



January 17, 2024

Submitted via OEHHA Website: <https://oehha.ca.gov/comments>

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Office of Environmental Health Hazard Assessment
P. O. Box 4010 Sacramento, California 95812-4010

Re: Notice of Modification of Proposed Regulation and Addition of One Document to Rulemaking File, Title 27, California Code of Regulations-Article 7 No Significant Risk Levels: Ethylene Oxide.

On December 19, 2023, the Office of Environmental Health Hazard Assessment ("OEHHA") released a proposed modification ("Proposed Modification") to an early April 7, 2023 draft document for public review that had summarized the carcinogenicity data and derived an updated cancer inhalation unit risk factor ("IUR") for ethylene oxide ("EtO") and a proposed "Updated No Significant Risk Level for Ethylene Oxide" ("NSRL"). In its Proposed Modification, OEHHA proposes to establish separate NSRLs for EtO for inhalation and oral exposure, with the proposed NSRL for oral exposure set at a level roughly 25 times higher than the proposed NSRL for inhalation exposure. Sterigenics US, LLC ("Sterigenics") previously provided comments on OEHHA's April 7, 2023 draft documents, and it appreciates the opportunity to provide comments on OEHHA's Proposed Modification.

As noted in our prior comments submitted on June 14, 2023, Sterigenics operates three facilities within California that sterilize medical devices and products with EtO utilizing a U.S. Food and Drug Administration ("FDA")-validated, non-invasive method to sterilize medical equipment prior to use. Sterilization prevents biological contamination in health care settings that can lead to patient infections, and in severe cases, deaths. Sterilization using EtO is the only method available for sterilizing large quantities of many types of packaged medical equipment. The Sterigenics EtO facilities within California sterilize over 90 million essential medical devices and products each year, including surgical kits, catheters, cardiac implants, stents, IV sets and more. After sterilization by Sterigenics, these products are supplied to nearly 100 healthcare product manufacturers as well as numerous hospitals throughout the state.

Sterigenics commends OEHHA for its willingness to take a closer look at the scientific data regarding EtO and carcinogenicity, and we believe that its proposed NSRL for oral exposure to EtO is now more consistent with the scientific data regarding EtO's potential carcinogenicity. Sterigenics is concerned, however, that OEHHA has of yet not taken the same closer look at the scientific evidence that likewise supports a higher NSRL for inhalation exposure to EtO.



Although not specified in its Proposed Modification, it appears that OEHHA's decision to revisit its April 7, 2023 draft document was prompted by comments submitted by the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas), which noted the disconnect between OEHHA's proposed NSRL and the much higher levels of EtO to which humans are routinely exposed on a daily basis from the ingestion of fruits and vegetables. As set forth in the IPEC-Americas comments, for example, "[e]ating an average-size red delicious apple ... would result in a person being exposed to ~6,360,000 ng ethylene oxide," a value that "exceeds the proposed NSRL by 110,665,000 times."

OEHHA should take similar note of other comments that highlight the disconnect between its proposed inhalation NSRL and background levels of EtO in the ambient air unrelated to any operations of medical sterilizers. As explained by the South Coast Air Quality Management District in its comments on the April 7, 2023 draft document, "if EtO indeed has the cancer potency [through inhalation] that OEHHA is proposing there are significant consequences for all Californians. The potential cancer risk [from EtO] at background levels would be about 1,000 chances in-a-million, more than double the cancer risk from all pollutants and sources combined in South Coast AQMD. It is unclear what sources are contributing to background levels of EtO – based on our monitoring data, it does not appear to be due to medical sterilizers."

Sterigenics detailed in its earlier June 14, 2023 comments the significant adverse consequences for public health that could arise from the establishment of an unrealistic and scientifically-unsupported NSRL for EtO, including the potential temporary or permanent closures of EtO sterilization facilities in California. Sterigenics submits these additional comments in the hope that OEHHA will continue its closer look at the scientific data and provide further modifications of its NSRL for inhalation exposure to EtO to more accurately reflect the full body of scientific evidence.

Sincerely,

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