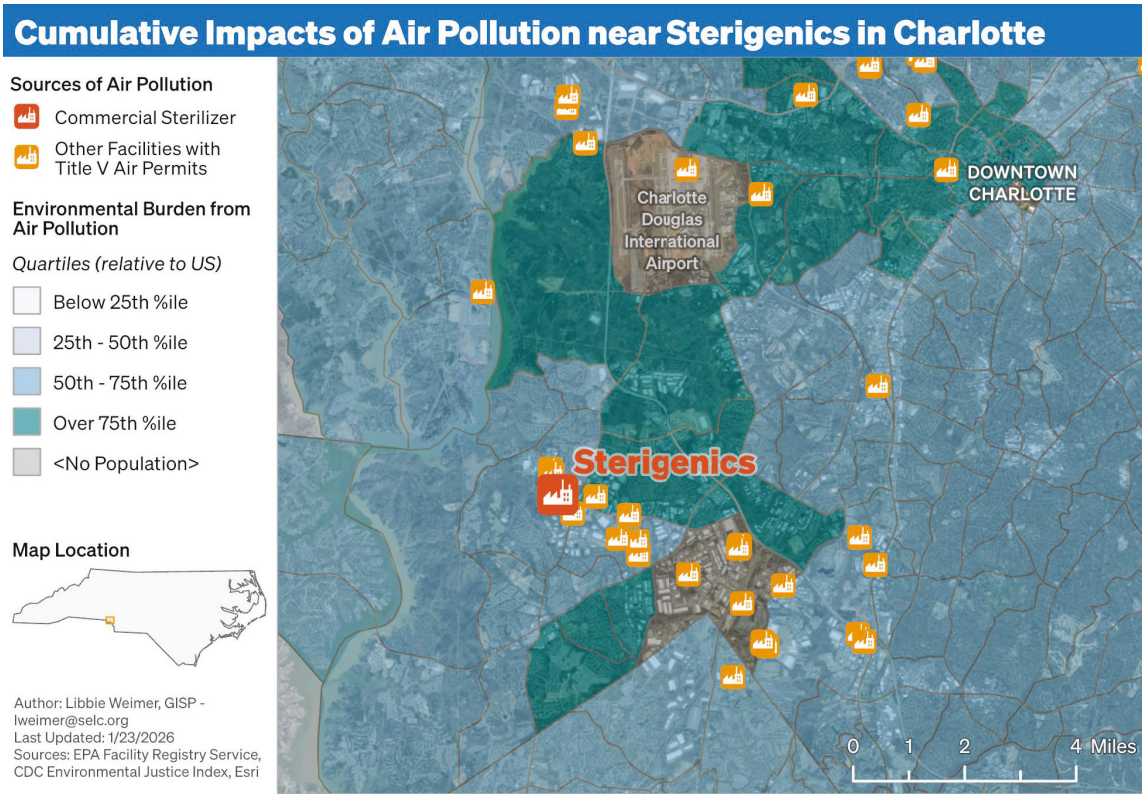
122. There are approximately 109,000 people and nearly 100 schools and childcare centers within five miles of the Sterilization Services of Virginia, including members, staff, and member congregations of Plaintiff Virginia Interfaith Power & Light. Within this five-mile radius, people of color make up three-quarters of the population, about 25 percent higher than

countywide average. *Id*. The proportion of people with low income is also 10 percent higher around the facility than the county average. *Id.*

123. In 2019, Sterilization Services of Virginia alone had a Risk-Screening Environmental Indicators ("RSEI") score of 3,367,796. RSEI is an EPA metric that estimates the relative potential human health risk from toxic chemical releases based on the quantity released, chemical toxicity, and population exposed. This score reflects a level of potential human health risk roughly 10,000 times the potential risk posed by all pollution sources combined in the entire state of Vermont. Tim Cywinski, Sierra Club, Air Toxins and Health Risk in Virginia 21 (2022), available at https://perma.cc/YA98-78QM (using data derived from EasyRSEI Dashboard, EPA, https://perma.cc/4K3L-UBVD).

124. Plaintiff CleanAIRE has several members and staff living near the exempted Sterigenics facility. The following map depicts the location of Sterigenics sterilizer in Charlotte, as well as nearby sources of air pollution, including facilities operating under Title V permits, and the Charlotte Douglas International Airport. The map shows that these pollution sources are in areas identified as experiencing environmental burdens in the 50$^{th}$–75$^{th}$ percentile range and in areas exceeding the 75$^{th}$ percentile.

**Map 3: Sterigenics in North Carolina**




125. Plaintiffs and their members stood to benefit from the emissions reductions required by the EtO Rule, scheduled to go into effect on April 6, 2027. As a result of the Sterilizers Proclamation, these facilities are now able to emit ethylene oxide at higher levels than otherwise permitted for years beyond the EtO Rule's compliance schedule. Plaintiffs' members are harmed by the excess emissions that will result from these exemptions.

