

January 25, 2016

Ms. Monet Vela
Office of Environment Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Sent electronically to: P65Public.comments@oehha.ca.gov

SUBJECT: Proposed Repeal of Article 6 and Adoption of New Article 6 – Clear and Reasonable Warnings

Dear Ms. Vela:

The Consumer Healthcare Products Association (CHPA) is the 135-year-old trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements (chpa.org). I am writing on behalf of CHPA members to address the most recent proposed reforms to the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) warning requirements as described in the Office of Environmental Health Hazard Assessment’s (“OEHHA”) Notice of Proposed Rulemaking to Article 6 in Title 27 of the California Code of Regulations dated November 27, 2015 (“Proposal”).

CHPA appreciates that OEHHA has addressed some of the concerns noted in our April 8, 2015 letter. However, we remain concerned about several aspects of the Proposal and the likelihood that if enacted, would result in increased frivolous litigation and consumer confusion. We have addressed each of our points of concern below and, in addition, have joined a coalition of organizations endorsing comments from the California Chamber of Commerce on the proposed draft regulations.

1. Specification of chemical name requirement - Section 25601(c)

While we appreciate that OEHHA is attempting to provide additional clarity to consumers regarding potential exposures, the proposal to require specific naming of chemicals is likely to create additional complexity and confusion for both manufacturers and consumers compared to the currently required safe harbor warning. Additional complexity will be created in those situations where a product contains more than one Proposition 65 listed ingredient, especially in those cases where one chemical is listed as a carcinogen and another which is listed as a developmental/reproductive toxicant. As outlined in more detail below, we do not believe that the research OEHHA has conducted on the specific naming of chemicals demonstrates that consumers would be provided with additional useful information.

Specifically, proposed section 25601 subsection (c) states as follows:

[A] warning meets the requirements of this article if the name of one or more of the listed chemicals for which the warning is being provided is included in

the text of the warning, to the extent that an exposure to that chemical or chemicals is at a level that requires a warning.

We are concerned that this language could be interpreted to suggest that a warning must include all chemicals for which a warning is being provided. Thus, those who specify only one chemical when warning for multiple listed chemicals may be targeted for enforcement actions and be required to defend themselves at potentially significant expense. As has been explained to us, OEHHA's intent is to allow businesses to specify one chemical in the warning, even if the warning is being provided for multiple chemicals. We request clarity on this point and recommend the following change (below, in bold and underline) to Section 25601(c) and to the Initial Statement of Reasons:

Section 25601(c)

Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals for which the warning is being provided is included in the text of the warning, ~~to the extent that an exposure to that chemical or chemicals is at a level that requires a warning.~~ **If a warning is being provided for more than one listed chemical, the warning meets the requirements of this article if the name of any one of the listed chemicals for which the warning is being provided is included in the text of the warning.**

ISOR at page 24

OEHHA has therefore determined that providing the name of a listed chemical in all warnings is consistent with and furthers the "right-to-know" purposes of the statute and provides more specificity regarding the content of safe harbor warnings. **Specifically, Section 25601(c) states that if a warning is being provided for one chemical, that chemical must be specified in the warning. If, however, a warning is being provided for more than one chemical, then the person providing the warning may specify any chemical it chooses in the warning. For example, if a warning is being provided for Proposition 65-listed chemicals A, B, and C, the warning may specify chemical A only, chemical B only, chemical C only, a combination of two of the three chemicals, or all three of the chemicals.**

As written, the proposal for specifying the name of a chemical risks consumer confusion when the potential exposure involves both a listed carcinogen and a reproductive toxicant. In addition, and as noted in our previous comments, we believe that the following statement "This product can expose you to a chemical [or chemical] known to the state of California to cause cancer," will also increase confusion both from a scientific and consumer standpoint as it assumes an outcome. In order to address these points, CHPA proposes that OEHHA simplify safe harbor language throughout the Proposal into the following which has previously been embodied in several consent judgments reviewed by the Attorney General's office and approved by state courts:

This product contains chemicals, including [name of one or more chemicals], known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/product.

2. Supplemental Information - Section 25600(d)

Proposed section 25600(d) states that “[a] person may provide information to the exposed individual that is supplemental to the warning” but that “[i]n order to comply with this article, supplemental information may not contradict the warning.”

We appreciate the fact that OEHHA has eliminated the terms “dilute” and “negate” contained in earlier Proposals related to the provision of supplemental information. However, we are concerned that the term “contradict” is not expressly defined in the Proposal or the ISOR. Instead, OEHHA provides an example of supplemental information and deems it contradictory to the warning without any explanation or citation. Rather than adopt this overly broad regulation, we request that OEHHA initiate fact-specific enforcement action, when necessary, under Section 17500 of the Business and Professions Code and/or under the federal Lanham Act.

The provision for supplemental information should be based on objective measures of accurate and non-misleading information which may be useful for a consumer. OEHHA should be promoting this type of information, not trying to suppress it by arguing something contradicts, dilutes, or negates the warnings. If OEHHA has these concerns, it suggests the warnings may not be warranted in the first place. The free flow of accurate information should be encouraged.

3. Section 25603 Consumer Product Exposure Warnings - Content

a) Section 25603(a)(1) - Pictogram

To comply with the requirements in this section, a Proposition 65 warning would need to include the American National Standards Institute (ANSI) symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. We are concerned that this symbol is associated with acute hazards where death or a serious potential injury is possible (*e.g.*, choking) compared to those existent under Proposition 65 (ANSI Z535.4-2011, clause E4.3, page 31) and may thus be misunderstood and/or not meaningful to the receiver.

