United States Environmental Protection Agency

Ethylene Oxide Commercial Sterilizers: Clean Air Act National Emission Standards for Hazardous Air Pollutants (NESHAP)

Risk Assessment Results and Plans for Outreach

Presentation for State, Local, and Tribal Air Agencies

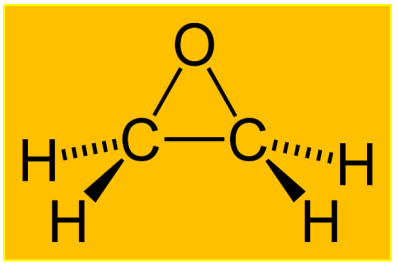
May 5, 2022

Overview

- We have identified elevated cancer risks for communities near some commercial sterilizers that use ethylene oxide (EtO).
- EPA will soon be proposing revisions to the Clean Air Act section 112 air emission standards for commercial sterilizers that use EtO.
- In the near-term, we would like to work with you, our co-regulators, to:
  - Reduce emissions at facilities and exposure to communities; and
  - Communicate with affected communities.
- In this webinar, we will provide:
  - Background on EtO and why it is a concern;
  - Approaches for addressing EtO emissions and exposure;
  - Information on the commercial sterilizer rule; and
  - Plans for outreach to communities.
- In a second webinar, scheduled for May 12, 2022, we will describe the emissions estimates for facilities and the dispersion and exposure modeling.

What is Ethylene Oxide?

- Flammable, colorless gas used to:
  - Make other chemicals that are used in making a range of products, including antifreeze, textiles, plastics, detergents and adhesives
  - Sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment (*> 20 billion medical devices each year)*
- EtO is one of 188 hazardous air pollutants (HAP) (“air toxics”) that EPA regulates under section 112 of the Clean Air Act
  - Extremely potent chemical
  - Human carcinogen



EPA's 2016 Assessment of the Risk from EtO

- In December 2016, the EPA issued its final toxicological assessment of EtO.*
- This included an updated Integrated Risk Information System (IRIS) cancer risk estimate ("unit risk estimate" or URE) that revealed EtO to be approximately 60 times more carcinogenic than previously understood.
  - Established a URE of 5×10^{-3} per $\mu g/m^3$.
- Included a finding that EtO is carcinogenic to humans by the inhalation route of exposure, based on:
  - Strong evidence in workers exposed to EtO.
    - Lymphohematopoietic cancers (cancers of the blood and immune system).
    - Breast cancer (in females).
  - Extensive animal evidence of carcinogenicity.
  - Strong evidence that EtO acts via a mutagenic mode of action.
    - Children are particularly susceptible to mutagenic carcinogens.
    - Approximately 50% of one's lifetime risk would be attributable to childhood exposures.

* The final IRIS EtO toxicological assessment is available at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf

Challenges to the IRIS EtO Cancer Risk Value

- American Chemistry Council (ACC) Request for Correction and Subsequent Request for Reconsideration
  - In 2018, the ACC requested that EPA "correct" the IRIS cancer risk value that was used in the EPA's 2014 National Air Toxics Assessment (NATA).
  - EPA denied the ACC's Request for Correction (RFC) on December 13, 2021.
  - On March 14, 2022, the ACC requested reconsideration of EPA's denial of the RFC.
- Miscellaneous Organic Chemical Manufacturing NESHAP (MON) Reconsideration
  - The 2016 IRIS EtO value was used for the risk review of the MON NESHAP (final rule published on August 12, 2020).
  - EPA granted requests for reconsideration of the MON, in part to allow for consideration of the TCEQ cancer risk value, which was still a draft value when the MON public comment period closed.
  - In the MON reconsideration proposal, EPA proposed to affirm its use of the IRIS EtO cancer risk value.
- Texas Council on Environmental Quality (TCEQ) Requests to the National Academy of Sciences, Engineering, and Medicine (NASEM) and to the EPA
  - In a March 25, 2022 letter, TCEQ requested that the NASEM review the IRIS and TCEQ EtO assessments.
  - On April 1, 2022, the Chairman of TCEQ sent a letter to the EPA Deputy Administrator asking EPA to "state its support or that it does not object to NASEM accepting this engagement."

