

EtO Sterilizer NESHAP – A New Paradigm?

9/27/2023

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Discussion Overview

- ▶ EtO Use, History, and Regulatory Background
- ▶ Draft EPA Risk Analysis of EtO Sterilizers
- ▶ Proposed Rulemaking
- ▶ New Paradigm?
- ▶ Q&A

EtO Use, History, and Background

Why the Concern Over Ethylene Oxide (EtO)

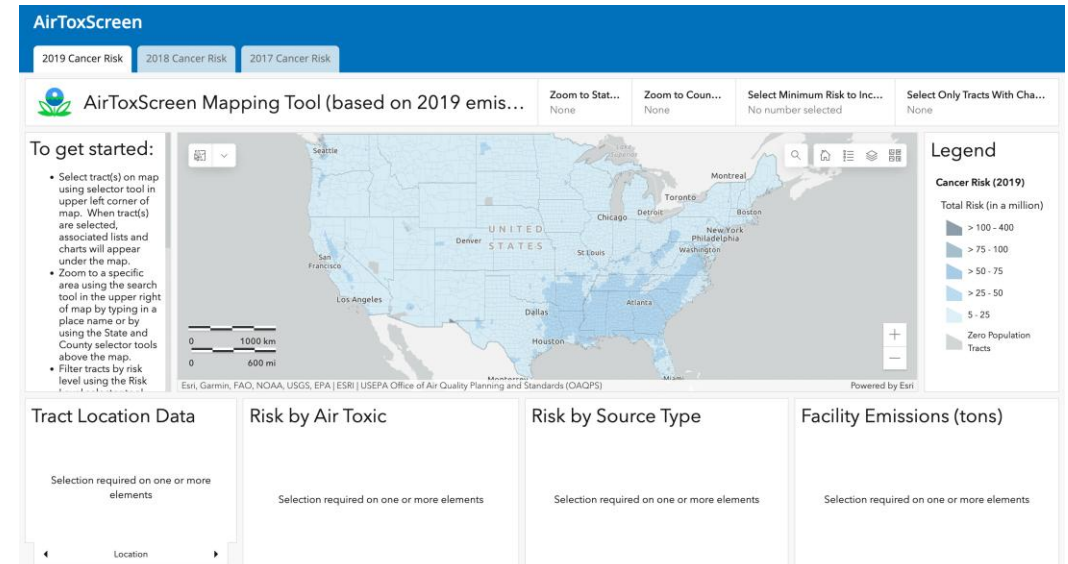
Ethylene Oxide (EtO) background

- ▶ Highly carcinogenic per USEPA
- ▶ Original Health Assessment Document published in 1985
- ▶ Industries that emit EtO
- ▶ As part of the 2014 National Air Toxics Assessment (2014 NATA), Ethylene Oxide risk value lowered
 - USEPA lowered the IRIS value (Inhalation Unit Risk) to $0.003 \mu\text{g}/\text{m}^3$ from $0.1 \mu\text{g}/\text{m}^3$
 - Inhalation Unit Risk = Concentration at which 1 cancer case is expected
 - Inverse is Unit Risk Estimate = Upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent over a lifetime at a concentration of $1 \mu\text{g}/\text{m}^3$ in air – multiply by concentration
 - ◆ Pre-2016 URE = $0.0001 (\mu\text{g}/\text{m}^3)^{-1}$
 - ◆ Post-2016 URE = $0.003 (\mu\text{g}/\text{m}^3)^{-1}$
 - Expected cancer impacts suddenly >30x higher

What do AirToxScreen/NATA do?

