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MCCV
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Inland Empire Economic Partnership
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Western Tree Nut Association
CMTA
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California Cotton Ginners and Growers Association
CCGGA
Carlsbad Chamber of Commerce
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Council of Business & Industries
CCEEB
Milk Producers Council
Serving the Dairy Industry Since 1949
Greater San Fernando Valley Chamber of Commerce
Greater Coachella Valley Chamber
California Metals Coalition
California Alliance of Small Business Associations
Dedicated to Environmental Progress & Economic Growth
safe food Alliance
Western Growers
Fresh produce from our families to yours
IEA
Industrial Environmental Association
Promoting Industry and Protecting the Environment
CFCA
California Fuels + Convenience Alliance
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Institute
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Industry Business Council
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Torrance Area Chamber of Commerce

July 29, 2026

Submitted via the OEHHA 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
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Sacramento, CA 95814

Subject: Joint comments on OEHHA's draft Inhalation Unit Risk Factor for Ethylene Oxide

Dear Dr. Woods:

The undersigned organizations appreciate this opportunity to comment on the Office of Environmental Health Hazard Assessment's (OEHHA) draft Cancer Inhalation Unit Risk Factor (IUR) for ethylene oxide (EO).[1] OEHHA and CARB have taken the unusual step of releasing two draft IURs for different chemicals at the same time, acrolein and ethylene oxide (EO). We appreciate OEHHA allowing an additional 30 days to develop these comments in recognition of the potential impact these draft IURs could have on existing state and local air toxics programs and the added complexity of the review and comment development process for organizations, industries, and businesses impacted by both proposals.

Among the commonalities between acrolein and EO are their apparent ubiquity in ambient air and the magnitude of the cancer potency estimated by OEHHA. If OEHHA adopts final IURs at or close to the draft levels, each of these chemicals would, by itself, present a cancer risk in many areas of the state that is greater than the cancer risk from all other state-regulated toxic air contaminants (TAC) combined. Taken together, they would represent an unprecedented health threat that would demand immediate actions and dedication of substantial resources by CARB and the air districts to mitigate the presumed cancer risk.

In addition, the regulatory actions that would be triggered by the proposed IUR are likely to result in adverse public health impacts. The effective sterilization of medical devices to remove potentially harmful germs and other microorganisms prior to use is "critical to our

[1] Office of Environmental Health Hazard Assessment, Air Toxics Hot Spots Program Ethylene Oxide Cancer Inhalation Unit Risk Factor, Technical Support Document for Cancer Potency Factors, Appendix B, Public Review Draft, May 2026.

health care system and a shortage — especially of life-saving, life-sustaining, or critical devices — can present a risk to the public health."[2] Sterilization by EO is the method with the broadest application available for medical products due to its effectiveness at lower temperatures and its general compatibility with a diversity of materials, resins and product types. The national capacity for EO sterilization is limited, and other methods of sterilization cannot replace the use of EO for many devices. Consequently, 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 meaningfully impact infection risks and negatively impact health care delivery and patient outcomes in California and elsewhere.[3]

Given these significant impacts, it is critically important that development of an updated EO IUR is based on and supported by strong scientific evidence. However, as demonstrated in comments submitted on this proposed IUR by the life sciences industry and the American Chemistry Council (ACC), OEHHA's interpretation of the available evidence is speculative, predicated on false assumptions about historical worker exposures[4] and visually fitting alternative dose-response curves to aggregated data that cannot be replicated in biological systems. Specifically, these comments, and new published, peer reviewed animal evidence demonstrate that the dose response pattern for genetic damage from inhalation of EO does not follow OEHHA's proposed two-spline model, where tumor responses increase sharply at low doses (which would indicate a highly potent genotoxic carcinogen); rather, the new evidence confirms a shallow, single slope linear dose-response relationship indicative of a weakly genotoxic carcinogen.[5,6] These findings are

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[2] U.S. Food and Drug Administration, Ethylene Oxide Sterilization Facility Updates, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates (last visited July 29, 2026).

