

COVID-19, Ethylene Oxide Sterilization, and Community Health: CAN WE RESPOND TO ONE HEALTH CRISIS WITHOUT CREATING ANOTHER?

THE BASICS: What is Ethylene Oxide (EtO) and what is it used for?

- Ethylene Ethylene Oxide (or EtO) is a colorless flammable gas with a mild odor, emitted from some industrial and sterilization facilities.
- EtO is used in many industrial applications, including producing component chemicals for antifreeze, polyester, detergents, and adhesives.¹
- Additionally, EtO is used as a medical-grade sterilizer for some medical equipment with which steam-based sterilization techniques are not appropriate.² In the US, EtO is used to sterilize nearly half of all medical devices that require sterilization.³

THE RISKS: What are the health risks associated with EtO?

- The National Toxicology Program⁴ and the Environmental Protection Agency (EPA)⁵ both classify EtO as a known human carcinogen.
- Long-term exposure to EtO can increase risk of cancers including non-Hodgkin's lymphoma, myeloma, lymphocytic leukemia, and breast cancer. There is also evidence that EtO is a reproductive toxicant that can cause miscarriages in exposed workers.⁶ At higher doses, it can also cause irritation to the eyes, skin, nose, and throat, and cause lung and nervous system damage.⁷
- Short-term exposure can cause headache, dizziness, nausea, fatigue, respiratory irritation, and gastrointestinal distress.⁸
- There are at least 288,000 people living in EtO "hot spots" where their cancer risk from EtO exposure is "at least 100 times greater than the level that triggers action under the Clean Air Act." These hot spots are disproportionately concentrated in low income communities and communities of color.⁹
- It's impossible to know who will be affected. According to the National Cancer Institute, "simply because a substance has been designated as a carcinogen, however, does not mean that the substance will necessarily cause cancer [in any individual person]. Many factors influence whether a person exposed to a carcinogen will develop cancer, including the amount and duration of the exposure and the individual's

¹<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/fact-sheet-epa-taking-steps-address-emissions-ethylene-oxide>

²<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/fact-sheet-epa-taking-steps-address-emissions-ethylene-oxide>

³<https://progressivereform.org/cpr-blog/peril-ethylene-oxide-replacing-one-public-health-crisis-another/>

⁴https://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/Ethylene_Oxide_Fact_Sheet/Ethylene_Oxide_Fact_Sheet

⁵https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf

⁶<https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf>

⁷<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/fact-sheet-epa-taking-steps-address-emissions-ethylene-oxide>

⁸<https://scdhec.gov/environment/air-quality/national-air-toxics-assessment-and-ethylene-oxide>

⁹<https://ej4all.org/campaigns-and-activities/ethylene-oxide>

genetic background.”¹⁰ However, we know conclusively that these increased rates of cancer will fall most heavily on people living on the fenceline of the facilities that release these chemicals. Fenceline communities who face the cumulative impacts of toxic exposures are most at risk, and disproportionately likely to be Black, Latinx, and impoverished.¹¹

- Dangerous releases of EtO come both from chemical production facilities and from medical sterilization facilities. While community members have raised concerns about both of these applications, medical sterilization facilities are currently attributing their increases in production to the COVID-19 pandemic.

Despite the health risks associated with EtO, and the availability of safer sterilization methods, it is still used to sterilize some medical equipment. When members of communities near EtO sterilization facilities get sick from EtO exposure they are being harmed by the very medical system whose mission it is to protect them. Communities have been pushing back, demanding safer alternatives, and winning regulatory victories in the past couple years that closed hazardous facilities in Illinois and Georgia. Now, under the guise of the COVID-19 pandemic, these facilities are re-opening.¹²

- Facilities that had been shut down in response to community pressure in Lake County, Illinois, and in Cobb County, Georgia, have reopened since the pandemic began.¹³
- The Inspector General of the EPA released a report in March 2020 alerting that the agency had taken inadequate action to inform people living near EtO facilities of their elevated cancer risks, which continue to increase due to these re-openings.¹⁴

FACT CHECK: Is there any need for expanded EtO use during the current pandemic?

