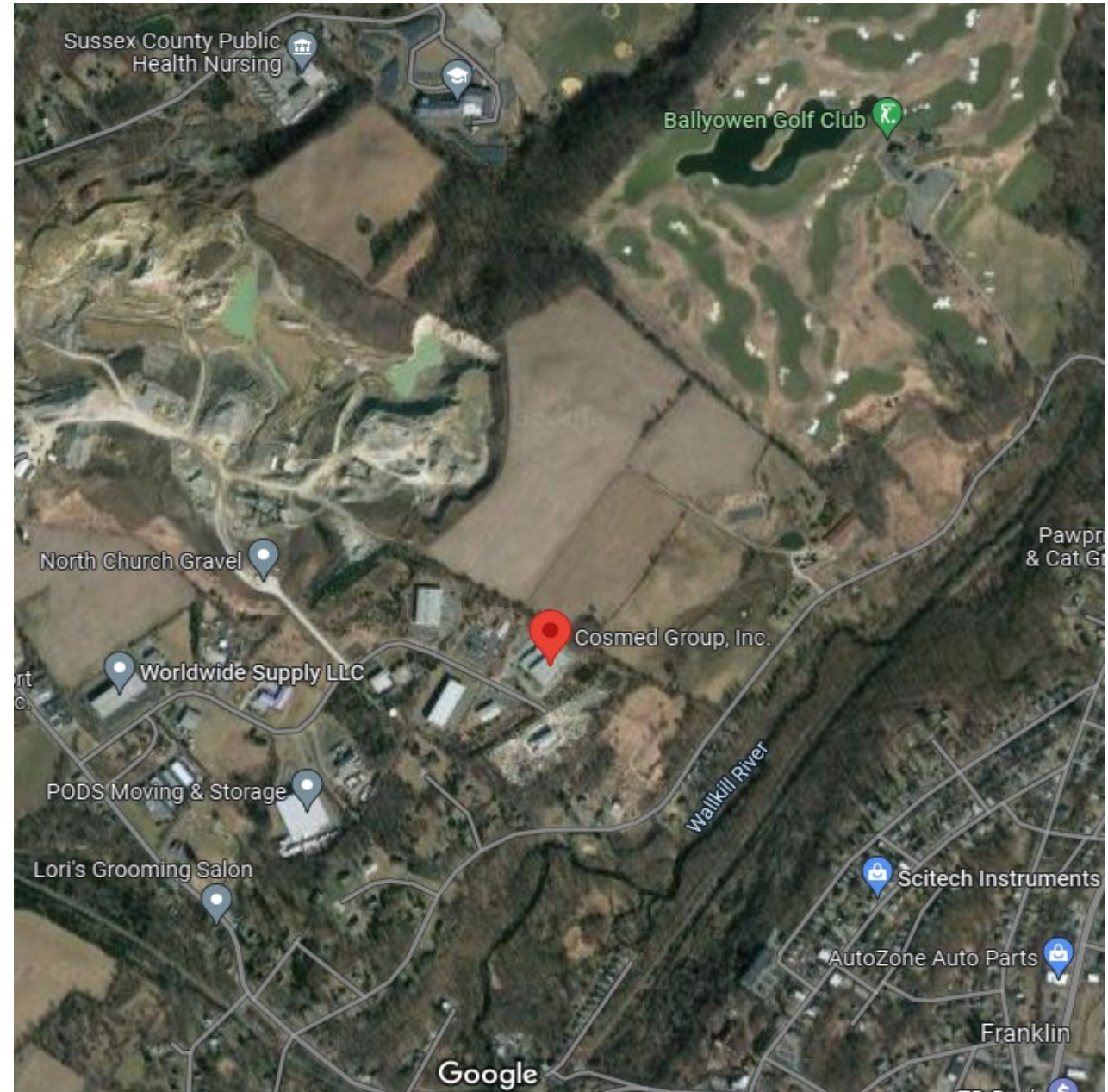


# Community Meeting on Ethylene Oxide and Risks in the Communities of Hardyston, Franklin, Hamburg, New Jersey to begin shortly.



