

November 11, 2014

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752-1234
Tel: (800) 876-9960
www.BostonScientific.com

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

Re: Boston Scientific Corporation 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:

Boston Scientific Corporation appreciates the opportunity to submit comments to the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC) on the consideration of the revised draft Integrated Risk Information System (IRIS) assessment on ethylene oxide (EO).

Boston Scientific is a global developer and manufacturer of medical devices and provides minimally invasive medical equipment and instruments to healthcare providers. Sterilization is critical to the medical device industry, rendering billions of devices safe from viable microorganisms that could cause life endangering infections. In particular, EO sterilization is the primary method approved by the FDA to reduce microbial contamination and the attendant risks of infection from viruses, bacteria and fungi. It is one of the most commonly used sterilization methods of the medical device industry, and counted on by manufacturers, doctors and patients around the world. Boston Scientific uses EO to sterilize 70% of its devices manufactured globally, and restricting the use of EO as a viable sterilization method would severely impact the availability of approximately 32 million devices sterilized annually, many of which are life-saving.

Adopting an overly conservative estimate of potential risks from exposure to EO, as has been proposed, would disrupt the availability of medical devices and equipment to healthcare providers, and seriously impair their ability to serve their patients. Given the importance of EO sterilization to preserve and promote public health, it is particularly important in this case that the CAAC not rely on models or exposure estimates that exaggerate potential cancer risk.

For many devices, EO sterilization is the only option. These devices are specifically designed with materials that are tolerant of EO. Other sterilization methods, such as e-beam, steam, or gamma radiation, could cause device damage and render them inoperable in a clinical setting. Furthermore, in many cases, EO is the only method of sterilization that can safely and effectively sterilize all parts of the device.

The safety of employees is of critical importance to Boston Scientific. Boston Scientific monitors its EO sterilization facilities for worker safety. Boston Scientific employs alarmed monitoring systems, protective equipment, and significant training to assure its employees are free of the exposure dangers of EO.

EO, therefore, is critical to the delivery of safe and sterile medical devices to the clinical community. Without it, or reduction in occupational exposure limits may result in the potential for severe risk of infection or, alternatively, inability to manufacture products that are necessary for patient care. In fact, a change in the requirements for sterilization technology may introduce risks of product integrity, toxicological safety and biological infection that may exceed the risks of EO sterilization itself.

The American Conference of Governmental Industrial Hygienists (ACGIH) set the EO workplace exposures for the Threshold Limit Value (TLV) Time Weighted Average (TWA) over 30 years ago. It was later reduced by the U.S. Occupational Safety and Health Administration (OSHA) to the current value of 1 ppm in 1984. This value is based on human exposure data generated from years of worker exposures and verified over subsequent years with follow up studies. Boston Scientific believes that a substantial reduction in EO workplace exposure limits based on an overly conservative estimate of risk, such as the CAAC is now considering, would be unnecessary and without scientific foundation. It also would be inappropriate, disruptive, and detrimental to public health.

In sum, Boston Scientific and other stakeholders are extremely concerned, not only with the accuracy of the IRIS assessment, but the very real negative impacts this assessment could have on the healthcare industry, public health, and patient safety. We strongly encourage the CAAC to carefully consider the potential impact of the IRIS assessment and weigh the risk/benefit analysis on the ability to provide sterile medical products to healthcare providers and the patients that need them.

Boston Scientific thanks you for the opportunity to provide comments to this proposal. Boston Scientific is committed to worker safety by employing occupational monitoring of EO levels in the workplace and proper capture and treatment of used EO to keep environmental exposure well below the unsafe levels that are proposed. The availability of EO for proper medical device sterilization is essential as a requirement for the safety and effectiveness of sterile devices.

Sincerely,

/s/

Edward E. Reverdy, PhD
Director of Global Toxicology and Biocompatibility

Jeffrey Brown
Director of Sterilization Operations