[3] *Id*. [expressing concern about "the supply chain effects of closures and potential closures of certain facilities that use ethylene oxide to sterilize medical devices prior to their use," and "the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care"].

[4] OEHHA's analysis assumes that sterilization workers in the National Institute for Occupational Safety and Health (NIOSH) cohort were exposed to ***lower*** concentrations of EO before 1978, even though it is well established that workplace exposure controls ranged from rudimentary to non-existent in this timeframe, and OEHHA has no actual exposure data to corroborate this assumption.

[5] B. Gollapudi, J. Bus, P. Cassidy, J. Weinberg, J. Bemis, D. Torous, S. Dertinger, K. Lu, R. Reiss, A. Li, Investigation of Ethylene Oxide Genotoxicity Dose–Response to Inform Cancer Risk Assessment, *Environmental and Molecular Mutagenesis*, June 2026 ["The dose response pattern for genetic damage, which is the first key event of the mutagenic MOA for the carcinogenicity of EtO, supports the biological plausibility of a shallow single-slope linear CPH dose response model for the derivation of inhalation unit cancer risk for this chemical."].

[6] C. Liu, J. Peng, J. Feng, H. Zhao, X. Wang, B. Gollapudi, A. Li, J. Bus, K. Lu, Molecular dosimetry of DNA adducts in mice exposed to ethylene oxide, *Toxicological Sciences*, July 2026 ["The results revealed a linear dose–response pattern for N7-HE-G adduct formation that was highly correlated with the levels of N-(2-hydroxyethyl)-L-valine (HE-V), supporting the use of HE-V as a surrogate biomarker of EtO dose to DNA. In

also consistent with the weight of the human evidence, including an updated assessment of EO manufacturing workers published in 2025.[7]

When one considers this new evidence in light of the many prominent deficiencies in OEHHA's revised draft IUR, it is unclear why OEHHA continues to defend what appears to be an increasingly indefensible approach to establishing a cancer slope factor and IUR for EO. How OEHHA responds to this additional, directly relevant scientific evidence will determine whether the agency is truly interested in utilizing and objectively evaluating the best available science in establishing an IUR for EO, or intent on defending the approach taken by USEPA in the 2016 update of the Integrated Risk Information System's (IRIS) toxicological assessment of EO. The latter approach would not advance the state of the science on assessment of inhalation risks from exposure to EO, and more importantly, it would cross an ethical line between reasonable differences in scientific interpretation and an outcome-oriented assessment.

This coalition endorses the life sciences industry and ACC comments. The methodological flaws discussed in these comments suggest that OEHHA is not focused on establishing an IUR that accurately reflects human health risk, but instead is focused on deriving a more stringent value. The objective of health risk assessment should be to predict potential adverse health outcomes as accurately as possible and then apply a margin of safety that reasonably addresses uncertainty in the underlying data and variability in the exposed population. Health risk estimates should not be predicated on data that is not fit for purpose, nor intentionally overstated in the interest of driving more stringent regulatory outcomes. Particularly where, as here, health risk assessment results are intended to support regulatory decisions and will have real world consequences, improper and speculative risk assessment will result in regulatory decisions that impose higher societal costs than are necessary to protect public health. Any such action that is likely to exacerbate existing affordability challenges without delivering a commensurate public health benefit should be strictly avoided.

This approach could also jeopardize public health protection by redirecting limited agency staff time and funding from identification and mitigation of documented health risks toward identification and mitigation of increasingly theoretical health risks. It is all the more

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contrast, the dose–response pattern for promutagenic O-HE-dG adducts provided critical molecular-level MOA data, essential for selecting a biologically plausible dose–response model. Taken together, these findings support the conclusion that the cancer risk to the general population from EtO exposure is conservatively modeled by assuming a MOA that is characterized by a shallow single-slope linear dose–response relationship."].