National Air Toxics Assessment (NATA)*

- EPA first applied the new IRIS URE to estimate EtO risks across the U.S. in the NATA released in August 2018.
- Assessments provide *screening-level* estimates of the risk of cancer and other serious health effects from inhalation of air toxics.
  - Assessments include 180 HAP, plus diesel particulate matter.
  - Results are reported at the *census tract* level.
- The assessment, which used data from the 2014 National Emissions Inventory, identified several areas in the U.S. as potentially having elevated cancer risks from long-term exposure (70 years) to EtO.
  - These had not been identified in previous versions of NATA.
  - An increased cancer risk estimate of 100-in-1 million ($1x10^{-4}$) is ordinarily the *upper end* of the range of acceptability.
- Commercial sterilizing and chemical manufacturing facilities were identified as sources of the EtO emissions.

* AirToxScreen (formerly known as NATA) results have been posted for the 2017 NEI (at https://www.epa.gov/AirToxScreen/2017-airtoxscreen-assessment-results).

Industrial Facilities that Use EtO

- Chemical manufacturing
  - Source categories regulated by the Clean Air Act's national emission standards include:
    - Miscellaneous Organic Chemical Manufacturing
    - Hazardous Organic Chemical Manufacturing
    - Polyether Polyols Production
- Sterilization facilities
  - Source categories regulated by the Clean Air Act's national emission standards include:
    - Commercial sterilizers
    - Hospital sterilizers

Examples of Industrial Sources of EtO

Chemical Plant
Lanxess – S. Charleston, SC

Commercial Sterilizer
Sterigenics – Willowbrook, IL

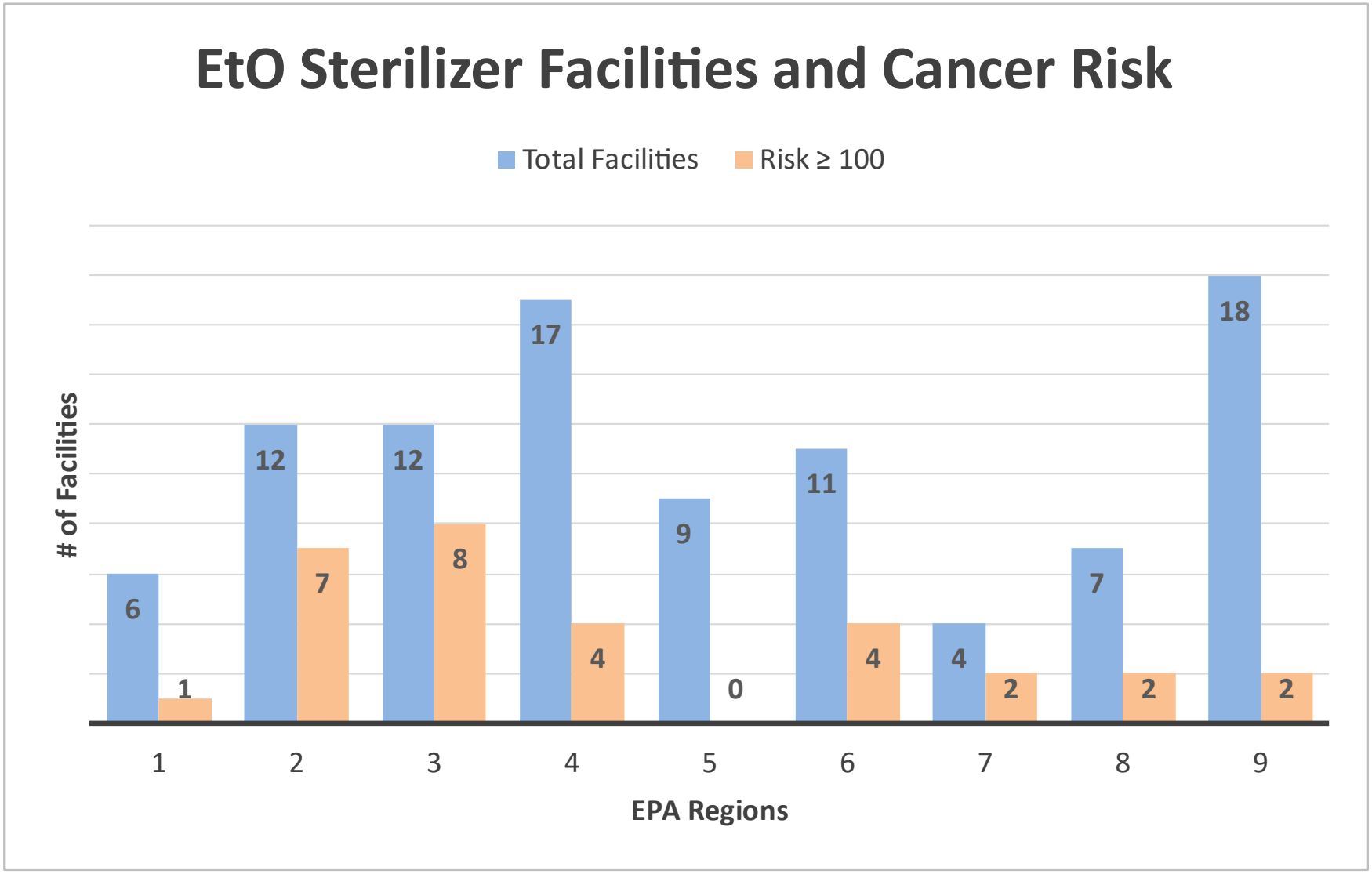
EtO Commercial Sterilizer Rule Risk Assessment Results

