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The People Living In The Shadow Of EtO Facilities

by [Hannah Daniel](#)

A report from the Union for Concerned Scientists found that EtO facilities are often located in communities of color, low-income communities, and communities in which many residents are not proficient in English.

Members of a Kingsbury community gathered in the Kingsbury Volunteer Hose Company in Hudson Falls, NY, on 16 February to speak to the US Environmental Protection Agency about a local hazard: A nearby commercial sterilizing plant [emitting ethylene oxide](#).

The EPA has identified 23 EtO-emitting facilities that are known to cause health risks for surrounding communities, and the EPA plans to hold meetings with each of them.

While EtO is a common sterilizer of medical devices the emissions have been linked with an elevated risk of white blood cell cancers and breast cancer in women. Children are particularly vulnerable to these emissions because their cells are dividing at a faster rate and are more susceptible to DNA mutations.

Aside from possible long-term effects, the EPA found that inhalation of EtO can cause respiratory issues, headaches, nausea and vomiting.

One prominent medical device sterilizer, Sterigenics, has been in the news recently for its class action lawsuits. Sotera Health, the owner of Sterigenics, settled a slew of suits for \$408 for claims that its Willowbrook, IL, facility caused cancer for its surrounding residents.

However, the company maintains that its facility did not pose a safety risk to community members. (Also see "[Sterigenics Reaches \\$408m Settlement In EtO Lawsuit](#)" - Medtech Insight, 11 Jan, 2023.)

So who are the people living in these communities closest to these facilities? The Union for

Concerned Scientists (UCS) recently published a [report](#) studying the communities who are at risk from hazardous EtO emissions, and UCS found that the emissions from plants disproportionately affect low-income communities, communities where many residents are not fluent in English, and people of color.

Margianlized Communities Surrounding Facilities

UCS studied 104 facilities across the US: 96 commercial sterilizers and eight additional miscellaneous organic chemical manufacturing (MON) facilities that also emit EtO.

Commercial EtO sterilizers are designated as MON facilities, and these facilities are allowed to emit EtO and other pollutants as byproducts. However, not all EtO-emitting facilities are MON facilities. Manufacturers making carbide, a type of polymer, also produce EtO emissions, but these facilities aren't always categorized as MON facilities.

The report defines a "community" as the people living within a five-mile radius of the facility studied. According to the report, 14.2 million people live in these communities.

Overall, the report found that EtO-emitting facilities are most often found in densely populated areas and with other sterilizers within five miles. The group calls these clusters of sterilization facilities sterilizer hotspots.

More than 25% of the sterilizers are found in these sterilizer hotspots. While being in a sterilizer hotspot doesn't guarantee a person will be exposed to EtO emissions, it does increase their likelihood of exposure due to multiple sources.

Of the more than 14 million people living in the communities studied, almost 8.5 million identified as people of color, 4.8 million identified as people with low income (those with an income of no more than 200% of the federal poverty level, or \$60,000 for a family of four as of 2022)), and 1.2 million identified as limited-English speaking (a population that reports speaking English "not well"). All demographic data was taken from the [US Census Bureau, 2016-2020 American Community Survey, 5-Year Estimates](#).

Compared to the national average, the communities surrounding EtO facilities have a higher proportion of low income, limited-English speaking people of color.

Facilities with EPA-identified elevated cancer risks:

- Elite Spice (Hanover, MD)
- Terumo BCT (Lakewood, CO)