126. Plaintiffs' members also stood to benefit from the continuous emissions monitoring requirements that are scheduled to go into effect on April 6, 2027. As a result of the unlawful Sterilizers Proclamation, exempted facilities are no longer required to implement continuous emissions monitoring and submit quarterly reports of continuous emissions monitoring data to EPA, which EPA in turn makes available to the public. Plaintiffs and their members are harmed both by the increased exposure to ethylene oxide, as well as by the loss of

emissions information that those reports would provide. The withheld emissions data would have allowed Plaintiffs and their members to evaluate their exposure and health risks, as well as to support advocacy, education, and outreach efforts to reduce air pollution and protect public health, which are core to their missions.

127. For example, CleanAIRE and its members would have used such information to raise public awareness of air pollution and to further their advocacy, education, and outreach efforts to reduce air pollution and protect public health.

128. Plaintiffs and their members will be deprived of information they would have used to evaluate their pollution exposure and health risks in areas affected by emissions from the exempted facilities. That information would also allow those Plaintiffs to make educated decisions about how they engage in advocacy to reduce air pollution.

129. Where facilities are no longer required to continuously monitor emissions, malfunctions and spikes will go undetected and unreported. Plaintiffs and Plaintiffs' members living and working near exempted facilities therefore face heightened exposure risks that they would not otherwise bear.

130. Without continuous emissions monitoring, Plaintiffs and their members cannot determine whether exempted facilities are complying with legal limits, malfunctioning, or operating in ways that create elevated emission events. The absence of required emissions data deprives Plaintiffs of information necessary to comment meaningfully on key regulatory decisions such as permits, renewals, state implementation plan submissions, enforcement actions, and future EPA rulemakings related to ethylene oxide.

131. Plaintiffs will have to spend additional time and resources to obtain alternative information, including through community monitoring, independent sampling, Freedom of

Information Act and state records requests, and technical analysis, to fill the information gap created by the exemptions. These expenditures divert resources from other advocacy, public education, and community activities.

132. Despite multiple inquiries, Plaintiff Sustainable Newton has not received up-to-date control system performance test results or continuous emissions monitoring data from the exempted Becton-Dickinson facility in Covington. Becton-Dickinson installed continuous emissions monitoring systems and is no longer required by its permit or the EtO Rule to conduct performance testing on its control systems. Georgia's Environmental Protection Division does not require data reporting for continuous emissions monitoring systems. Because of the exemption, Sustainable Newton and its members have lost access to information they would otherwise have been able to access.

133. Plaintiffs and their members are therefore harmed by the Sterilizers Proclamation exemptions.

## CLAIMS FOR RELIEF

### COUNT ONE:
### Unlawful Executive Action in Violation of the Clean Air Act
### (Nonstatutory Review for Violations of Federal Law by Federal Officials; Against All Defendants)

134. Plaintiffs incorporate by reference Paragraphs 1–133.

135. The President has limited authority to exempt a stationary source from duly promulgated hazardous air pollutant regulations solely by virtue of the authority delegated by Congress in 42 U.S.C. § 7412(i)(4). The President lacks any independent authority under the U.S. Constitution to issue such an exemption.

136. Section 7412(i)(4) permits the President to exempt "any stationary source" from a hazardous air pollutant standard only if "the President determines that the technology to

implement such standard is not available" and if an exemption "is in the national security interests of the United States."

137. Whether technology to implement a standard is not available is a discrete, yes-or-no factual inquiry that limits the President's discretion to grant exemptions.

138. Section 7412(i)(4) establishes a judicially manageable standard with clear and precise limits of the sort federal courts routinely construe to determine whether officials have acted consistent with law.

139. There is no statutory basis for the President's indiscriminately broad determinations that technology to implement the EtO Rule is not available or that granting exemptions from that Rule is in the national security interests of the United States. The Sterilizers Proclamation patently misconstrued the statutory terms "technology" and "not available" in purporting to exercise the Section 7412(i)(4) exemptions authority.

140. The Sterilizers Proclamation's purported determination that the technology needed to implement the various standards of the EtO Rule is not available is a conclusory statement without specific findings as to any particular standard, technology, or facility.

141. Technology to implement the EtO Rule is in fact available. The relevant technologies to implement each aspect of the EtO Rule standards are commercially available and have been used in and demonstrated feasible for use in the commercial sterilization industry.

142. The purported determination that the technology to implement the standards is not available is directly contradicted by factual evidence, and the Sterilizers Proclamation's cursory and conclusory statements to the contrary cannot be credited.

143. The President's purported determination that the technology to implement the EtO Rule is not available rests on overly broad interpretation of the authority conferred by Section 7412(i)(4) of the Clean Air Act.

144. Because the President grossly exceeded the bounds of his statutory authority by purporting to exempt dozens of stationary sources from standards for which the technology to implement is available, the Sterilizers Proclamation is plainly in excess of the President's delegated powers and contrary to the statute's specific limitations on those powers.