AirToxScreen / NATA Overview

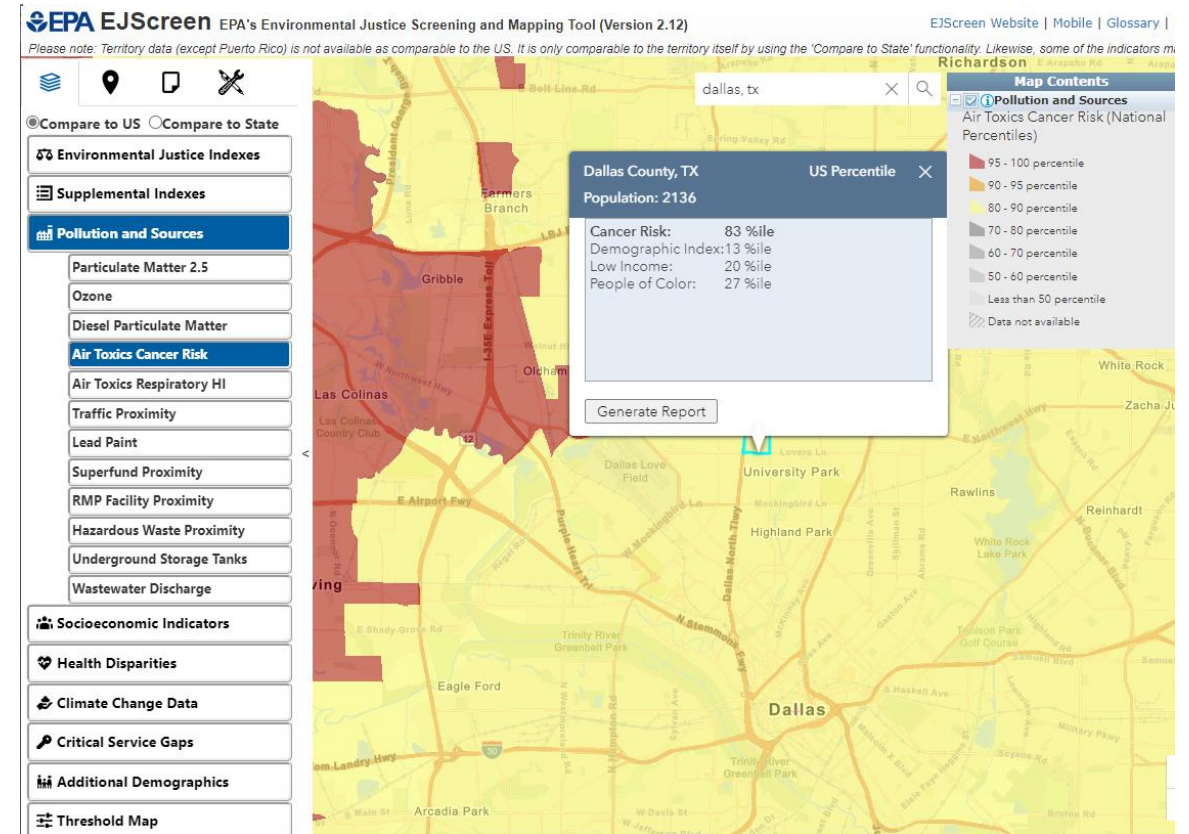
- ▶ Ongoing review of Air Toxics in the US
- ▶ Used to learn which air toxics and emission source types may raise health risks in certain places
- ▶ Only considers risks from breathing these hazards
- ▶ AirToxScreen / NATA is for larger areas – accounts for exposure and population-specific data and can be combined with demographic data to generate EJ Indices
- ▶ EtO emissions have impact on AirToxScreen / NATA
 - May influence local/state air toxics programs



Why the Concern Over Ethylene Oxide (EtO)

Ethylene Oxide (EtO) background

- ▶ Census tracts now considered overburdened without any change in emissions.
- ▶ Sterilizers located in GA, CO, FL, MA, MD, MO, NE, NJ, OK, PA, TN, TX, VA, & UT
 - Cancer risk can be 100 in 10^6 as far as 1 mile away from a sterilization facility based only on USEPA modeled results of the EtO facility
 - This update affected how these states implement EJ programs (air toxics programs) – PA (AMS), NJ, GA
 - Drew attention to EtO Sterilizers based on EJ Concerns



Impact of EtO on Cancer Risk Results

- ▶ Conservative modeling inputs
- ▶ Several Census Tracts that were below Cancer Risk of 1 in 10^6 MM were now over 50 in 10^6 after 2016 toxicity change for EtO
 - ◆ Contributes to being classified as an overburdened census tract
- ▶ Most of the impact is due to air emissions
 - ◆ EtO in water will chemically breakdown
- ▶ US EPA 2018 NATA update showed Cancer Risk over 500:1 MM at several EtO facilities
- ▶ Summer 2022 – EPA looked at over 20 sterilizers where cancer risk is above 100/million and reaching out to impacted communities.
- ▶ Will cover public outreach in the next section

State and Local Involvement on EtO Emissions

▶ South Carolina

- SCDHEC began collecting samples in 2019
 - ◆ 1 in 10^6 cancer risk is 0.01 ppb
 - ◆ Sampling locations were between 1.5 ppb to 2.5 ppb

