

March 29, 2021

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

Re: Comments of the American Chemistry Council on Proposed Amendments to Article 6, Clear and Reasonable Warnings Short-Form Warnings

Dear Ms. Vela:

The American Chemistry Council (ACC) appreciates the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's ("OEHHA") Notice of Proposed Rulemaking: Amendments to Article 6, Clear and Reasonable Warnings Short-form Warnings dated January 8, 2021 ("Proposed Rulemaking"). ACC is also a signatory to the Coalition comments filed by the California Chamber of Commerce and the Consumer Brands Association, and incorporates those Coalition comments in full by reference here.

Our additional comments follow.

1. The Proposed Rulemaking is a Substantial Change that is Highly Disruptive and Burdensome to Businesses.

OEHHA's proposed changes are not mere clarifications to non-binding "guidance." OEHHA is proposing changes that will require all businesses currently using the short-form warning to change that form everywhere it is used. This could potentially be hundreds of thousands of discrete "displays" of the warning on products and packaging, online, and in Safety Data Sheets (SDSs). Many businesses referencing the current short-form warning in their SDSs would also need to change those, magnifying the fiscal impact. For example, for just one ACC member company, a change to the short-form warning would also require changes to hundreds of SDSs currently in use – changes that are not valuable from an information communication standpoint since SDSs already contain substantial health and safety information. The requested regulatory impact analysis should take these compounded costs and burdens on business into account.

For a given chemical manufacturer, the potential burden of just making the short-form label changes themselves is substantial. For example:

• For on-demand labels, a manufacturer would need to reprogram labeling templates to accommodate the new requirement.



• For pre-printed labels, <u>all</u> labels would need to be revised. If chemical names are also added, this adds another layer of complexity to the process of managing labels, because it is not just a function of adding a chemical name. A manufacturer will also then need to monitor for changes to those names (both due to formulation changes, as well as to newly added Prop 65 chemicals). For example, for <u>one</u> ACC member company, the estimated cost to make a label change to add a chemical name to the short-form label is \$250,000.

Clarity and consistency with respect to the Warning Regulation is important. It serves an important purpose. Proposition 65 is an extremely burdensome program for businesses across the U.S., in no small part due to the ambiguity related to how to achieve compliance built into the statute itself. Many chemistries on the Proposition 65 list are essential or inherent to products and cannot simply be formulated out of them, meaning that the only de facto compliance option is to issue a warning. And, to be able to issue a compliant warning, the rules must be clear upfront, ex ante. This is basic due process: a person or business who will be affected by a government decision, or enforcement action, must be given advance notice of what the government plans to do – in other words, what the government requires and how to comply with that requirement. In the case of Proposition 65, there is no other readily available option to businesses to achieve this level of compliance certainty; to date, few Safe Use Determinations have been issued, and when they have, they are limited in scope. OEHHA has acknowledged the need for warning requirements to provide certainty for businesses who must comply with the warning requirements of the Act.

2. OEHHA Does Not Justify The Proposed Change with Respect to Label Size.

OEHHA proposes to change Section § 25602. Consumer Product Exposure Warnings - Methods of Transmission as follows:

- (4) A short-form warning on the <u>product</u> label that complies with the content requirements in Section 25603(b). The short-form warning may only be used if:
 - A. The total surface area of the product label available for consumer information is 5 square inches or less, and;
 - B. the package shape or size cannot accommodate the full-length warning described in Section 25603(a), and;
 - C. The entire warning is printed must be in a type size no smaller than the largest type size used for other consumer information on the product. In no case shall the warning appear in a type size smaller than 6-point type.

OEHHA does not appear to have conducted any market-based review, survey, or other analysis to understand how widely the short-form warning is used, when, and why. Further, it has not examined or sought input from business on how they make labeling determinations, or examined what other state and federal requirements apply that may affect label text, size, placement, and other factors. For example, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) makes selling and distributing a pesticide in package sizes that have not been approved by EPA or with labeling that does not conform with EPA-accepted labeling a violation potentially subject to civil and criminal penalties. The Federal Hazardous Substances Act (FHSA) also requires product labeling. The Fair Packaging and Labeling Act (FPLA) requires labeling on consumer



commodities. The Uniform Packaging and Labeling Regulation (UPLR) requires consumer packaging to bear a label making certain specifications including net quantity of contents. Products imported into the United States are subject to country of origin marking regulations. Particular product categories, such as electronics, food, medical devices, and so forth, are also covered by regulations from their respective federal regulatory agencies. In addition, all 50 states have packaging and labeling requirements in effect. Any given product may need to be in compliance with multiple sets of labeling requirements from multiple agencies.

Since OEHHA has not undertaken this review, the potential consequences of proposing a 5-square inch limitation are not well-analyzed and could be severe. Any change to label size, placement, font size, color, or other requirements has potential impacts on all the labeling on a package. Without this analysis, the total burden on industry cannot be well understood.

The current short-form warning regulation has now been in place for three years, and businesses have been able to adopt and implement it, including making the substantial investments and expenditures needed to adopt it. This burden is costly and complex. We recommend that OEHHA withdraw the proposal, and if it wishes to recommend a size change, that it conduct a thorough review of the potential regulatory cost to business of making an additional change, including consideration of feasibility, taking other state and federal labeling requirements into account. Cases where a Proposition 65 labeling requirement conflicts with federal requirements, or where compliance with both is impossible, should also be taken into account as part of this review.

