BUSINESS

EPA warns of elevated cancer risk near Kingsbury sterilization plant

Sterigenics, which sterilizes medical devices, is in midst of a permit review by DEC, which is vowing to make the facility safer for the public

Larry Rulison

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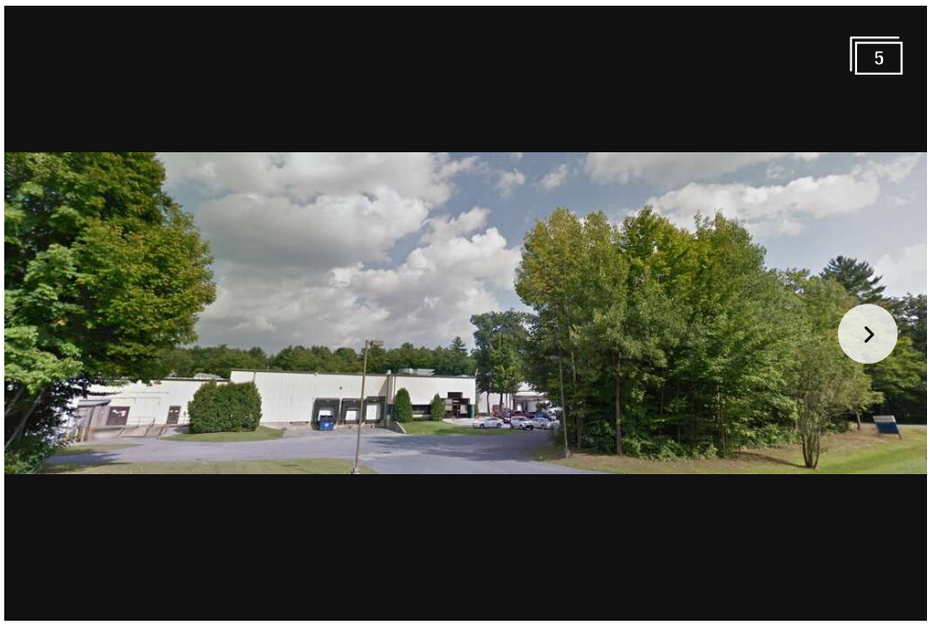

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Sterigenics has its 30-person medical equipment sterilization facility in the town of Kingsbury in Washington County.

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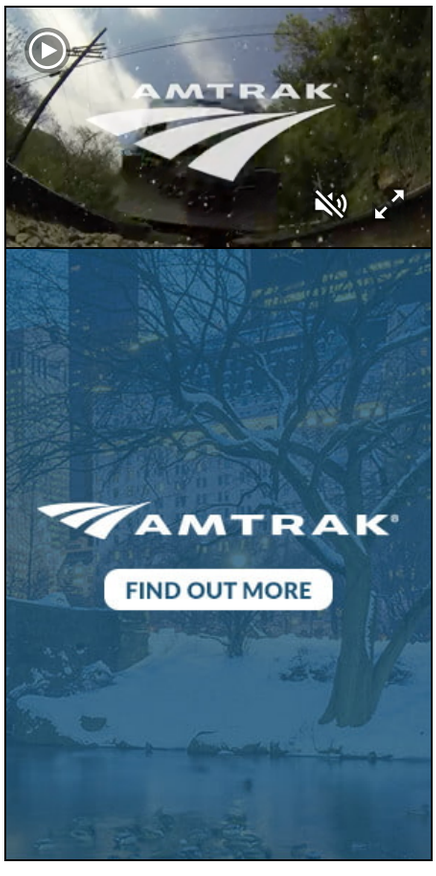

KINGSBURY — The U.S. Environmental Protection agency sounded the alarm Thursday about the elevated risk of cancer for those working and living near the Sterigenics medical device sterilization plant in the town of Kingsbury, which is located about five miles outside of Glens Falls and near the Queensbury town line.

The EPA, which hosted an online community meeting outlining its concerns and plans to mitigate the health risks to the public, says it is in the process of tightening federal oversight of the use of the main chemical used in the plant — ethylene oxide, a toxic gas linked to breast and blood cancers in people who inhale it over a long period of time. Roughly 80 people participated.

The EPA says the lifetime cancer risk immediately around the Sterigenics plant is 100 in 1 million, or 1 in 10,000, a number the agency says needs to go down in order to protect workers and local residents.

"We're taking this issue seriously," said Lisa Garcia, the administrator, or leader, of the agency's Region 2 that includes New York. "We're really trying to address it."

A 2021 EPA letter written to Alicia Lempka, the general manager of the Sterigenics facility, noted that 47,634 people, including 2,858 children under the age of 5, live within a five-mile radius of the plant. There are also 20 schools within that area, which the EPA noted was a concern.