# Getting Started:

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



To un/mute

To view participants

To participate in Spanish

To turn video on/off

To open chat box

To view closed captioning

Shereen Kandil (she/her)

Unmute Start Video Security Participants 1 Polls Chat Share Screen Record Live Transcript Interpretation Reactions More

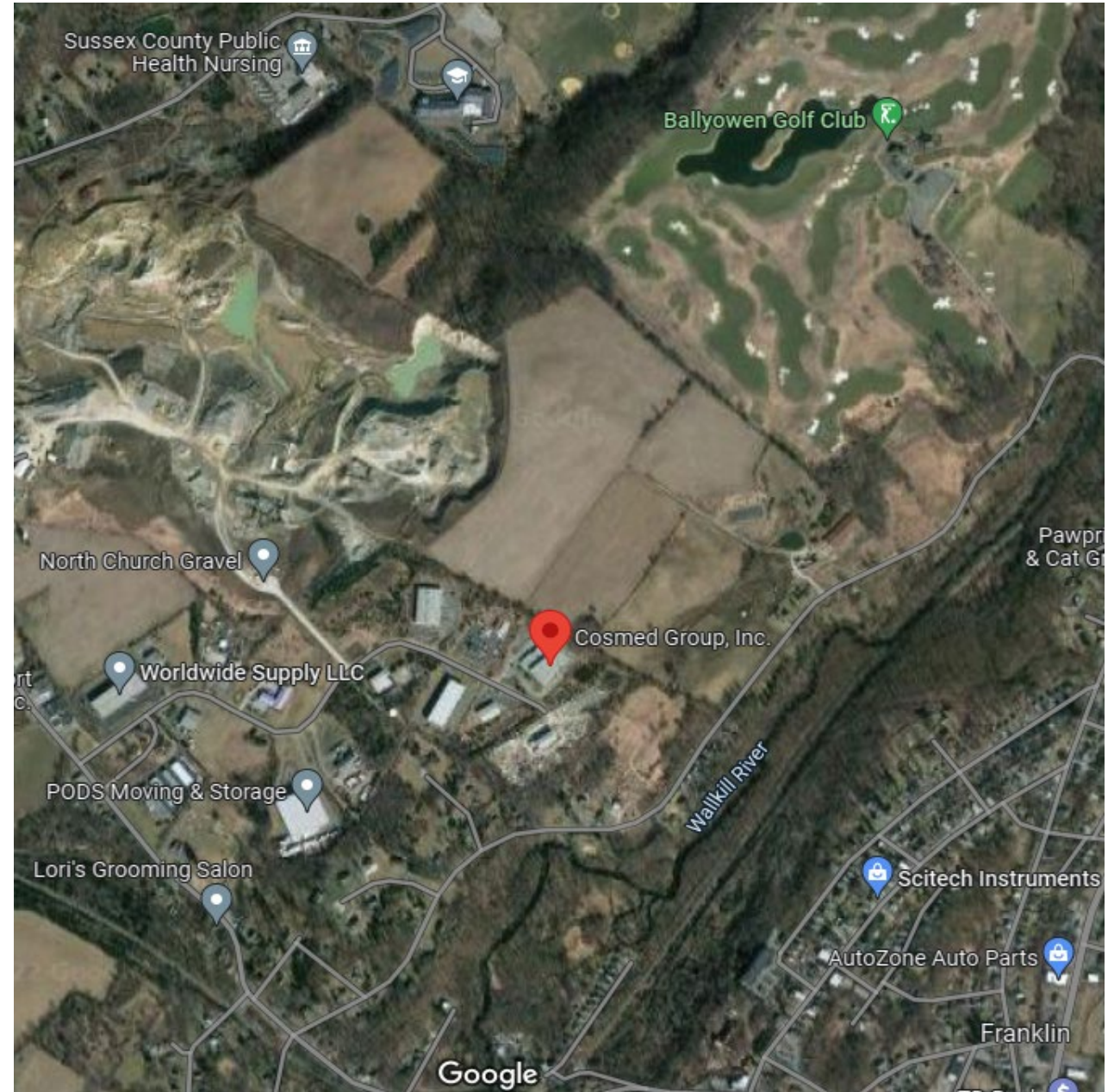
End



**Please give us a call if you  
are having technical  