- The Center for Disease Control (CDC) has **NOT** recommended that EtO be used to sterilize masks used by healthcare workers during the pandemic. In fact, using EtO to sterilize masks may harm the wearer and increase chemical risk for healthcare workers if these masks are insufficiently aerated after sterilization.¹⁵
- 3M (the manufacturer of many N95 respirator masks)¹⁶ and the Occupational Safety and Health Administration (OSHA)¹⁷ have also sounded alarms on the dangers of using EtO to sterilize masks.
- In spite of this, Medline Industries (a major sterilizer of medical equipment using EtO) has been lobbying for federal permission to go against this guidance and expand EtO use to include sterilization of masks. They have asked the Trump administration to ignore the findings of a peer-reviewed EPA study and instead adopt standards promoted by industry-funded research.¹⁸ They seem to be trying to take advantage of the uncertainty of this moment and the shortage of protective equipment to change long-term regulations that will allow them to continue polluting long after the pandemic has ended.

¹⁰<https://www.cancer.gov/about-cancer/causes-prevention/risk/substances>

¹¹<https://comingcleaninc.org/latest-news/in-the-news/report-life-at-the-fenceline-understanding-cumulative-health-hazards-in-environmental-justice-communities>

¹²<https://grist.org/justice/ethylene-oxide-sterigenics-medline-covid/>

¹³<https://progressivereform.org/cpr-blog/peril-ethylene-oxide-replacing-one-public-health-crisis-another/>

¹⁴<https://www.epa.gov/office-inspector-general/report-management-alert-prompt-action-needed-inform-residents-living-near>

¹⁵<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>

¹⁶<https://multimedia.3m.com/mws/media/18248690/decontamination-methods-for-3m-filtering-facepiece-respirators-technical-bulletin.pdf>

¹⁷<https://www.osha.gov/memos/2020-04-24/enforcement-guidance-decontamination-filtering-facepiece-respirators-healthcare>

¹⁸<https://www.chicagotribune.com/news/environment/ct-trump-medline-masks-ethylene-oxide-cancer-20200429-vyutifcyhvekljpn4rqxkpl3i-story.html>

- **There are alternatives.** Hydrogen peroxide is a safer alternative that effectively sterilizes many kinds of medical equipment, and it is recommended by the CDC for sterilizing masks. The CDC has also recommended ultraviolet germicidal irradiation (UVGI) for sterilizing masks.¹⁹ Each method of sterilization has its own range of applications, and some may cause damage to certain materials. Scientists and engineers continue to pursue sterilization practices that are safe for communities and equipment.
- **Conclusion:** Given the complex nature of the healthcare system, it is difficult to know all of the factors that are driving demand for EtO sterilization right now. However, given that EtO facilities are actively lobbying for permission to expand what they are allowed to sterilize (rather than just increasing operations to meet increasing demand), it seems that the reopening of plants is likely not happening out of necessity, but that EtO sterilizers see an opening to create more demand for the long term. The lax regulatory standards that are being put in place under the guise of the pandemic, and the widespread uncertainty as our nation struggles to respond, are making it easier for corporations to spread misinformation and advance corporate interests at the expense of communities.