[7] C. Valdez-Flores, A. Li, T. Bender, J. Teta, Use of updated mortality study of ethylene oxide manufacturing workers to inform cancer risk assessment, *Risk Analysis*, 2025; 1-15.

concerning when one considers that many potential anthropogenic sources of EO are already highly regulated, and natural sources are inherently difficult if not impossible to control. It is unclear how CARB would reconcile the state's very high preliminary health risk estimates with subsequent findings that there are very limited opportunities to meaningfully reduce risks from exposures to EO.

Limitations in monitoring data should preclude speculation about potential cancer risks

The agencies acknowledge that the draft cancer risk estimate presented on CARB's Learn About Ethylene Oxide website ("EO website"),[8] is "based on limited air monitoring data with known limitations and notable uncertainties." CARB acknowledged that it does not have adequate information on many sources of EO or the true background level, much less an understanding of which sources are the primary drivers for ambient EO concentrations. CARB noted that "ambient measurements of EtO are limited – two air monitoring sites in Southern California since 2020." We particularly appreciate CARB's acknowledgement of the many shortcomings in the existing EO monitoring data. However, while CARB is reasonably forthcoming regarding the many limitations in the available air monitoring data for EO, it fails to offer any reservations regarding the preliminary findings in OEHHA's draft Technical Support Document (TSD) for the revised draft EO IUR.

It is likely that significant time, staff resources, and funding will be dedicated to addressing these knowledge gaps, and it is equally likely that CARB and the air districts will conclude that there is little opportunity for additional risk reduction for many sources beyond actions that have already been taken or are under development. At a minimum, and before committing significant additional resources to EO at the expense of other regulatory priorities, CARB and the air districts must be certain that OEHHA's proposed updated IUR is based on a reasonable interpretation of adequate and reliable scientific evidence, and that fundamental flaws in existing emissions data are resolved.

Given the substantial shortcomings the agencies have identified in the existing emissions data, their inability to obtain accurate measurements at the present time, and the many scientific deficiencies in the draft EO IUR discussed in the life sciences industry and ACC comment letters, it is irresponsible for the agencies to speculate about potential cancer risks from ambient exposures to EO. Such assertions tend to incite fear and anger among community representatives, much of which is directed toward known and potential sources, especially those specifically identified by regulatory agencies. This approach is

[8] California Air Resources Board, Learn About Ethylene Oxide (EtO), Where It Comes From, How It Affects Your Health, and What California Is Doing to Protect You, May 14, 2026.

also likely to foster greater distrust of CARB, OEHHA, and the air districts if future research proves the initial speculation to be misdirected or unfounded. The agencies should publicly withdraw these statements pending completion of the IUR development process, and the research necessary to fill the many data gaps noted above.

CARB and OEHHA should be more forthcoming about potential impacts on existing air toxics programs

CARB and OEHHA fail to explain the potential impact of the draft IURs for EO and acrolein on state and local air toxics programs in the agencies' public-facing informational materials. CARB states on its EO website that "an IUR can impact implementation for a broad number of programs that consider health impacts of air toxics," and then proceeds to describe in general terms the process for developing IURs and how they are used in those state and local air toxics programs. What it fails to address, however, is the high probability of significant impacts on existing work streams that would stem from the extremely high risk estimates attached to these particular TACs, or how future agency responses involving reallocation of resources within state and local air toxics programs could impact public health locally, regionally, and at the state level.

Given the preliminary cancer risk estimates cited by the agencies for exposure to ambient acrolein and EO (1,300 in one million and 980 in one million and respectively), CARB, and particularly the air quality management districts, are likely to face an increase in workload under the Toxic Air Contaminant Identification and Control Program and the Air Toxics Hot Spots Program that is arguably unlike anything they have experienced since CARB listed diesel exhaust particulate as a TAC in 1998. And as CARB separately acknowledges, the air districts will face the additional challenge of incorporating evaluation of cancer risks from these chemicals into their air toxics new source review programs. This probable step-change impact in workload is a function of both the relative magnitude of the cancer risk estimates for acrolein and EO relative to those of other state regulated carcinogenic TACs, and the agencies' limited understanding of acrolein and EO concentrations in ambient air and contributions from various anthropogenic and natural emissions sources. This concern was previously expressed by the South Coast Air Quality Management District (SCAQMD) in comments it submitted to OEHHA in June 2023 on OEHHA's first draft IUR for EO.[9]

