

January 26, 2024

Members, Scientific Review Panel on Toxic Air Contaminants  
Submitted via [comment submission portal](#)

Re: Comments on Draft Updated Cancer Inhalation Unit Risk Factor for Ethylene Oxide (Agenda Item No. 2, Scientific Review Panel Meeting on February 2, 2024).

Sterigenics appreciates this opportunity to submit these comments for consideration by the Scientific Review Panel on Toxic Air Contaminants (SRP) in connection with Agenda Item No. 2 at the SRP's February 2, 2024 meeting on the Office of Environmental Health Hazard Assessment's (OEHHA) draft update of the inhalation unit risk factor (IUR) for ethylene oxide (EtO).

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

Sterigenics has been actively participating in EtO regulatory efforts at the federal and state level, including the IUR update before the SRP. On April 7, 2023, OEHHA released the draft updated cancer IUR for EtO for public review and comment. Sterigenics submitted comments on the draft IUR in a letter dated June 14, 2023, and on a separate OEHHA proposal to update the Proposition 65 "No Significant Risk Level" (NSRL) for EtO.<sup>1</sup> Subsequently, on December 19, 2023, OEHHA released a proposed modification ("Proposed Modification") to its draft updated NSRL that summarizes the EtO carcinogenicity data and proposes a new NSRL for oral exposures that deviates substantially from OEHHA's draft NSRL for inhalation exposures. Sterigenics submitted further comments on this revised draft in a letter dated January 17, 2024. While the proposed NSRLs would apply only in the context of Proposition 65 implementation, OEHHA's reinterpretation of the scientific evidence, which it now views as supporting a separate NSRL for oral exposure to EtO, calls into question the validity of OEHHA's conclusions regarding the risk from inhalation of EtO. We believe OEHHA's proposed changes to the Proposition 65 NSRL are directly relevant to the SRP's independent evaluation of the available evidence on inhalation cancer risk.

As explained in Sterigenics' January 17, 2024 comments on OEHHA's proposal to update the EtO NSRL, OEHHA's reassessment of the scientific data regarding the carcinogenicity of EtO and proposed modification of its earlier draft documents resulted in the conclusion that risks associated with *oral* exposure to EtO are substantially lower than indicated in OEHHA's April 7, 2023 draft NSRL.

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<sup>1</sup>Updated No Significant Risk Level for Ethylene Oxide, Office of Environmental Health Hazard Assessment, April 7, 2023.

Sterigenics supports this proposed modification, but we submit that OEHHA has failed to conduct a similar reassessment of the scientific data with respect to *inhalation* exposure.

Furthermore, the regulatory actions that would be triggered by the proposed IUR are likely to result in adverse public health impacts that have been well documented in the public record for this proceeding. The South Coast Air Quality Management District (SCAQMD) noted in its June 14, 2024 comments (on OEHHA's April 7, 2023 draft EtO NSRL and IUR updates) that OEHHA's proposals call into question the level of risk associated with widely occurring background levels of EtO. The SCAQMD stated that "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." The SCAQMD further stated that "These background levels are ... consistent with monitored EtO levels found a few hundred feet from sterilization facilities in South Coast AQMD, indicating that the sterilization facilities are likely not the leading source of EtO emissions contributing to background levels found nearly everywhere throughout our region and the nation."

Most notably, if the IUR is updated as currently proposed, there would be a greater risk of both temporary and permanent shutdowns of in-state facilities that sterilize medical devices, leading to medical product shortages that would impact health care delivery and patient outcomes in California and elsewhere, as explained further in our prior comments to OEHHA. We ask that the SRP consider whether the greater risk of these outcomes is warranted in light of the limited weight of the scientific evidence supporting the proposed IUR, and the inconsistency of the proposed IUR with other evidence, as outlined in our prior comments to OEHHA.

Accordingly, we request that the SRP consider these materials as it conducts its scientific review of OEHHA's proposed EtO IUR, and that the SRP advise OEHHA to reconsider the proposed IUR in light of this information. Our June 14, 2023 and January 17, 2024 comments to OEHHA are included with this letter.

We appreciate this opportunity for comment.

Sincerely,



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