



## **Ethylene Oxide Frequently Asked Questions**

The Ethylene Oxide Panel of the American Chemistry Council (ACC) is comprised of producers of ethylene oxide and is a leading source of product stewardship and regulatory information on this important chemical product.

### **What is ethylene oxide (EO)?**

Ethylene oxide is a versatile and valuable compound that's used to help make countless everyday products. Ethylene oxide is used to make household cleaners and personal care items, create fabrics, and manufacture raw materials into more useful forms. A small but important use of ethylene oxide is the sterilization of medical equipment. It's estimated [that more than 50 percent](#) of all medical devices are sterilized with ethylene oxide.

Learn more about the applications of ethylene oxide [here](#).

### **Where is ethylene oxide produced?**

At the end of 2018, ethylene oxide was being produced in the U.S. at 15 facilities in 11 locations by 9 companies. In the U.S., ethylene oxide is primarily produced in two states: Texas and Louisiana.

### **Is the general population exposed to ethylene oxide?**

Ethylene oxide is present in the environment and is created by various sources, including plants and cooking oils. The human body also creates ethylene oxide. Exposure to ethylene oxide varies across urban, suburban and rural environments.

Ethylene oxide emissions from industrial manufacturing and other applications are strictly regulated under federal and in some cases state and local laws.

### **What is the public health risk of EO?**

Protecting the health and safety of the public is a top priority for the producers and users of ethylene oxide and our industry. Companies that make and work with ethylene oxide are actively investing in research and cutting-edge product stewardship technologies so that they can continue to help protect the health of our communities. They continuously revise and improve industry's safety practices and procedures. As a



result of these actions, industrial ethylene oxide emissions have already fallen nationwide by over 80% since 2002. Moreover, [one comprehensive lifetime exposure](#) study of workers in EO production facilities found no statistically significant excess cancer risk due to EO exposure. A similar result was [recently found in Michigan](#) when the state analyzed the population near a facility that used EO in Grand Rapids.

As an intermediate chemical used to make other products, almost all of the EO is reacted with other substances to form new products. Potential exposure, if any, to the general public from EO manufacturing emissions regulated by EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) rules is likely to be negligible.

### **Is it true that the EPA has warned there is an elevated risk of cancer due to EO exposure levels?**

In 2016, the EPA Integrated Risk Information System (IRIS) program released an updated cancer value based on modeling. ACC believes the value is significantly flawed.

For many years, ACC has raised substantive and serious concerns about EPA's IRIS program and its lack of transparency, failure to incorporate best available science, and resistance to any reform. ACC is not alone in its concerns.

A number of independent reviews also question the IRIS program and its findings. For instance, the Texas Commission on Environmental Quality (TCEQ) has said that, 'the USEPA unit risk factor (URF) for ethylene oxide is not scientifically justified.'

Additionally, in 2011, the National Academy of Sciences (NAS) criticized IRIS assessments generally for their poor scientific quality (a result of the IRIS program's unnecessary reliance on overly conservative and default assumptions and outdated scientific information) and made specific recommendations that were not incorporated into the EO assessment. Two EPA Science Advisory Boards also outlined additional key issues with the EO IRIS assessment.

In its failure to incorporate the 2011 NAS recommended improvements, the EO assessment suffers from the same shortcomings as the IRIS program. The EO assessment also includes significant errors in modeling historical exposures to EO. The result is a value that is significantly flawed, based on selective science, and results in an overly conservative cancer value to the point of absurdity.

***In fact, the EO cancer value derived from EPA's modeling is 19,000 times lower than the normal, naturally-created levels of EO in the human body.*** In 2018, [ACC submitted](#) a petition under the Information Quality Act seeking correction of the use of the EO IRIS value in EPA's National Air Toxics Assessment (NATA).



