Ms. Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
Sacramento, CA 95812-4010

Via portal at: https://oehha.ca.gov/comments

Dear Ms. Vela:

The California Chamber of Commerce, the Consumer Brands Association and the below-listed organizations (hereinafter, "Coalition") thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's Modification to Proposed Amendments to Regulations Clear and Reasonable Warnings, Safe Harbor Methods and Content, dated June 13, 2024 ("Modified Proposal"). The Coalition consists of more than 39 California-based and national organizations and businesses of varying sizes that collectively represent nearly every major business sector that would be directly impacted by OEHHA's Modified Proposal. The Coalition hereby incorporates by reference its

January 3, 2024 comments submitted on the original Proposal dated October 27, 2023 to the extent relevant to this Modified Proposal.

While the Coalition appreciates the additional time to comply, changes to the internet and catalog warning sections and clarification regarding a retail seller's obligations, the very basis for the Modified Proposal upending short-form warnings under Proposition 65 is flawed and unsupported. Accordingly, the Coalition respectfully requests that OEHHA withdraw its Modified Proposal.

1. OEHHA's Rationale for the Modified Proposal is Unsupported and Will Not Address the Root Causes of Overwarning

OEHHA's Initial Statement of Reasons states that "OEHHA anticipates that if a business must identify a chemical exposure, businesses will be less likely to use the warning prophylactically and more likely to warn only when the Act requires it." See Initial Statement of Reasons (Oct. 27, 2023). OEHHA fails to explain how it arrived at this cause-and-effect relationship, which overlooks the root causes of overwarning and is based not on any data or even consultation with affected businesses but instead on pure supposition.

Indeed, the Modified Proposal manufactures an explanation for the phenomenon of overwarning, placing the blame on businesses rather than on overly aggressive private enforcers of Proposition 65 who exploit the statute's burden-shifting structure and the ambiguities in its application that OEHHA has neglected to clarify despite decades of experience. Indeed, the Modified Proposal sidesteps the business community's most pervasive concerns that actually explain why most companies simply decide to warn—and likely will continue to warn—even when they believe it may be unnecessary. The Modified Proposal does not address the true culprits of overwarning, namely Proposition 65's unique burden-shifting framework, the vague standards for warning thresholds, and the heavy expense and time involved in litigation.

A private enforcer need only present a single lab result showing a detection of a listed chemical at some level in order to satisfy their prima facie burden. Once that low bar is satisfied, the defendant business bears the expense of proving that the level of chemical in the product is sufficiently low that no warning is required. That is very difficult and expensive to do, as courts have acknowledged on multiple occasions. See, e.g., CalChamber, 29 F.4th at 480 (9th Cir. 2022) ("Proving the [chemical] level is lower than the No Significant Risk Level requires expensive testing and costly expert testimony. . . . [which] smaller businesses often cannot afford") (cleaned up); CalChamber, 529 F. Supp. 3d at 1109 (E.D. Cal. 2021) ("[G]iven the high standard of scientific proof required by [the statutory exemption], 'it may take a full scale scientific study to establish the amount of the carcinogen is so low that there is no need for a warning.'") (quoting Consumer Def. Grp. v. Rental Hous. Indus. Members, 137 Cal. App. 4th 1185, 1215 (2006)).

First, the Proposition 65's warning thresholds are exceedingly low, particularly for reproductive toxicants, where the threshold is 1,000 times lower than the level shown in animal studies to cause no reproductive harm. These levels sometimes challenge analytical chemistry techniques and require precision that no other regulatory regime in the world requires.

Second, the exposure level cannot be determined simply by measuring the concentration of the chemical in the product; it also involves an evaluation of the rate of usage or consumption of the product by average consumers, requiring data that is often unavailable and sometimes subject to dispute by experts. Prop 65 Bounty Hunters exploit this by extracting "shake down" settlements. The burden, expense, and unpredictability of proving a negative lead many businesses to elect to provide prophylactic warnings – it is *not* because short form warnings do not require a chemical as OEHHA states. Businesses do not want to warn potential customers of the risk of cancer unnecessarily.

The solution to the perceived problem of prophylactic warnings is not to further increase the burden of compliance on businesses. Instead, the solution should be to make it harder on private enforcers—who are overwhelmingly motivated by mercenary considerations as opposed to the public interest — to leverage

the uncertainty and expense of Proposition 65 litigation to their advantage. If the agency would lower the notorious uncertainty and expense of Proposition 65 litigation, businesses will have incentives to stand behind their assessments that warnings are not required.

2. The Modified Proposal Will Impose Significant Costs and Disruption on Businesses.

Businesses operating in California need regulatory certainty, especially when it comes to Proposition 65 which is often enforced by private Bounty Hunters acting in place of the Attorney General. Regulatory certainty ensures stable and predictable operating conditions for businesses that are trying to allocate resources efficiently, manage costs predictably, and maintain consistent operations in California.

In 2016, OEHHA substantially amended the "clear and reasonable" safe harbor warning regulations to create the "long-form" and "short-form" warnings. This rule was adopted after extensive, multi-year consultation with all stakeholders, including many members of the Coalition, forcing businesses to revamp their labels, signs, and website and catalog labeling-- all at great expense.