[9] Letter from South Coast Air Quality Management District to the California Air Resources Board dated June 14, 2023, commenting on the Office of Environmental Health Hazard Assessment's first draft IUR for Ethylene Oxide: https://oehha.ca.gov/sites/default/files/media/dockets/21072/21122-south_coast_aqmd/oehha_eto_-_south_coast_aqmd_comment_letter_6-14-23.pdf

> "… if EtO indeed has the cancer potency that OEHHA is proposing, there are significant consequences for all Californians. The potential cancer risk at background levels would be about 1,000 chances in-a-million, more than double the cancer risk from all other pollutants and sources combined in South Coast AQMD. It is currently unclear what sources are contributing to background levels of EtO …"
>
> "With population-wide risks of this level, we believe it is imperative that CalEPA take a much more active role in identifying the sources of the risk, as well as appropriate measures to reduce it. This effort will take significant coordination among the state, air districts, and others as well as substantial resources."

The $2.5 million earmarked in the fiscal year 2026-2027 state budget to "fill the scientific gaps surrounding acrolein and ethylene oxide" acknowledged by CARB and OEHHA is only a small down payment on the funding and agency resource commitments that will be necessary to support the development and deployment of new air quality monitoring methods, statewide and regional emissions inventory updates, source assessment and apportionment, facility-specific emissions inventory updates, new health risk assessments, additional public notifications, development of new risk management plans and risk mitigation measures, new source review for new and modified sources of acrolein and EO, new state and local rulemakings, and other regulatory actions.

If, as indicated in the separate comments on the revised draft EO IUR submitted by ACC and the life sciences industry, the science underpinning the proposed EO IUR is speculative, then the resource shifting and new spending that would result from this proposal is likely to create gaps in public health protection by diverting limited resources from regulation of other TACs and criteria pollutants where the public health basis for regulation is more clearly established. At a minimum, CARB and the air districts should evaluate the potential programmatic impacts of both the draft acrolein and EO IURs, including but not limited to additional staffing and funding needs and the potential for shifting resources from current areas of focus to assessment and management of health risks from acrolein and EO, and disclose that information to the public.

CARB should clarify the potential role and limitations of mobile monitoring data as a potential guidepost for future regulatory actions

CARB's EO website notes that CARB collected acrolein data as part of the Statewide Mobile Monitoring Initiative (SMMI) and then states that this "high time resolution data is expected to support improved understanding of pollutant variability and potential sources of EtO."

Apart from the extensive limitations in the available EO data acknowledged by CARB, this language appears to overstate the potential utility of the EO data collected through the SMMI. CARB has posted separate information on its SMMI webpage highlighting the appropriate uses and limitations of mobile monitoring data. For example, CARB has posted a Frequently Asked Questions document on its SMMI website, last updated on June 24, 2026,[10] which includes the following statements to guide interpretation and future use of the SMMI data:

> "Not intended for regulatory determinations: Mobile monitoring is best for screening, mapping, and prioritizing follow up. Regulatory decisions under the Clean Air Act rely on fixed site monitors that use U.S. EPA approved Federal Reference or Equivalent Methods (FRM/FEM) and meet siting criteria.
>
> If results are needed for regulatory purposes, a follow-up study using U.S. EPA approved methods would be required."
>
> "Mobile sensor data also shouldn't be used to quantify individual or community health risks, and U.S. EPA does not set health-based standards for the short-term sampling typical of many sensor readings."
>
> "The mobile sensors' ability to collect accurate results can also be affected by temperature, humidity, co-pollutants, and variable environmental conditions so routine checks, calibration, and corrections are needed."
>
> "Depending on the source of concern and pollutants to be measured, monitoring was assigned to Aclima's vehicles or to Partner Mobile Laboratories (PMLs). The three PMLs—operated by UC Berkeley, UC Riverside, and Aerodyne—collected air toxics measurements and were deployed to high-priority areas identified through community engagement. Because PMLs are limited, communities received only a few days of these specialized measurements."
>
> "While the dataset may help inform future work, it is not intended to directly drive regulatory or policy decisions."

