March 15, 2023

Submitted via: MGA website

The Senate of Maryland
Education, Energy, and The Environment Committee
Miller Senate Office Building
11 Bladen Street, Suite 2 West
Annapolis, Maryland 21401

Re: SB0916- Comments of the American Chemistry Council's Ethylene Oxide Panel

The Ethylene Oxide (EO) Panel of the American Chemistry Council (ACC), hereby submits comments on SB0916- prohibiting a person from using, manufacturing, selling, offering for sale, or distributing ethylene oxide (EO) in the State of Maryland. The EO Panel includes the major producers and users of EO in North America. ACC strongly opposes SB0916. The Bill is overreaching, premature, and should it be implemented, will severely restrict crucial uses and products of EO, especially if restrictions proposed by Maryland are widely adopted.

EO is a versatile building block of chemistry. It helps make many of the products we use every day, such as plastics, safety glass, adhesives, and textiles. In addition to EO's critical use in sterilizing medical products and spices, it is used as a building block chemical for producing active ingredients in pesticides and the production of bioethanol. As the US continues to grow, so do our nation's food needs. Overly conservative restrictions on the production, use, or distribution of ethylene oxide could put the needs of the agriculture sector and its derivatives at risk.

A family of EO derivatives -- ethanolamines are used to allow for cleaner burning fuels resulting in less air pollution. EO and its derivatives are used in natural gas purification to reduce corrosion and scale in oil and gas processing, freeze protection for finished goods, gas dehydration, and carbon capture in gas processing, which ultimately helps enable energy transition.

Additionally, ethylene oxide is also a critical chemistry in the production of electric vehicle battery electrolytes. Given Govern Moore's stated intent to transition the state to electric vehicles by 2035 and the intent of the Inflation Reduction Act to onshore battery production,

restrictions on EO could preclude Maryland from participating in industries that will drive this transition.

SB0916 is overreaching and premature. At the federal level, the US EPA is nearing the publication of proposed air toxics rules for EO that will impact commercial sterilizers and industrial manufacturers and users of EO. The proposals are scheduled for late March or April 2023, and are designed to tighten current regulations on EO air emissions. The rules may include requirements for additional monitoring of process and fugitive EO emissions, and ambient air monitoring. Even now, according to the EPA National Emissions Inventory, industrial EO emissions have already fallen nationwide by over 80% since 2002.

The heightened concern over EO emissions and perceived risk arose when EPA applied its IRIS risk value to the 2018 National Air Toxics Assessment. Updated modeling in 2022 again used theoretical calculations, not emissions measurements to identify "hot spots" of elevated cancer risk due to exposure to EO. The lifetime cancer risk modeling of 100 in a million for the spice treatment facilities in Hanover and Jessup and the medical sterilization facility in Salisbury were all benchmarked against the unrealistic EO IRIS value.

The IRIS value of 0.1 parts-per-trillion (ppt), which is used in modeling calculations, is unrealistic. Current measured background ambient EO air concentrations across a wide range of US geographies all exceed the IRIS value by orders of magnitude. Thus, if the EO IRIS Assessment is to be believed, breathing background ambient air alone should cause substantial concern for elevated cancer risks. Almost all states and localities that have been evaluated by states show no statistically significant increased cancer risk from just breathing EO in ambient air.

The problem presented by the EPA risk value is further emphasized by the fact that ambient air is not even the primary source of potential human background ethylene oxide exposures. Ethylene oxide is produced in our bodies as part of everyday normal metabolism (endogenously produced ethylene oxide). Endogenously produced ethylene oxide is equivalent to an external exposure to 1,900 ppt ethylene oxide, and is 19,000-times higher than the EPA-estimated 1 in a million cancer risk. The EPA EO IRIS value would lead one to conclude that the levels of ethylene oxide produced by normal human metabolism and/or breathing ambient air are sufficient to present an elevated cancer risk far in excess than the risks posed by industrial sources. This conclusion is non-sensical and raises questions about the use of the value for regulatory purposes.

Additional shortcomings of the EO IRIS value include the following issues:

**I.** The EO IRIS value (2016) used visual fit comparisons to categorical data, which misrepresents the individual data modeled. This flawed visual fit as the basis for the IRIS selection of a risk model leads to unrealistic inhalation risk estimates.

**II.** The IRIS modeling process did not make a simple correction in statistical analysis that led to an incorrect conclusion that the model (steep slope) used in the IRIS has a superior fit compared to the traditionally used Cox Proportional Hazard (CPH) model. The use of

the EPA model leads to incorrect conclusions of risk acceptability and uncertainty, especially at lower EO concentrations.

**III.** IRIS (2016) did not consider the biological plausibility of models based on biological mode of action and toxicological evidence, which support a shallow linear exposure-response at lower exposures. IRIS has not offered any biologically plausible mode of action analysis accounting for a steeper dose-response of EO in the low-exposure range. The IRIS risk specific concentration of 0.1 ppt is overly conservative to the point of lacking regulatory utility because it is 4 orders of magnitude lower than average human background (predominately endogenous) exposure levels and variability.

ACC urges that SB0916 be rejected. The State of Maryland should wait until the new federal air toxics regulations are promulgated and then reassess whether additional legislation is warranted. Thank you for your attention.

Sincerely,

*William Gulledge*

William P. Gulledge
Senior Director
Chemical Products & Technology Division
Manager, EO Panel