



## NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION

## FACT SHEET Ethylene Oxide (EtO) Air Emissions from Commercial Sterilizers

### SUMMARY

On August 3, 2022, the United States Environmental Protection Agency (USEPA) [announced the results](#) of air quality simulation modeling that identified potential health risks from long-term exposure to ethylene oxide (EtO) emissions from commercial sterilization facilities across the United States, including two New Jersey facilities located in Linden, Union County and Hardyston, Sussex County (the facility located in Hardyston is referred to as being in neighboring Franklin Borough in USEPA information). USEPA has indicated that exposure to certain levels of EtO over many years could increase one's lifetime cancer risk. However, based on current projections, USEPA does not expect EtO levels in outdoor (ambient) air in the vicinity of the identified facilities to be high enough to cause acute (immediate) non-cancer health impacts.

The New Jersey Department of Environmental Protection (NJDEP) is the state government agency responsible for protecting public health and the environment from potentially adverse effects of air pollution through regulation and permitting of certain facilities. NJDEP currently regulates the Linden and Hardyston facilities for some, but not all, potential EtO emissions. NJDEP is working with these facilities to identify and address uncontrolled EtO emissions.

On August 10, 2022, USEPA informed NJDEP, that a revised analysis performed for the Hardyston facility [showed a lower impact than previously reported](#) and listed on the USEPA webpage.

### ETHYLENE OXIDE (EtO)

EtO is an organic compound that can exist as a colorless, often odorless gas (at room temperature) or in liquid form. It is frequently used in the production of other chemicals for various industrial applications and is present in common consumer products, including household cleaners, personal care items, and fabrics. A small but important use of EtO is as a sterilizer and fumigant.

EtO is used in the medical field to sterilize devices or instruments that cannot be sterilized using steam or radiation, such as some medical and dental equipment. According to the U.S. Food and Drug Administration, approximately 50 percent of sterile medical devices are treated with EtO, which amounts to approximately 20 billion devices each year. EtO is also used to sterilize some food products, including spices, dried herbs, dried vegetables, sesame seeds, and walnuts.

The Linden facility sterilizes spices, and the Hardyston facility sterilizes medical instruments.

### HEALTH RISKS OF ETHYLENE OXIDE (EtO) EXPOSURE FROM STERILIZER FACILITIES

High concentrations of EtO have been found in the air near some commercial sterilizers in Illinois and Georgia. Actual on-site emissions from the Linden and Hardyston, New Jersey facilities were not measured by USEPA, but potential emissions were projected by USEPA through air quality simulation modeling.

Inhalation of EtO at these levels, over many years, can increase the lifetime risk of getting cancer. However, based on current information, EPA does not expect EtO levels in the outdoor air around facilities that release it to be high enough to cause immediate non-cancer health effects.

## PRESENCE OF ETHYLENE OXIDE IN OUTDOOR (AMBIENT) AIR IN NEW JERSEY

The NJDEP operates thirty air monitoring stations throughout the state to measure the quality of our air. This information is available to the public on [NJDEP's Air Monitoring website](#), which includes maps of the latest data. Four of these monitoring sites measure outdoor concentration of a category of pollutants known as "air toxics," which includes EtO. Exposure to air toxics is a widespread problem that occurs throughout the entire state. These pollutants come from a variety of sources, including traditional industrial and utility sources, smaller manufacturing and commercial sources, mobile sources (such as diesel trucks, cars, and buses), construction equipment and residential activities (such as oil burning for home heating or using gas-powered lawn equipment). New Jersey's specific air toxics monitors are in Camden, Elizabeth, New Brunswick, and Chester.

In 2019, the USEPA began an analysis of ambient air samples collected by NJDEP to detect the presence of EtO, which was found at each of the four air toxics monitoring sites. These data show the presence of EtO in ambient air across the state, even in rural areas away from industrial operations, suggesting that there is a background level of EtO in New Jersey's ambient air. More information is available on [NJDEP's Air Toxics website](#).

## USE OF ETHYLENE OXIDE AT NEW JERSEY FACILITIES

EtO is known to be in use at chemical plants and sterilization facilities in New Jersey. The Hardyston facility sterilizes health related products. The Linden facility sterilizes spices.

**Linden Facility:** In this operation, EtO vapors are used to sterilize spices. Following several washing cycles and off-gassing of the product, emissions are routed to a scrubber pollution control system, which accounts for a 99% emission reduction. However, residual emissions are not captured by this pollution control system. These "fugitive" emissions occur from EtO dispensing, vacuum pump operation, sterilization room residuals and following aeration as material continues to off-gas prior to shipping. These fugitive emissions may exit the facility through doors, windows, and vents.