In addition, should OEHHA later decide to re-propose a new size requirement, we note ambiguity that should be resolved. For example, it is unclear whether the 5 square inch or less total surface area requirement applies to a container or the label, or just the portion of the label with consumer information. Clarification is also needed with respect to manufacturers using fold-out/accordion labels. Further, it is unclear what part of the label is counted - the outside visible surface, or total printable surface inside and out.

3. OEHHA Does Not Justify The Proposed Change with Respect to the Content of the Short-Form Warning.

OEHHA also proposes changing the text of short-form warnings to include identification of specific chemicals and to add the term "risk," which would revise Section § 25603 Consumer Product Exposure Warnings - Content as follows:

- (b) A short-form warning may be provided on the product label <u>pursuant to Section</u> <u>25602(a)(4)</u> using all the following elements:
 - (1) The symbol required in subsection (a)(1).
 - (2) The word "WARNING:" in all capital letters, in bold print.
 - (A) For exposures to listed carcinogens, the words, "Cancer www.P65Warnings.ca.gov." "Cancer Risk From Name of one or more chemicals known to cause cancer Exposure www.P65Warnings.ca.gov" (B) For exposures to listed reproductive toxicants, the words, "Reproductive Harm—www.P65Warnings.ca.gov." "Risk of Reproductive



Harm From [Name of one or more chemicals known to cause reproductive toxicity] Exposure - www.P65Warnings.ca.gov"

(C) For exposures to both listed carcinogens and reproductive toxicants, the words, "Cancer and Reproductive Harm—www.P65Warnings.ca.gov." "Risk of Cancer From [Name of one or more chemicals known to cause cancer] And Reproductive Harm From [Name of one or more chemicals known to cause reproductive toxicity] Exposure—

www.P65Warnings.ca.gov"

(D) For exposures to a chemical that is listed as both a carcinogen and a reproductive toxicant, the words, "Risk of Cancer and Reproductive Harm From [Name of one or more chemicals known to cause cancer and reproductive toxicity] Exposure - www.P65Warnings.ca.gov"

(c) A person providing a short form warning on the product label pursuant to subsection (b) is not required to include within the text of the warning the name or names of a listed chemical.

OEHHA is apparently making several <u>assumptions</u> that underlie its regulatory proposal to reach a conclusion that these changes will deliver meaningful improvements to the information conveyed. That said, it appears that the agency is making mere assumptions without any underlying fact-based review or analysis. The agency has undertaken no analysis to evaluate whether consumers will pay more attention to the newly proposed short-form warning; better understand the information; gain actionable information in a manner that will support better decision making; actually act on that information; and how they will understand and interpret the differences between the long-form and short-form warning text.

In our view, including the name of a specific chemical in a hazard-based warning does not by itself provide meaningful or actionable information to consumers where the risk presented from the chemical is in fact insignificant. Providing the name of a specific chemical may be outright misleading and counterproductive, as it could imply that there is a significant risk presented from the chemical where no such risk is in fact presented. A given product could present actual significant risks from composition, assembly, or use that are then disregarded or not recognized by a consumer. Given that specific chemicals have been included in long-form warnings for several years now, OEHHA should survey against the long-form warning language to better understand how consumers understand and act on the information before proposing changes to the existing short-form warning. Such a survey might reveal, for example, that the short-form warning is actually more effective in gaining attention, comprehension, or driving consumers to request more information about specific products. We recommend that this work be conducted in accordance with accepted principles and best practices in the fields of consumer risk perception and decision making.

OEHHA also proposes including the term "risk" in the short-form warning language. We recommend against this for several reasons. First, it creates another inconsistency with the long-form language itself, and may cause consumer confusion. Second, it is misleading. We believe that a "risk" statement will (falsely) imply to consumers in some cases that there is in fact a significant risk presented when in fact this may not be the case for any particular product. Third, the word "risk" tells consumers nothing about the degree, severity, likelihood, probability, and



frequency of risk. Risk assessment matrixes generally code risk by ranking levels of severity against levels of probability. The lowest level of risk expressed by most such exercises approaches zero ("negligible risk") but never reaches a true zero ("no risk") level. Proposition 65 consumer-facing "warnings," as hazard-based warnings, are inherently deficient because they communicate only severity, but not probability, which leaves consumers without the information necessary to make informed decisions about risk – consumers are left to make their own assumptions about exposure and thus the probability of the risk.

Merely inserting the term "risk" into Proposition 65 warning text does not convert the communication to a meaningful expression of risk, and as noted, in our view we believe consumers will likely interpret the use of the term as meaning that the risk is significant, which may not be the case. OEHHA should not make this change. Further, any future change to warning text should be preceded by and informed by appropriate survey work conducted in accordance with accepted principles and best practices in the fields of consumer risk perception and decision making.

4. If OEHHA Later Proceeds with Changes to the Short-Form Warning, the Sell-Through Date Should also Apply to Pre-printed Label Stock.

Many manufacturers purchase an advance supply of pre-printed label stock. It is very costly, and environmentally wasteful, to toss them out every time a regulation changes. If OEHHA ultimately proceeds with changes to the short-form warning, manufacturers should be allowed a grandfather period to be able to use, rather than discard, existing label stock. The sell-through period should thus apply to not only product manufactured and labeled before the operational date, but also to the label stock that was produced before the operational date.

ACC requests that the Proposed Rulemaking amending the short-form warning requirements under Article 6 be withdrawn. If you need additional information about these comments, please feel free to contact me at karyn_schmidt@americanchemistry.com or Tim Shestek, Senior Director, State Affairs, at tim_shestek@americanchemistry.com.

Very truly yours,

Karyn M. Schmidt

Senior Director, Regulatory & Technical Affairs

American Chemistry Council

cc: Tim Shestek, Senior Director, State Affairs