Public Comment Guide: Tell EPA to Strengthen Regulations for Sterilization Facilities that Emit Cancer-Causing Ethylene Oxide

On April 11, 2023, the Environmental Protection Agency (EPA) issued a proposed rule that strengthens emissions standards for commercial sterilization facilities that emit ethylene oxide (EtO), a colorless, cancer-causing gas. These facilities use EtO to sterilize medical equipment and some dried food products. Updated standards are nearly a decade overdue, even though EPA determined in 2016 that breathing EtO over a long period of time can increase your risk of developing certain types of cancer. While the proposal is a necessary step forward to protect public health, it could go further to limit toxic emissions and ensure that communities are adequately informed about the hazards.

Written comments must be submitted to the regulatory docket by June 12.

How to Submit a Comment
Go to the public comment page on Regulations.gov for the proposed policy (docket EPA-HQ-OAR-2019-0178-0154). Make sure all documents contain your name and contact information. Be sure to submit your comment by June 12, 2023, at 11:59 PM ET and check your email for a confirmation. While a submission can be typed directly into the website, uploading a separate document may be easier for you to edit, save, and submit.

Tips for Writing a Comment
The most effective comments are thorough, unique, and specific. If you are a scientist, technical expert, community member that lives near or works in a commercial sterilization facility, work in the healthcare/medical sector, and/or are a member of another impacted group, indicate this in the comment. The public comment process allows the public to help agencies understand the full range of consequences of a proposed rule. Arguments made during this process can also be used as evidence for any future court challenge.

Below is a summary of key points in the rule and the arguments UCS and allies have identified. You can use these talking points to build your argument – see the sections in red for more detail on what to comment on. You do not need to cover every category, pick one or two to focus on.

Some additional best practices:

- **Read** the background of the rule (see also EPA’s factsheet) as well as the summary of proposed changes to understand the context of the agency’s current proposal.
- Write concisely but provide the relevant details.
- Lay out and provide evidence for the facts the agency has ignored or overlooked.
- Describe the personal impact of the proposed rule, including how it will affect public and worker health and safety.
- Address potential negative impacts, flaws in EPA’s justifications for its proposals in the rule, overlooked impacts, and intended or unintended consequences, and when available, attach key studies and research so they are on the record.
- Address the benefits to public and worker health and safety provided by EPA’s proposed rule and point out where it falls short.
- It is not sufficient to simply disagree with the agency’s policy judgments. Explain why you disagree.
Summary

Ethylene oxide (EtO) is a colorless gaseous chemical that is used in a number of industrial processes, including to manufacture certain chemicals, and to sterilize medical equipment and some dried herbs and spices. Roughly half of all sterile medical equipment in the United States is sterilized with EtO. EtO is emitted as an air pollutant by the facilities that use it.

EtO also causes cancer (it is a carcinogen). Studies show that breathing EtO over a long period of time is associated with increased risk of developing white blood cell cancers like non-Hodgkin lymphoma and lymphocytic leukemia, as well as breast cancer in women. Children are especially susceptible to the effects of EtO because it is mutagenic, meaning it can damage a cell’s DNA. Since children’s cells divide more rapidly than adults’ as they grow, they are more susceptible to harm from exposure to mutagens.

Under the federal Clean Air Act, EtO is regulated as a hazardous air pollutant. The EPA is required to establish emissions standards for such pollutants, called National Emissions Standards for Hazardous Air Pollutants (NESHAPs). These emissions are regulated by their industrial sources or processes, known as “source categories.” Facilities that use EtO for sterilization of medical devices and spices are known as commercial sterilizers. Unlike large chemical manufacturing facilities, commercial sterilizers are usually in nondescript warehouses and do not have large smokestacks. Many are in or adjacent to residential areas, and oftentimes people are unaware that a facility emitting a cancer-causing gas is operating in their community. It should also be noted that commercial sterilizers are just one of several types of facilities that emit EtO.

EPA first set emissions standards for commercial sterilization facilities in 1994, and last updated them in 2006. Under the Clean Air Act, EPA is supposed to update NESHAPs every eight years. Here, EPA was required to update EtO standards and controls for commercial sterilization facilities in 2014. But this did not happen. Even more, in 2016, EPA completed an updated risk assessment for EtO and determined that it is a carcinogen. In its assessment, EPA determined that EtO was up to 60 times more toxic than previously understood. Yet still, the standards were not updated to account for these risks.

