



CENTER FOR TRUTH IN SCIENCE

Seeking integrity in the pursuit of scientific knowledge.

Ethylene Oxide Issue Primer

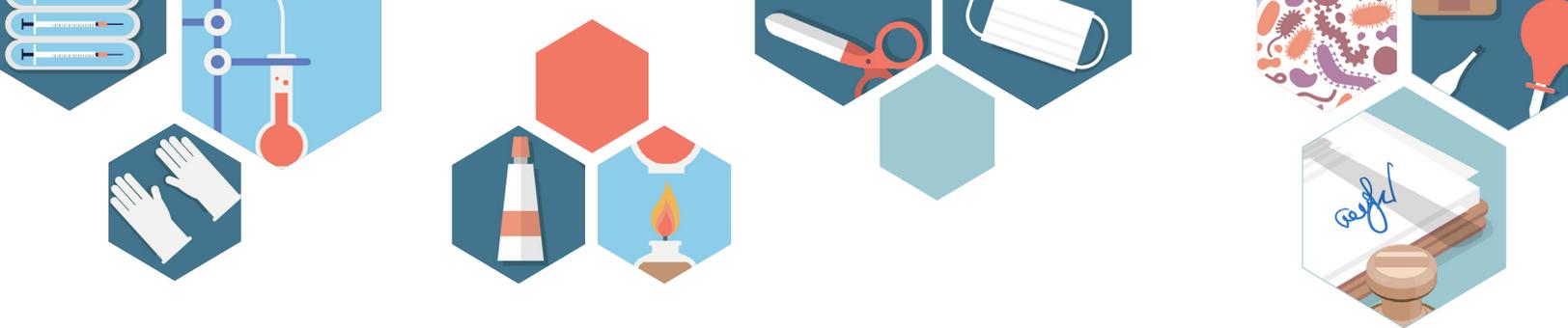
Overview

Ethylene oxide is a flammable gas with a somewhat sweet odor that has been used in many industries for over a century, including as an ingredient of ethylene glycol used in antifreeze and polyester. It is also used in the sterilization of personal protective equipment and other medical equipment, up to 20 billion medical devices each year. In fact, approximately 50 percent of medical supplies in the United States are sterilized by ethylene oxide annually, making it necessary for the protection of frontline health care workers.

Ethylene oxide has been studied and monitored by agencies and regulators globally since the 1920s and has regularly been found non-toxic or not harmful to humans. Despite these consistent findings, concerns arose in the mid-2000s regarding a possible link between ethylene oxide and damage to the respiratory and nervous systems including cancer, resulting in hundreds of class action lawsuits and the closure of some businesses that utilize ethylene oxide in their products.

Fast facts

- Ethylene oxide, or EtO, is a flammable gas with a sweet odor that has been used in many industries for over a century, including as an ingredient of ethylene glycol used in antifreeze and polyester.
- Approximately [50% of medical supplies](#) in the United States are sterilized by EtO annually, making it necessary for the protection of frontline health care workers.
- Ethylene oxide has been extensively investigated for toxicity and carcinogenicity for decades.
- While certainly poisonous, there is no definitive research showing EtO is carcinogenic at any level of exposure likely to be encountered in household, medical or industrial production environments.
- Despite these consistent findings, concerns arose in the mid-2000s regarding a possible link between ethylene oxide and damage to the respiratory and nervous systems including cancer, resulting in hundreds of class action lawsuits and the closure of some businesses that utilize ethylene oxide in their products.
- New EPA rules finalized in 2020 are expected to [reduce emissions](#) of EtO by approximately 0.76 tons per year.



Timeline

1859: Ethylene oxide first discovered by French chemist Charles-Adolphe Wurtz.

1930s-1940s: Ethylene oxide first used to fumigate hospital rooms and equipment, and as an insecticide in food stores.

1948: First study supporting the hypothesis that EtO is carcinogenic appears.

1955: Air Pollution Control Act passed, authorizing the U.S. Surgeon General to conduct research “relating to air pollution and the prevention and abatement thereof,” but made no provisions for the federal government to actively enforce regulations.

1963: Congress passes the Clean Air Act—reducing air pollution by setting emissions standards for stationary sources such as power plants and steel mills.