We strongly recommend that OEHHA not insist on misuse of an existing and well recognized standard symbol. Current and proposed warning requirements already provide substantial prominence to the Proposition 65 warning, possibly at the expense of other mandated product label warnings. There is no credible information that indicates there is a consumer driven need for even greater prominence to the warning. It is also unclear how this symbol was selected as being appropriate by OEHHA. We recommend that OEHHA adopt a “P65” or “65” within a symbol that relates to the basis for provision of the warning being given.

b) Section 25603(a)(2) – Safe Harbor language - “can expose” versus “contains”

In a previous version draft (March 2014) of the warning regulation OEHHA proposed a change in the safe harbor language from “this product contains” a certain chemical to the use of the

phrase “will expose you to a chemical”. In our June 2014 comments, we noted how use of this language was vague and would not likely result in enhanced consumer understanding. In the January 2015 proposal as well as in the most recent proposal, OEHHA has proposed use of the phrase “this product can expose you” to one or more chemicals. While we noted in our April 2015 comments to OEHHA that “can expose” represented an improvement over “will expose”, we continue to believe that the current Proposition 65 language stating “this product *contains* [emphasis added] a chemical known to the state of California to cause” adequately conveys the necessary information and is most recognizable to consumers.

4. Font size – Section 25602 (Consumer Product Exposure Warnings – Methods of Transmission)

OEHHA must allow manufacturers to provide the information required by Federal and State regulations and not mandate unreasonable requirements. The U.S. Food and Drug Administration requires that over-the-counter drug products provide a substantial amount of information including warnings, directions for use dosing information, and active/inactive ingredients. As a result, label space is at a huge premium. The same is true for other classes of regulated products such as medical devices and dietary supplements. The space limitations become magnified for small packages.

In this proposal, OEHHA is arbitrarily imposing a minimum font size requirement without regard to the products and packages involved and other mandated text requirements. In several places within Section 25602, specifically subsections (a)(1), (a)(3), (a)(4), (b) and (c), the proposed text notes that the warning must be in a type size no smaller than one half the largest type size used for “other consumer information.” This provision requires clarification as the term “other consumer information” is broad and likely to lead to unnecessary and frivolous litigation unless further guidance is provided by OEHHA. For example, is the statement of net quantity information covered by “other consumer information”? What about the “Statement of Identity”?

We strongly recommend that OEHHA carefully consider a requirement which is clear and can be reasonably applied to all consumer products requiring a warning. Further, we ask that the regulation and/or the ISOR be revised to specifically identify what constitutes “other consumer information” in this context.

5. Survey results

CHPA appreciates the fact that OEHHA contracted with the University of California-Davis to undertake a study of consumer understanding of Proposition 65. However, consumer understanding of Proposition 65 warnings is paramount to the development and enactment of new warning requirements and we feel that this study suffers from a number of limitations which seriously impact the ability to make meaningful conclusions. Below we list a number of aspects of the study which would benefit from a more in-depth analysis and explanation. We respectfully ask that OEHHA acknowledge and address these concerns.

a) Knowledge of Proposition 65

We could find no discussion in the results for the following Survey Question found in Appendix B:

Have you heard about Proposition 65 before today?

We request that OEHHA provide a separate breakdown of those participants who viewed the new warning favorably into two groups - those familiar or not familiar with Proposition 65 regulations. This would help to remove speculation that those viewing the “new” warning favorably compared to the “old” did so primarily because of a perception that new is better than old. Stated differently, study participants unfamiliar with Proposition 65 could be biased towards the perception that “new” is always better than “old”.

b) Inclusion of Specific Chemical Names

Results from the survey found that two-thirds of the participants selected the warning with specific chemical names as being more helpful than the general warning (with no reference to chemical names). OEHHA also mentions that the “most frequent reaction was that the inclusion of the chemical names made people feel better able to make an informed choice”. However, the sum of the percentage of subjects who responded indicating that the inclusion of chemical names either “confused” or “scared” them (~20%) was similar to the percentage of those who responded that this “made the sign more helpful”. Again, this is an area where it would be informative to compare results obtained in groups familiar/unfamiliar with Proposition 65 regulations.

c) Knowledge of Chemicals

To identify which chemicals are known by the public, subjects were queried on their familiarity with six (6) chemicals (acrylamide, chlorinated tris, phthalates, lead, mercury, and carbon monoxide). We request that OEHHA provide additional information on why these particular chemicals were chosen. Further, 50% (3/6) of the chemicals were clearly not widely recognized by the respondents (acrylamide, chlorinated tris, and phthalates). Coupled with the finding that ~40% of subjects noted that they would either not visit or likely not visit a website listed in the new warning for further information (see p. 45 of UC Davis Survey) it is not clear how this represents an improvement over the previously mandated warning.

d) Inclusion of a QR Code

Amongst survey participants there appeared to be a very low recognition of the benefits of including a QR Code on the Proposition 65 warning (<40%). QR codes are actually a dying proposition for businesses, based on a number of issues including lack of consumer interest and understanding; codes directing users to non-mobile optimized sites; and size restrictions on already crowded packaging. OEHHA has not included provision of a QR code in the latest proposal and we support this.

CHPA asks that OEHHA carefully review the concerns expressed in this letter and consider the possible negative effects that some of these proposed changes may have on companies doing

business in California. We believe that the significance of the proposed changes requires additional disclosures from OEHHA regarding how these changes would improve the currently mandated warnings and enhance consumer understanding of exposures and ways in which to avoid them.

Thank you for the opportunity to provide these comments. Should you have any questions or require additional information please do not hesitate to contact me.

Respectfully submitted,

A handwritten signature in blue ink that reads "Jay Sirois". The signature is written in a cursive style with a horizontal line above it.

Jay Sirois, Ph.D.
Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association