EOSA **The Ethylene Oxide Sterilization Association, Inc.**

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Public Information and Records
Integrity Branch (PIRIB) (7502c)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Attention: Docket ID Number EPA-HQ-OPP-2005-0203

Re: Ethylene Oxide Revised Risk Assessments
71 Fed Reg 9110, February 22, 2006

Dear Sir or Madam:

I am writing again on behalf of The Ethylene Oxide Sterilization Association, Inc. (EOSA) to provide our association's comments on EPA's revised health risk assessments on ethylene oxide (EtO) released by EPA on February 22, 2006. 71 Fed Reg 9110.

EOSA is an independent, not-for-profit trade association of those having any interest in ethylene oxide (EtO) used for sterilization purposes. The Association's purposes are to foster and disseminate truthful communications with regard to the safe use of EtO, to promote reasonable regulation, and to address proactively issues of interest to the membership. EOSA members have interests as diverse as: sterilant suppliers, sterilizer equipment manufacturers, sterilization facility operators, spice fumigation facilities, medical device manufacturers, medical packaging companies and materials suppliers, laboratory service providers, analytical instrumentation manufacturers, emissions control suppliers, and healthcare worker protection.

EOSA represents nearly all U.S. contract sterilization facilities. EOSA members currently process virtually all medical product sterilized using EtO, which equates to over fifty percent of total medical product used and produced domestically. Thus, EOSA member companies and their employees provide the sterilization critical to the public health system. Accordingly, EOSA's members and their employees are greatly concerned with the revised health risk assessment.

General Comments:

EOSA fully supports and agrees with the Comments of the Ethylene Oxide/Ethylene Glycols Panel of the American Chemistry Council (Dated May 19, 2006). We strongly urge the Agency to adopt the American Chemistry Council comments in their entirety.

EOSA concurs with EPA's commitment to provide complete, up-to-date and understandable information pertinent to the public health and safety implications of exposure to chemicals. In that EtO provides a crucial and irreplaceable tool for the protection of public health, EPA's

assessment of the risks and benefits of EtO is all the more important, and EOSA urges EPA to be mindful of the implications of the conclusions it reaches with respect to EtO.

We believe that other commenters, including the American Chemistry Council, have already expertly addressed the scientific aspects of the Revised Human Health Risk Assessment, and EOSA will not repeat them here. However, we strongly urge the agency to correct the current flawed risk assessment and offer the following specific recommendations:

- EPA should reconcile its EO risk assessment with recently completed and ongoing EO risk assessments conducted by other EPA program offices, as well as the International Standards Organization (ISO) 10993-7:1995 Standard.

- EPA is overestimating risk to workers by overestimating exposure to workers. First, EPA is relying on monitoring devices that are not able to measure relevant concentrations, such that the information is incomplete and any assessment results based on them are flawed. Further, errors in estimates of cumulative exposure can arise from incorrect estimates of duration of exposure, and EPA is incorrectly assuming workers are exposed for eight hours a day. EPA should use assumptions regarding actual exposure that are closer to reality.

- EPA should rely on the wealth of epidemiological data to derive a cancer unit risk factor (URF) rather than California Environmental Protection Agency's (CalEPA) animal based URF. EPA's continued reliance upon CalEPA's URF leads to overestimation of the predicted risk to human populations by as much as three orders of magnitude.

- EPA should consider the available significant toxicological and empirical evidence that strongly support a nonlinear dose-response relationship for EO and leukemia. EPA ignores its own Cancer Risk Guidelines, which state a general preference for epidemiological data, and is thereby inconsistent with those guidelines as well as the 1994 National Research Council report, the 1996 Safe Drinking Water Act amendments, the 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management report, and the January 2006 proposed bulletin on risk assessment that the Office of Management and Budget issued.

- EPA considered only one of several studies available to assess the dose-response relationship for noncancer effects and should instead rely on benchmark dose modeling. With regard to calculating a no observed adverse effect level for neurotoxicity endpoints, EPA should rely on more recent, comprehensive studies rather than the 1984, Snellings, *et al.* study.

Specific Comments:

In our comments below, EOSA is addressing the specific questions raised by the Agency in OPP-2005-0203-0056 and OPP-2005-0203-0057.

ESOA strongly suggests that appropriate EPA staff visit an EOSA member facility. We believe that an in-person visit would further enhance the Agency's understanding of our industry and the nature of the extensive and appropriate existing worker protective measures already in place. As

an introduction to the processes and controls that are part of our industry, we have prepared a PowerPoint presentation, "Overview of a Typical Ethylene Oxide Medical Device Sterilization Facility", submitted as Attachment A. We believe that this presentation will help provide an understanding of the actual EtO sterilization process.

Occupational Exposure: questions presented in OPP-2005-0203-0056.

The risk of occupational exposure discussed in this document was based on limited monitoring data provided by both OSHA and the registrant. EOSA has begun an initial survey of its members and determined that actual workplace times in areas where EtO exposure is possible are considerably less than estimates used by the Agency (Attachment B). Furthermore, the survey results illustrate the use of personal protective equipment (i.e.: respirators) in areas where there is potential exposure to EtO.

- What risk management ideas or proposals might address these risks?