▶ Georgia

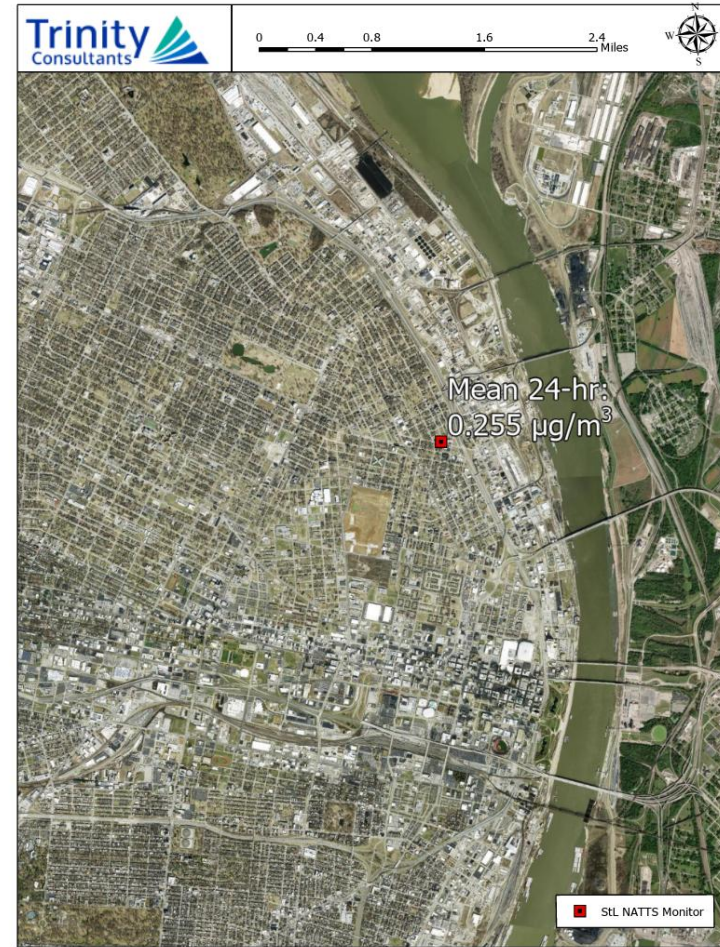
- GA EPD – Installed background monitors near sterilization facilities
 - ◆ Monitors near sterilization plants gave readings with calculated Cancer Risks of 1,300 in 10^6
 - ◆ Monitor 300 km from nearest sterilization plant showed Cancer Risk of 1,000 in 10^6

▶ Texas

- ◆ TCEQ – Pushed back on USEPA
- ◆ TCEQ has own value for their air toxics program
 - USEPA rejected the TCEQ IUR of $0.43 \mu\text{g}/\text{m}^3$ (URE of $2.33\text{E}-06 (\mu\text{g}/\text{m}^3)^{-1}$; EPA value 1,290x higher)

Region 7 EtO Monitors?

- ▶ One National Air Toxics Trends Site in the Region – St. Louis



- ▶ Using URE of $0.005 (\mu\text{g}/\text{m}^3)^{-1}$
- ▶ Estimated 1,275 in 10^6 Cancer Risk

Draft EPA Risk Analysis of EtO Sterilizers

EPA's Community Engagement Website

Community Engagement on Ethylene Oxide (EtO)

[English](#) | [Español](#) | [عربي](#) | [中文: 简体版](#) | [中文: 繁體版](#) | [한국어](#) | [Русский](#) | [Tagalog](#) | [Tiếng Việt](#)

Past outreach efforts to residents with elevated risk

In August 2022, EPA completed an analysis that showed that ethylene oxide (EtO) emissions from some commercial sterilizers in the U.S. contribute to elevated cancer risk for people living in nearby communities. Specifically, exposure over the course of a lifetime (24 hours a day for 70 years) to EtO at concentrations expected to be found near some commercial sterilizers can increase a person's risk of developing cancer to at or above 100 in one million.

Over several months, EPA engaged with communities where risk to people who live near commercial sterilizers was the highest to hear about their concerns and answer their questions as we shared details about this risk assessment, community risk, and efforts to reduce this risk. For more information about the specific outreach dates and any available materials for a specific community, please visit the relevant community pages at the links below.