difficulties**

**212-637-4333**

# Ethylene Oxide and Risks in the Communities of Hardyston, Franklin, and Hamburg, New Jersey



# Why we are here tonight

- 1 Pollution is increasing health risks in some American communities.
- 2 We are working to reduce this risk.
- 3 We want to hear from you.



Website:

<https://www.epa.gov/eto>

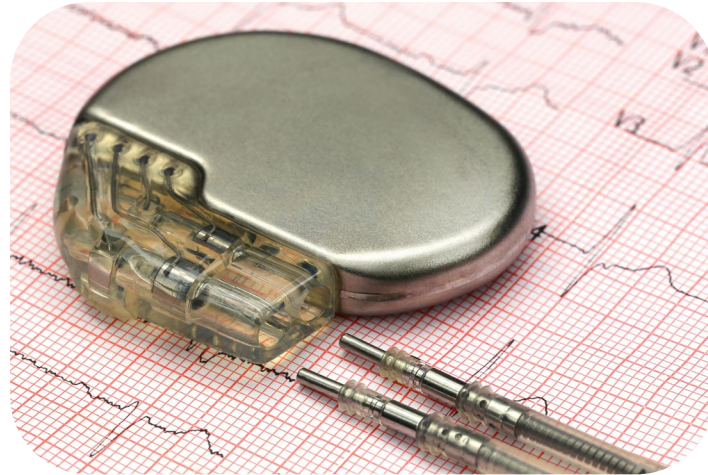
Email:

[eto@epa.gov](mailto:eto@epa.gov)