[10] California Air Resources Board, Statewide Mobile Monitoring Initiative (SMMI): Frequently Asked Questions, June 24, 2026: https://ww2.arb.ca.gov/resources/fact-sheets/smmi-frequently-asked-questions-faq

> "Before releasing [SMMI] results, CARB must complete extensive quality checks and prepare plain-language explanations and visuals so the public can use the information confidently. This kind of dataset is both powerful and easy to misinterpret without clear context. Mobile sensor data involve short, non-continuous samples and lower-cost instruments, which expand coverage but add uncertainty. Because of this, the results require extra interpretive care compared with fixed-site monitors. Taking time to review, verify, and contextualize the findings helps ensure the results are reliable and actionable."
>
> "This data provides a starting point, especially in communities that previously lacked sufficient air-monitoring data, so that future monitoring can investigate the air quality benefits of actions to reduce emissions."

While not expressly stated in the SMMI FAQ, these limitations support the conclusion that SMMI data is not appropriate for quantifying localized ambient concentrations of individual TACs or for source attribution analysis.

It is unclear why CARB did not carry the guidance in the SMMI FAQ forward into the informational materials it is now presenting on EO, but as a matter of transparency and consistency in interpretation of available data, it should immediately remedy that oversight. To the extent that CARB continues to reference SMMI data as a source of information to help inform future regulatory actions related to EO, we strongly recommend that CARB include this information in all of its public-facing materials on these substances.

CARB should complete state-funded research before air districts incorporate final IURs into their Hot Spots regulatory programs

Local air district regulations implementing the Air Toxics Hot Spots Program, such as the Bay Area District's Regulation 11, Rule 18, and the South Coast Air Quality Management District's Rule 1402 include a public notification component which is triggered in cases where cancer risks from individual stationary sources exceed 10 in one million at receptors beyond the facility fenceline (e.g., homes, schools, hospitals, other businesses). These sources will be targets of opportunity for community groups and air districts, even if CARB concludes that the majority of emissions for both acrolein and EO originate from mobile, indirect, and natural sources.

The adoption of new IURs for acrolein and EO will likely result in air districts reprioritizing facilities subject to the Hot Spots program, which will result in requirements for new and

updated air toxics emissions inventories and facility wide health risk assessments. Facilities whose risk assessments indicate cancer risks greater than 10 in one million at receptor locations beyond the facility fenceline will be required to issue public notifications stating that facility operations are exposing individuals at the identified locations to an excess cancer risk. To the extent the draft IURs are based on overstated health risks that cause affected facilities to exceed air district public notification thresholds, new notifications will cause unnecessary and counter-productive public alarm in communities where the background risk from ambient concentrations of acrolein and EO may dwarf individual contributions from stationary sources.

CARB also has not addressed the potential for the IUR to be completed before the new research on acrolein and EO emissions and potential sources funded in the current state budget. A worst-case scenario would involve immediate actions by air districts under Hot Spots and air toxics new source review regulations and policies following OEHHA approval of new IURs for acrolein and EO, before the state-funded research is completed. In that scenario, air districts would be using emissions data they know to be inaccurate as a basis for estimating facility risk, and at least in some cases, imposing new regulatory requirements on affected sources. This approach would be a recipe for imposing additional and perhaps unsustainable administrative, public relations, operational, and economic burdens on affected facilities without first having a clear understanding of whether those burdens would result in a meaningful public health benefit. We strongly encourage CARB and the air districts to complete the additional state-funded research before incorporating new IURs for acrolein and EO into their air toxics programs.

