



# The Ethylene Oxide Sterilization Association, Inc.

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June 14, 2023

Via Electronic Submission

Esther Barajas-Ochoa  
Office of Environmental Health Hazard Assessment  
P. O. Box 4010  
Sacramento, CA 95812-4010

**Re: Notice of Proposed Rulemaking Title 27, California Code of Regulations – Amendment to Section 25705(b) Specific Regulatory Levels Posing No Significant Risk: Ethylene Oxide**

Dear Ms. Barajas-Ochoa:

On behalf of its members, the Ethylene Oxide Sterilization Association, Inc. (EOSA) appreciates the opportunity to comment on the Office of Environmental Health Hazard Assessment's (OEHHA) proposed changes to Section 25705, revising the safe harbor No Significant Risk Level (NRSL) for ethylene oxide (EtO) from 2 µg/day to 0.058 µg/day.

EOSA members represent a broad spectrum of the U.S. ethylene oxide (EtO) sterilization industry. EOSA is a nonprofit organization that represents EtO suppliers, spice processors, contract sterilizers, sterilization equipment manufacturers, medical device manufacturers, analytical equipment and systems suppliers, and laboratories. EOSA members work diligently to assist in providing life-saving sterile healthcare products around the world, over 50% of which are sterilized using EtO, and assist in providing safe and wholesome spices for consumers. EOSA works to educate industry, regulators, and the public on the essential uses and benefits of EtO sterilization, for which no direct replacement is currently, and not for the foreseeable future, available. EOSA also works to improve safety standards, foster industry communication, and provide a forum for many subjects related to EtO sterilization.

EOSA and its members believe that the safety of surrounding communities and workers in the EtO sterilization industry is critically important. The EtO sterilization industry has historically undertaken, and will continue to undertake, significant efforts to reduce the emissions and potential worker exposure of EtO. EOSA is providing these comments to ensure that regulatory decisions reflect accurate facts, the best available science, and proven technologies and practices.

EOSA agrees with, and adopts by reference, the comments submitted by the American Spice Trade Association (ASTA) on the draft OEHHA NSRL. As discussed in the ASTA comments:

- It is important to note that the use of EtO in spices is critical to support public health by ensuring that spices are treated to control food safety

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hazards, while also complying with U.S. Food and Drug Administration (FDA) food safety regulations. Dietary exposure to residues of EtO in spice commodities has been concluded to pose no public health concern by both FDA and the U.S. Environmental Protection Agency (EPA);

- Exposure to EtO residues from the consumption of spices does not pose a public health risk. The proposed safe harbor NSRL of 0.058 µg/day has been derived from several inhalation studies in humans and animals and no studies involving ingestion. This value would therefore not be applicable to calculated risk from dietary exposure, which would be a consumer's primary route of exposure to EtO residues from the consumption of spice products;
- OEHHA should adopt a higher safe harbor NSRL for EtO residues in food based on "sound considerations of public health." It is essential for OEHHA to consider the importance of EtO in the pasteurization of spice products to prevent and/or reduce microbiological contamination for the purpose of ensuring food safety and not discouraging consumers from using spices that have been treated with EtO due to the presence of a Proposition 65 warning; and
- OEHHA should have taken into consideration the economic impacts when it proposed the revised NSRL. Reducing the safe harbor level for EtO to less than 34 times the currently established level that businesses have been abiding by since 1988 also risks imposing significant costs on California businesses. OEHHA must carefully consider these costs before it sets a new standard that will have ripple effects throughout the food industry and all California business entities.

Thank you for your consideration of these comments. It is critical that OEHHA consider the information outlined in these comments, and the extensive comments provided by the ASTA. It is of paramount importance not to overestimate the potential risk of EtO from its critical pasteurization use, and to be able to continue using this life sustaining, life-saving, and irreplaceable substance, to sterilize healthcare devices and pasteurize certain food products.

Sincerely,



Meibao Zhuang  
Senior Manager  
The Ethylene Oxide Sterilization Association, Inc.