At the same time, some communities near commercial sterilization facilities became aware that they were being exposed to a very toxic chemical. In Illinois, Georgia, and Texas, for example, advocates began asking questions, calling for accountability, and advocating for commercial sterilizers to be monitored, and in some cases, shut down. In 2020, the EPA’s Office of the Inspector General (OIG) called out the agency for failing to notify communities about the risks of exposure to EtO. And then in 2021, the OIG published a report urging EPA to update risk reviews and NESHAPs for facilities that emit EtO.

In an effort to expand public awareness, in 2022, EPA published a list of commercial sterilization facilities that were emitting EtO at levels that exceed the agency’s “acceptable” risk threshold of 100 additional cancer cases per one million people. While EPA held meetings in some of these communities, many people are still unaware of the risks.

In early 2023, UCS published a report and interactive map identifying where commercial sterilizers are located in the U.S. and Puerto Rico and who may be most at risk of exposure to EtO from these facilities. The UCS analysis found that:

- Nearly 14 million people live within five miles from a commercial sterilization facility. There are nearly 10,000 schools and childcare centers in this area. All of them may not be exposed to
hazardous levels of EtO, but without adequate monitoring and emissions reporting, it remains unclear.

- Cancer risks from toxic air pollutants are nearly three times greater in census tracts with a commercial sterilization facility compared to the US average.
- In 12 metro areas, there are hotspots of EtO with two or more commercial sterilizers located less than 10 miles apart. People who live, work, or attend school in these areas may be exposed to EtO from more than one sterilization facility.
- The proportion of people of color, people with low income, and people who do not speak English as a first language is greater within five miles of these facilities compared to US averages. Spanish speakers are especially impacted, and there are a disproportionate number of higher risk facilities in Puerto Rico.

Now, nearly a decade after these rules were supposed to be updated—with pressure from community organizing and a lawsuit—the EPA finally published a proposed rule and updated residual risk assessment. The proposed standards require stricter controls, cover previously unregulated emissions sources, and affirm EPA's use of the 2016 EtO risk assessment. According to EPA, if implemented, the rule will result in an 80 percent reduction in EtO emissions from commercial sterilization facilities.

While the proposal is a positive step forward, there are also major gaps that need to be addressed. For example, the proposal does not adequately account for public health risks, it does not require fenceline monitoring, and it does not cover off-site warehouses that are a source of EtO emissions. As described below, EPA must adopt the strongest possible rule to protect the public from cancer-causing EtO emissions, and alleviate the disproportionate harm to communities of color, lower income communities, and non-English speaking communities.

Below are specific points to focus on in your comment—remember you do not have to cover everything; we suggest you focus on one or two areas.

I. EPA must finalize emissions standards and continue relying on the best available science

The proposed rule strengthens ethylene oxide standards by requiring emissions reductions across various processes and equipment in a sterilizer facility, including sterilization and chamber exhaust vents. The rule also covers, for the first time, “room air emissions,” which includes emissions from EtO storage and handling and sterilized material (categorized as Group 1 and Group 2 emissions). For most of these emissions standards, but not all, EPA selected the more stringent and protective requirement, citing the public health benefits. EPA should finalize the proposed standards and, for all emissions sources, use the most health-protective standard possible.

The rule’s proposed emissions standards were developed using the EPA’s Integrated Risk Information System (IRIS) 2016 assessment of the risks related to inhaling EtO. This risk assessment determined that EtO is a carcinogen and up to 60 times more toxic than previously understood. This risk assessment is the latest and best available science on the cancer-related effects of EtO exposure. In recent years, the chemical industry has attempted to sow doubt about the scientific strength of the assessment and has tried to weaken the cancer risk value to evade stronger emissions controls. Despite these efforts, EPA recently affirmed that it will continue to rely on this risk assessment. Nevertheless, industry continues to push back on EPA’s use of the 2016 IRIS assessment, thus commenters should convey support for the agency’s use of the best available science on the cancer-causing risks of EtO exposure.
II. EPA is underestimating public health risks and must account for cumulative impacts

For the proposal, EPA conducted a “residual risk assessment”—an assessment of “additional” risk beyond what is deemed “acceptable”—for EtO emissions from commercial sterilizers. The assessment estimates ambient air concentrations, accounts for exposure, and estimates potential human health risks from these exposures. There are assumptions and decisions made in every risk assessment that may result in an under- or over-estimation of risks to human health. In EPA’s residual risk assessment, the agency failed to account for cumulative impacts—the fact that people are not exposed to one chemical at a time, and may face other environmental burdens, as well as social stressors that can amplify harms from pollution exposure.

