

# Op-ed: What Laredo needs to know about ethylene oxide



TERRY CHANG, J.D., M.D. | SEPTEMBER 18, 2022

On Thursday, the U.S. Environmental Protection Agency (EPA) held a public meeting in Laredo to discuss new regulations to be issued around the use of ethylene oxide (EO), a naturally occurring chemical used to sterilize medical devices.

Many questions were asked and answered. But three specific questions fundamental to public understanding merit closer attention. Answers to these questions may not only help clarify a complicated issue, but also could help people form their own opinions. The questions are: Why are we talking about EO now? Why does society use EO? Is EO safe?

## Why are we talking about EO now?

Though it has been used for more than 80 years to sterilize medical devices, EO is in the news because of a decision made by the EPA in December 2016. As part of that decision, the EPA increased EO's hypothetical cancer risk estimate by 30 times. Crucially, this change was based not on new scientific evidence, but through new mathematical modeling. In other words, the EPA changed EO cancer risk through new math, not new science.

There is some value to over-estimating hypothetical cancer risk out of an abundance of caution when establishing regulation. But, to put this particular risk over-estimate into perspective, according to the EPA, someone would need to breathe in EO 24 hours on every day, every year for 70 years continuously, an extremely unlikely scenario.

There also has been considerable debate about risk over-estimation even in the regulatory community. The Texas Commission on Environmental Quality (TCEQ) researched the same issues extensively and disagreed with EPA's estimate. Without question, this is a complex issue with many sides that are not easily understood. But an honest public dialogue about EO is possible only when all facts are addressed openly, not just ones favorable to one group.

## Why does society use EO?

Devices necessary for open-heart surgeries, C-sections, hip replacements, knee replacements, dialysis treatment, among many other procedures, are sterilized with EO before they are used with patients. As a result, patients are better protected against harmful infections that lead to longer hospital stays, injury, and/or death.

While there are other sterilization methods, including gamma radiation and steam, EO is the only Food and Drug Administration (FDA)-approved, scientifically proven sterilization method that does not damage the physical integrity of a wide range of medical devices.

EO's ability to preserve the physical integrity of medical devices/instruments explains why more than half of all medical devices sold in the United States – more than 20 billion – are sterilized with EO. EO is regulated by several agencies, including the FDA, which recognizes the substantial public health benefit of EO. Because of its effectiveness, and due to the lack of alternatives, EO remains an essential sterilization method that ultimately helps keep patients safe whenever they receive care from a healthcare professional.

EO's ability to preserve the physical integrity of medical devices/instruments explains why more than half of all medical devices sold in the United States – more than 20 billion – are sterilized with EO. EO is regulated by several agencies, including the FDA, which recognizes the substantial public health benefit of EO. Because of its effectiveness, and due to the lack of alternatives, EO remains an essential sterilization method that ultimately helps keep patients safe whenever they receive care from a healthcare professional.

## Is EO safe?

Put simply, EO is safe for sterilization use because it is heavily regulated by federal and state rules, which substantially restrict EO emissions. Many commercial sterilizers not only meet already comprehensive emissions rules, but exceed them. In Laredo, Midwest voluntarily captures and eliminates 99.9% of all combined EO emissions annually, surpassing Clean Air Act requirements. Even when new rules are established, Midwest will continue to proactively look to further reduce its combined EO emissions—just as it has already.

But even if there were no commercial sterilizer industry, EO would continue to be in the air at concentrations higher than the EPA's own risk estimate. That's because EO is emitted by natural sources, like ripening fruit and decaying plants, and short-term emitters, including charcoal grills, lawnmowers, and SUVs.

EO also is emitted by semi-trailer trucks like those traveling to and from Mexico and elsewhere. Consistent with data of the Centers for Disease Control and Prevention (CDC), tobacco smoke is identified as the single largest source of EO exposure to the general population.

The key difference is that these everyday EO sources are not subject to the same extensive regulatory requirements to which commercial sterilizers are bound. Moreover, unlike the everyday EO sources, the commercial sterilizer emissions have been and will continue to trend downward.

Looking ahead, the answer is not pitting millions of patients who depend on sterilized medical devices against community members who rightly expect and deserve to breathe clean air. Nor is it banning the use of EO, as activists call for, which would lead to commercial sterilizers closing their doors and lead to medical device scarcity. Closures, according to the FDA, "will be difficult to reverse, and ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care."

The answer is to ensure continued EO regulatory compliance and to preserve access to sterilized medical devices that benefit millions of people annually. Getting this answer right not only means safer healthcare for patients and clean air for residents, but peace of mind for all.

**Terry Chang, M.D., J.D., is the Vice President, Assistant General Counsel, and Director, Legal & Medical Affairs of the Advanced Medical Technology Association (AdvaMed).**



Originally published, subscription only: [t.ly/1TF6](https://t.ly/1TF6)