



**Flawed Science and Modeling by EPA Result in Inappropriate Conclusions  
That Could Have Disastrous Adverse Public Health Impacts**

***The Ethylene Oxide IRIS Assessment and Recent Federal Reports on Ethylene Oxide  
Emissions***

Ethylene oxide (EO) is used by members of the healthcare community to sterilize a wide variety of medical devices and equipment. EO is also an important “building block” chemical that is used in the production of numerous everyday products including detergents, adhesives, antifreeze, plastics, textiles, and other items. While small amounts of EO are emitted to the air as part of these uses, the presence of EO in the air can be attributed to a variety of sources. EO is also emitted from sources such as vehicle emissions, cigarette smoke, cooking oil, and plant decay. In fact, EO is also produced by the human body as part of its normal metabolic function.

Since its discovery as an effective sterilant in 1938, EO has played a critical role in the sterilization of medical devices and pharmaceutical products that protect the general public. Decades later, EO is now used to sterilize more than 20 billion (20,000,000,000) healthcare products each year in the U.S. alone. This represents more than 50 percent of all medical devices sterilized annually. EO sterilization is critical in the safe delivery of sterile devices to the healthcare field, and is essential to a functioning and effective healthcare system. In summary, the use of EO sterilization provides unparalleled benefits to society.

**Recent Reports on the Carcinogenicity and Emissions of EO**

The U.S. Environmental Protection Agency’s (EPA) Integrated Risk Information System (IRIS) program developed an EO carcinogenicity assessment in 1985. The initial draft was published in 1998, followed by another in 2006. EPA’s Science Advisory Board (SAB) reviewed the 2006 draft the following year. Revisions based on the SAB review and public comments were subsequently made and a second SAB review was conducted in 2014-2015. In December 2016, EPA published its final *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*.<sup>1</sup> The IRIS assessment used flawed science to determine that exposure to EO at a concentration of 0.1 part per trillion (ppt) poses a one in a million lifetime cancer risk -- a concentration that is orders of magnitude below the levels of EO produced within the human body and what is normally present in air. The flawed science that was used, and the extreme risk value that was obtained -- orders of magnitude below what all of us are already exposed to from other everyday sources -- lead to the conclusion that EPA’s IRIS results are not valid.

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<sup>1</sup> EPA, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Final Report), EPA/635/R-16/350F (2016).

In August 2018, EPA published the 2014 National Air Toxics Assessment (NATA) update report, which is a national report that presents data on air toxic emissions.<sup>2</sup> (The NATA report helps state and local agencies identify pollutants for further study of possible risks to the public health.) The NATA report is based on assumptions regarding emissions data and limited self-reported emissions. It is therefore unable to provide specific exposures and risks. The 2014 NATA report also relied on the 2016 IRIS assessment for EO. As a result of using this flawed assessment, it highlighted EO as a chemical of concern and possible public risk.

Additionally, in August 2018, the Agency for Toxic Substances and Diseases Registry (ATSDR) released a technical report on recent air emissions monitoring performed near a sterilization facility.<sup>3</sup> This report was based on emissions monitoring that was conducted over a limited period during worst-case weather conditions, and it too used the risk factors from the EO IRIS assessment. It was intended to “inform and support the regulatory decisions being made by the state & EPA to reduce emissions from that facility to protect public health.” The ATSDR report does not account for other emissions sources of EO, nor does it consider recent voluntary upgrades at the sterilization facility that have significantly reduced emissions. The ATSDR based its conclusions “on estimated cancer risks that are calculated using conservative assumptions about a lifetime exposure to the highest levels of [EO] that were measured....” The measured levels of EO were extremely low -- approximately 1,000 times **lower** than the levels associated with cancer risks in studies of workers exposed to EO.

This report generated significant public concern leading ATSDR to issue a follow-up statement to allay the public concern, in which it clarified that the emissions of EO “**are not an immediate threat to public health and are not considered an emergency situation.**” Further supporting this, EPA issued its own statement that, “based on an examination of available data, U.S. EPA does not expect [EO] levels in the air to be high enough to cause immediate harm to health.”<sup>4</sup>

### **Flawed Science Behind the EPA IRIS Assessment for EO**

The flawed SAB analysis of the National Institute for Occupational Safety and Health (NIOSH) epidemiological study led to inaccurate conclusions regarding the lifetime cancer risk estimate. As a result, the IRIS assessment incorrectly concludes that the inhalation of

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<sup>2</sup> EPA, 2014 NATA Emissions Updates (as of August 22, 2018).