Note: The risk information on the following pages, from July 2022, is no longer current. EPA is archiving these maps and pages because they no longer portray everything we know about risk. In a number of cases, commercial sterilizers have made improvements or changes to operations that have reduced risks to residents. EPA has proposed two new actions to address emissions of ethylene oxide from commercial sterilizers and to reduce risks for people who live, work, or go to school near these facilities. [Learn more.](#)

[Lakewood, CO](#)

[Groveland, FL](#)

[Taunton, MA](#)

[Hanover, MD](#)

[Jessup, MD](#)

[Salisbury, MD](#)

[Jackson, MO](#)

[Columbus, NE](#)

[Franklin, NJ](#)

[Linden, NJ](#)

[Queensbury, NY](#)

[Ardmore, OK](#)

[Allentown, PA](#)

[Erie, PA](#)

[Zelienople, PA](#)

[Añasco, PR](#)

[Fajardo, PR](#)

[Salinas, PR](#)

[Villalba, PR](#)

[New Tazewell, TN](#)

[Memphis, TN](#)

[Athens, TX](#)

[Laredo, TX](#)

[Sandy, UT](#)

[Henrico, VA](#)

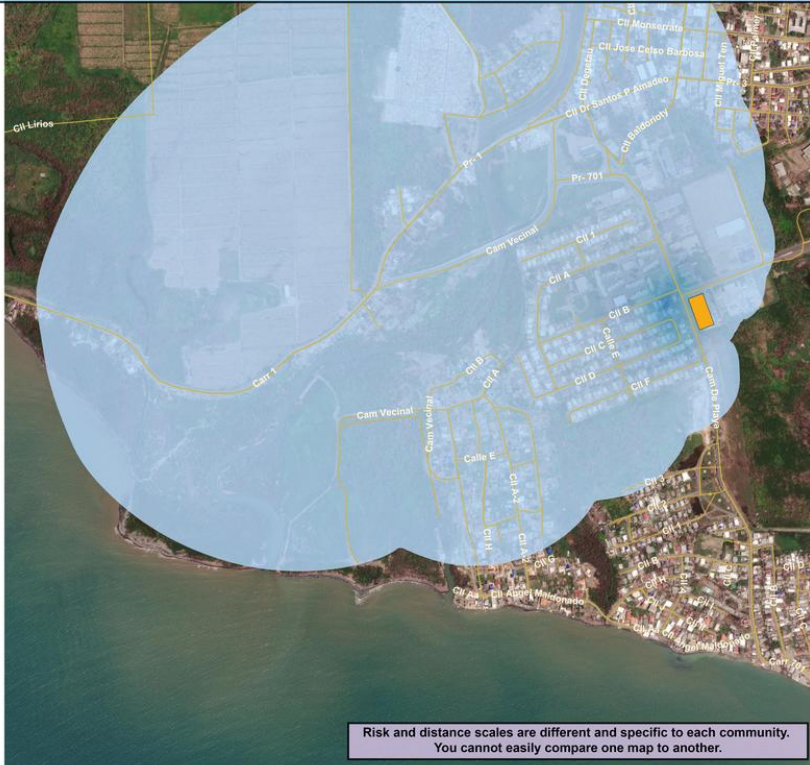
[Review a full list of all commercial sterilizers in the United States.](#)