The EO IRIS assessment and resulting cancer value are substantially flawed. A more accurate cancer risk estimate could be developed by using the modeling approach published by Valdez-Flores et al. (2010). This approach models potential mortality excesses for lymphohematopoietic tissue (LH) cancers from the two strongest epidemiological studies (NIOSH and Union Carbide Corporation (UCC)) using a log-linear Cox proportional hazard model. Valdez-Flores et al. (2010) estimated ranges for the maximum likelihood estimate (MLE) and the 95% lower confidence limit of the environmental concentration corresponding to an extra risk of one in a million [LEC (1/million)] of, respectively, 1.5-9.2 parts per billion (ppb) and 0.5-1.2 ppb.

### **How is ethylene oxide regulated for worker safety and air emissions?**

For workers in or near facilities where ethylene oxide gas is present, the Occupational Safety and Health Administration (OSHA) has set exposure limits. In addition, employers must provide protective clothing and equipment to employees who may be exposed to ethylene oxide. The [National Institute of Occupational Safety and Health \(NIOSH\)](#) and the [American Conference of Governmental Industrial Hygienists \(ACGIH\)](#) also provide guidance for industrial exposure to ethylene oxide.

Sources of EO emissions to the atmosphere are regulated under EPA's NESHAP rules. These regulatory standards require, among other things, the installation of control devices to reduce emissions, emissions monitoring, performance testing, site-specific operating parameters, and continuing reporting and recordkeeping requirements to ensure compliance with the NESHAP rules. The most recent EPA National Emissions Inventory (NEI) is a testament to the effectiveness of these standards, reporting a significant continuing downward trend in national EO emissions for the industrial sector (716.49 tons per year in 2002 to 153.16 tons per year in 2014).

### **What efforts are being made to continue to study EO safety?**

At this time, the EPA is [undertaking multiple efforts](#) to address EO emissions, review existing regulations and gather additional information as needed. Additionally, similar efforts are underway at the state level. Read more here: <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide>

### **What are companies that work with ethylene oxide doing to ensure the safe handling of EO?**



Companies that make and work with ethylene oxide are actively investing in research and cutting-edge product stewardship technologies so that they can continue to help protect the health of our communities. This starts with the regulations set out by EOA and state agencies. But these companies go beyond simply following regulations. They continuously revise and improve industry's safety practices and procedures. They are making progress in three ways:

First, these companies have invested millions of dollars in the research and development of rigorous product stewardship guidelines. Second, they use advanced, cutting-edge technologies to track emissions and help avoid accidents before they happen, as well as new technologies that support long-term safety. Third, they share best practices for safely producing, shipping, and handling ethylene oxide across the industry.

There has already been great progress, but companies that make and work with ethylene oxide are not stopping there. They are constantly using what they've learned to improve best practices, striving to minimize emissions every day.

The Ethylene Oxide Panel is a leading source of product stewardship and regulatory information on ethylene oxide. The panel promotes the principles of [Responsible Care®](#) with respect to the safe handling and use of ethylene oxide.

Responsible Care® is the chemical manufacturing industry's environmental health, safety and security performance indicator. Responsible Care® provides a foundation for the ACC Ethylene Oxide Panel member companies to safely operate and protect the health and safety of their employees, the communities in which they operate and the environment as a whole.

Ethylene Oxide Panel member companies implement safety technology and practices at every step of the production process – from plant design, to personnel safety precautions, equipment maintenance and preparation, transportation, and loading and unloading operations.

The Ethylene Oxide Panel supports policies based on the best available science and research on health, safety and environmental issues arising from the production, use, storage, transportation and disposal of ethylene oxide.

Ethylene Oxide Panel member companies:

- Share information to enhance operational and emergency response practices to protect public health and our environment
- Produce product stewardship guidance that documents rigorous guidelines for facility design, production, safe handling, and shipment of ethylene oxide, including guidelines for the protection of workers



- Sponsor product stewardship seminars to support the safe manufacture, handling and transportation of ethylene oxide
- Conduct and/or actively participate in toxicology and environmental research to ensure the best available science is publicly available