EPA made several decisions in conducting the residual risk assessment that likely underestimate the risks. First, EPA chose to use actual reported emissions rather than allowable emissions—the maximum amount the facilities are allowed to emit—in assessing risks. EPA explains that since the actual emissions result in unacceptable risks, their use is justified. This is not an appropriate justification since the risks after the rule is implemented would be higher if based on allowable emissions. Second, the risks may be underestimated since they are not based on modeled concentrations in residential areas just beyond the fenceline of the facilities, and rather reflect the risks in the center of census tracts. The census tract center could be located a significant distance from the maximum air concentration and therefore could underestimate air concentrations. Basing a risk assessment on modeled concentrations in a residential area at the fenceline of the facilities better protects frontline communities.

The rule also discusses the potential for other carcinogenic hazardous air pollutant (HAP) exposures and EPA states that there is a low probability of a significant contribution from the other carcinogenic HAPs at commercial sterilizers. The EPA further explains that including other carcinogenic HAPs to inform this rule would incorporate too much uncertainty. This is unfortunate and will underestimate risk. Commenters should urge EPA to base the proposed limits in the rule using a multiple chemical approach centered on emissions of carcinogenic HAPs, since carcinogenic risk is the driver in this assessment.

Another component of cumulative risk assessment would be to include nearby facilities, which EPA explains away in the following sentence, “that analysis determined that the vast majority of sterilization facilities are not located nearby other significant sources of HAP as most are isolated or located within office parks.” A “vast majority” is not an adequate explanation for not considering nearby facilities that emit EtO and other carcinogenic HAPs. Commenters should urge EPA to be inclusive of nearby emissions of EtO and other carcinogenic HAPs in the residual risk assessment.

[Commenters should urge EPA to consider all toxic and cancer-causing air emissions – including other EtO emissions sources – from sterilizers and other nearby sources in setting these standards. Commenters should also urge EPA to apply existing environmental justice screening tools, such as the White House Climate and Economic Screening Tool and the Centers for Disease Control and]
Prevention’s Environmental Justice Index, to prioritize and set strict standards for facilities in already overburdened and disadvantaged areas.]

III. EPA must require fenceline monitoring and compliance through continuous emissions monitoring systems

Air monitoring is an important tool to ensure that facilities are complying with required emissions standards and operational limits and public and worker health is protected. The proposal considers enhanced monitoring requirements, including whether to require facilities to demonstrate compliance through an annual compliance demonstration or through continuous emissions monitoring systems (CEMS). Unlike an annual demonstration, CEMS involve continuous monitoring of a pollutant emitted by the facility on a time interval (such as every 15 minutes) to ensure that the facility is complying with emissions limits and operational requirements over short and longer time frames. Facilities would also be required to submit CEMS data to EPA to confirm compliance with hourly emission rate limits. This option is preferred over annual demonstrations, which only happen once a year and do not capture higher short-term emissions events. Commenters should urge EPA to require all facilities to demonstrate compliance through CEMS and to make these data available to the public, and no longer allow facilities to show compliance through annual demonstrations.

The proposal also falls short in not requiring all commercial sterilization facilities to install fenceline monitors—air monitors that are installed near the property line of a facility to measure concentrations that reflect community-level exposures. Fenceline monitoring can also indicate if there are fugitive or uncontrolled emissions. EPA’s failure to require fenceline monitoring is concerning, particularly given that the agency acknowledges in the rule that there were “a substantial number of comments from front-line communities supporting the use of fenceline measurements to address potential room air emissions from Commercial Sterilization Facilities.”

In the proposal, the agency states that the proposed emissions standards and monitoring requirements are sufficient to ensure uncontrolled emissions are captured. However, evidence suggests that the proposed standards alone are not enough. For example, fenceline monitors were installed near a Sterigenics commercial sterilization facility in Ontario, California. The facility is a little over a mile from a residential area and school. In 2022, the facility installed a permanent total enclosure of its sterilization operations, similar to what EPA will require facilities to install in this rule. This system should have decreased emissions to safe levels. And while emissions did decrease, they still exceeded California’s public health thresholds. As a result of the fenceline monitoring data and an enforceable action level, the South Coast Air Quality Monitoring District was able to pursue corrective action, such as issuing notices of violation, initiate an investigation of facility operations, and require a plan of action. Fenceline monitoring saves lives, and EPA should require all commercial sterilization facilities to install fenceline monitors with real-time data made available to the public. EPA should also establish an enforceable action level for emissions at CEMS and fenceline monitors that triggers corrective action if exceeded.