# What is Ethylene Oxide?

- **Gas**
- **Colorless**
- **Flammable**
- **Odorless**

*(in concentrations  
we find in communities)*



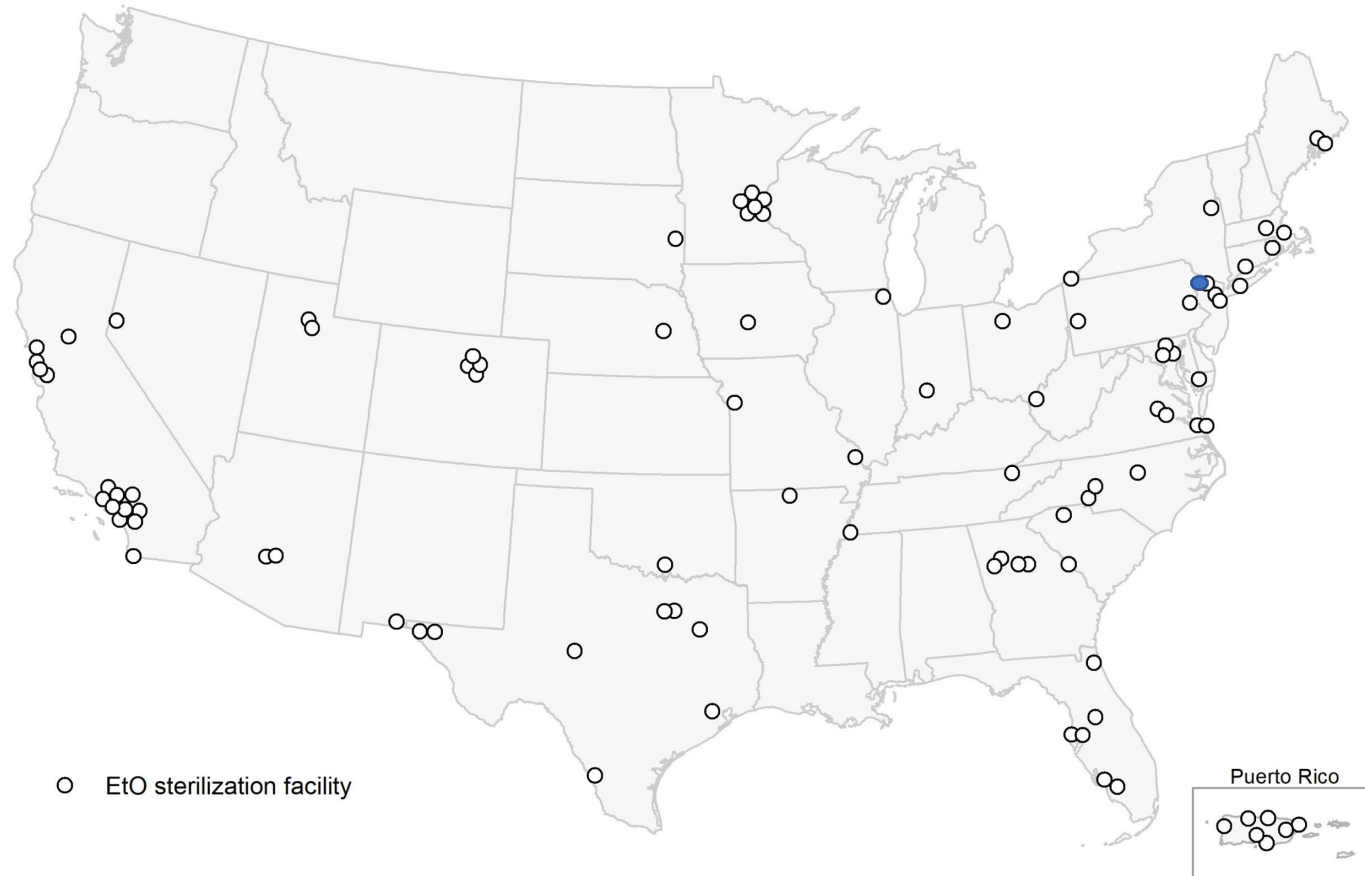
# EtO Uses

- Used to Make Other Products
- Sterilizes





# National Context for Sterilizers



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

# Preliminary Results and Now

- 2016: EPA sets new EtO toxicity level
- 2018: Initial analysis elevated risk near some facilities.
- 2020-2022: Collected data and new analysis to know exactly where there may be elevated risk.
- July 2022: preliminary analysis showed emissions from Cosmed cause an elevated risk level.
- **August 2022: Cosmed informed EPA of improvements to the facility; shows emissions to the atmosphere were less than our preliminary analysis indicated.**
- **We will update our analysis; the risk level should be lower.**
- **EPA will continue to work with Cosmed and other partners to lower risk.**

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.



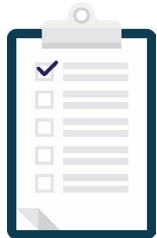
# Special Considerations about Risk



Workers may be exposed at higher levels.



Children and babies may be at higher risk.



