EPA United States Environmental Protection Agency

SESARM 2019 Fall Meeting

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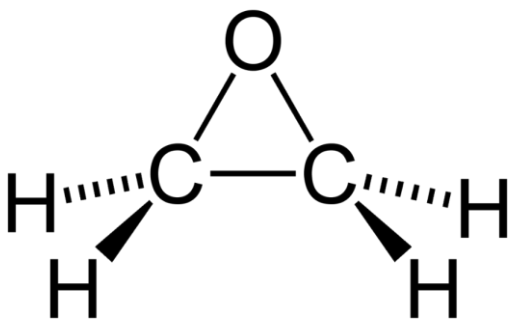
Ethylene Oxide (EtO)



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The EPA National Air Toxics Assessment

- Every few years, EPA estimates health risks from air toxics across the country.
  - We estimate potential health risks from long-term exposures – 70 years
- We estimate these risks using a computer modeling assessment known as the National Air Toxics Assessment, or "NATA"
- NATA is what we call a "screening tool" – a broad look at *potential* risk in areas across the country
- NATA can't tell any one person if your risk is elevated
- The purpose of NATA is to help EPA and state and local air agencies know if there are areas, or pollutants, that we may need to look at more closely
- Our most recent NATA – the one issued in August 2018 – showed us that we need to look more closely at ethylene oxide

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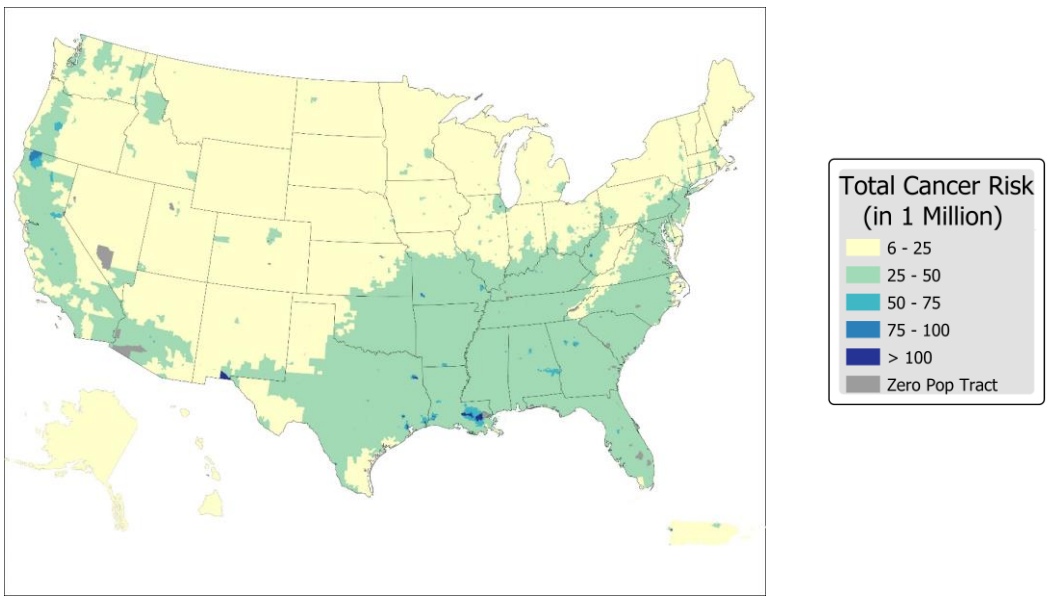
https://www.epa.gov/nata

The EPA National Air Toxics Assessment

- EPA uses the most recent information about emissions (what goes into the air) and health science information that is available when we put NATA together
- For the NATA we released in August 2018, the emissions data are from 2014
  - That's the most recent available. So follow-up is needed in any area where NATA shows we may need to look at risk more closely
- The most recent health science information for ethylene oxide is from 2016
  - That's when EPA updated the information that we use to estimate the risk of developing cancer if we are exposed to ethylene oxide for 24-hours a day, 365 days a year, for 70 years
  - The 2016 information we have on how toxic ethylene oxide is has changed from what we previously knew (it is more toxic)