  EOSA member companies must comply with the OSHA EtO standard (29 CFR 1910.1047). This standard requires the use of engineering controls to limit worker exposure, in addition to exposure monitoring, employee medical surveillance, and hazard communication.
  In addition to engineering controls, typical sterilization facilities employ personal protective equipment (i.e.: respirators) to limit worker exposure.

- How many workers perform fumigation/sterilization activities at an average facility?

  A typical contract sterilization facility employs approximately 5 to 20 workers that perform sterilization activities, depending on the facility size.

- How many days a year is fumigation/sterilization occurring?

  A typical contract sterilization facility maintains operations 365 days per year. An individual worker, however, will typically work no more than 240 days per year.

- Are there any ambient air monitoring data for areas of the plant/hospital away from a fumigation/sterilization chamber?

  In a typical contract sterilization facility, ethylene oxide area monitors are often placed in locations where EtO may be present. EtO monitors are installed to provide warning if EtO concentrations are detected above a set-point. Monitoring data is typically not available.

- Are there any worker monitoring data broken down by exposure (i.e., periods of increased exposure, periods where respiratory protection is worn)?

  As noted above, EOSA has surveyed its member companies in order to provide the Agency with a representative approximation of periods of potential exposure. This data is discussed in Attachment B.

Medical Uses of ETO: questions presented in OPP-2005-0203-0056 and OPP-2005-0203-0057.

- Would it be feasible for hospitals or other users of EtO to change to another sterilization measure, such as hydrogen peroxide plasma? In what timeframe could this be accomplished?

EOSA endorses and agrees with the comments concerning this question that are being submitted by AdvaMed on May 19, 2006. As noted by AdvaMed, "In general, it is not feasible for medical device manufacturers to change to any other sterilization method."

- Would an EO Express-type technology be feasible for hospitals or other ETO users? In what timeframe could this be accomplished?

  EO Express is a trade name that describes an all-in-one EtO sterilization method. This method involves the application of multiple sterilization steps, including preconditioning and aeration, in a single chamber. In hospitals, EtO sterilization is typically done in a single piece of equipment, which in many ways is already analogous to the all-in-one method of processing.
  In traditional large-scale sterilization facilities (e.g.: Contract Sterilizers and OEMs), all-in-one processing has become a useful EtO sterilization method. It cannot, however, completely replace traditional EtO sterilization. Many materials cannot withstand the deeper vacuum pressures and increased number of gas washes that are required by the all-in-one method.

- Can ETO Chambers be re-located to alternative areas of the workplace that would reduce emissions and exposure to workers?

  EOSA cannot comment specifically concerning the location of EtO sterilization equipment in hospitals. In contract sterilization facilities, EtO chambers and other areas where concentrations of EtO may be present, are typically segregated from other areas.
  Also, the OSHA EtO Standard (29 CFR 1910.1047) already requires that all facilities establish a regulated area; that access to the regulated area shall be limited to authorized persons; and that regulated areas shall be demarcated to minimize access. We believe that compliance with this standard addresses the intent to limit potential employee exposure.

Other Uses: questions presented in OPP-2005-0203-0056.

- How is ETO used on archival material, library objects and bee keeping equipment?

  The process for treatment of archival material and library objects with EtO is essentially the same as the process for treatment of medical devices. EOSA understands that the registrants do not support the use of EtO on bee keeping equipment.

- How important is ETO for archival material, library objects and bee keeping equipment?

  Again, EOSA understands that the registrants do not support the use of EtO on bee keeping equipment.
  EOSA believes that the use of EtO on archival material and library objects is a very small percentage of the total sterilization usage. However, when sterilization of such material is required, EOSA understands that there are problems with alternative methods of sterilization. In many cases, EtO is the only suitable method available that will not damage the items. For example, data on magnetic tapes may be damaged by other methods of sterilization. Some printed documents may be discolored or damaged by other methods of sterilization. EOSA suggests that the Agency contact the Library of Congress, National Archives, or other depository institution for further comments on this issue.

Summary of Impacts:

As summarized in AdvaMed's comments, the net effect of the proposed reduction in worker EtO exposure would cripple our industry's ability to provide sterile product. The immediate impacts of the proposal's implementation would be:

- Over 50 percent of all medical products provided in pre-sterilized packaged form would become unavailable.
- More than one-third of all reusable devices currently sterilized by hospitals or their services would become unusable.
- Numerous essential or life-saving medical devices could no longer be sterilized.
- Redesigning current EtO sterilization systems to meet the proposed lower limits will be extremely difficult.
- The cost of healthcare will increase substantially.
- The risk of infection through inadequate sterilization will increase significantly.

Conclusion:

EOSA is deeply concerned that the current proposed EtO risk assessment would severely impair the healthcare community's ability to sterilize critical medical devices. As currently proposed, the flaws in the assessment magnify to an unreasonable and scientifically unsupportable degree the risk associated with the use of EtO. Because of these flaws, and because of the regulatory changes that would result if they are not corrected, the EtO sterilization industry would be severely and adversely impacted, and the healthcare community would lose a vital tool. The damage to public health, as well as to the medical device industry and healthcare sector in general, cannot be underestimated.

Very truly yours,

Kathleen A. Hoffman
President, EOSA
Vice President, Regulatory Affairs and Quality Assurance –
Sterigenics

cc: EOSA Membership
Hadley & McKenna