<sup>3</sup> ATSDR, Letter Health Consultation, “Evaluation of Potential Health Impacts from Ethylene Oxide Emissions.” (Aug. 21, 2018).

<sup>4</sup> The Village of Willowbrook, Illinois, Statement from US EPA (Aug. 27, 2018), available at <http://www.willowbrookil.org/CivicAlerts.aspx?AID=362>.

EO at levels below that which occurs naturally in the environment, and in our bodies, can cause cancer. The unrealistically low acceptable EO concentrations that result from this study conflict with human and animal scientific observations. Furthermore, the use of modeled data rather than actual individual data resulted in significant errors, including the overestimation of the risk associated with the use of EO, by many orders of magnitude.

EPA's IRIS assessment is not scientifically supportable when one considers that it is based on an inadequate body of evidence and it ignored other more accurate and recent studies that referenced historical exposure levels that are much higher than current occupational exposure limits. Public comments addressed these shortcomings that were ultimately, and inexplicably, disregarded by the SAB during its review.

Follow-up detailed analyses by industry-leading toxicology experts, using the full body of available study data, as well as more appropriate data analysis methods, strongly suggest that the toxicity risks associated with EO are lower than indicated by IRIS. The analyses suggest that the IRIS value overestimates the risk by a factor of 1,000 or more.

### **Benefits of EO Sterilization**

Hundreds of thousands of medical, hospital, and laboratory processes rely on EO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. For the majority of these healthcare products, EO sterilization is the most effective and efficient, and often the only viable, sterilization technology. The gentle yet thorough nature of EO allows for the sterilization of many critical healthcare products and devices that would otherwise be destroyed and rendered unusable by other sterilization methods.

In addition to the high level of efficacy that EO provides, it is highly compatible with a wide variety of medical device materials of construction, enabling medical device companies to manufacture many devices that would not be possible without EO. The high level of performance and effectiveness of medical devices when sterilized by EO is well understood. If EO could not be used for sterilization of healthcare products, there would certainly be significant, and likely disastrous, adverse public health consequences. Elimination of this sterilization technology would introduce the real risks of increased morbidity and mortality.

### **Worker and Community Protection**

Sterilization processes are designed to ensure public safety. Workplace efficacy and safety practices continuously improve as EO sterilization equipment and processes advance with the introduction of advanced technology. The EO sterilization industry is committed to safety and closely monitors this issue.

Applicable EO sterilization practices have been approved by the U.S. Food and Drug Administration (FDA) for use in the health care industry. The Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI) have developed consensus-based standards, which are recognized and enforced by FDA.<sup>5,6,7</sup> The U.S. Occupational Safety and Health Administration (OSHA) also developed its standard for EO.<sup>8</sup> The OSHA standard addresses matters such as permissible exposure limits (PEL), monitoring, engineering controls, and compliance. Sterilization facilities utilize emissions control and abatement systems to assure compliance with all regulatory standards. By following these standards, hospitals and commercial sterilization facilities are well equipped to ensure the safe and effective use of EO sterilization in compliance with all public health and environmental requirements.

### Conclusions

The IRIS assessment for EO is scientifically flawed and significantly overestimates cancer risk. These grossly inflated risk factors, recently relied upon by EPA, have resulted in inaccurate results, caused undue concern, and are misleading the public. EPA should reevaluate the conservative nature of the current EO IRIS risk assessment, limit the use of the current risk assessment for such studies as the 2014 NATA report and ATSDR reports, and consider alternative risk assessments to more realistically estimate the EO cancer risk. The safe and compliant use of EO sterilization needs to continue as it is a critically important and irreplaceable method of sterilization, which helps improve and save lives every day.

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<sup>5</sup> ANSI/AAMI ST41:2008(R)2012. *Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness.*

<sup>6</sup> ANSI/AAMI ST24:1999/(R)2013. *Automatic, General-Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities.*

<sup>7</sup> ANSI/AAMI/ISO 10993-7:2008. *Biological Evaluation of Medical Devices -- Part 7: Ethylene Oxide Sterilization Residuals.*

<sup>8</sup> OSHA. 1910.1047. Ethylene Oxide. Occupational Safety and Health Standards. Toxic and Hazardous Substances. 77 Fed. Reg. 17574, 17783 (Mar. 26, 2012).