EPA's Community Engagement Website

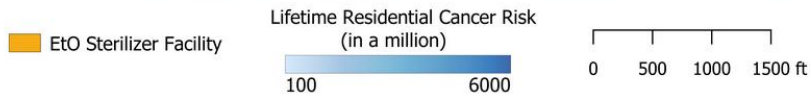
Announcement

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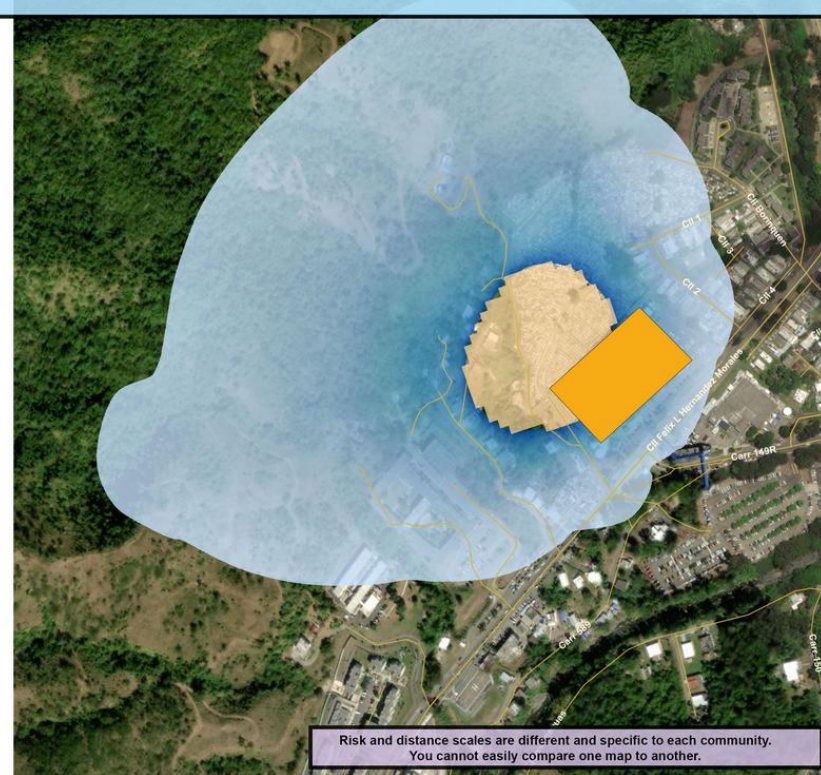
Risk and distance scales are different and specific to each community. You cannot easily compare one map to another.



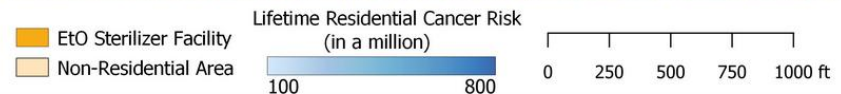
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EPA's Community Engagement Webinar

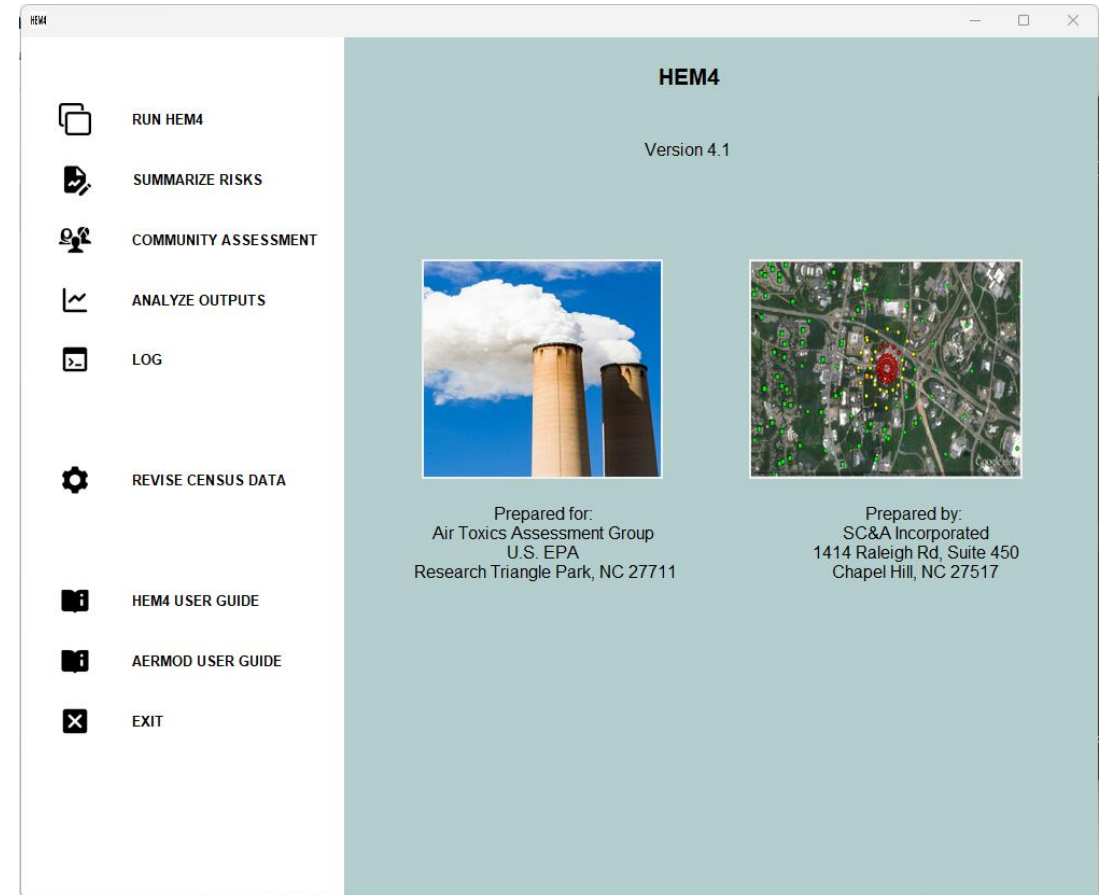
- ▶ Unprecedented EPA engagement with the community on health risks
- ▶ 628 views on YouTube, >700+ participants when the webinar was live
- ▶ Questions about:
 - Cancer cases around facilities
 - Worker safety
 - “Why is EPA taking so long?”
 - “How do we have confidence in data reported by the facilities?”
 - Data on cancer clusters?
 - Risks at other communities?
 - Etc.