The IUR development process is premature

CARB's EO website and the Governor's May Revise budget proposal[11] both acknowledge that preliminary risk estimates are predicated on limited data. The May Revise states that "critical, foundational scientific research [is] needed to support additional actions to reduce cancer risk from acrolein and ethylene oxide." OEHHA's decision to move ahead with development of an updated EO IUR, despite the Newsom Administration's recognition that the best available science currently is not sufficient to support additional action to reduce cancer risk from exposure to EO, is arbitrary and likely to distract OEHHA and risk managers at CARB and the air districts from more clearly established air quality and public health priorities. Where the best available science is not a sufficient basis for risk assessment and risk management, OEHHA should not move forward with development of an IUR.

[11] See: 2026-27 MR Budget Summary.

CARB's EO website states that "CARB will continue working to improve our understanding of EtO levels in the air and will refine the cancer risk estimates as better data becomes available." These statements suggest that it is acceptable for the state to adopt new IURs based on limited, flawed, or otherwise inadequate scientific evidence, because CARB and OEHHA can "refine" them at a later date. The possibility that an IUR might be supported by sufficient scientific evidence in the future is not a rational basis for developing an IUR without adequate scientific support at the present time. This approach disregards the many impacts on state and local regulatory agencies and the regulated community related to emissions monitoring, risk assessment, risk management, and risk communication that an improperly derived IUR is likely to cause. The agencies' current posture also overstates the likelihood that CARB and OEHHA will promptly update an IUR based on the future availability of new scientific evidence, which has not been the agencies' practice to date.

OEHHA's Involvement in Supplemental Research Cited in the Revised Draft IUR for Ethylene Oxide

During the three years between OEHHA's public release of its first draft IUR for EO on April 7, 2023 and the subsequent release of its revised draft IUR on May 14, 2026, OEHHA participated in new research, both as a co-author and a co-sponsor, focused on two specific deficiencies in its first draft IUR identified by the Scientific Review Panel on Toxic Air Contaminants (SRP) and by EO stakeholders related to: (1) an alleged heathy worker effect in the occupational cohort OEHHA used to derive the IUR, and (2) the contribution of endogenously produced EO to total EO exposure. These studies appear to be designed to generate results that support lines of argument OEHHA has already offered in defense of its first draft IUR (April 2023), and both studies have methodological flaws and limitations that diminish the reliability of their results.

Picciotto et al. (2026) overstates the impact of the "healthy worker survivor effect" on cancer risk estimates

Picciotto et al. (2026) is the latest reassessment of the National Institute of Occupational Safety and Health (NIOSH) study that is the primary basis for OEHHA's proposed update of the IUR for EO. This paper was funded through an interagency agreement between NIOSH and OEHHA. The authors assert that the original study and subsequent reassessments, including by the Texas Commission on Environmental Quality (TCEQ, 2020), fail to account for the "healthy worker survivor effect," (HWSE) which they interpret as underestimating lymphohematopoietic and breast cancer risks. The authors acknowledge that "the presence of a healthy worker survivor effect does not provide clear evidence of the exact correct shape of the exposure-response curve" but assert that it does "lend credibility to curves that have a sharp rise followed by a flattening over higher levels of exposure."

Picciotto et al. relies on nested assumptions of causality – that exposure ***<u>can</u>*** affect employment, that employment affects future exposures, and that employment relates to health through unmeasured health status. This approach generates bias in evaluating the true relationship between exposure and health outcomes. The study authors recommend utilizing advanced causal methods to derive unbiased estimates, but they did not employ such methods in their analysis.

The authors also arbitrarily exclude from their analysis anyone employed for less than one year, which conflicts with the assumption that the most highly exposed workers are the first to leave. Excluding workers employed for less than one year would likely bias the results high (i.e., create an artificial appearance of a healthy worker effect) since workers with shorter work histories or pre-existing conditions were excluded from the study. This approach also complicates comparison of findings in reference and study populations as the reference group has been altered.

