Ethylene Oxide Air Issues

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Ethylene oxide (EtO)

- One of 187 pollutants known as “air toxics” that EPA regulates under the Clean Air Act
  - extremely potent chemical – comparable to arsenic and berrylium
- 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

    > 45 billion medical devices each year (more than half)

National Air Toxics Assessment (NATA)

- EPA's periodic review of air toxics in the United States, based on modeled air quality
  - Covers 180 air toxics, plus diesel particulate matter
  - Screening tool for EPA, state, local and tribal air agencies
  - Intended to help agencies identify areas, pollutants or types of pollution sources that need further examination to better understand risks to public health
- Most recent NATA (issued August 2018) used data from the 2014 National Emissions Inventory and the latest scientific information on air toxics and health
  - Identified several areas as potentially having elevated cancer risks from long-term exposure (70 years) to the chemical *ethylene oxide*
  - Elevated risks -- not identified in previous versions of NATA -- largely driven by "unit risk estimate" updated in late 2016

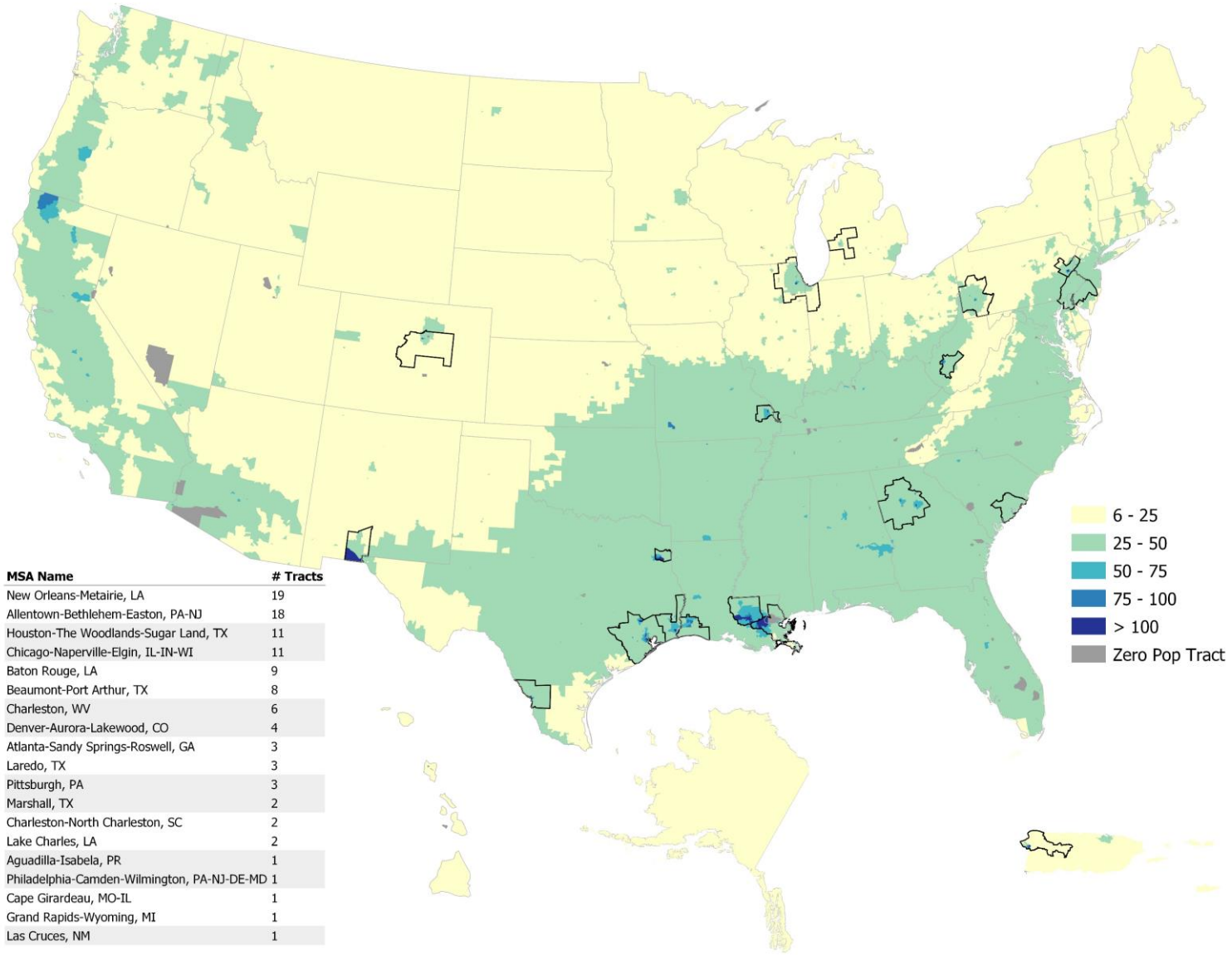
NATA results: 19 areas with elevated cancer risks (≥100-in-1 million)