**Hardyston Facility:** In this operation, medical products are loaded into a sterilization chamber where EtO is applied. After sterilization is complete, the product is then transferred to an aeration cell, where EtO continues to off-gas. Emissions from both the sterilization and the aeration cell are routed to a catalytic oxidizer pollution control system, which accounts for a 99% emission reduction. Once aeration is complete, the product is transferred to the shipping warehouse. However, residual emissions are not captured by this pollution control system. These "fugitive" emissions occur from EtO dispensing, sterilization rooms residuals and following aeration as material continues to off-gas prior to shipping. Recent USEPA analysis indicates fugitive emissions from the Hardyston facility were lower than initially estimated and are being released in a manner that reduces impacts to the community.

## REGULATION & CONTROL OF AIR EMISSIONS OF ETHYLENE OXIDE

The USEPA conducted a health effects assessment of exposure to EtO in 1985 and the United States Congress designated this chemical as a hazardous air pollutant in the 1990 amendments to the Clean Air Act. Analysis of health effects of hazardous air pollutants are updated regularly by USEPA, most recently in 2016, when USEPA update the health benchmarks for EtO.

Emissions of air pollutants, including EtO, from regulated equipment are evaluated by NJDEP and

required to be controlled by air quality permits, often using air pollution control technology. However, “fugitive” emissions that are not generated by the equipment that is regulated under existing laws are often not subject to the same permitting and control requirements. The USEPA analyzed these currently unregulated fugitive emissions in concluding that long-term exposure to EtO emissions from the Linden and Hardyston sterilization facilities present a cancer risk.

### USEPA ANALYSIS OF EtO EXPOSURE RISK FROM COMMERCIAL STERILIZERS

During the past four years, USEPA conducted analyses to identify facilities that may pose increased cancer risks from EtO emissions. Using a published cancer unit risk factor and facility specific operation information submitted by the facilities, USEPA developed emission factors and conducted air quality simulation modeling for each EtO facility in the US. USEPA sought to identify those facilities projected to exceed a benchmark EtO level associated with greater than 100 in 1 million (1 in 10,000) incremental increase in cancer risk, i.e., where 100 out of 1 million (1 in 10,000) people exposed to such levels continuously for a period of 70 years could develop cancer. Importantly, the USEPA analysis was based on predictions of air quality simulation modeling and not the direct measurement of outdoor ambient air at the identified sites or the immediate vicinity. To best protect human health and the environment, these estimates are necessarily conservative, which means that they tend to overestimate rather than underestimate air pollution levels. Further analysis may be necessary to quantify detailed site-specific risks from the Hardyston and Linden facilities. USEPA revised analysis indicates that the Hardyston facility cancer risk has been reduced due to more accurate estimates of fugitive emissions and their release into the atmosphere.

### PROTECTING NEW JERSEY COMMUNITIES THROUGH IMPROVED EtO CONTROLS

Although the sterilization processes at the Linden and Hardyston facilities are equipped with state-of-the-art air pollution controls, these facilities continue to emit uncontrolled fugitive emissions of EtO from off-gassing of treated products or other uncaptured sources. Discussions between the facilities, USEPA and NJDEP have been initiated to identify options to address fugitive emissions from these facilities and to reduce or eliminate uncaptured and controlled emissions. Capturing these fugitive emissions where possible and directing them through state-of-the-art air pollution controls should reduce potential impacts to ambient air and the host communities. USEPA is drafting revisions to the existing air pollution regulations that will require facilities to reduce or eliminate uncaptured emissions and will be seeking comments from the public and other stakeholders in early 2023. NJDEP continues to recommend reduction or elimination of uncaptured emissions and will be reviewing USEPA's rule proposal to ensure emissions from New Jersey facilities will be adequately reduced for the protection of public health.

NJDEP will update the host communities as we receive additional information and these efforts advance.

### ADDITIONAL RESOURCES

What's In My Community?

[njdep.maps.arcgis.com/apps/webappviewer/](https://njdep.maps.arcgis.com/apps/webappviewer/)

Air Quality Monitoring

[njdep.maps.arcgis.com/apps/webappviewer/](https://njdep.maps.arcgis.com/apps/webappviewer/)

Air Toxics in New Jersey

[dep.nj.gov/airplanning/airtoxics/](https://dep.nj.gov/airplanning/airtoxics/)

Ethylene Oxide

[dep.nj.gov/airplanning/airtoxics/2002-2014-pollutants-of-concern-additional-information/#ethyleneoxide](https://dep.nj.gov/airplanning/airtoxics/2002-2014-pollutants-of-concern-additional-information/#ethyleneoxide)

USEPA Information on Ethylene Oxide Risk from Commercial Sterilizers

<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/ethylene-oxide-risk-commercial-sterilizers>