The screenshot shows a video player interface. On the left, a dark blue slide contains the text: "Over your lifetime Breathing in EtO over many years can cause breast cancer and lymph cancer." To the right of the slide is a row of green silhouettes representing a human life cycle from infancy to old age. A small video inset in the top right corner shows a woman speaking. At the bottom of the video player, a subtitle reads: "breathe in the ETO that is near this facility every single day". The video player controls show a progress bar at 15:00 / 1:24:48, and the video title is "EPA Ethylene Oxide National Public Webinar".

Preliminary Risk Assessment Methodology

- ▶ EPA used Human Exposure Module 4 (HEM4) for the analysis
 - Pre-populated Meteorological Data
 - AERMOD defaults
 - Used S114 Request Data and/or estimates
 - Looks at impacts on a census-tract level - doesn't pinpoint exact locations
 - Can define specific receptors if interested in a refined assessment



Proposed Rulemaking

Regulatory Fallout of new EtO Standards

- NESHAP – Subpart FFFF (MON), Final Rule Addressing the toxicity of EtO
 - ◆ Revised as part of the RTR (Residual Risk & Technology Review) - updated 2023 revisions
- NESHAP – Subpart O – Sterilization Plants
 - ◆ Section 114 requests collected, with back and forth
 - ◆ Proposed rule
 - EJ is a significant focus in EPA’s proposed rule analysis
 - ◆ Draft RTR aimed for <math><100</math> in - 0.02 $\mu\text{g}/\text{m}^3$ concentration (~11 parts per trillion EtO)
- ◆ Set different standards for different EtO usage groups

Table 2—Summary of Cancer Risk Reductions

	Current cancer risks	Cancer risks if proposed amendments are finalized
Maximum Individual Risk (MIR) ¹	6,000-in-1 million	100-in-1 million.
Number of People with Cancer Risks >100-in-1 million	18,000	0.
Number of People with Cancer Risks \geq 1-in-1 million	8.3 million	1.26 million. ²
Estimated Annual Cancer Incidence (cases per year)	0.9	0.1.

A New Paradigm?

Rule Development – What else?

- ▶ PFAS and PFOS
- ▶ Risk and Technology Review for existing Maximum Achievable Control Technology standards
- ▶ Primary Copper Smelting next?
- ▶ Coke Ovens: Pushing, Quenching, and Battery Stacks
- ▶ Additional MACT standards will continue to be evaluated
- ▶ DOJ Comprehensive EJ Enforcement Strategy
 - Prioritize Cases to reduce public health and environmental harm
 - Strategic use of all available tools
 - Meaningfully engage with impacted communities
 - Be transparent about EJ efforts, as well as results of those efforts



What does this hold for the future?

- ▶ Environmental Justice is a concern everywhere
- ▶ EPA has started updating AirToxScreen annually
- ▶ More focus on specific hazardous pollutants vs criteria pollutants
- ▶ New science on health values can show a pollutant as suddenly more carcinogenic
- ▶ EPA is working on potential health risk effect data for per- and polyfluoroalkyl substances (PFAS)
 - Now a reportable substance under Toxic Release Inventory (TRI)
- ▶ Additional public interest in Environmental Justice Issues

What does this hold for the future?

- ▶ ProPublica report is an example of public interest
 - “The Most Detailed Map of Cancer-Causing Industrial Air Pollution in the US”
 - Used EPA Risk-Screening Environmental Indicators (RSEI) Model



How to Prepare?

- ▶ Be aware of AirToxScreen impacts via EJScreen or AirToxScreen mapping tool
- ▶ Assure TRI reported data is accurate and not overly reported
- ▶ Foster ongoing community engagement
- ▶ Be aware of hazardous air pollutants of interest (heavy metals, EtO, PFAS, etc.)