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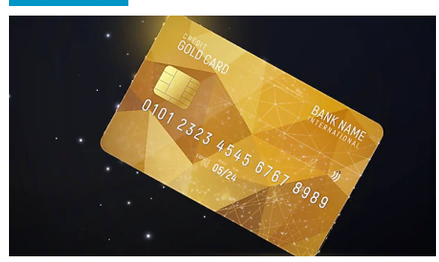

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"Because (ethylene oxide) is mutagenic (i.e., it can change the DNA in a cell) and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns EPA," Michal Freedhoff, the EPA's assistant administrator for the Office of Chemical Safety and Pollution Prevention, wrote Lempka at the time.

At the same time, the facility, which opened in 1994 and employs 30 people, can't just be forced to shut down overnight. The plant, which used 157 tons of ethylene oxide in 2021, is one of just 100 such commercial sterilization plants that are vital to cleaning medical equipment and devices used in everyday medical treatment.

Kristin Gibbs, chief marketing officer of Sotera Health, the parent company of Sterigenics, told the Times Union the company is "committed to the continued safety of our employees and the surrounding Queensbury community" and noted that 20 billion medical devices are sterilized through the same process in the U.S. every year.

"We are proud of the critical role we play in safeguarding public health by sterilizing millions of essential medical devices and supplies at our Queensbury facility each year," Gibbs added. "Sterigenics has consistently outperformed regulatory standards for decades, including the standards in New York that exceed EPA requirements, and we are committed to continuing to implement industry-leading emissions control enhancements across our facilities to further improve our already safe operations."

Indeed, Sterigenic's air permit with the state Department of

Environmental Conservation, which has stricter standards than the EPA, is currently under review for renewal. Although DEC officials who participated in the meeting said that Sterigenics had a good regulatory track record, the agency is working to put more stringent safeguards in place under the new permit.

"New York is very tough on (ethylene oxide), and this facility was operating very well," said Paul Sierzenga, an air pollution control engineer with DEC. "We are looking to get the facility under better control."

DEC's goal is to get the cancer risk down to 1 in a million, which is substantially lower than the current threshold. One of the solutions is to put the building under negative pressure to better control emissions, including so-called fugitive emissions, which are small leaks of the gas that happen throughout the supply chain and the process.

Ethylene oxide has long been considered ideal for sterilizing medical devices because it can penetrate packaging to kill bacteria and germs on devices such as catheters that are used on hospital patients every day.

However, the EPA discovered in 2016 that ethylene oxide was much more dangerous to the public than previously known. Although the Sterigenics facility was deemed safe by the company in 2018 in a story published in the Times Union, it appears that notion has changed since then, at least among public health agencies.

Follow-up research using data collected since then found that the toxic gas is even more dangerous to humans, and the EPA said it is targeting 23 facilities around the U.S. that have elevated lifetime cancer risk levels above 100 in 1 million.

Legal pressure on the industry has also increased. Sotera, Sterigenic's parent company, recently agreed to pay out $408 million to several hundred residents who live near one of its former plants outside of Chicago after a jury awarded a 70-year-old woman who lived near that plant and developed breast cancer

$363 million.

The Sterigenics facility in Kingsbury, which is located in an industrial area across the highway from Queensbury airport, is "close to the level that we find unacceptable," Garcia added.

A map the EPA developed shows an oval-shaped area of concern around the Sterigenics plant that is bordered by Queensbury Avenue to the west, Casey Road and Ferguson Lane to the north, Dean Road to the east and Park Road to the south. Although the Sterigenics plant is located in an industrial park, there are a number of residential properties nearby on Casey and Dean roads.

The Queensbury and Glens Falls area is known as Catheter Valley due to all the medical device manufacturers located in the region.

Across the street from Sterigenics is AngioDynamics, a medical device and catheter manufacturer that uses Sterigenics for sterilization services, according to records with the U.S. Food & Drug Administration.

The FDA says it is concerned that the recent closure of commercial sterilization plants due to ethylene oxide concerns could lead to shortages of available medical devices, causing an unintended public health risk.

Several residents who said they lived a mile or closer to the plant spoke during the event. They said a strange odor would sometimes come from the building that smelled like a campfire or burnt marshmallow even though ethylene oxide is considered odorless.

Some said there were a half-dozen cases of breast cancer they knew of in that area. A man who said he was a former engineer for Sterigenics said he developed health problems from exposure to ethylene oxide.

"I suffer from this stuff every single day of my life and I know what it's like to get sick from it," said the man, whose identity could not immediately be confirmed.

The EPA and DEC aren't the only oversight agencies concerned about the Sterigenics plant, which is only one of two commercial sterilizing plants using ethylene oxide in New York state. The other is on Long Island.

"We are looking forward to reviewing the proposed (new EPA) rules," Sarah Kam, an assistant attorney general with the state Attorney General's Environmental Protection Bureau, said toward the end of the meeting.

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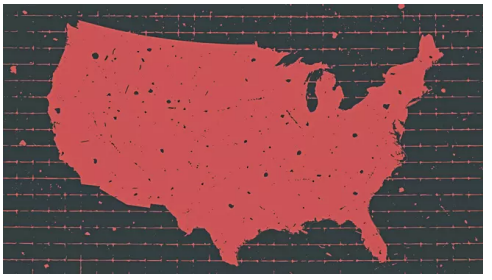

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