Modeled Lifetime Maximum Individual Cancer Risk (MIR) for the Affected Facilities in the Source Category

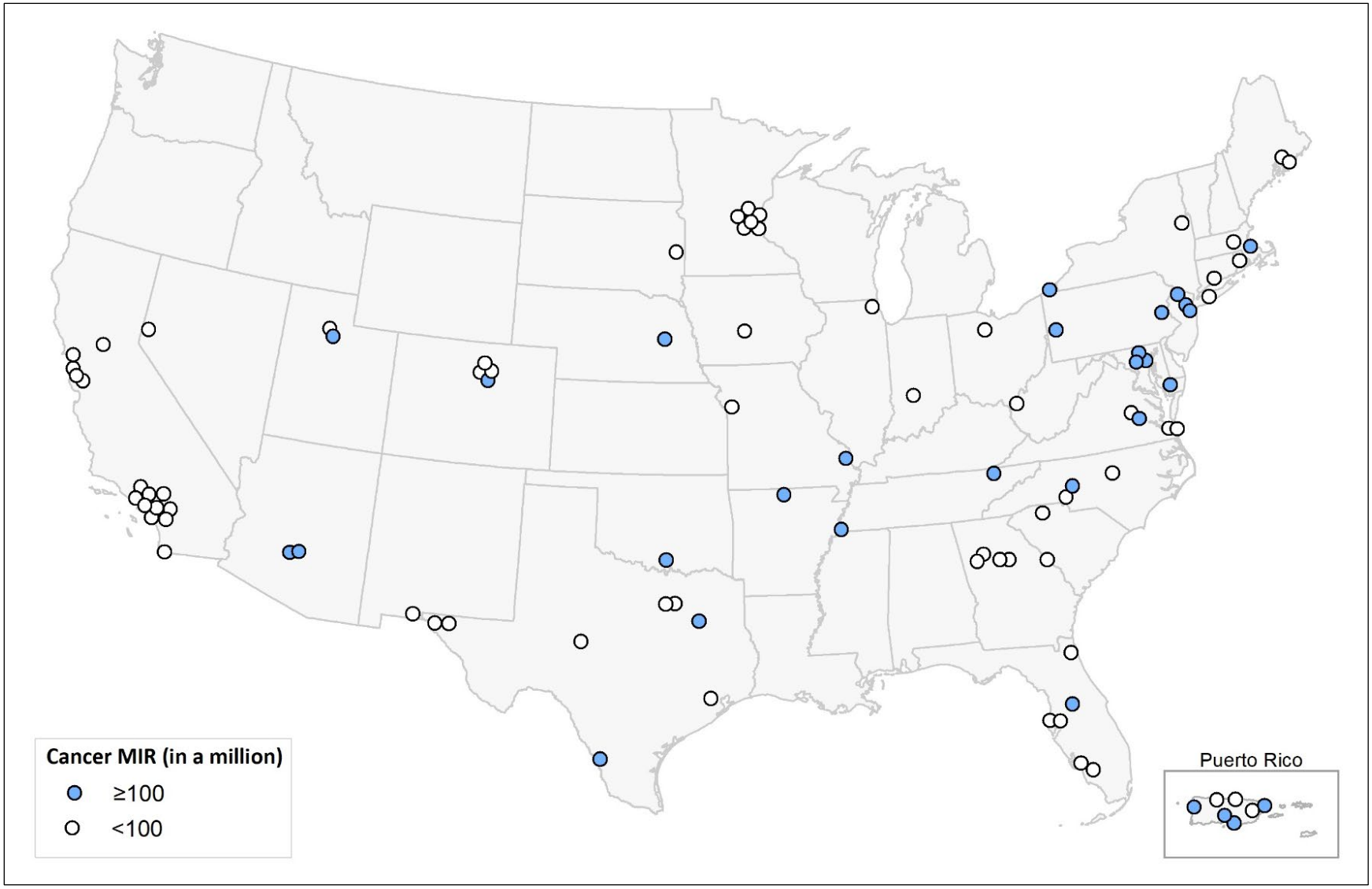
MIR per Million People	Number of Facilities
MIR ≥ 100*	30
MIR < 100	66
	96