This risk assessment and the rule it supports are focused on community risk, not worker 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  
( $\geq 100$  in 1 million; or 1-in-10,000)

# Details about this analysis

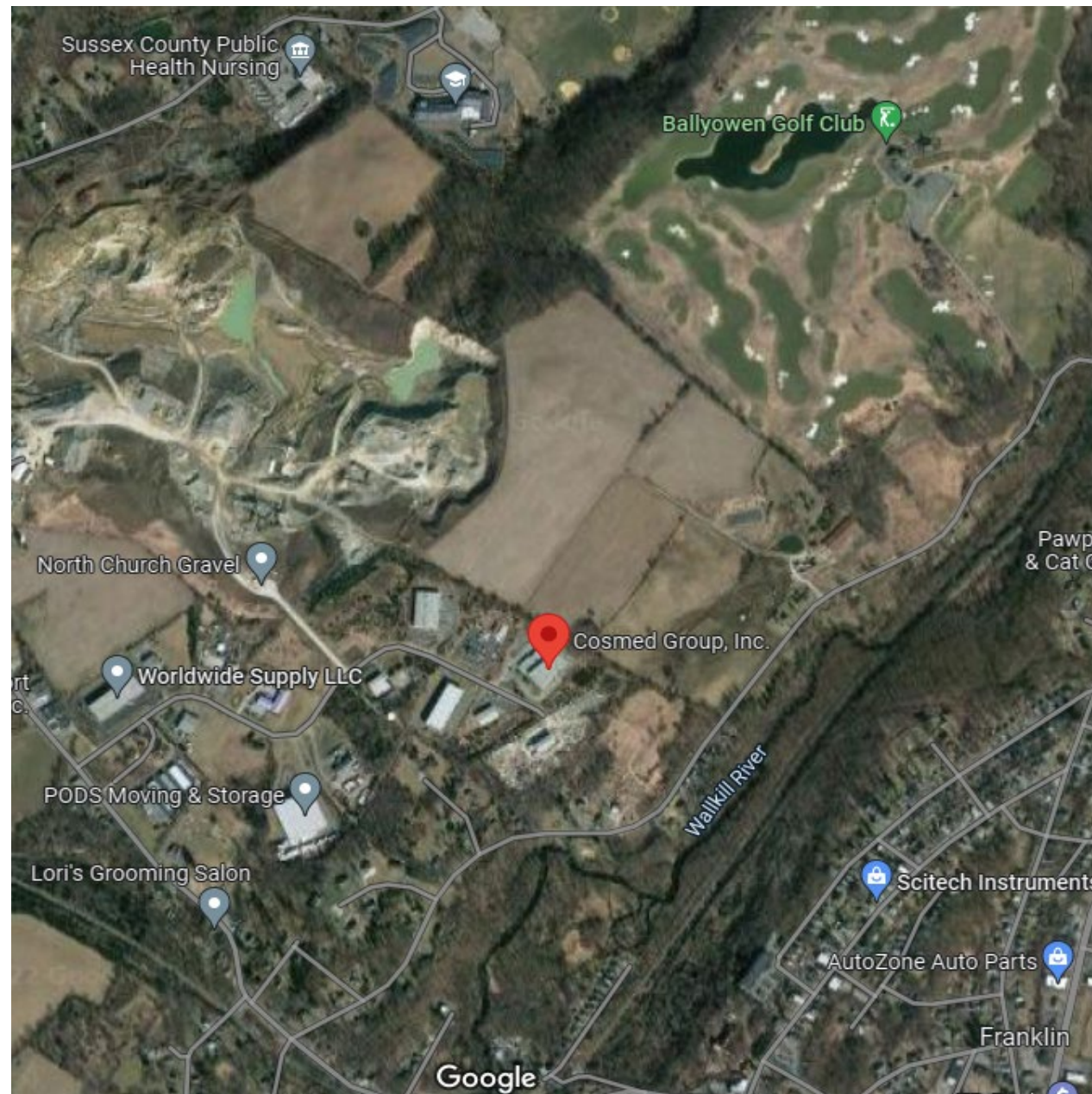
- EtO Uses
- Facility Processes
- Facility Equipment
- Community Details
- Weather