The Healthy Worker Effect (HWE) has been reported to be less pronounced for cancer deaths than for chronic diseases such as cardiovascular disease, diabetes, and nonmalignant respiratory disease.[12] In fact, the authors of the largest NIOSH occupational EO study acknowledge that "[t]he healthy worker effect would seem an unlikely explanation for the lack of cancer excesses in the exposed versus non-exposed comparisons."[13] Additionally, studies using cancer incidence data suggest that cancer risk for women is less influenced by the HWE than for men,[14] which calls into question the author's speculation that the positive findings for lymphohematopoietic and breast cancers reported among women in the NIOSH cohort are "underestimates."

There are other likely sources of bias and error in this paper, including but not limited to restricting follow up on health outcomes to workers hired after 1960, errors in exposure measurement (and lack of exposure measurement after 1980), and failure to evaluate other causes of death or retirement for non-health-related reasons. Moreover, neither Picciotto et al. (2026) nor the NIOSH cohort study can quantify the magnitude of the alleged HSWE and we are not aware of any analysis that can confirm that a HWE/HSWE would have any impact on the results of these studies.

Lin et al. (2025) contributes very little useful information to the interpretation of the sterilization worker exposure data and nothing to the IUR derivation

[12] Kirkeleit et al., 2013, pp. 1218
[13] Steenland et al., 2004, pp. 6
[14] Kirkeleit et al., 2013, pp. 1219

Lin et al. (2025) evaluates internal and external ethylene that is metabolized by the body to create endogenous EO. It is not a study of exogenous EO and does not attempt to link exposure levels to human health effects. The authors suggest that 80% of human exposure to EO originates from exogenous sources that ***might*** include (1) sterilization facilities, (2) residue on medical devices, and (3) passive/secondhand smoke, but then dismiss these sources as meaningful contributors and leave open the possibility of some unknown source. The authors also acknowledge that they employed a novel method to evaluate the relationship between ethylene exposure and endogenous EO levels - using hemoglobin adduct data obtained from a literature search as inputs to a physiologically based pharmacokinetic model - that has not been tested or replicated in any other research.

Lin et al. (2025) asserts that endogenous EO (EO produced by the human body) is a small contributor to overall EO exposures, and that the majority of total EO exposures originate from external sources. The findings from this study appear to be predicated on the false premise that EO from exogenous sources is somehow chemically different or toxicologically more potent than endogenous EO.

Neither study addresses the biological plausibility of OEHHA's draft cancer risk assessment

As indicated in the comments prepared by Exponent, the weight of evidence from DNA testing strongly indicates that cancer risk increases slowly with increasing exposure over time, not sharply at low levels of exposure as OEHHA has suggested. Mechanistic studies of the interactions between EO and DNA demonstrate exactly the opposite effect – that mutagenic responses occur only at very high exposures. It is unclear why OEHHA is investing in research that focuses on peripheral issues while ignoring more compelling research that is now available in the published literature.

OEHHA has not been forthcoming regarding its involvement in additional EO research

Industry representatives and scientific consultants met with OEHHA management and technical staff multiple times to discuss interpretation of both available and emerging scientific evidence for purposes of updating OEHHA's April 2023 draft IUR. At least three meetings occurred over an 18-month period between April 2024 and September 2025. At no time during those discussions, or in any public forum or written correspondence, did OEHHA disclose that the above-noted research was in progress, much less that OEHHA was directly involved in it.

OEHHA's lack of transparency concerning its involvement in this additional research, coupled with deficiencies in study methodology, and statements in the published articles that border on scientific advocacy, suggest intentional bias toward the goal of producing

results that can be characterized as supporting OEHHA's prior science policy positions. OEHHA's citing of these papers in the TSD for the revised draft IUR as a partial basis for defending the analysis and recommendations in its April 2023 draft IUR reinforces this perception of bias.