* MIR is calculated at the census block level. An MIR of 100-in-1 million ($1x10^{-4}$) is typically the *upper end* of the range of acceptability.

Regional Distribution of EtO Sterilization Facilities



Locations of Commercial EtO Sterilization Facilities Across the U.S. and Their Modeled Cancer Risks



* Circles on map have been enlarged to better display the cancer risk level for each facility.

Commercial Sterilizers Associated with Elevated Risk Due to EtO

Region	Facility Name	Location
1	PCS	Taunton, MA
2	Cosmed	Franklin, NJ
--	EtO Sterilization Plant #2*	Linden, NJ
--	Steris Isomedix	South Plainfield, NJ
--	Customed	Fajardo, PR
--	Edwards*	Añasco, PR
--	Medtronic	Villalba, PR
--	Steri-Tech*	Salinas, PR
3	Elite Spice	Hanover, MD
--	Elite Spice	Jessup, MD
--	Fuchs North America	Hampstead, MD
--	Trinity Sterile	Salisbury, MD
--	B Braun Medical	Allentown, PA
--	Cosmed*	Erie, PA
--	ACS	Zelienople, PA
--	Sterilization Services of VA*	Richmond, VA

Region	Facility Name	Location
4	International Sterilization Lab	Groveland, FL
--	Centurion	Salisbury, NC
--	DeRoyal	New Tazewll, TN
--	Sterilization Services of TN*	Memphis, TN
6	Baxter*	Mountain Home, AR
--	Sterigenics**	Santa Teresa, NM
--	LEMCO Ardmore	Ardmore, OK
--	Midwest*	Laredo, TX
--	Steritec	Athens, TX
7	Midwest*	Jackson, MO
--	Becton Dickinson	Columbus, NE
8	Terumo*	Lakewood, CO
--	Becton Dickinson	Sandy, UT
9	ACS*	Chandler, AZ
--	Stryker	Phoenix, AZ