**Analysis**

**Mapped  
Location of  
Modeled Risk  
Caused by EtO  
from a Facility**



# Location of Cosmed 19 Park Dr. Franklin NJ



# Cosmed Hardyston Township, New Jersey

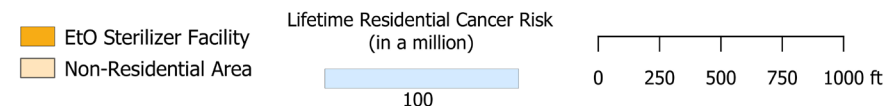
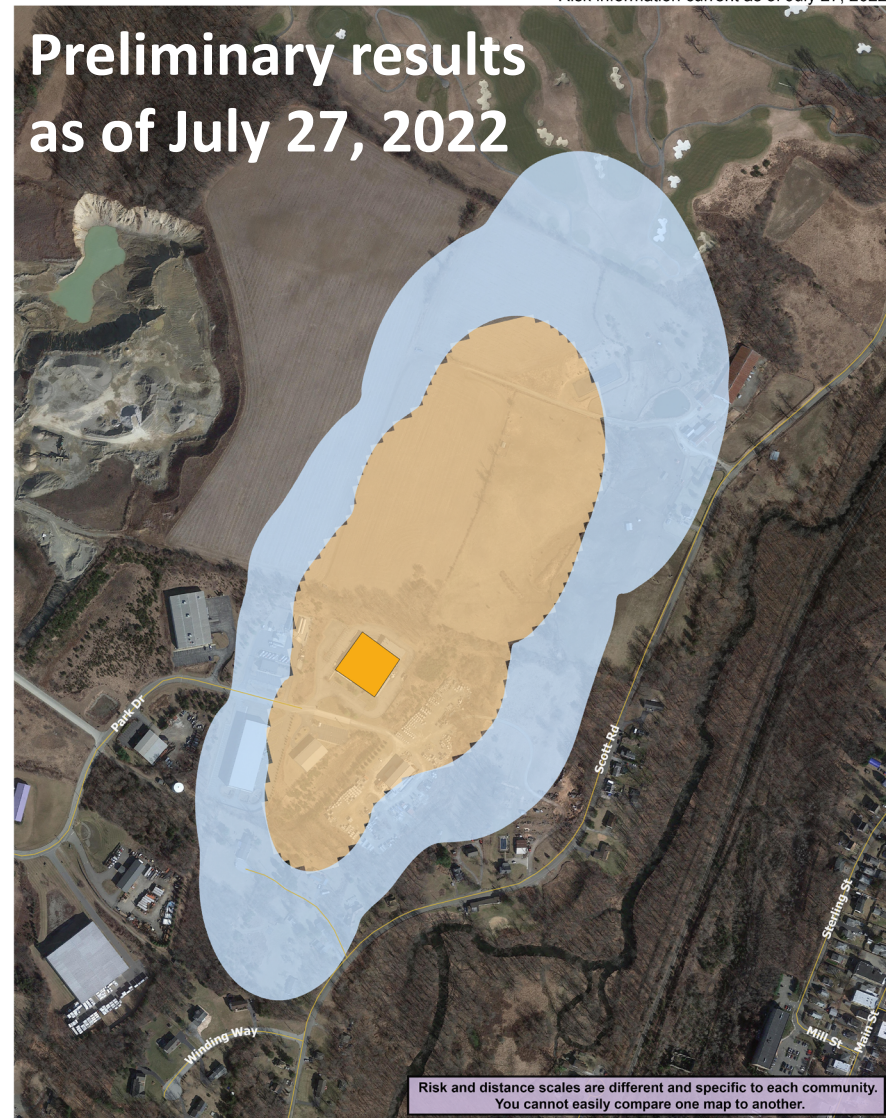
Lifetime cancer risk - breathe air containing EtO at the level estimated at that location for 24 hours a day, every day for 70 years.

