

DRAFT

**Oral Statement of Balchem Corporation
To the EPA Science Advisory Board for Presentation for the Review of the Draft
IRIS Cancer Risk Assessment for Ethylene Oxide**

January 18, 2007

Hello, my name is David Ludwig and I am the Vice President and General Manager and an Officer of Balchem Corporation. Balchem is one of the technical registrants under FIFRA for ETO. I appreciate the opportunity to address the SAB in person concerning its review of the draft IRIS cancer risk assessment for ETO. We have carefully reviewed the draft cancer risk assessment. Our initial comments from that review were timely submitted to the docket.

First, let me state that we fully support the position of the Ethylene Oxide/Ethylene Glycols Panel of the American Chemistry Council. We had previously encouraged the SAB to review in detail the extensive comments submitted by the Panel on the draft cancer risk assessment prior to this review meeting. We trust that you have done this and now encourage you to listen closely to what the ACC will say today.

In addition to the charge questions posed to the SAB and the ACC Panel's questions we posed some additional questions which I will review in a minute but first we feel it is important to review again the critical use of ETO as a sterilant to the medical field. I reviewed some of these critical uses in my comments on the public call in December. Because the use of EO is so critical to public health, they are worth reviewing.

ETO provides unmatched and irreplaceable public health benefits to society via its use by the medical community. In the United States alone ETO is used successfully to sterilize approximately 20 BILLION medical devices every year. The regulatory actions that could result from this risk assessment could limit or prevent ETO from being used as a sterilant for medical devices and thus potentially cause great harm to public health. If this happens:

- Over 50 percent of all medical products provided in pre-sterilized packaged form would become unavailable; items such as syringes, IV tubing, surgical trays, catheters, orthopedic implants, vascular stents, and many other devices including simple items like band-aids.**
- More than one third of all reusable devices currently sterilized by hospitals or their contract sterilization services would become unusable; such as surgical scalpels, endoscopes, laparoscopes, and many other reusable devices could no longer be safely sterilized or re-sterilized.**

- Numerous essential or life-saving devices could no longer be sterilized; such as pacemakers, implantable defibrillators, and hundreds of other devices with electronic components.

Per AdvaMed's comments to the RED docket back in May of this year – I quote “In general, it is not feasible for medical device manufacturers to change to any other sterilization method within any realistic timeframe. For the vast majority of medical and laboratory products, ETO is the most efficient and effective means of sterilization available. In fact, for many products, ETO is the only acceptable method of sterilization.”

Per the CDC “Healthcare Associated Infections (HAI) currently account for an estimated 2 million infections, 90,000 deaths, and \$4.5 billion in excess health care costs annually.” This is occurring even with ETO being used. Indeed, medical, hospital, and laboratory, settings rely on ETO to sterilize equipment to protect patients from the very real risks of infectious disease caused by bacteria and viruses. If ETO could no longer be used we could see a staggering increase in these infection figures.

If the medical device industry is forced to abandon ETO sterilization as its primary means of providing sterile medical devices, they will have to turn to alternatives that are either unreliable or certainly unproven. The result will most probably be a dramatic increase in the risk of infection through utilization of inadequately sterilized medical devices.

Let me give you a real life example: This past December at White Memorial Hospital in Los Angeles two babies died in its neonatal intensive care unit. The deaths of these babies were traced to the improper sterilization of laryngoscope blades – an instrument used to look inside a patient’s mouth. The hospital had changed the method of sterilization and obviously the new method was not as effective as they thought it would be. I cannot tell you if they had been using ETO sterilization because that information has not been made available. My point of using this example is changing from any sterilization method to an unproven technology can end with a tragic result. ETO is the MOST effective sterilant and is universally accepted for use with ALL devices. ETO plays a major and critical role in the healthcare of this country. The healthcare industry should not be forced to abandon ETO because of an unrealistic and flawed risk assessment.

We urge this panel to recognize and correct the critical scientific deficiencies found throughout the Draft Risk Assessment and offer the following specific observations and recommendations:

- Based on the extensive database of toxicological and epidemiological studies on EO, the cancer risk posed by EO is thousands of times less than portrayed in EPA’s risk estimates.**

- EPA’s lymphohematopoietic cancer risk estimates for EO are based entirely on a single NIOSH retrospective study whose cohort was**

large, diverse, and consisted of more women than men. While a slight increased risk of lymphohematopoietic cancer was observed in males, no increase was observed in females and all other cancer risks were found to be lower than expected. It must also be pointed out that the majority of this study's cohort were exposed to levels of ETO that were often 50+ times higher than today's allowable exposure levels. The majority of the people in this NIOSH study worked in facilities where it was acceptable by then existing government standards to work without any personal protection in and around chambers when the level of ETO was 50PPM or higher. Under today's OSHA ETO Standard, worker exposure is limited to 1PPM as an 8 hour time weighed average. These discrepancies raise fundamental questions about the EPA's sole reliance on this study population.

- The Agency's estimates of extra lifetime cancer incidence and mortality risk assume 85 years of exposure in contrast to the more-generally accepted and already-conservative assumption of 70 years of exposure. This unjustifiable increase of more than 20% adds further uncertainty and considerable increased conservatism into the excess lifetime cancer risk estimates for ETO.

EPA's risk estimate is implausible because it is significantly lower than natural background levels of ETO in the atmosphere and the natural

biological production of ETO in the human body itself. If this risk estimate were accurate then the cancer rates and mortality rates within the general public would already be thousand's of times higher than they actually are.

We urge the Panel to revise this Draft Risk Assessment substantially by incorporating the foregoing comments along with those submitted by the American Chemistry Council EO/EGs Panel. The SAB must take into account the seriousness of the potential outcome of this risk assessment – it could have a catastrophic effect on the healthcare system here in the United States and it will have potential worldwide implications as well.

Thank you for your attention.