MSA	#Tracts ≥100-in-1 million	Highest Risk Tract in MSA (-in-1 million)	MSA	#Tracts ≥100-in-1 million	Highest Risk Tract in MSA (-in-1 million)
New Orleans-Metairie, LA**, †	19	2,000	Pittsburgh, PA**, †	3	100
Allentown-Bethlehem-Easton, PA-NJ	18	600	Charleston-North Charleston, SC	2	100
Chicago-Naperville-Elgin, IL-IN-WI†	11	300	Lake Charles, LA	2	100
Houston-The Woodlands-Sugar Land, TX	11	300	Marshall, TX	2	200
Baton Rouge, LA	9	200	Aguadilla-Isabela, PR	1	300
Beaumont-Port Arthur, TX	8	300	Cape Girardeau, MO-IL	1	200
Charleston, WV	6	400	Grand Rapids-Wyoming, MI	1	100
Denver-Aurora-Lakewood, CO†	4	500	Las Cruces, NM	1	200
Atlanta-Sandy Springs-Roswell, GA	3	200	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD†	1	100
Laredo, TX	3	100			

** With the exception of New Orleans-Metairie, LA (chloroprene) and Pittsburgh, PA (coke oven emissions), the primary risks are driven by emissions of ethylene oxide from point sources.

† The following 5 MSAs were also in the 2011 NATA as MSAs with elevated cancer risks: Chicago-Naperville-Elgin, IL-IN-WI; Denver-Aurora-Lakewood, CO; New Orleans-Metairie, LA; Philadelphia-Camden-Wilmington, PA-NJ-DE-MD, and Pittsburgh, PA.

NATA results



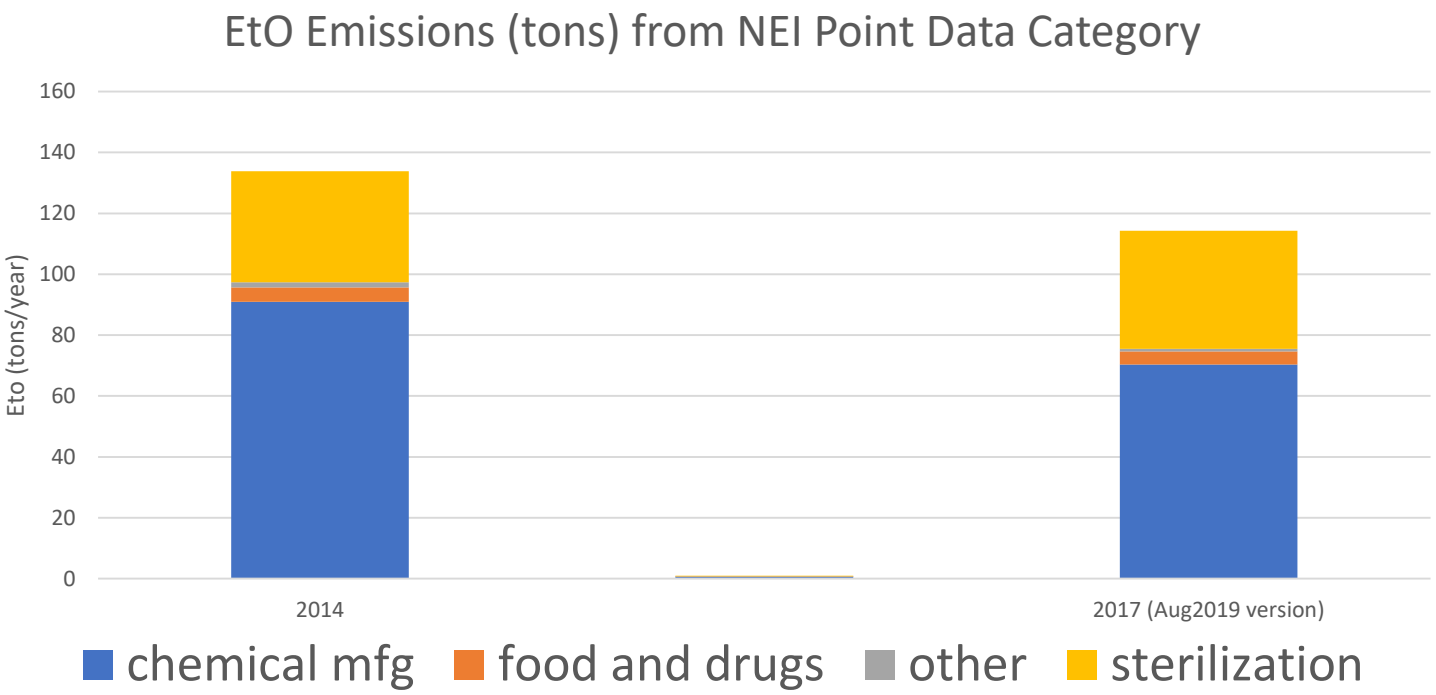
MSA Name	# Tracts
New Orleans-Metairie, LA	19
Allentown-Bethlehem-Easton, PA-NJ	18
Houston-The Woodlands-Sugar Land, TX	11
Chicago-Naperville-Elgin, IL-IN-WI	11
Baton Rouge, LA	9
Beaumont-Port Arthur, TX	8
Charleston, WV	6
Denver-Aurora-Lakewood, CO	4
Atlanta-Sandy Springs-Roswell, GA	3
Laredo, TX	3
Pittsburgh, PA	3
Marshall, TX	2
Charleston-North Charleston, SC	2
Lake Charles, LA	2
Aguadilla-Isabela, PR	1
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	1
Cape Girardeau, MO-IL	1
Grand Rapids-Wyoming, MI	1
Las Cruces, NM	1

