

EOSA Oral Comments to SAB Committee

I am Joe Hadley with the Ethylene Oxide Sterilization Association. EOSA is the association of those interested in ethylene oxide (EtO) sterilization. We represent the contract EtO sterilization facilities.

Our members process virtually all medical product sterilized with EtO, over 55% of that produced and used domestically. EtO is the most material-friendly, most-compatible and most-widely used of sterilants. Many of the products sterilized with EtO cannot be sterilized with an alternative sterilization process because of materials compatibility limitations.

Today we express our concerns about EPA's draft "Evaluation of the Carcinogenicity of Ethylene Oxide," and its potentially devastating effects on the sterilization industry. If left unaltered this assessment would provide regulators with a wholly inaccurate risk mitigation roadmap.

EtO usage for sterilization is small but vitally important to the public health and welfare.

Medical device uses

Because almost anything can be sterilized with EtO, medical device manufacturers use over 90% of the EtO produced for sterilization. Medical device, diagnostic and laboratory products are undeniably critical to the public health. EtO is overwhelmingly the sterilization method of choice for manufacturers because not only is it the most efficient and effective method of sterilization, for many products it is the only acceptable sterilant.

Medical devices are designed to be sterilized via a specific method. Changing the method would require changing the design of the device. Therefore, the device manufacturer would have to retest and re-qualify not only the new sterilization method, but the new device design as well. Redesigning and revalidating product for alternative

sterilization methods would be infeasible and/or economically prohibitive for most products.

Thus, any action that would severely limit EtO sterilization would adversely affect public health.

"The Evaluation"

In its risk assessment the Agency went out of its way to exclude certain data, particularly much of the epidemiology, and relied on selected and strained interpretations of some findings.

Additionally, the evaluation suggests unattainable, immeasurable exposure levels for our workers, our neighbors, and our customers. Known sterilization and treatment equipment cannot attain the levels suggested. No instrument is available to measure the extreme levels listed and their range is completely beyond current technology.

We fear that, left unchanged, this draft would result in more-stringent, unreasonable, and unnecessary controls.

Conclusion

Current EtO sterilization process would not be able to meet the extremely conservative EtO levels suggested.

The impact of this risk assessment on our industry would be catastrophic. If the EtO levels were reduced to the levels suggested, it would force contract sterilizers to cease using EtO. Most of the product currently sterilized with EtO could not be sterilized by other methods because the materials of construction are not compatible to the likes of radiation or steam.