

**Statement of Kathleen Hoffman**  
**Sterigenics International, LLC**  
**Meeting of the Science Advisory Board Chemical Assessment Advisory Committee**  
**Augmented for the Ethylene Oxide Review**  
**November 18, 2014**

Good Morning. I am Kathleen Hoffman, Senior Vice President of Global Environmental, Health & Safety for Sterigenics International, LLC. I would like to thank the U.S. Environmental Protection Agency (EPA) for providing the opportunity to comment during this meeting of the Science Advisory Board and Chemical Assessment Advisory Committee for the revised IRIS ethylene oxide review.

First, I agree and support the comments made by the American Chemistry Council (ACC) and the Ethylene Oxide Sterilization Association (EOSA). They provide information on the technical aspects to the IRIS assessment. I would like to focus my comments more on the EO sterilization industry, the EO sterilization customers and potential impacts on public health.

Sterigenics is the global market leader in contract sterilization services. We have 39 global contract sterilization facilities and utilize four different types of sterilization technologies that treat medical and food products. These technologies include EO processing, cobalt gamma radiation, electron-beam radiation, and x-ray radiation. So, we are technology neutral and utilize all sterilization methods to best treat our customers' products.

With our EO processing technology, we sterilize medical device and pharmaceutical products as well as reduce the bioburden on some spice products. Some of the medical device and pharmaceutical products that we treat with EO can only be sterilized with EO processing. EO sterilization plays a critical role in protecting public health and reducing the risk of infection.

As users of EO, the accuracy of the scientific basis for the draft IRIS assessment is extremely important to Sterigenics and our customers. Sterigenics has significant concerns regarding the U.S. EPA's cancer risk estimates for EO and the revised draft IRIS assessment as a whole. The EO levels that are deemed to be "safe" in this risk assessment are significantly lower than natural background levels of EO in the atmosphere and endogenous EO levels in humans. If this assessment is finalized, EO would also be identified as one of the most potent chemicals within the IRIS database. This exaggerated risk will not only severely and adversely impact the EO sterilization industry, but it will significantly disrupt an established sterilization method for medical devices essential to the general public. I urge the CAAC to consider the benefits of EO sterilization as they review this draft IRIS risk assessment.

Next, I would like to discuss the EO worker exposure levels. Prior to when OSHA established its first 8-hour time-weighted average (or TWA) limits, there were limited efforts made by the industry to control worker exposures. It was during this time frame when NIOSH began tracking employee

exposure data used in the IRIS risk assessment. In fact, Sterigenics had a couple of facilities included in the original NIOSH studies. Sterigenics contends that the IRIS study should encompass all EO worker exposure data, including that from the Union Carbide study. In fact, the original NIOSH data is not representative of the worker exposures for EO sterilization workers today.

Today, the EO sterilization industry employs a variety of techniques to reduce its worker exposure limits. The industry employs best practices including operating within a sealed vacuum sterilizer under continuous vacuum conditions, welded EO piping in and out of the sterilizer, use of PLC controls to handle the injection of EO and the entire sterilization process, ventilation equipment to remove residual EO, respirators, and other means to minimize workers exposure to EO. This industry ensures all employees do not exceed the current 1.0-ppm EO TWA limit.

The draft IRIS assessment evaluates occupational exposure EO risk estimates in Section 4.7. From the IRIS risk estimates, we calculated an acceptable worker exposure level to less than 1 parts-per-billion. Current worker exposure levels in the sterilization industry range from 0.1 to 1.0 ppm. With current technology, it would be impossible to accurately and reliably measure or achieve worker exposure levels at the 1 ppb exposure limit.

As mentioned previously, EO plays a critical role in antimicrobial sterilization to protect public health. It is used to sterilize more than 20 billion medical devices each year in the U.S. alone. This represents more than 50 percent of all medical devices that are sterilized. In fact, some medical products and surgical kits can only be sterilized with EO. The use of EO sterilization provides unparalleled benefits to society and the medical community. EO sterilization is critical in the delivery of sterile devices and safe medical care.

If EO sterilization was not available, the medical community would be profoundly impacted. Current medical device and pharmaceutical companies might have to look to less effective sterilization technologies. Medical devices are frequently designed for a specific sterilization method. Any change to the sterilization technology would likely require such medical products to be redesigned, resulting in significant costs and timing. In the United States, these redesigns and alternative sterilization methods may require submissions of new 510(k)s or premarket approvals (PMAs) to the Food and Drug Administration (or FDA).

In its current form, the revised draft IRIS assessment would render useless more than 50 percent of all medical devices and over 90% of pre-sterilized surgical kits. These kits include devices such as syringes, endotracheal tubes, catheters, vascular stents, and many other components required for surgeries. The inability to sterilize these products and equipment with EO would significantly increase the risk of infection and impact public health. Such risks are far greater than those suggested by the draft IRIS assessment.

Thank you again for the opportunity to provide comments today.