January 19, 2024

Office of Environmental Health Hazard Assessment (OEHHA)
1001 I Street, 12th Floor
Sacramento, CA 95814

Re: Draft Cancer Inhalation Unit Risk Factor for Ethylene Oxide

Members of the Scientific Review Panel:

On behalf of AdvaMed, Biocom California, and California Life Sciences, we appreciate the opportunity to provide comments on OEHHA's draft cancer inhalation unit risk (IUR) factor for Ethylene Oxide (EtO). Our medical technology members are the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Effective sterilization of medical technology is critical to public health and this draft IUR risks disrupting patient access to it. We urge OEHHA to leverage its own expertise and, as suggested by Dr. Lucy Fraiser in the attached review and analysis, revise the draft IUR to protect public health.

EtO sterilization of medical devices is crucial for preventing infection in patients undergoing surgical procedures and other medical treatments. Both the U.S. Food and Drug Administration (FDA), which regulates medical device safety and effectiveness, including sterility assurance, and the Environmental Protection Agency (EPA), which regulates EtO emissions in the air, agree EtO is a critical medical device sterilization method.[1,2] Notably, the EPA has released two draft regulations on emissions controls for, and the use of, EtO by commercial sterilizers.

EtO is used to sterilize approximately 50 percent of all medical devices – 20 billion – in the United States each year, including surgical kits, heart valves, and pacemakers, and is the only viable modality for many devices.[3] Other methods destroy or render these critical medical devices unusable. The appropriate sterilization method is determined during the concept and design phase of a device. It is specific to each device and must meet design specifications, FDA requirements, patient safety, and the large-scale demand for devices, all while ensuring effective sterilization that does not degrade the device or impact performance.

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[1] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[2] https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information
[3] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

Hundreds of thousands of medical, hospital, and laboratory processes rely on EtO-sterilized devices and equipment to protect millions of patients from the real risks of infection caused by bacteria, viruses, and fungi. Any disruption in the availability of sterile medical devices and supplies could lead to delays in patient care – an outcome disastrous to patient health, the daily practice of medicine, and overall public health in the United States.

Reflecting our shared level of concern, AdvaMed requested an independent scientific review and analysis of the draft IUR from Board Certified Toxicologist Dr. Lucy Fraiser. Dr. Fraiser provides a thorough review of the science used by the U.S. Environmental Protection Agency's (EPA) to develop its most recent Integrated Risk Information System (IRIS) standard for EtO – which serves as the basis for OEHHA's IUR for EtO. Notably, Dr. Fraiser points out that the EtO IRIS is set magnitudes below ambient levels of EtO. Adopting this standard – and its resulting use in regulations across California – jeopardizes public health through disruptions and delays in medical care – from routine exams to life-saving surgery.

We urge OEHHA to protect public health by revising the draft IUR consistent with the expert analysis provided.

Thank you again for the opportunity to comment.

Sincerely,

/s/
Greg Crist
Head of External Affairs
AdvaMed

/s/
Sam Chung
Vice President, State Government Relations
California Life Sciences

/s/
Claire Conlon
Senior Director, Government Affairs
Biocom California

Attached: Letter from Dr. Lucy Fraiser, Board Certified Toxicologist