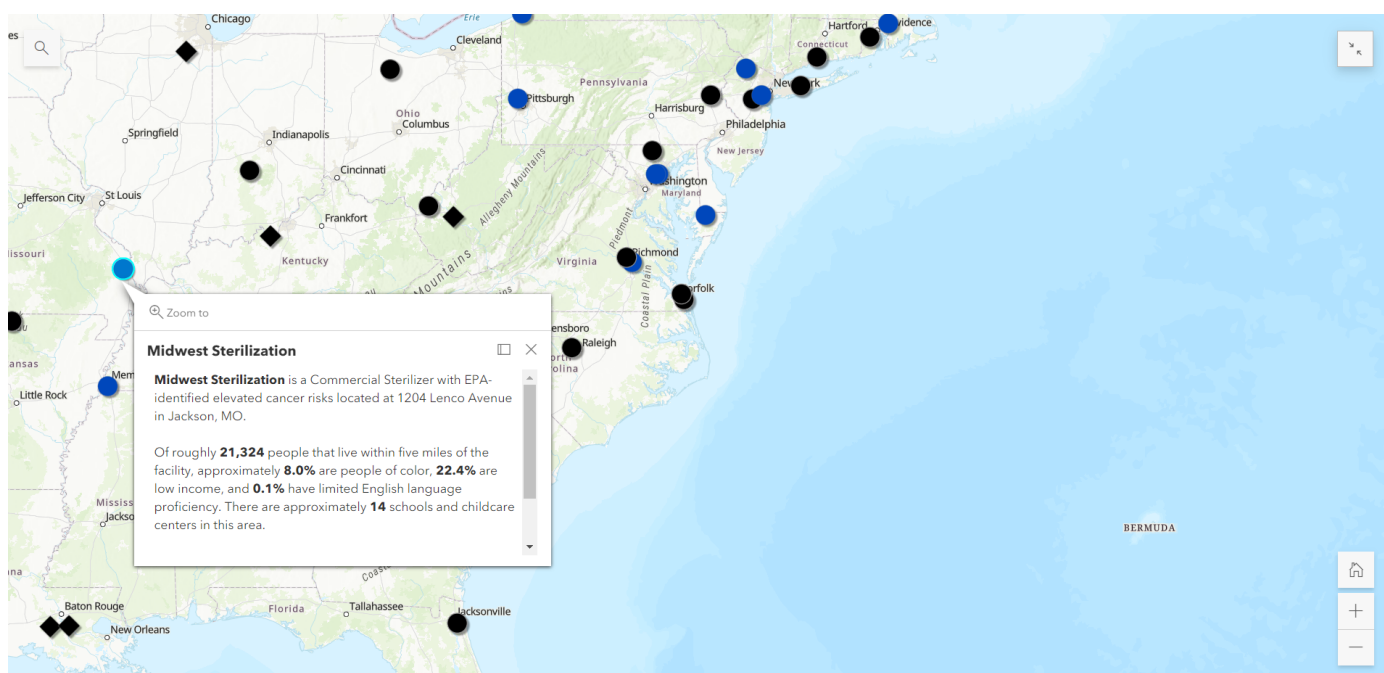
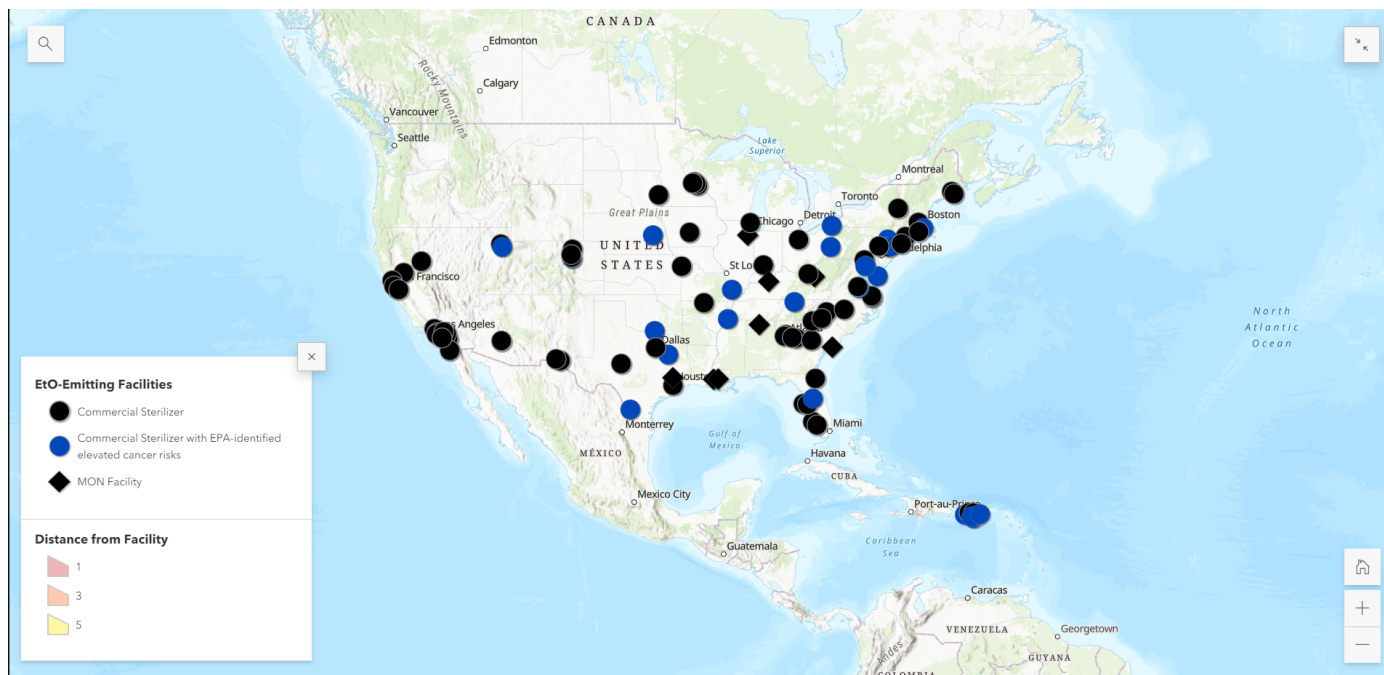
- Elite Spice (Jessup, MD)
- Sterilization Services of Virginia (Henrico, VA)
- Cosmed Group (Franklin, NJ)
- Medtronic (Villalba, PR)
- International Sterilization Laboratory (Groveland, FL)
- Trinity Sterile (Salisbury, MD)
- Becton Dickinson Pharmaceutical Systems (Columbus, NE)
- Lemco Ardmore (Ardmore, OK)
- Cosmed Group/Medical MFG (Erie, PA)
- Sterilization Services of Tennessee (Memphis, TN)
- EtO Sterilization (Linden, NJ)
- Midwest Sterilization (Laredo, TX)
- Professional Contract Sterilization (Taunton, MA)
- Midwest Sterilization (Jackson, MO)
- American Contract Systems (Zelienople, PA)
- Customed (Fajardo, PR)
- Steri-Tech (Salinas, PR)
- Edwards Lifesciences Technology (Añasco, PR)
- DeRoyal Industries/Royal Sterilization (New Tazewell, TN)
- Steritec (Athens, TX)
- BD Medical (Sandy, UT)