Industrial sources of EtO

Chemical Plant
Lanxess – S. Charleston, SC

Commercial Sterilizer
Sterigenics – Willowbrook, IL

Industrial sources of EtO



Note, commercial sterilizers represent…

* usage: <1% of EtO produced each year (TRI)
* emissions: 30% of annual EtO emissions (NEI)
* risks: about half of the higher risk areas (NATA)

EPA response: two-pronged strategy

- Prong 1: Review Clean Air Act regulations for facilities that emit EtO to ensure that they protect the public from significant risk
  - Two reviews in progress:
    - NESHAP for Miscellaneous Organic Chemical Manufacturing (the "MON)
    - NESHAP for Commercial Sterilizers
- Prong 2: For areas with higher risk, gather additional information on emissions of EtO
  - To support regulatory review
  - To seek near-term emission reduction opportunities

Public response: Willowbrook, IL

Residents outraged after EPA report links Willowbrook facility to carcinogens

Angry Willowbrook residents pack meeting on carcinogenic gas

Willowbrook residents voice concerns over cancer risks at community meeting

Editorial: The urgent Sterigenics question in DuPage: How much cancer risk?

Willowbrook Residents Want Sterigenics Plant Shuttered Amid Health Scare

Politicians Speak Out Against Sterigenics, EPA

A report from the Chicago Tribune details the Rauner administration knew of the toxic emissions from Sterigenics.

'Cancer Was Not on My Radar': Willowbrook Residents to Meet Over Hazardous Emissions Report

What progress have we made on the two-pronged strategy?

- National rulemaking:
  - MON: Notice of Proposed Rulemaking (final rule under court order for signature by March 13, 2020)
  - Commercial Sterilizers:
    - Advance Notice of Proposed Rulemaking
    - CAA section 114 letters
    - Small Business Review Panel
    - Notice of Proposed Rulemaking
- State/local actions (higher risk areas):
  - Where: 12 states/territories - PR, WV, DE, PA, GA, SC, IL, MI, MO, LA, NM, CO
  - What: Reviewed emissions, reduced emissions, conducted ambient monitoring, and/or engaged local communities

What have we learned?

- Ambient monitoring: Limitations
- “Background”: Recent ambient monitoring studies show lower, yet measurable levels
  - About 0.1 – 0.3 ug/m^3, indicating there may be other sources/background. Near-source levels much higher.
- Emission inventories: Gaps
- Risk communication: Challenging

Which other federal agencies are involved?

- HHS/ATSDR
  - Conducting individual area/facility health consultations
  - Considering national cancer incidence study
- FDA
  - Ethylene oxide challenge (July 15 – Oct 15, 2019)
  - FACA meeting (November 6-7, 2019)
- EPA/OCSPP
  - FIFRA risk assessment (March 2020)

Key takeaways

- EtO is a challenging public health issue
  - It's a HAP ("carcinogenic to humans"), but it's necessary to have clean medical devices and make certain products
- EPA/state actions have/will reduce emissions of EtO (and associated risks)
- Our knowledge of EtO has increased over the last year, but there is still much more we don't know

For more information

- NATA website: *https://www.epa.gov/nata*
- EPA ethylene oxide website: *https://www.epa.gov/ethylene-oxide*