



The Ethylene Oxide Sterilization Association, Inc.

Ethylene Oxide Sterilization Association, Inc. Accomplishments and Advocacy Efforts

March 2013

The Ethylene Oxide Sterilization Association, Inc. (EOSA) is a non-profit organization formed in 1995 whose members share a common interest in promoting the use of ethylene oxide (EO). Its 20+ members include medical device manufacturers, sterilization consultants, EO suppliers, laboratories, contract sterilizers, and equipment manufacturers. EOSA strives to ensure that domestic and international agencies and decision makers are aware of EO's critical use as a sterilizer for medical and health care purposes and the public health value of this essential substance.

Below is a sampling of the issues and activities in which EOSA has and will continue to engage in over the next year.

U.S. Regulatory Issues

- ***Monitoring EPA's Integrated Risk Information System (IRIS) Review of EO:*** EOSA and others expressed significant concerns regarding the 2006 draft report from the U.S. Environmental Protection Agency (EPA) National Center for Environmental Assessment on its evaluation of EO carcinogenicity. Stakeholders indicated that the report did not reflect the best available science and could have substantial impacts on the continued use of EO as a sterilant. A 2011 revised draft, no longer available on EPA's website, proposed even more stringent limits on EO. The final assessment was scheduled to be posted by the end of September 2012. EOSA communicated its concerns to EPA and expressed its desire for further review and comment opportunities. EPA revised the timeline indicating the assessment will undergo further review resulting in a subsequent public comment period. EOSA will continue to monitor IRIS activities, engage EPA, and coordinate with the American Chemistry Council's (ACC) EO panel on advocacy matters.
- ***Continued Monitoring of EPA Review of EO Pesticide Products:*** In March 2008, EPA issued its Reregistration Eligibility Decision (RED) for Ethylene Oxide, concluding that products containing EO are eligible for reregistration provided that certain risk mitigation measures identified by EPA are implemented and certain label amendments are made. EPA has noted that it may revisit the RED depending upon the outcome of the IRIS

review (see above). EOSA will continue to monitor EPA's views on EO pesticide products.

- ***U.S. Occupational Safety and Health Administration Hazard Communication Standard:*** The U.S. Occupational Safety and Health Administration (OSHA) announced on March 20, 2012, that it has revised the Hazard Communication Standard (HCS), aligning it with the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The final HCS rule will be implemented in various phases with full implementation by **2016** and, according to OSHA, will benefit workers by reducing confusion about chemical hazards in the workplace, facilitating safety training, and improving understanding of hazards, especially for low literacy workers. The EOSA Environmental, Health, and Safety (EH&S) Committee is currently developing guidance materials specific to the EO industry and will present them to members in 2013.

International Regulatory Issues

- ***European Union Scientific Committee on Occupational Exposure Limits:*** In March 2010, EOSA submitted detailed technical comments in response to the European Union Scientific Committee on Occupational Exposure Limits (SCOEL) April 2009 recommendation to lower the exposure limit for EO. The SCOEL proposal is to establish an 8-hour time weighted average (TWA) exposure limit of 0.1 ppm (0.183 mg/m³) based on a theoretical one in one million risk for hemato/lymphopoietic cancer. EOSA argued that the cancer risk value should be based on one in 10³ excess risk, that the occupational exposure limit should be based on the most current information, and that data show EO is a weak mutagen and at most, a weak carcinogen. EOSA will continue to monitor and engage in this process.
- ***Germany Occupational Exposure Limit (OEL):*** EOSA is monitoring the regulatory requirements for worker exposure limits in Germany, including the German Technical Rule on Hazardous Substances 513 (TRGS 513) and the German Technical Rule on Hazardous Substances 900/910. A 0.1 ppm OEL was approved and will be considered a trial limit for three years. EOSA is looking to organize conference calls with international stakeholders. EOSA will continue to monitor and engage on this issue wherever possible.

- ***Canadian Proposed Re-Evaluation Decision on EO:*** In August 2010, EOSA submitted comments opposing the proposal to establish an 8-hour TWA exposure limit of 0.1 ppm. EOSA submitted additional comments in January 2011. Members continue to work with Health Canada on this matter. EOSA will continue to monitor and engage on this activity as necessary.

Safety Education

- ***Safety Presentations at Annual Membership Meetings:*** Twice a year, EOSA hosts a general membership meeting. In addition to the invaluable networking opportunities afforded by these meetings, members also share information on environmental, health, and safety issues. Meetings are scheduled for May 22, 2013, and October 14, 2013.
- ***Process Hazard Analysis:*** In 2012 and 2013, the EH&S Committee will compile members' input on "lessons learned" for those companies engaged in process safety management/process hazard analysis. In addition to presentations at general membership meetings, the EH&S Committee is preparing product stewardship materials to assist EOSA members in matters regarding Process Hazard Analysis and Process Safety Management. A member-only webinar is under consideration for this initiative.
- ***Materials Compatibility:*** In 2012, the EH&S Committee compiled a resource list on aspects of materials compatibility. This resource is available on the members-only website.
- ***OSHA EO Standard:*** In 2012, the EH&S Committee began work on a guidance and information document regarding the OSHA standard 1910.1047(j)(1)(ii)(A). The document will include background information, resources, and other information for EOSA members.
- ***Use of Respirators in Warehouses:*** The EH&S Committee is undertaking an initiative to address the use of respirators while operating forklifts in warehouses. The final document will address issues regarding availability, options, alternatives, and other key information.

Communication and Outreach

- ***EOSA Website:*** EOSA maintains a website for the public and its members at www.eosa.org. The site highlights the importance of EO's use in medical sterilization processes, provides updates on recent regulatory or scientific work on EO, outlines the benefits of EOSA membership, and provides links for further information.
- ***E-mail and 1-800 Line for EOSA:*** EOSA staffs an 800 line and e-mail for members and the general public to request information on EO. Over the last two years, more than 75 inquiries were submitted via these venues.

Administrative

- ***General Membership Meetings:*** In 2012, EOSA held two general membership meetings in conjunction with the Association for the Advancement of Medical Instrumentation (AAMI). Two membership meetings are also scheduled for 2013.
- ***Membership:*** In 2012, EOSA membership reached a record 29 member companies. Four companies joined EOSA in 2012 and several have expressed an interest in joining the organization in 2013.

EOSA members benefit from efficient and effective notifications of potential international, federal, and state regulatory issues through regular updates and information posted on the EOSA members-only website. Decisions on needed advocacy engagement are made by the EOSA Executive Committee, which meets monthly via conference call.