Ethylene Oxide Sterilization Association, Inc.
Accomplishments and Advocacy Efforts

January 2011

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. The final IRIS report could be issued in 2011. EOSA anticipates that the final report could present significant challenges for its members.

- ***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.

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/m^3) 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 10^3 excess risk, that the occupational

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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. The next stage for the proposal will involve stakeholder input on cost and feasibility; EOSA will actively participate in that process.

- ***Germany Occupational Exposure Limit:*** 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.

- ***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 will continue to engage on this issue in 2011, including submitting additional comments in January 2011.

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.

- ***Evaluating Options for EO Respirator Cartridges:*** For two years, the EOSA Environmental, Health and Safety (EH&S) Committee explored options for developing a replacement air-purifying respirator for EO, including testing available cartridges and testing potential cartridge media. The research indicates that for the present time, there is no suitable, cost-effective alternative for the sterilization industry.

- ***Considerations for Sterilizing Battery-Powered Devices:*** In 2010, EOSA prepared a document that provides relevant information for EO sterilizers and their customers regarding the use of EO to sterilize battery devices or other devices with stored energy.

- ***Industrial Hygiene Guidelines for OSHA Compliance Checklists:*** In 2010, EOSA prepared a document that identifies specific factors regarding industrial hygiene air sampling that should be considered when performing a workplace exposure assessment of employees to EO for Occupational Safety and Health Administration (OSHA) compliance purposes.

- ***Process Hazard Analysis:*** In 2011, the EH&S Committee will begin to compile members' input on "lessons learned" for those companies engaged in process safety management/process hazard analysis.

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 65 inquiries were submitted via these venues.

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.