[Commenters should urge EPA to require all commercial sterilization facilities to demonstrate compliance through continuous emissions monitoring systems (CEMS). Commenters should also urge EPA to require all facilities to install fenceline monitors and set a protective “action level” for both CEMS and fenceline monitors which, if exceeded, will trigger corrective action. CEMS and fenceline
monitoring data should also be made available to the public. Finally, commenters should urge that the initial compliance demonstration be required sooner than the currently proposed 180-day timeframe. The EPA should take this step to more rapidly reduce community members’ exposure to EtO. If you live in a community with a commercial sterilizer, talk about the people and places that are near these facilities and why it is important to have public access to air monitoring data.

**IV. EPA should expand coverage of the rule to include off-site warehouses**

The proposal expands coverage of the rule to EtO emissions across a commercial sterilization facility, including from warehouses or storage areas on the facility property. EPA’s decision to expand coverage of the rule is a necessary step forward and commenters should urge the agency to finalize proposals to regulate all EtO emissions sources in a commercial sterilization facility.

The proposal, however, does not cover off-site warehouses or other storage areas operated by a third party. As EPA acknowledges in the rule, newly sterilized equipment can continue to off-gas, or emit, residual EtO for hours or even days. Most commercial sterilization facilities transport newly sterilized medical equipment to off-site warehouses, where they are stored until they are ready to be distributed for use. Most of these warehouses are not regulated under the Clean Air Act at all, and EPA has indicated that it does not know where most of them are. Even though EPA requested information on off-site warehouses in an Information Collection Request, few facilities fully answered the question and many either left it black or only indicated that they send products to a warehouse but did not provide additional information.

Yet, evidence suggests that off-site storage warehouses can generate significant hazardous EtO emissions. For example, in 2019, the Georgia Environment Protection Division issued a notice of violation to Becon, Dickinson, and Company, a medical sterilization company, for operating an off-site warehouse in Covington without an air quality permit. The facility was generating more than 5,000 pounds of uncontrolled EtO emissions per year. In effect, these warehouses are serving as “secondary off-gassing rooms” without any of the same controls required for on-site storage at sterilization facilities. Commenters should urge EPA to expand the rule to cover off-site warehouses used to store sterilized equipment and require emissions controls and monitoring to ensure workers and nearby communities are not exposed to hazardous, uncontrolled EtO emissions.

[Commenters should urge EPA to finalize the proposal to cover all facility emissions sources, including on-site warehouses, and expand coverage to all off-site warehouses, including those operated by a third party. Off-site warehouses act as “secondary off-gassing rooms” and should be required to monitor and limit emissions of EtO.]

**V. EPA must enhance enforcement and remove reporting loopholes**

The proposal strengthens enforcement and compliance requirements by, for the first time, requiring all facilities to obtain a Title V permit under the Clean Air Act. Title V permits are overseen by EPA and provide for greater reporting, transparency, and enforcement. Under Title V, there are also more opportunities for public engagement in facility permitting and enforcement processes. Currently, some of the largest users of EtO are not required to seek a Title V permit, even though they pose a significant
risk to surrounding communities. Commenters should urge EPA to finalize the proposal to require all commercial sterilization facilities to seek Title V permits.

The draft rule also proposes to eliminate the exemption for compliance during startup, shutdown, and malfunction (SSM) events. Currently, when commercial sterilization facilities experience a malfunction—for example, if equipment breaks or monitors stop operating—there is a loophole that allows facilities to evade compliance and reporting. Furthermore, as EPA acknowledges in the proposal, startups and shutdowns are routine and planned, so should not be exempt from emissions standards. In essence, the SSM loophole is a free pass to pollute, with instances of large concentrations of a toxic chemical released at one time without consequence. As EPA states in the proposal, removing this exemption is also consistent with a 2008 court decision that held that the SSM loophole is illegal under the Clean Air Act. Commenters should support EPA’s proposal to remove the SSM loophole.

[Commenters should urge EPA to finalize proposals to require all commercial sterilization facilities to obtain a Title V permit, which will expand opportunities for public input and enforcement under the rule. Commenters should also urge EPA to remove the illegal SSM exemption, which endangers the health of workers and frontline communities.]

VI. EPA must expedite compliance with the rule and proactively communicate the public health risks to affected communities

EPA is proposing to require commercial sterilization facilities to comply with the rule within 18 months of publication of the final rule. Right now, EPA estimates that the final rule will likely not be finalized in 2023, which means that it is possible that facilities may not be required to comply with the new regulations until 2025. This is unacceptable, as EPA has known since at least 2016 that EtO is a potent carcinogen. The agency is also nearly a decade overdue in updating these standards, as required under the Clean Air Act. Communities, especially those already overburdened by pollution and social stressors, should not continue to be subject to toxic emissions of EtO. In accordance with the Biden Administration’s commitments to environmental justice, EPA should require compliance with the final rule faster than 18 months. The agency has the authority to require compliance sooner and should do so to ensure safer air for the people who live, work, pray, and play near commercial sterilization facilities.