1965, 1966, 1967, 1969: Congress passes additional amendments to the Clean Air Act.

1970: Environmental Protection Agency (EPA) founded. The EPA regulates EtO emissions under this act and subsequent amendments.

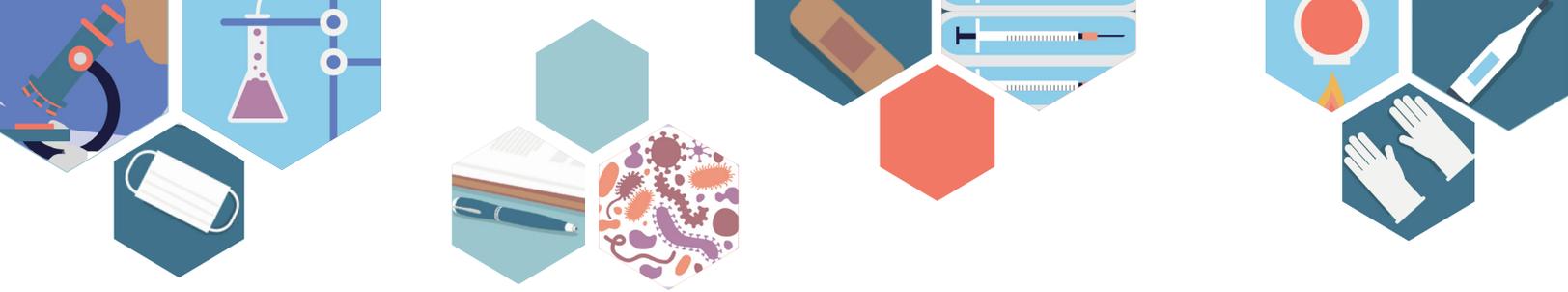
1982: The Ethylene Oxide Industry Council (EOIC) is formed by manufacturers to evaluate the results of an animal study that is expected to affect Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) regulatory decisions on ethylene oxide.

1986: The Ethylene Glycol Panel is formed to augment the ethylene glycol (EG) toxicological database. It performs testing focusing on developmental toxicity, renal effects and pharmacokinetics in animals and humans. The panel addresses federal, state and international risk assessment initiatives involving ethylene glycol and product stewardship.

2003: The Ethylene Glycol Panel combines with the EOIC to form the Ethylene Oxide/Ethylene Glycols Panel. It focuses on the evaluation and dissemination of information relevant to the safe handling and environmental and health effects arising from use and disposal of ethylene oxide and ethylene glycols.

2019: EPA continuously updates [website](#) with latest studies, reviews, changing guidelines, regulatory information and reports site-specific concentrations of ethylene oxide.





How EtO is regulated in the U.S.

Environmental Protection Agency

Ethylene oxide emissions are governed by the EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) rules, which require installation of control devices to reduce emissions, emissions monitoring, performance testing, site-specific operating parameters, and continued reporting and record-keeping.

Anyone using or producing EtO commercially is required to [obtain permits](#) from the EPA that establish EtO detection limits specific to the given working environment. The EPA regulates EtO emissions in [five different spheres](#): commercial sterilizers, miscellaneous organic chemical manufacturing, hospital EtO sterilizers, polyether polyols production and the synthetic organic chemical manufacturing industry.

Occupational Safety and Health Administration

OSHA's EtO standard requires employers where ethylene oxide is present in the workplace to [monitor employee exposure](#). Employers must also provide appropriate protective gear to employees who may be exposed to ethylene oxide.

Every two weeks, businesses that use EtO test equipment such as sterilizers, pipes, tanks, and fittings to confirm there are no leaks. Portable EtO detection meters are available to check for leaks around equipment such as sterilizers, tanks, fittings, and pipes that contain EtO. If a test sample result is equal to or greater in concentration than a certain "[action level](#)" (0.5 ppm), the employer must start certain required activities such as exposure monitoring and medical surveillance.

The Center's Focus

The Center for Truth in Science seeks to determine if there is conclusive, consistent scientific evidence that demonstrates a link between exposure to ethylene oxide and the development of cancer or other chronic illnesses.

The Center also seeks to examine the potential economic impact of government-imposed limits or bans on the use of ethylene oxide.