NATA estimated average cancer risk: 30 in 1 million



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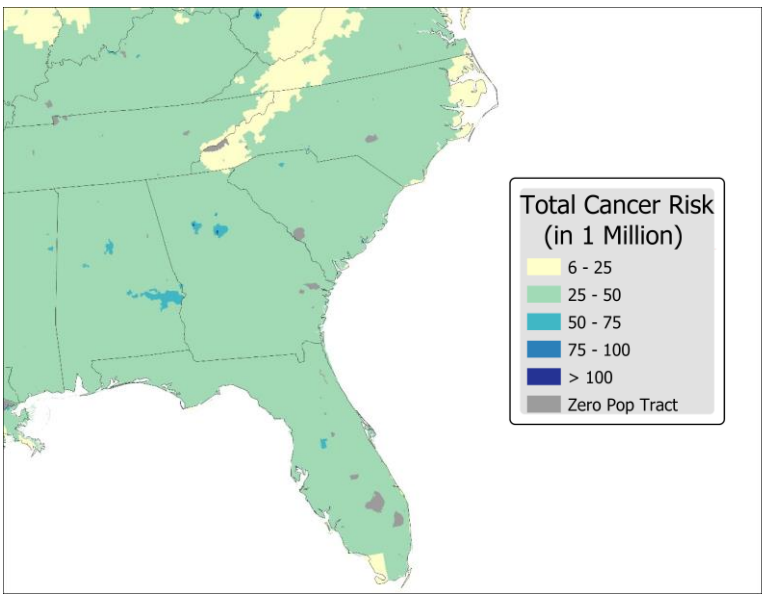
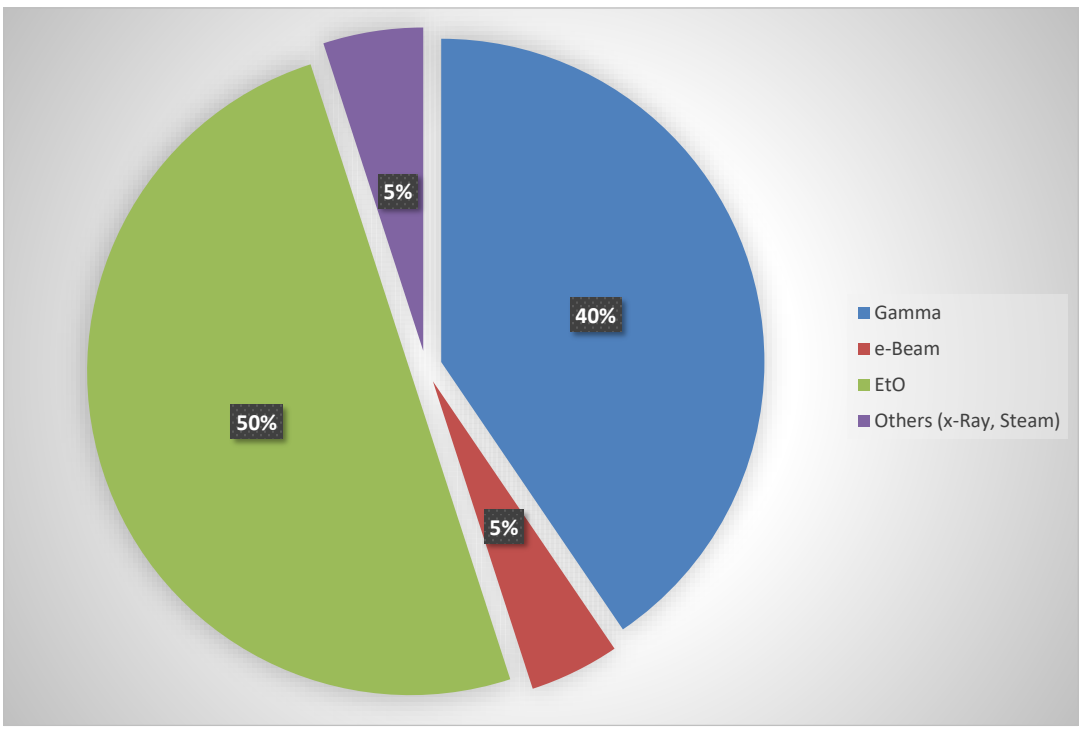
NATA estimated average cancer risk – Southeast



NATA estimated potentially elevated risk in some areas

- In some areas (census tracts), NATA estimated cancer risks greater 100 in 1 million - mostly from EtO
- This number refers to the upper end of what EPA *generally* has considered to be acceptable risk in its rulemaking process.
- 100 in a million (1 in 10,000) is not a standard or a regulatory action level – it tells us we need to look more closely to see if there is an issue.

Global Sterilization Market



"A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technology for the Industrial Sterilization of Medical Devices and Healthcare Products," Gamma Industry Processing Alliance, Aug 31, 2017.

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National Review of EPA's EtO-related Rules

- EPA will review Clean Air Act regulations for facilities that emit ethylene oxide to ensure that they protect the public from significant risk, starting with:
  - Air toxics emissions standards for commercial sterilizers: **ANPRM expected this Fall**
  - Air toxics emissions standards for miscellaneous organic chemical manufacturing (MON): **Proposal is at 0MB undergoing interagency review and will be issued following completion of that review; final by March 2020 (court ordered)**

https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide

EPA

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Nationally…

- EPA is also gathering additional information on industrial emissions of ethylene oxide, which may include data from testing at some types of facilities
  - This information will help EPA as it evaluates opportunities to reduce ethylene oxide emissions as part of its regulations review
  - It also will help the Agency determine whether more immediate emission reduction steps are necessary in any particular locations
- Continue our evaluation of background concentrations and the sources that may be contributing to them

https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide

Background Ambient EtO Concentrations

- Ethylene oxide can last in the air for weeks and can be transported with prevailing winds
- At higher temperatures, especially above 50 degrees Fahrenheit, and stronger winds, we would expect ethylene oxide to transport farther away from the emission source more effectively
- EPA is working with our state partners to better understand the distribution of EtO in air and to identify potential sources