



September 26, 2019

Toxicology Division
Texas Commission on Environmental Quality

Toxicology Division:

The Advanced Medical Technology Association (AdvaMed), the national association of medical technology providers, supports the Texas Environmental Quality Commission's (Commission) reasonable, risk-based approach to the exposure assessment for ethylene oxide and we also support the Commission's rejection of the faulty Integrated Risk Information System (IRIS) approach.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed encourages public policies that assure patient access to the benefits of medical technology.

We support the Commission's comprehensive approach to the updated exposure risk assessment that follows well-established, traditional scientific measurements of exposure risk used by the US Environmental Protection Agency (EPA). Generally, we also appreciate the honest acknowledgement that naturally occurring or other non-industrial sources of ethylene oxide create background levels of the chemical that far exceed limits contemplated by new assessment methodology, such as the IRIS approach.

We oppose using the EPA's new and unproven IRIS assessment approach. We fully share in the concerns raised by the American Chemistry Council's (ACC) EO Panel and the Ethylene Oxide Sterilization Association, Inc. (EOSA). We are deeply concerned about the reliability and accuracy of the IRIS assessment and the potential negative impact the assessment could have on the healthcare industry and, most importantly, patient health and safety.

Although medical device sterilization accounts for less than 1% of the overall EO usage in the U.S., it is probably the chemical's most critical use, as our members currently sterilize hundreds of millions of medical devices each year in the U.S. with EO. Many of these devices cannot be sterilized in any other way because of the sensitive nature of the device materials, the components, or the complexity of design. The majority of these devices are not resistant to damage caused by moist heat, radiation, and other modes of sterilization. Examples of devices that can only be sterilized using EO include implantable devices containing electronic components and batteries, anesthesia products, combination products (devices that contain

drugs), MRI conditional/safe devices and IV devices. For a number of other types of products, our members utilize other modes of sterilization, such as gamma irradiation and electron beam sterilization when possible, but for many devices there is currently no viable alternative technology to EO.

The direct impact of any elimination or severe restriction on the use of EO as a sterilant would compromise the U.S. healthcare system. At best, inventory shortages would likely result, and at worst, many life-sustaining medical devices such as pacemakers and implantable cardioverter/defibrillators would no longer be available to patients. It should also be noted that changes in sterilization processes and methods would require clearance or approval by the FDA prior to implementation. Supporting evidence would have to be provided by the manufacturer demonstrating that the new sterilization process does not adversely affect the device and that the same level of sterility is achieved.

Delivery of excellent patient care, particularly for those facing life-threatening disease states, including cancers, motivates everything the medical technology community does. Ensuring sterility of safe and effective medical products and preventing introduction of dangerous infectious diseases, including multidrug resistant organisms like methicillin-resistant *Staphylococcus aureus* (or MRSA) is also an important consideration that requires the use of powerful tools like ethylene oxide sterilization until viable alternatives can be developed.

Given the importance of sterilized devices for providing necessary healthcare to the patient community, decision-making about an important sterilizing agent like EO which is integral to providing life-saving treatment, must be grounded in supportable fact-based assessments like the Commission in order to avoid unintended negative consequences for the healthcare system. We applaud the Commission's work to engage in fact-based, scientifically rigorous decision-making.

Please contact me if you have any questions.

Sincerely,



Fielding Greaves
Director, State Government & Regional Affairs