

July 29, 2026

Submitted Via Comment Portal: [Comment Submissions - Inhalation Unit Risk Factor \(IUR\) for Ethylene Oxide - OEHHA](#)

Dr. Rima Woods, Chief
Air Toxicology and Risk Assessment Section
Office of Environmental Health Hazard Assessment (OEHHA)
1001 I St., 12th Floor
Sacramento, CA 95814

RE: Inhalation Unit Risk Factor (IUR) for Ethylene Oxide (EtO)

Dear Dr. Woods:

The Ethylene Oxide Panel (EO Panel) of the American Chemistry Council (ACC) appreciates the opportunity to provide comments to OEHHA on the proposed revisions to the IUR. The EO Panel includes major producers and users of EtO in North America.

The EO Panel continues to have significant concerns regarding the scientific underpinnings of the proposed IUR, particularly the Commission's reliance on the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) assessment for EtO to develop the health-based IUR. Reliance on the EtO IRIS-derived toxicity value has resulted in health-based standards that are overly conservative and not supported by the weight of the scientific evidence.

The EO Panel has consistently raised substantial concerns regarding scientific deficiencies in the IRIS assessment, including:

- The USEPA's 2-slope spline model is comprised of a steep slope in the low-dose region with a high-dose plateau.
- A steep slope in the low dose region is inconsistent with the epidemiology data. Signals for LH, lymphoid and breast cancer are weak and inconsistent across available studies.
- A steep slope in the low-dose-region is inconsistent with the biological evidence.
- EPA's 2-slope model overpredicts risk.
- The log-linear CPH model is preferred.

The weight of scientific evidence demonstrates that OEHHA's draft risk assessment relies on a biologically untenable dose-response framework. A scientifically robust IUR must reject the implausibly steep low-dose slopes driven by a small fraction of cases. Independent benchmarks—including the UCC manufacturing cohort, modern molecular dosimetry, and empirical "reality checks" from heavily studied smoker cohorts—stand in direct contradiction to deriving an exceptionally high inhalation IUR.

We urge OEHHHA to correct its study quality criteria and evaluations, abandon incorrect and subjective visual fit comparisons, and align its final risk assessment with the overwhelming biological evidence that supports applying the standard log-linear CPH model to the NIOSH data.

The attached comments, and new published, peer reviewed genotoxicity papers demonstrate that the dose response pattern for genetic damage from inhalation of EtO does not follow OEHHHA's proposed two-spline model, where tumor responses increase sharply at low doses (indicating a highly potent genotoxic carcinogen). The new studies confirm a shallow, single slope linear dose-response relationship.

We also attach our July 19, 2024, comments to the National Academies of Sciences, Engineering, and Medicine (NASEM) Committee reviewing the Texas Commission on Environmental Quality's Ethylene Oxide Development Support Document (TCEQ DSD) and the comments of the Ethylene Oxide Sterilization Association (May 15, 2026) that includes our comments on alternative values and the newly published studies addressing both the relevant epidemiology cohorts.

Should you have any questions, please contact me at bill_gulledge@americanchemistry.com or (202) 249-6714.

Sincerely,

Bill Gulledge

Bill Gulledge, Senior Director
Chemical Products & Technology Division
American Chemistry Council

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