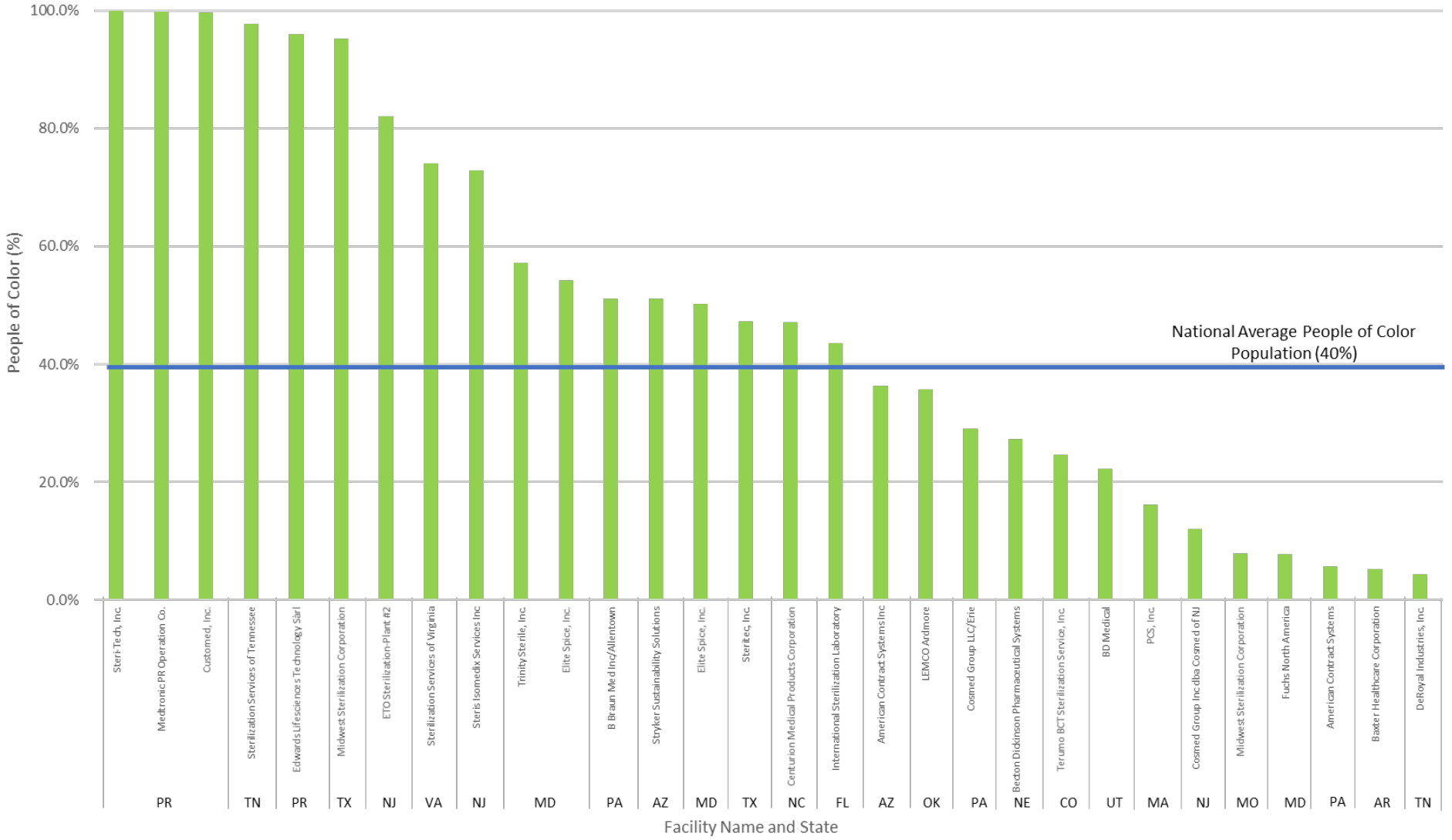
* Facility is also located in a census tract identified in the March 2022 AirToxScreen results (based on 2017 emissions data) as having elevated EtO cancer risks.

** This facility no longer has elevated risk; however, in the 2018 NATA, it was identified as having elevated risk. As part of the Office of the Inspector General (OIG) management alert, EPA has committed to outreach to the community near this facility. Additional information is available at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/inspector-general-follow-ethylene-oxide-0

Impacts to Communities

- Many commercial sterilization facilities are located near residences and schools (i.e., potentially sensitive populations).
- EtO emissions from many sterilizers impact communities of color and low-income communities.
  - About half of the high-risk facilities have greater percentages of residents of color in the community than the national average.
  - About half of the high-risk facilities have greater percentages of low-income residents in the community than the national average.
  - Demographic data were assessed for each sterilization facility, with all census blocks within 5km of the facility included.