WHAT WE CAN DO: We must protect both healthcare workers and public health

- Hydrogen peroxide and UVGI sterilization are alternative methods that are safer and equally effective for many sterilization needs. Unlike EtO, these have been approved by the Food and Drug Administration (FDA) and recommended by the CDC for sterilizing protective respirator masks used by healthcare workers to combat the pandemic.²⁰
- The FDA is actively working to support innovation and promote alternatives to EtO sterilization.²¹ Now is not the time to double down on a toxic system by increasing use of EtO while we are working to replace it with safer alternatives.
- We should not address one public health crisis (the pandemic) by creating another. We must address the COVID-19 pandemic without sacrificing the health and safety of the community members most impacted by EtO pollution.
- It is beyond question that medical device sterilization operations are necessary. Entirely phasing out EtO for all medical sterilization needs will require time, a luxury we unfortunately don't have in the midst of this pandemic. However, rather than bend to the will of sterilization companies seeking to regain power and money, FDA should continue seeking safer alternatives to EtO and limit reopened facility operations to critical medical equipment that cannot be adequately sterilized with hydrogen peroxide.²²
- EPA should update its regulation for EtO emissions from medical sterilization facilities and include cancer risks in its review; and it should require companies to monitor and report emissions.²³
- Finally, EPA and the National Institute for Occupational Safety and Health (NIOSH) must address EtO releases in chemical production facilities by conducting an industry assessment to identify best practices for chemical production and determine why releases are occurring. The industrial use of EtO to produce other chemicals such as antifreeze should be an entirely closed process; yet some of the highest community levels of EtO, often in low income communities and communities of color, come from these facilities.²⁴

¹⁹ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>

²⁰ <https://www.chicagotribune.com/news/environment/ct-trump-medline-masks-ethylene-oxide-cancer-20200429-vyutifcyhvekljpn4rqxkpl3i-story.html>

²¹ <https://www.fda.gov/news-events/press-announcements/statement-new-steps-advance-innovation-medical-device-sterilization-ethylene-oxide>

²² <https://progressivereform.org/cpr-blog/peril-ethylene-oxide-replacing-one-public-health-crisis-another/>

²³ <https://progressivereform.org/cpr-blog/peril-ethylene-oxide-replacing-one-public-health-crisis-another/>

²⁴ <https://www.chicagotribune.com/news/environment/ct-met-ethylene-oxide-trump-epa-outreach-failure-20200403-545u3u4vbjdoxopox4npegpcje-story.html>

THE BOTTOM LINE:

No one should be exposed to a toxic chemical at home or at work. The operations of our healthcare system, and the companies that sterilize its equipment, should not be increasing cancer risk. EtO sterilization of masks and other personal protective equipment is not necessary because of the current pandemic. In fact, mask manufacturers and government agencies recommend NOT using EtO to sterilize masks. Alternatives to EtO for most medical sterilization needs already exist. Federal, State, and Local agencies should act aggressively to require elimination of EtO emissions and transition to available safer alternatives for medical sterilization. Proposals to expand EtO sterilization to masks should be rejected. Any proposals to re-open EtO sterilization facilities or increase operations in response to the pandemic should only be approved when independently documented to be immediately necessary for critical medical equipment that cannot be sterilized through other means, and should be ended as soon as possible.

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KEY TALKING POINTS

- Ethylene Oxide (EtO) is known to cause cancer, and it is widely used to sterilize medical equipment. The operations of our healthcare system should not be increasing cancer risk.
- Safer alternatives to EtO exist for most sterilization needs. Over the past several years, community pressure and government actions have led to the closure of EtO sterilization facilities, without causing a shortage in sterilized medical equipment.
- Now, in response to the pandemic, shuttered EtO sterilization facilities are re-opening, and existing facilities are attempting to increase operations by expanding the products they are allowed to sterilize to include N95 respirator masks. The CDC, OSHA, and 3M (the manufacturer of the masks) all have advised against this.
- We need safe and sterile medical equipment to combat the COVID-19 pandemic, but we can't trade one public health crisis for another. The healthcare system should utilize existing safer methods of sterilization that don't put communities at risk.
- Federal, State, and Local agencies should aggressively work to eliminate EtO emissions and require transition to safer alternatives. Any proposals to re-open EtO sterilization facilities or increase operations in response to the pandemic should only be approved when independently documented to be immediately necessary for critical medical equipment that cannot be sterilized through other means, and should be ended as soon as possible.