**Updated Maximum Risk Level: Less than 100/Million, or 1/10,000:**

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

**Blue:** Preliminary estimated lifetime cancer risks of 100 in a million (1 in 10,000) or greater.

For more information and to view this map online: <https://www.epa.gov/eto/>

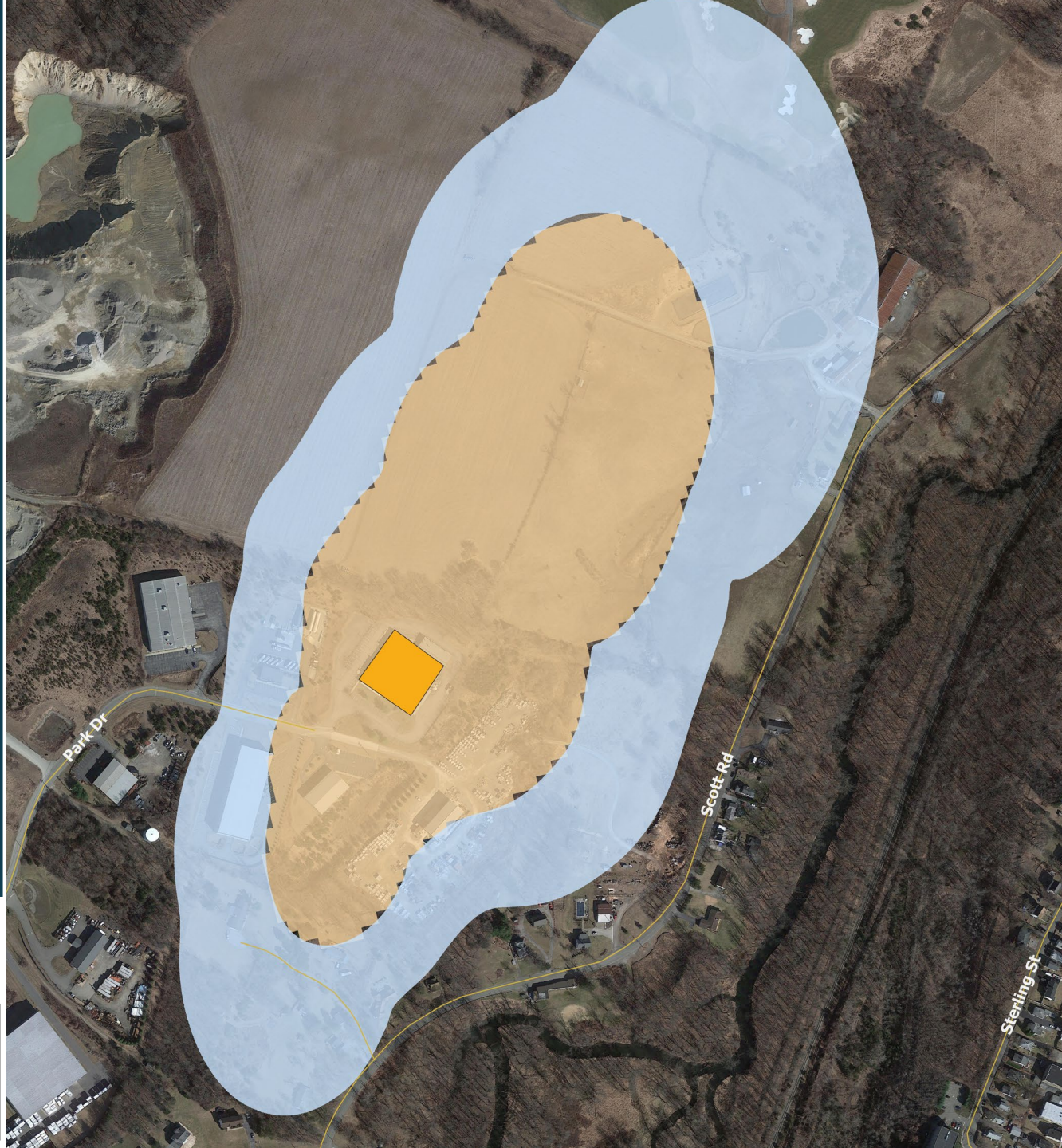


This map shows EPA's estimates of lifetime cancer risks from EtO near Cosmed Group, Inc. in Franklin, NJ. Risk decreases with distance from the facility. The area in blue shows estimated lifetime cancer risks of 100 in a million or greater from breathing air containing EtO emitted from the facility. A lifetime cancer risk of 100 in a million means that if 1 million people were exposed to this level of EtO in the air 24 hours a day for 70 years, 100 people would be expected to develop cancer from that exposure.