Percent of the Population Who Are People of Color and Living Within a 5km Radius of a Facility With Estimated Risk ≥ 100-in-1 million



Addressing EtO Elevated Risks

- Following the release of NATA, EPA began work to mitigate risks.
- EPA is reviewing CAA regulations for facilities that emit EtO to ensure that they protect the public from significant risk.
  - In August 2020, EPA published a final Miscellaneous Organic Chemical Manufacturing NESHAP that requires additional controls on certain equipment and processes that emit EtO to reduce risk to surrounding communities.
  - EPA is currently reviewing the NESHAP for commercial sterilizers and will soon be proposing revisions to the NESHAP.
- We have been gathering additional information on emissions of EtO to:
  - Support regulatory review, and
  - Identify opportunities for near-term reductions.

Commercial Sterilizer NESHAP

- The original NESHAP for commercial sterilization facilities, promulgated on December 6, 1994, established emission limits for point sources.
- In 2001, we revised the rule to remove chamber exhaust vent control requirements due to safety concerns.
- In EPA's risk and technology review (RTR) NESHAP, promulgated on April 7, 2006, no changes were made to the emission standards.
- For the current review of the NESHAP, as a result of the extensive data collected and analyzed, we have a much better understanding of EtO usage, emissions, and control options for commercial sterilization facilities.
- In general, the high risk is being driven by fugitive emissions.
  - Fugitive emissions of EtO, which are currently unregulated, often disperse laterally and in relatively high amounts.
  - EPA is working to address fugitive emissions as part of the upcoming regulatory proposal.

Data Gathering for Commercial Sterilizers

- EPA has been gathering information over the last several years.
  - In December 2019, EPA requested information from 9 companies, covering 41 facilities.
  - In December 2019, EPA also issued an advance notice of proposed rulemaking (ANPRM) soliciting information and requesting comment on:
    - potential control measures for reducing EtO emissions,
    - potential impacts on small businesses,
    - usage data for individual facilities, and
    - additional data contained in the modeling files used to evaluate the impact of emissions from EtO commercial sterilizers.
  - EPA also convened a Small Business Advocacy Review Panel in 2020 and completed this small business engagement in April 2021.
  - In 2021, EPA sent a CAA section 114 information collection request (ICR) to <u>all</u> facilities.
    - Responses were due by Nov 19, 2021.
- Data from the ICR responses improved our understanding of facility processes and emissions.
- EPA's risk assessment is based on the best data available on the commercial sterilizing facilities.

Near-Term EtO Emission Reductions

- EPA and states have worked in partnership to successfully reduce EtO emissions at a number of sterilization facilities and drive risk below 100 in a million.
  - Voluntary installation of controls, such as scrubbers
  - Voluntary construction of permanent total enclosures to eliminate fugitive emissions
  - Inspections and enforcement, including of state-specific air toxics and capture rules
- In advance of public meetings, we encourage you to engage with facilities.
  - Get onsite to learn more about the facility's operations and potential for near-term reductions
  - Let the facility know public meetings are coming; community, media and political interest have motivated near-term reductions
- Building credibility with the community is easier when early emission reductions are in the works.

Plans for Outreach

- Phase 1: National Launch
  1. State Webinars: May 5 (Today, general overview), May 12 (focused on more technical details of emissions and modeling)
  2. Posting of Risk Results (http://epa.gov/eto) Early June.
  3. National Public Webinar: Early June
- Phase 2: Community Engagement
  - EPA will participate in community meetings in every community where modeled risk levels are at or above the 100/million level
  - Approximately 30 Locations (June-Late Summer)
- Phase 3: Ongoing Engagement
  - Additional follow up as needed and determined through regional office partnerships.

Risk Communication Objectives

- Inform residents about risks from EtO and what EPA, state, and facilities are doing about those risks. Include an understanding of multiple key components of this complicated message.
- Increase community involvement in the rule-making process. Increase cases of partnership between communities, states, and facilities to lower risk.
- Increase trust that EPA is taking this issue incredibly seriously and is dedicated to making change.

Next Steps

- On May 6th, you will receive:
  - a link to register for the May 12th webinar, and
  - the slides shown today.
- Between now and early June, we will send you the link to register for the public webinar