



November 11, 2014

Via E-Mail

Mr. Aaron Yeow
Designated Federal Officer (DFO)
Science Advisory Board Staff Office
U.S. Environmental Protection Agency
1200 Pennsylvania, Avenue, N.W.
Washington, D.C. 20460-4164

Re: Ethylene Oxide Sterilization Association, Inc. Comments to the Chemical Assessment Advisory Committee for the Integrated Risk Information System Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft -- August 2014)

Dear Mr. Yeow:

STERIS Corporation appreciates the opportunity to submit these comments to the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC) for consideration in responding to the draft charge questions for the revised draft Integrated Risk Information System (IRIS) assessment for ethylene oxide (EO).

STERIS Corporation is a leading provider of disinfection and sterilization technologies and solutions worldwide. STERIS provides these products and services to healthcare facilities, industrial and institutional facilities, and medical device manufacturers. STERIS also provides ethylene oxide contract sterilization services to the medical device and spice industry through its STERIS Isomedix Services ("Isomedix") business segment. The company has a great deal of experience and knowledge in working with ethylene oxide sterilization processes and equipment in hospital and industrial settings.

Isomedix is a business unit of STERIS Corporation, operating 19 facilities in North America. Isomedix offers a comprehensive array of sterilization services, using gamma irradiation and 100% EtO technologies. As such, Isomedix operates 9 EtO facilities offering both traditional and EOExpress® processes.

EtO plays a critical role in antimicrobial sterilization to protect public health. The EtO sterilization process has been employed by the health care industry to sterilize medical devices since the early 1940s and is used to sterilize more than 20 billion medical devices a year in the U.S. alone. Numerous medical, laboratory, and hospital processes rely on EtO to sterilize equipment to protect patients from the real risks of infectious disease from bacteria and viruses.

Many important medical devices can only be sterilized by EtO due to the adverse affects on the devices from alternative technologies (e.g., gamma radiation, heat, election beam, etc). The inherent nature of EtO sterilization allows for the sterilization of healthcare products and devices that would otherwise be destroyed and rendered inoperable by the effects of radiation, high heat, harsh chemicals, and/or other properties of alternative sterilization methods. Examples of such devices include surgical components, anesthesia products, pharmacological devices, and catheters. EtO sterilization is critical in the safe delivery of sterile devices and medical care.

While EtO sterilization in hospitals has decreased significantly over the last decade, EtO processing via contract sterilization services is now used to process over 50% of all medical devices used in the United States. Therefore, the accuracy and completeness of the scientific basis for the draft IRIS assessment is extremely important. STERIS Corporation has significant concerns regarding the U.S. Environmental Protection Agency's (EPA) cancer risk estimates for EtO and the IRIS revised draft IRIS assessment as a whole. STERIS Corporation believes signification revisions to the draft IRIS assessment are necessary to accurately reflect best available science and weight-of-evidence in compliance with both the EPA Guidelines for Carcinogen Risk Assessment (Cancer Guidelines) and Information Quality Act (IQA) Guidelines.

In addition to our specific comments provided below, we fully support all comments submitted by the American Chemistry Council's (ACC) EO Panel and the Ethylene Oxide Sterilization Association (EOSA). We believe that the current assessment results in the risk of EtO being inappropriately overstated by more than three orders of magnitude. The risk estimates result in limits that are significantly lower than natural background levels of EO in the atmosphere and endogenous levels in humans. Based on the draft inhalation unit risk values, EtO would be identified as one of the most potent chemicals within the IRIS database. This exaggerated risk will severely and adversely impact the EtO sterilization industry and its ability to provide sterilization services for medical device applications which will result in significant perceived adverse public health impacts. STERIS Corporation asks that CAAC consider the loss of benefits of EtO sterilization resulting from the adverse impacts on public health that would result from inappropriately lowered risk estimates and exposure levels presented in the draft IRIS assessment.

In particular STERIS Corporation is concerned regarding the following issues in the draft assessment:

- EPA should follow Science Advisory Board (SAB) recommendations to consider both linear and non-linear modeling approaches;
- EPA should consider the Union Carbide Corporation study data in the exposure assessment to enhance the dose-response assessment and evaluate the use of the



NIOSH EtO Cohort data as its availability is not public and seems to be counter to EPA's stated goal of transparency;

- EPA should re-examine its overall risk determination in light of ambient and endogenous exposures to ethylene oxide that seemingly contradict the conclusions drawn by the draft assessment; and
- The extra risk estimates for occupational exposures potentially leading to occupational exposure limits at least one thousand times lower than those currently promulgated by OSHA (based on the calculated extra risk estimate). Detection of EtO in the low parts per billion range is not practicable or technically feasible with any methods currently available.

STERIS Corporation believes the current draft IRIS assessment will have significant adverse impacts on the ability to sterilize healthcare products. By inappropriately magnifying the risk associated with the use of EtO, users could be forced to switch to less effective, impractical alternatives with significant adverse public health consequences or potentially change the processing time of the medical devices. A change in sterilization technology could introduce the real risks of medical device integrity and biocompatibility issues that may exceed the currently known risks of EO sterilization. For some medical devices and pharmaceutical products, proper sterility assurance levels might not be achieved with any change in sterilization technology.

Changes necessary to lower airborne concentrations of EtO within the workplace by orders of magnitude may lead to an increase in processing time required for medical devices. The amount of time products needed to remain in a sterilization chamber could increase in order to reduce residual levels of EtO in the product and therefore the airborne concentrations in the workplace. This would effectively reduce the number of devices able to be processed in a period of time, causing a reduction in the number of devices and products available for medical procedures. Alternative strategies to minimize employee exposure could include increased workplace ventilation and exhaust. However, most facilities currently utilize such strategies and may not be able to increase this method of engineering control due to technical limitations and environmental considerations.

Regardless, any change to a sterilization method could require a complete redesign of the product to be sterilized. Even a redesign may not allow the product to be sterilized adequately without the use of EtO. Furthermore, it is not feasible within a realistic timeframe for medical device manufacturers to change to alternative sterilization methods. A change in sterilization technology or the availability of the methods currently validated to meet Food and Drug Administration requirements could introduce risks of medical device integrity that may exceed the currently known risks of EtO sterilization. Switching to any alternative sterilization technology for many products would simply exchange one risk for another. This would result in



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delays, inadequate sterilization, increased risks to public health, the inability to perform certain medical procedures, and increased healthcare costs.

The current draft assessment will have significant impacts on our Customers who use EtO to sterilize medical devices as well as the medical community. By inappropriately magnifying the risk associated with the use of EtO, EPA may force users to switch to less effective, impractical alternatives with severe adverse public health consequences.

STERIS Corporation appreciates the opportunity to submit these comments. We urge the CAAC to review this information, and the comments submitted by the ACC EO Panel, EOSA, and other medical device manufacturers as it develops draft responses to the charge questions.

Sincerely,

Robert Moss
Senior Vice President and Group President
STERIS Corporation

