

## Comments for IRIS Assessment for EO

1. On behalf of ARC Specialty Products (ARC), a Balchem Corporation (Balchem), thank you for this opportunity to provide comments to the Committee in connection with the Committee's consideration of the draft charge questions related to the revised draft Integrated Risk Information System (IRIS) assessment for ethylene oxide (EO).
2. We hold registrations for EO products widely used to sterilize medical devices used in almost every surgical procedure.
3. As a sterilant, EO is unique, exceptionally effective, and essential to a functioning U.S. healthcare system.
  - a. EO effectively sterilizes healthcare products and devices that would otherwise be destroyed by the high heat, harsh chemicals, or gamma radiation of the next most widely used sterilization method.
  - b. Because it can eliminate microorganisms at low temperatures, EO is used on critical, sensitive medical devices such as pacemakers, fiber optics, vascular stents, heart-lung and kidney dialysis machines. But it is also used on simple everyday items such as sutures, syringes, catheter tubing, scalpels, and bandaids to mention a few. EO sterilization is not just the most effective and efficient sterilization technology for many critical medical devices; it is the only acceptable method. Sutures, for example, cannot be sterilized any other way including gamma radiation. EO uniquely penetrates packaging materials, destroying pathogens and assuring sterility of both the product and package. Due to its unique properties and versatility, EO is the most widely used sterilant method for healthcare products and is essential to the healthcare industry.
  - c. EO is used to sterilize more than 20 billion medical devices each year in the U.S. alone. Many medical, hospital, and laboratory processes rely on EO to sterilize devices and equipment, protecting millions of us.
  - d. Because of critical public health protection needs and because of its unique and essential properties, EO as a sterilization method has grown in the last 15 years from 48 percent to 56 percent of devices sterilized in the U.S. The practice of EO sterilization continues to combat the increase in hospital acquired infections. For example, an article in The Wall Street Journal recently highlighted a hospital in Illinois that discovered a direct link to infections in six patients from an endoscope sterilized with a non-EO method. That hospital has switched to EO for all endoscopes going forward. I am sure none of you would want a procedure done with instruments and devices that were not sterilized properly, yet that very scenario could become common if the draft report's values are adopted. Do you want to go in for your next procedure, say a routine colonoscopy, and have to worry about getting a deadly infection? That very well could be reality.

4. The importance of and need for EO sterilization products to ensure the safety of a wide number of essential medical procedures and surgical methods underscores how important the Committee's discussions are. Ensuring the accuracy and completeness of the scientific basis for the draft IRIS assessment is essential. The draft assessment currently does not reflect appropriate scientific rigor, and the conclusions it reaches, if relied upon, could potentially -- and unnecessarily -- devastate the sterilization and healthcare industries, causing enormous adverse effects on public health.
5. Under the current draft, potential risks of EO are vastly and unrealistically overstated. Natural background levels of EO in the atmosphere and endogenous levels in humans would be far below the levels found acceptable in the draft. Based on the draft inhalation unit risk values, EO would be identified as one of the most potent chemicals within the IRIS database.
6. These conclusions are clearly erroneous. Neither the science nor the facts support these conclusions. ARC/Balchem concur with and support the scientific positions stated by the Ethylene Oxide Sterilization Association (EOSA) and the American Chemistry Council (ACC) EO Panel, and I will not repeat them here, but would urge you to consider them fully, especially given the enormous adverse effect that not doing so will have.
  - a. It is important, however, to put the values the Committee is considering into a real world context.
    - i. For example, The National Institute for Occupational Safety and Health (NIOSH) study that the draft report relies upon involved practices that resulted in extremely large EO exposures -- exposures over 50 to 100 times the potential exposures of the present day. The early NIOSH cohort study members put medical devices in a metal pan, poured EO on top of them, and then placed a metal lid on top. The lid was not even a sealed top. Exposures were extremely high; levels would have been well over 100 parts per million (ppm). There are reports of workers smelling EO, which means the exposure levels were closer to 1,000 ppm. Even with these extremely high exposure levels, the NIOSH data show, at best, a very weak possible link to cancer. Today, sterilization is done in a vacuum sealed chamber only and no employees come in direct contact with EO. The Occupational Safety and Health Administration (OSHA) regulated exposure level is less than one ppm eight hour Time Weighted Average (TWA), which is an appropriately safe level. Based on this risk

assessment, the value could drop to 0.001ppm. This level just could not be attained in a commercial or hospital setting.

- ii. As another example, endogenous levels of EO are substantially above the level that the draft report considers acceptable. If the IRIS value were correct, the incidences of cancer should be widespread and we simply do not see this in the real world.
  - iii. You just cannot take out data points because the data do not fit the model the U.S. Environmental Protection Agency (EPA) wants to use. It is like they have already decided what they want the answer to be and now just need to pick and choose the data to use to get there. They are cherry picking which cancers they see from the data because the “big” picture does not demonstrate a strong link between EO and cancer. If there was such a strong link, where are all the cancers from those hospital workers who had over 50-100-1,000 TIMES the exposure today’s workers have??? They are just not there!
- b. These facts must be taken into account along with all of the other scientific issues that ACC and EOSA have raised with regard to the IRIS analysis. The values that the draft states will gravely damage essential public health practices without any real benefit to those exposed to the very low levels of EO resulting from sterilization practices.
7. If the values in the draft are not revised to reflect the available science and data, many Americans will face significant adverse public health consequences. Everyday people like the people in this room.
- a. For example, if the draft values were used for regulatory decisions, more than 56 percent of all medical products that are used in pre-sterilized kits would become unavailable. This means that surgical kits that include devices such as syringes, endotracheal tubes, catheters, vascular stents, and many other components would not be available.
  - b. It would also mean that life-saving medical devices used in difficult to reach enclosed areas, such as IV tubes and endoscopes, that can only be sterilized by EO would be severely compromised. Products such as pacemakers and implantable defibrillators that contain sensitive electronic components that cannot withstand the heat and harshness of alternative methods would also be unavailable

or severely compromised. The inability to sterilize these products and equipment with EO would significantly increase the risk of infection.

- c. These risks to public health of so adversely affecting the ability to sterilize these devices are enormous and cannot be ignored. WE MUST GET THIS RIGHT!!!

- 8. On behalf of ARC/Balchem, thank you for this opportunity to comment.

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