Now, just a few years later, the Modified Proposal will impose yet again another round of major changes to the "clear and reasonable" safe harbor warning regulations that will inevitably force businesses to revamp their Proposition 65 warning programs at further expense – an expense Californians may ultimately bear through higher prices. Because businesses find it critical to stay within this safe harbor in order to reduce the expense of fending off the increasing proliferation of "shake down" Proposition 65 lawsuits, this Modified Proposal forces businesses to abandon their current warning programs that were carefully designed based on OEHHA's implicit promise that the safe harbor regulations adopted in 2016 would provide certainty and confidence inherent in a long-term regulatory program. If adopted, the Modified Proposal imposes costly label changes on every product that currently bears a short-form warning. Each short-form warning label will have to be reviewed and revised to identify a chemical for each toxicity endpoint. These changes, as well as others discussed below, will entail a cost- and time-intensive overhaul of any company's warning program, without delivering benefits to consumers. OEHHA estimates the costs of the Modified Proposal on short-form warnings at $14,538.327.67, or $4,273.46 per business. We reiterate as we did in the last set of comments that these estimates are premised on a number of unwarranted assumptions about both the number of affected businesses and the costs for each business, including:

- **Assumption:** Proposition 65 exempts businesses with fewer than 10 employees. **Reality:** This exemption has proven illusory in practice because larger businesses in the stream of commerce require that smaller businesses indemnify and defend them against Proposition 65 claims. For example, if a business with 8 employees wishes to sell its products online, the online retailer – who will be subject to suit under Proposition 65 – will require the small business to provide the warning on its products and to provide the retailer with the warning language to be posted on the product description page. The impacts of the Modified Proposal therefore will fall on many more businesses than OEHHA has estimated.

- **Assumption:** The Modified Proposal does not impose regulatory requirements on businesses, but instead provides businesses with an option for safe harbor compliance.
  Reality: Despite OEHHA's characterization, in reality the safe harbor warnings are not simply "nonmandatory guidance." Because of the enormous risk and expense of litigation that comes with using warnings that vary from those the agency has approved as safe harbors, businesses have no practical choice but to comply with the safe harbor regulations. Cal. Chamber of Commerce v. Becerra, 529 F. Supp. 3d 1099, 1119 (E.D. Cal. 2021) (noting that "the seas beyond the safe harbor are so perilous that no one risks a voyage," and thus businesses "almost uniformly use[] the safe harbor [warning]"); Cal. Chamber of Commerce v. Council for Educ. & Rsch. on Toxics, 29 4th 468, 479 (9th Cir. 2022) (affirming district court's finding that "only the safe harbor warning is actually useable in practice"). As a result, the Modified Proposal will – as a practical matter – impose regulatory requirements on many more businesses than OEHHA has estimated.

- **Assumption:** The expense of changing a label on a product is $4,273 per business.

Reality: OEHHA's estimate fails to account for a variety of costs. Among other things, OEHHA's estimate fails to account for the time of a company's employees, as well as outside consultants such as regulatory professionals and attorneys, to oversee and review analytical testing, draft revised language, and review drafts of revised labels. Furthermore, OEHHA has not adequately accounted for the added expense of communicating new warning language to each of a company's retailers.

- **Assumption:** Only manufacturing businesses in California will incur costs as a result of the new short-form warning regulations.
  Reality: OEHHA's economic impact assessment ignores the significant expense that retailers and distributors will incur as a result of the Modified Proposal's new safe harbor warning requirements. In fact, OEHHA's singular focus in its economic impact analysis is the manufacturing sector, which excludes all of the other businesses that occupy the rest of the supply chain, including distributors and retailers. Manufacturers of many consumer products that reach California consumers are located overseas and one or more steps removed from the retailer who sells the product.

- **Assumption:** OEHHA is adequately equipped to estimate the percentage of products that provide Proposition 65 safe harbor warnings.
  Reality: OEHHA's expertise does not include the insight into the labeling decisions that California businesses make. Before OEHHA can credibly estimate the percentage of products affected by the new safe harbor warning, it should consult the businesses that are responsible for deciding whether and how to label their products. In its economic analysis, OEHHA did not engage with Coalition Comment manufacturing businesses or trade associations, instead relying on its "experience and professional judgment." Any estimation based on this incomplete data is a poor reflection of the real-world business environment that is guaranteed to underestimate the Modified Proposal's economic impacts.

3. OEHHA Has Better Ways to Address its Concern About Overwarning Than by Imposing Excessive and Unnecessary Costs on Businesses.

Instead of upending the rules businesses operating in California have come to rely on by reversing its approach to short-form warnings, OEHHA should adopt new safe harbor levels that are based on the concentrations of listed chemicals in common products. Providing businesses with a concentration-based standard would eliminate the costly back-and-forth about the appropriate usage or consumption rates, which plays a significant role in a business's decision to warn as a prophylactic measure. This undertaking would not be novel. OEHHA already established concentration-based standards for acrylamide in some categories of food, see 27 Cal. Code Regs. § 25506, but this regulation affects a very small percentage of the products covered by Proposition 65 and just one listed chemical. OEHHA should undertake this process on more listed chemicals across a broader span of products.