EPA must also adequately communicate the risks of EtO exposure to communities near commercial sterilization facilities. A 2020 alert issued by the EPA’s Office of the Inspector General pointed out the agency’s failure to inform residents near facilities that emit EtO about the risks to their health. While the agency did hold several community meetings in areas with higher risk facilities in 2022, engagement cannot stop there. Many commercial sterilization facilities are in or adjacent to residential areas and many community members remain unaware that they live or work near a facility that emits a cancer-causing gas. EPA must continue working with regional offices and state agencies to host meetings and conduct outreach to communities with higher risk facilities, as well as communities overburdened by hazardous air pollutant emissions. Furthermore, EPA should follow-up with the communities with higher risk facilities to communicate how the rule will impact emissions at the facilities and what will happen if the facilities fail to meet these standards. Finally, given the concentration of commercial sterilization facilities in Puerto Rico and Latine communities in the United States, this information must be available in Spanish, and other community-appropriate languages.
Commenters should remind EPA that they are nearly a decade overdue on updating EtO standards for commercial sterilization facilities and urge the agency to require compliance with the rule sooner than 18 months. The shortest possible timeline is needed to ensure that communities near commercial sterilization facilities are no longer exposed to harmful levels of EtO. Commenters should also urge EPA to proactively engage with affected communities about the risks of EtO exposure, and how the new rule will affect facilities in their communities, particularly those already overburdened by hazardous air pollutant emissions. This information must be available in Spanish and other languages appropriate to affected communities.

VII. EPA must determine whether 11 research facilities are covered by the rule

The proposal covers 86 commercial sterilization facilities but identifies 11 additional research and development facilities that may or may not be covered by the rule. EPA is determining whether these facilities will be covered by the commercial sterilization rule, or whether the agency will need to develop another category of EtO emissions standards for research facilities. While research and development facilities in general emit less EtO than commercial sterilization facilities, they should still be required to control and monitor their emissions.

This process highlights the unnecessarily cumbersome nature of EPA’s facility-by-facility approach to regulating hazardous air pollutants. Adding an additional set of standards is burdensome for communities affected by EtO emissions and further delays stricter emissions controls that are overdue at these facilities.

[Commenters should urge EPA to clarify whether the 11 research and development facilities are covered by this rule, and if not, EPA must promptly develop regulations that require emissions controls at these facilities.]

VIII. EPA must eventually phase out the use of ethylene oxide for sterilization

While these proposals are necessary to reduce immediate hazards to workers and communities near commercial sterilization facilities, EtO is still a potent carcinogen. EPA estimates that under the proposal, no community will be exposed to cancer risks above the agency’s threshold of 100 cases per one million, but this estimate does not consider the cumulative impacts of exposure to various toxic air pollutants and social stressors that can exacerbate poor health outcomes. Under the proposal, some communities (especially Black and Latine communities) will still face above-average cancer risks from exposure to toxic air pollutants. In addition to requiring emissions reductions, EPA must also phase out the use of EtO as much as safely possible. It is possible to sterilize spices and other dried food products without the use of EtO, and safer alternatives for medical sterilization exist.

Medical sterilization is also regulated by the US Food and Drug Administration (FDA), which is currently implementing two innovation challenges to identify alternative sterilization methods to EtO. EPA is unlikely to ban the use of EtO for medical sterilization without FDA approving additional sterilization alternatives. The EPA and FDA must work together to approve safer alternatives, such as hydrogen peroxide, and phase out the use of EtO where it is safe to do so.
Commenters should urge EPA to work with FDA to ban the use of EtO for sterilization of dried food products, identify and approve safer alternatives for medical sterilization, and restrict the use of EtO to only those uses where there are no viable alternatives. Commenters should remind the EPA that the agency’s threshold for “acceptable risk” is too high, particularly given the disparities in EtO exposure from commercial sterilization.

Additional Resources

- An interactive map in English and Spanish with locations of sterilization facilities and information about the impacted communities.
- An explainer blog about what ethylene oxide is and how it is regulated.
- The 2021 report by the EPA Office of the Inspector General calling on the agency to conduct new risk reviews for source categories that emit ethylene oxide.
- The 2022 lawsuit filed by Earthjustice for EPA’s failure to update regulations for commercial sterilization facilities for nearly a decade.

Once you’ve submitted a comment, please let us know by filling out this form. And please let us know if and how this guide has been useful.