We encourage careful and thorough consideration of these comments by OEHHA, CARB, and the Scientific Review Panel on Toxic Air Contaminants (SRP), and we look forward to reviewing a revised draft IUR that addresses the technical deficiencies discussed above and in the comments submitted by the life sciences industry and ACC. If you have any questions, please do not hesitate to contact Jon Kendrick of the California Chamber of Commerce at (916) 594-6540.

Sincerely,

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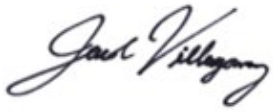

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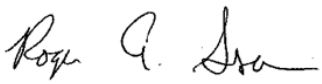

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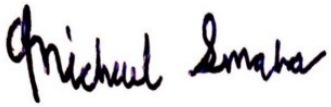
California Strawberry Commission

Nick Chiappe, Vice President of Government Affairs
California Trucking Association



Mike Smaha, VP Government Affairs
Can Manufacturers Institute

Bret Schanzenbach, President & CEO
Carlsbad Chamber of Commerce

Lisa Johnson, Executive Director
Chemical Industry Council of California

/S/
Richard Atmore, Chair
Coastal Energy Alliance

Rauly Butler, Executive Director
Council of Business and Industries

Brendan O'Donnell, President & CEO
DFA of California and Safe Food Alliance

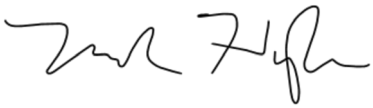
Dr. Rima Woods
July 28, 2026

Janelle Capra, President and CEO
Greater Bakersfield Chamber of Commerce

/S/
Brandon Marley, President & CEO
Greater Coachella Valley Chamber of Commerce

Mark Creffield, President/CEO
Greater High Desert Chamber of Commerce

Nancy Hoffman Vanyek, Chief Executive Officer
Greater San Fernando Valley Chamber of Commerce



Mark Hughes, Executive Director
Industrial Association

Jack Monger, CEO
Industrial Environmental Association

Joanne McClaskey, Executive Director
Industry Business Council

Paul Granillo, President and CEO
Inland Empire Economic Partnership

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Tracy Leach, Director
Kern Citizens for Energy

Jeremy Harris, President/CEO
Long Beach Area Chamber of Commerce

Stacey Kollmeyer Johnson, Executive Director
Manufacturers Council of the Central Valley

Kevin Abernathy, General Manager
Milk Producers Council

Patrick Ellis, President & CEO
Murrieta/Wildomar Chamber of Commerce

Manuel Cunha, Jr., President
Nisei Farmers League

Suzanne Singh, VP of Economic Development & Government Affairs
Santa Maria Valley Chamber

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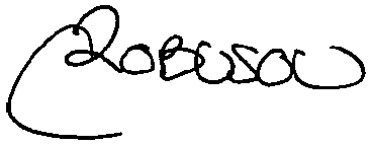
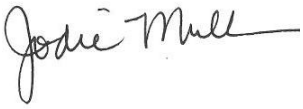


Christian Robinson, Senior Director of State Government Affairs and Grassroots
Specialty Equipment Market Association

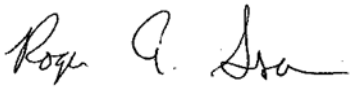
Sarah Wiltfong, Chief Advocacy and Public Policy Officer
Supply Chain Federation

Donna Duperron, President & CEO
Torrance Area Chamber of Commerce

Matthew Allen, Vice President, State Government Affairs
Western Growers Association



Jodie Muller, President and CEO
Western States Petroleum Association



Roger Isom, President/CEO
Western Tree Nut Association

Attachments

cc: Dr. Kristina Thayer, Director – Office of Environmental Health Hazard Assessment
Dr. David Edwards, Chief Deputy Director – OEHHA
Lauren Sanchez, Chair, California Air Resources Board

CARB Members
Dr. Steven Cliff, Executive Office – CARB
Rajinder Sahota, Deputy Executive Officer – CARB
Edie Chang, Deputy Executive Officer – CARB