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**Statement of the Ethylene Oxide Sterilization Association**

# EPA's flawed risk assessment of Ethylene Oxide could unnecessarily restrict the use of this vital product and threaten public health.

Washington, DC - Today, the Ethylene Oxide Sterilization Association (EOSA), an industry organization with the mission to promote the safe use and handling of ethylene oxide for sterilization purposes, expressed great concern about the potential negative impact of the EPA's announced risk assessment of Ethylene Oxide (EtO) and associated draft regulatory requirements.

EtO has been thoroughly evaluated and re-evaluated by scientists and regulatory bodies worldwide for over 70 years and was first approved for use by the U.S. government in 1950, and additionally by the EPA in 1971, shortly after the agency was formed.

After disregarding a significant amount of scientific and peer-reviewed data, including an assessment from the Texas Commission on Environmental Quality (TCEQ), the EPA has decided to move forward with its deeply flawed conclusion that EtO is dangerous at levels so low that the EtO emitted from ubiquitous natural sources, such as plant decay and generated within the human body, are hazardous to human health.

In making its final determination on EtO, the EPA relied on only a narrow subset of the available data, conducted a flawed analysis of that data, and dismissed other data that contradicted its evaluation. This flawed approach sets a dangerous precedent for public policy as it allows government regulations to be selected based on significantly flawed science and inaccurate conclusions.

The EPA's estimate claims that sterilizer workers currently face a 1 in 10-lifetime risk of cancer for a 35-year career. This risk estimate is unrealistic in the face of numerous peer-reviewed studies, including an epidemiologic study that showed no risk at far higher exposures than currently allowed.

EOSA agrees with EPA that EtO should continue to be approved for use but is strongly concerned that EPA's vast overestimate of potential risk from EtO exposure has resulted in

unwarranted significant alarm and has the potential to severely limit or prohibit the use of EtO, which would cripple the U.S. healthcare system. Without EtO, the nation would face shortages of medical devices as there would not be a way to sterilize many critically needed medical devices.

As federal, state, and local health and environmental authorities review the latest announcement from the EPA, we encourage them to consider the extensive data on EtO and the decades of its safe use as a substance vital to public health. We also urge the EPA to consider appropriate implementation timelines consistent with historical standards.

EtO manufacturers and sterilizers have a long record of regulatory compliance and remain highly collaborative with the EPA and state and local governments in an ongoing effort to protect our employees and the communities surrounding EtO facilities. EOSA looks forward to working with the EPA to ensure that all new requirements use appropriate science to protect public health and worker safety while not disrupting medical device supply.

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**About the Ethylene Oxide Sterilization Association**

The Ethylene Oxide Sterilization Association (EOSA) is a non-profit organization whose members include medical device manufacturers, sterilization consultants, laboratories, contract sterilizers, and equipment manufacturers with a common interest in promoting the safe use of ethylene oxide. More information can be found here: https://www.eosa.org