Where Are The Facilities Located?

UCS added [an interactive map](#) detailing its research, where users can click on the facilities to find statistics on surrounding communities and EtO emissions.

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Source: Darya Minovi. 2023. *Invisible Threat, Inequitable Impact: Communities Impacted by Cancer-Causing Ethylene Oxide Pollution*. Cambridge, MA: Union of Concerned Scientists.

Policy Suggestions

The EPA is likely to propose controls for ethylene oxide emissions in the coming months. Currently, it's reviewing two parts of the Clean Air Act: The air toxics rule for MONs and the rules for EtO sterilizers.

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In August 2020, the EPA published a final rule that places additional controls on “certain equipment and processes that emit ethylene oxide,” which encompasses a broader range of chemical plants than just EtO commercial sterilizers.

Late last year, the EPA also said it wanted to create stronger standards for MON facilities, according to the report.

The Clean Air Act requires an update to emission rules for “hazardous air pollutants” every eight years, but the EPA was “was due to update its commercial sterilizer rule in 2014,” making it nine years overdue for an update, the report explains.

The EPA needs to increase penalties for companies in violation of the Clean Air Act as well, the UCS says. One Sterigenics facility in Charlotte, NC, paid around \$11,500 in penalties in 2020, but as the report points out, this is just a “drop in the bucket” for a company reported almost \$1bn in revenue in 2021.

The UCS has its own policy recommendations as well, including a stricter enforcement of the Clean Air Act overall, and revisions to remove loopholes. The group further recommends that the EPA updates air toxicity rules for all types of EtO-emitting facilities, not just commercial sterilizers and MON facilities.

The Union also strongly suggests the EPA place controls on fugitive EtO emissions, such as EtO storage containers, pipes and pumps that allow emissions into the air outside of the smokestacks. Finally, the group is asking the agency to collect data on the effect of EtO on surrounding communities and a thorough risk review with a “margin of safety” to protect public health.

“In its EtO review, the EPA must prioritize having an ample margin of safety to ensure protection for children and other people especially at risk of harm from EtO exposure,” the report says.

Community education is a big piece of the UCS’s goals, both with public policy and their own communications. Communities at risk from EtO emissions should have direct communication with the EPA, and public databases with risk information should be easier to access and ensure that the language used is accessible, they say.

A Future Beyond EtO?

Finally, UCS advocates for a replacement for EtO sterilization, and urges the EPA to plan to phase out EtO.

In the past, medtech industry groups have defended the use of commercial ETO sterilizers both because the method is considered effective and because of the sheer volume of devices these

facilities sanitize a year, as well as the disruption that would be caused by a switch.

There are only about 100 sterilizers in the US that sterilize around 20 billion devices a year, approximately half of all devices used in the US.

AdvaMed is open to regulations to EtO facilities and emissions, but urges policymakers not to shut down facilities without considering the potential harm to American public health. (Also see "[AdvaMed Urges Biden Administration Not To Shut Down EtO Sterilization Facilities](#)" - Medtech Insight, 20 Jan, 2023.)

The Food and Drug Administration is currently looking into EtO alternatives and launched a pilot program in November 2019 to approve alternative sterilization processes more quickly. (Also see "[US FDA Looks To Balance Device Sterilization With Environmental Concerns](#)" - Medtech Insight, 4 Aug, 2022.)