Community Meeting on Ethylene Oxide and Risks in the Communities of Kingsbury, Queensbury, **New York** to begin shortly.





Getting Started:

How to participate on Teams - How to participate via phone line





Ethylene Oxide and Risks in the **Communities of Kingsbury and** Queensbury, New York





Why we are here tonight

Pollution is increasing health risks in some American communities.

2 We are working to reduce this risk.

We want to hear from you.





What is Ethylene Oxide?

- Gas
- Colorless
- Flammable
- Odorless

(in concentrations we find in communities)





EtO Uses

- Used to Make Other
 Products
- Sterilizes









National Context for Sterilizers



- Approximately **100** commercial sterilizers in the United States
- More information on all facilities at <u>https://www.epa.gov/eto</u>



Recent Steps Taken to Learn about Risk and Reduce It:

- July 2022: Completed analysis showing where, and in which specific communities, risk is highest for people who live nearby.
- Continue to seek more reductions of EtO coming out of facilities.

Previous work:

- 2016: Learned EtO is more dangerous when breathed in than previously known.
- 2018: Initial analysis showed that EtO might be causing elevated risk near certain types of facilities.
- 2020-2022: Collected and verified data and completed analysis to understand more exactly where there is elevated risk and why.

Current knowledge suggests the following risks are not a concern

No indication of risk:

- From soil or water
- Acute or emergency health impacts
- From consumer use of products made with or sterilized with EtO



Over your lifetime

Breathing in EtO over many years may cause breast cancer and lymphoid cancer.



Special Considerations about Risk



Reducing EtO coming out of the facility is the best way to reduce risk.



How EPA Measures Risk

- **Risk** is measured as the number of estimated cancer cases in a total population of 1 million people
- Lifetime cancer risk of "1-in-1 million" means that for every 1 million people who are continuously exposed to a certain level of pollution over 70 years, one person may develop cancer.
- Elevated Risk is when the estimated cancer cases is greater than or equal to 100 in a total population of 1 million people

(≥ 100 in 1 million; or 1-in-10,000)

Details about this analysis

• EtO Uses

- Facility Processes
- Facility Equipment
- Community Details
- Weather

Analysis

Modeled Risk Caused by EtO from a Facility Location of Sterigenics 84 Park Road Queensbury, New York



Lifetime Residential Cancer Risks - EtO Sterilization Sterigenics, Queensbury, NY





EtO Sterilizer Facility
Non-Residential Area

Lifetime Residential Cancer Risk (in a million)

Sterigenics Kingsbury, New York

Lifetime cancer risk - breathe air containing EtO at the level estimated at that location for 24 hours a day, every day for 70 years.

Maximum Risk Level: Around 100/Million, or 1/10,000, which from a regulatory decision-making perspective is the level where we consider the risk unacceptable

This estimated risk is in addition to cancer risk from other causes.

Lifetime Residential Cancer Risks - EtO Sterilization Sterigenics, Queensbury, NY



	Lifetime Residential Cancer Risk					
EtO Sterilizer Facility	(in a million)					
Non-Residential Area		0	250	500	750	1000 ft
	100					

Sterigenics Operations

- Started operations in 1994.
- Sterilizes medical devices.
- Used 157.5 tons of EtO in 2021.
- Controls emissions with:
 - A catalytic oxidizer (installed in 1993)
 - A wet scrubber (installed in 1995)
- Ethylene oxide sterilization process is regulated and approved by the US Food and Drug Administration (FDA).
- Subject to 40 CFR Part 63 Subpart O Ethylene Oxide Emissions Standards for Sterilization Facilities.

General Sterilization Process

- **Pre-conditioning** Products are kept at high temperature and humidity.
- Sterilization The sterilization cycle consists of: the injection of EtO, exposure, evacuation, and air washes. The sterilization cycle depends on the type of product and can range from less than a day to a few weeks.
- Aeration Once the sterilization cycle is completed, the product is removed from the sterilization chamber and placed in an aeration room, where any residual EtO within the product is removed.
- **Storage** Processed storage area where sterilized product is placed until it is shipped back to customers.

Where EtO Comes from at the Facility

There are two types of EtO emissions from facilities: Controlled **Fugitive Emissions Emissions** -0

In this community, the majority of the risk is being caused by fugitive emissions

Stack vs. Fugitive Emissions

Stack Emissions

- Controlled by the wet scrubber and catalytic oxidizer
- The most recent performance test demonstrated:
 - Sterilization chamber control efficiency greater than 99.99%
 - Aeration room control efficiency greater than 99.9%
 - A 99.6% control efficiency for the back vent.

Fugitive Emissions

- Not emitted from the stack
 - E.g. emitted from warehouse
- Sources of fugitives include:
 - Indoor EtO storage containers
 - EtO dispensing pipes
 - Vacuum pumps
 - Pre-aeration handling of sterilized products
 - Post-aeration handling of sterilized products

Work in Progress

- Facility is currently up for a permit renewal, which requires them to perform an air toxic risk analysis
- NYSDEC requires the facility to be below a "10/million" threshold





Timeline

- New regulation proposed in coming months
- 60-day public comment period
- Final rule end of this year.
- Facilities typically have 3 years to comply
 <u>https://www/epa.gov/eto/comment</u>
- New risk information for workers at facilities and people who work or attend school nearby ("Pesticide Rule")
- Proposal for EtO-allowed-use in facilities this year
- Typically, several years for pesticide labels to be updated and take effect

https://www.epa.gov/ingredients-usedpesticide-products/ethylene-oxide-eto

Additional Resources

ATSDR EtO FAQs

Link:

https://wwwn.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=733&toxid=133

EtO Email Address for CDC:

eto@cdc.gov

Next Steps



- New regulation proposed in the coming months.
- EPA continuing to work with State partners and Sterigenics to reduce EtO emissions from facility.
- Submit questions to EPA via <u>eto@epa.gov</u> or Brian Marmo at <u>Marmo.Brian@epa.gov</u> or 212-637-4352

How to Ask Questions

- Type question in chat
- Raise virtual hand
 - *5, if on phone
 - *6 to unmute/mute



Thank You!

Please do not hesitate to reach out with any questions:

Marmo.Brian@epa.gov



Key Points



EPA has learned that EtO is causing health risk in some American communities.

We are working to reduce this risk by:

- 1. Working across government and industry to reduce EtO coming from sterilization facilities.
- 2. We are updating air pollution regulations to be more protective of your health.
- 3. We are sharing these risk results with you, so you have the same information we have.