145. The President's action is contrary to the Clean Air Act and is ultra vires.

146. The Court possesses inherent equitable power to "grant injunctive relief . . . with respect to violations of federal law by federal officials." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326–27 (2015). Congress has nowhere foreclosed review of the interpretation and application of 42 U.S.C. § 7412(i)(4). There is no alternative statutory procedure for review of Plaintiffs' claims.

147. Because the Sterilizers Proclamation violates the Clean Air Act and is ultra vires, EPA actions implementing or giving effect to the proclamation likewise violate the Clean Air Act and are ultra vires.

**COUNT TWO:**
**Ultra Vires, De Facto Rulemaking Without Statutory Authority**
**(Nonstatutory Review of Action in Excess of Statutory Authority by Federal Officer; Against All Defendants)**

148. Plaintiffs incorporate by reference the allegations of Paragraphs 1–133.

149. Congress requires EPA to provide for existing sources' compliance with hazardous air pollutant standards "as expeditiously as practicable," and set a firm limit that compliance deadlines occur "in no event later than 3 years after the effective date of such standard." 42 U.S.C. § 7412(i)(3)(A).

150. Congress gives EPA and state permitting authorities discrete, limited authority to grant an existing source "up to 1 additional year to comply" with standards promulgated under subsection (d) "if such additional period is necessary for the installation of controls." 42 U.S.C. § 7412(i)(3)(B).

151. Congress further conferred discrete, limited authority on EPA to stay the effectiveness of rules, including hazardous air pollutant standards, for no more than three months. 42 U.S.C. § 7607(d)(7)(B).

152. Congress directed EPA to provide for public notice and comment on EPA actions to revise hazardous air pollutant standards, their compliance dates, or to grant source-specific deadline extensions. 42 U.S.C. § 7607(d)(5), (h).

153. The exemption authority in Section 7412(i)(4) must be construed congruously with the authorities and limitations Congress enacted in Sections 7412 and 7607.

154. EPA and the President are bound by the Clean Air Act's requirements when implementing Section 7412(i)(4) exemptions, including following rulemaking procedures, and being bound by lawfully adopted regulations.

155. Reading Section 7412(i)(4) to authorize sweeping exemptions for a large swath of the regulated source category, from every single standard and other requirement of a rule, without facility- or standard-specific justification tied to the statutory factors, is contrary to the content, purpose, and structure of the Clean Air Act.

156. The Sterilizers Proclamation's extremely broad sweep reflects an interpretation of the Section 7412(i)(4) authority that effectively nullifies statutory limits.

157. The content, context, and scope of the Sterilizers Proclamation demonstrates that the Proclamation is not a true "exemption" within the meaning of Section 7412(i)(4).

158. The Sterilizers Proclamation is functionally a rulemaking or stay pending reconsideration, issued without adherence to the statutory procedures governing such actions as Congressionally required under Sections 7412 and 7607 of the Clean Air Act.

159. EPA explicitly invited requests for presidential exemptions in the context of its announced reconsideration of the EtO Rule.

160. EPA stated that the exemptions are offered "while EPA reconsiders" the underlying rule. *Id.*

161. The President granted sweeping exemptions from all compliance obligations of the EtO Rule without particularized consideration of the specific standards, technologies, or practices needed to comply, all of which is necessary to determine whether technology is not available to implement the standards.

162. In doing so, the Sterilizers Proclamation is effectively a rulemaking or stay authority that the Clean Air Act grants only to EPA and only after following certain procedures in certain circumstances not present here.

163. The Sterilizers Proclamation exceeds the narrow bounds of Section 7412(i)(4) to achieve improper goals prohibited by other provisions of the Clean Air Act. In granting compliance relief that far exceeds the Section 7412(i)(4) authority, the President bypassed and contravened the statutory requirements on rulemaking and reconsideration to accomplish sweeping compliance exemptions unauthorized by law and in excess of the President's statutory authority.

164. The Sterilizers Proclamation is beyond the authority conveyed by the Clean Air Act and is ultra vires.

165. Because the Sterilizers Proclamation is beyond the Clean Air Act authority and ultra vires, EPA actions implementing or giving effect to the proclamation are similarly ultra vires.

**RELIEF REQUESTED**

WHEREFORE Plaintiffs request that the Court:

A. Declare that the Sterilizers Proclamation is unlawful and invalid and that the Annex I sources remain subject to the EtO Rule as promulgated;

B. Issue injunctive relief:

   i. prohibiting EPA and Administrator Lee Zeldin from implementing, relying on, or giving effect to the Sterilizers Proclamation, including through implementation of the Clean Air Act's Title V operating permit program; and

   ii. directing EPA to promptly notify, in writing, the operators of facilities listed in Annex I and relevant state, local, and/or Tribal permitting authorities that the Sterilizers Proclamation is unlawful and invalid, and that any facilities that the Sterilizers Proclamation purported to exempt may not lawfully delay or avoid compliance with the deadlines promulgated by the EtO Rule by relying on the Sterilizers Proclamation.

C. Award Plaintiffs their fees and costs of litigation as authorized by law;

D. Grant such other relief as the Court deems just and proper.

Dated: January 28, 2026

Respectfully submitted,

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