



**Ethylene Oxide Sterilization Association, Inc.
Accomplishments and Advocacy Efforts**

January 2010

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). 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.

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) 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. According to EPA staff, the final IRIS report, which should include resolution of the conclusions put forward by the EPA Science Advisory Board in October 2006, should be issued by June 2010. EOSA anticipates that the final report could present significant challenges for its members and expects to expend substantial time and energy in addressing those challenges.
- ***Chemical Facility Anti-Terrorism Standards (CFATS):*** In 2007, EOSA successfully advocated for an increased threshold quantity for EO in the final Department of Homeland Security (DHS) rulemaking. As part of that advocacy effort, EOSA developed relationships with key DHS officials. EOSA continues to monitor this crucial regulation and, as needed, will develop advisories and educational materials 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.

- ***Termination of Special Review of EO:*** In the March 2008 RED report, EPA noted that a notice closing out the EO Special Review would be issued in the near future. EPA has not yet issued a formal notice in this regard. EOSA will work with EPA to provide EO stakeholders with formal notification of the termination of the special review.

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 specific safety issues. In 2009, these safety presentations focused on sterilization of battery-pack devices and handling of ethylene glycol from EO sterilization process.
- ***Evaluating Personal Protective Equipment (PPE) Options:*** EOSA continues to actively investigate media and PPE system options in response to the terminated production of the only approved EO respirator cartridge in the United States. This effort includes a survey to EOSA members regarding current respirator usage, encouragement to vendors to develop new respirator systems, and consideration of applying for U.S. approval for existing systems currently used in Europe.
- ***Recommended Practice Guidelines and Compliance Checklists:*** The EOSA Environmental, Health and Safety Committee intends to develop an overview of best practices regarding use of EO sterilization for battery-pack devices. It also plans to develop a quick reference document on how to conduct EO sampling for Occupational Safety and Health Administration (OSHA) compliance.
- ***NIOSH's "Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities":*** EOSA was instrumental in the National Institute for Occupational Safety and Health's (NIOSH) publication of the referenced document and received a letter of commendation from the Chemical Safety Board Chairman, Dr. John Bresland, in September 2009.
- ***Stakeholder Outreach on OSHA's "Small Business Guide for Ethylene Oxide":*** EOSA engaged in outreach to its members and other stakeholders regarding OSHA's 2009 guidance document. EOSA noted that the OSHA guide is very useful for employers to understand the EO standard and provides good explanations on how to monitor the air quality in workplaces where EO is processed, used, or handled.

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.

- ***Email 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. In 2009, more than 35 inquiries were submitted via these venues.

In addition to the above, EOSA will monitor and comment as needed on other domestic and international regulatory and science policy issues, such as EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) and other air rules relating to EO, the International Agency for Research on Cancer's (IARC) review of the carcinogenicity of EO, and the National Fire Protection Association (NFPA) standards relevant to EO sterilization and fumigation.

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.