OEHHA should also strengthen its regulations on Safe Use Determinations (SUDs). See 27 Cal. Code Regs. § 25204. Although OEHHA has encouraged the use of SUDs and has improved its internal procedures for consideration of SUDs to be more efficient and timely, the SUD regulations need to be reformed in several respects. First, the SUD regulations provide that OEHHA will not undertake a SUD once an enforcement action has commenced, but businesses usually do not become aware of the need for a SUD until private enforcers target a new product category and chemical. It makes no sense for the lead agency with expertise in the application of Proposition 65 to be barred from applying that expertise in the public interest by the mere service of a 60-day notice by a private enforcer. See id. § 25204(b)(2).

Additionally, the SUD regulations provide that SUDs apply only to the requesting party and "are not intended to affect other individuals or organizations." See id. § 25204(k). Private enforcers, when referred to a SUD that applies to the specific alleged violation in every way other than the identity of the business at issue, respond by citing this regulation. It makes no sense for the agency to permit its expertise and effort to be so easily disregarded by those seeking to exploit the expense and risk of litigation.

Finally, several years ago, OEHHA clarified that the SUD regulations are no longer simply advisory opinions that are not binding in court and now "represent[] the state's best judgment concerning the application of the Act to the particular facts presented in the request." See id. § 25204(a). OEHHA intended this change to "give OEHHA's determinations presumptive effect in an enforcement proceeding," but the language does not so provide. OEHHA should revise Section 25204 so that the regulations make clear that SUDs the agency has issued have binding effect in enforcement proceedings.

4. Further Clarification Needed with Chemical-Specific Short-Form Warning

Should OEHHA not rescind its Modified Proposal, the rule could create significant litigation risk for businesses selling in California. While OEHHA changed the bracketed text in its earlier Modified Proposal for the short-form warning from "[name of one or more chemicals known to cause cancer]" to "[name of chemical]," the modification still fails to clarify the prior ambiguity whether a business can avail itself of the safe harbor if it names just one chemical per major endpoint.

Without OEHHA's clear statement of what language provides businesses with a safe harbor, this new regulation invites private enforcers to exploit newfound ambiguity with more frivolous lawsuits. If OEHHA proceeds with its Modified Proposal, the Coalition recommends that Section 25601(b) be modified to conclude with the sentence, "Nothing in this subarticle requires any warning to identify more than one chemical for any endpoint (cancer or reproductive harm)" and to further clarify this in its Final Statement of Reasons.[1]

5. The Modified Proposal Must Be Clear that Court-Approved Warnings are Unaffected.

OEHHA does not explicitly state in its Initial Statement of Reasons whether shortform warnings provided pursuant to a consent judgment are protected. If OEHHA moves forward with its Modified Proposal, the Coalition reiterates its request that the agency expressly state that these new warnings would not disturb the certainty afforded by present court-approved short-form warnings. In past rulemakings, OEHHA has explained that "[t]o the extent warnings are being provided pursuant to a consent judgment, the terms of that judgment supersede the [new] regulations." Final Statement of Reasons (Sept. 1, 2016). That statement finds supports in OEHHA's regulations. See 27 Cal. Code Regs. § 2600(e) ("A person that is a party to a court-ordered settlement or final judgment establishing a warning method or content is deemed to be providing a 'clear and reasonable' warning for that exposure for purposes of this article, if the warning complies with the order or judgment."). Nevertheless, the Coalition strongly believes that a clear pronouncement from OEHHA in its Final Statement of Reasons regarding the continued protection from a consent judgment's short-form warnings is beneficial and necessary in light of the aggressive private enforcement environment.

In short, several problems with the Modified Proposal warrant OEHHA's careful reexamination of its revisions to the safe harbor regulations that became effective in 2018. By walking back on key safe harbor provisions that businesses rely on, OEHHA threatens to disrupt more than just their reasonably formed expectations. OEHHA's justification for this overhaul— that the current short-form warning contributes to the problem of overwarning—is without evidence or analysis. To address the overwarning issue, OEHHA should aim its efforts toward the root causes of overwarning, instead of adopting new and onerous requirements for
businesses.

The Coalition appreciates the changes made to the Modified Proposal, providing more time, eliminating dual-warning requirements and clarifying retailer obligations. Nevertheless, we respectfully request that OEHHA's Modified Proposal be withdrawn or at least further modified for all of the reasons stated.

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[1] The Coalition recommends that OEHHA include the same instruction that it provided in its Final Statement of Reasons (at 113) for the 2016 safe harbor regulations: "[A] business may choose to name any one or more chemicals for which the warning is being provided. All warnings must include the name of at least one chemical, but some warnings must include one chemical for each endpoint."

Respectfully submitted,

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American Herbal Products Association, Jane Wilson
American Sportfishing Association, Mike Leonard
American Supply Association (ASA), Stephen Rossi
Association of Home Appliance Manufacturers, John Keane
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Cc: Christine Aurre, Office of the Governor