EPA cannot predict whether an individual person will develop cancer.

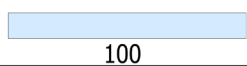
# Lifetime Residential Cancer Risks - Cosmed

July 27, 2022



- EtO Sterilizer Facility
- Non-Residential Area

Lifetime Residential Cancer Risk  
(in a million)



0 250 500 750 1000 ft

This map shows EPA's estimates of lifetime cancer risks from EtO near Cosmed Group, Inc. in Franklin, NJ. Risk decreases with distance from the facility. The area in blue shows estimated lifetime cancer risks of 100 in a million or greater from breathing air containing EtO emitted from the facility. A lifetime cancer risk of 100 in a million means that, if 1 million people were exposed to this level of EtO in the air 24 hours a day for 70 years, 100 people would be expected to develop cancer from that exposure.

EPA cannot predict whether an individual person will develop cancer.

# Cosmed Operations

- Started operations in 1997.
- Sterilizes medical devices.
- Used 10.5 tons of EtO in 2020.
- Controls emissions with a catalytic oxidizer
- 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.

# Work in Progress

- EPA learned Cosmed is routing emissions from its sterilizer room to the catalytic oxidizer
- Warehouse has been re-configured
- As a result of these updates, the emissions and the risk level have decreased





## Recent Steps Taken to Learn about Risk and Reduce It:

- July 2022: Complete 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.

# Timeline

- New regulation to be proposed this year.
- The public comment period will last 60 days.
- Final rule is expected in 2023.
- Once the rule is final, facilities typically will have 3 years to comply with new requirements.
- Additional resources on the comment process are available here:  
<https://www.epa.gov/eto/comment>

Su	Mo	Tu	We	Th	Fr	Sa
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				


# Timeline (continued)

Additional actions this year on EtO:

- New risk information for workers at EtO facilities and people who work or attend school nearby
- Proposed changes to EtO allowed use inside facilities expected in 2022
- Public comment period.
- Once changes in allowed use are final, it typically takes several years for changes to take effect
- Learn more about EPA's review of EtO use as a pesticide: <https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto>



# Next Steps

- 
- New regulation proposed by end of the year.
  - EPA continuing to work with Cosmed and its partners to reduce EtO emissions from facility.
  - Submit questions to EPA via [eto@epa.gov](mailto:eto@epa.gov) or Brian Marmo at [Marmo.Brian@epa.gov](mailto:Marmo.Brian@epa.gov) or 212-637-4352

# 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](mailto:eto@cdc.gov)

New Jersey Department of Health Environmental and Occupational Health  
Surveillance Program

Email: [EOHSP@doh.nj.gov](mailto:EOHSP@doh.nj.gov)

# Key Messages

- EPA has learned that EtO is causing health risk in some communities across the U.S.
- EPA is working with facilities and partners to further reduce EtO coming from sterilization facilities.
- Risk to the community near the Cosmed facility is lower than previously thought.
- EPA is updating air pollution regulations to be more protective of your health.
- We are sharing these risk results with you, so you have the same information we have.

# How to Ask Questions

- Type question in chat
- Raise virtual hand
  - \*9, if on phone
  - \*6 to unmute
- In person



# Thank You!

Please do not hesitate to reach out with any questions:

[Marmo.Brian@epa.gov](mailto:Marmo.Brian@epa.gov)

