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**Hach's Comments regarding Notice of Modification to Text of Proposed Regulation:
Amendments to Article 6, Clear and Reasonable Warnings Short-form Warnings**

Hach Company (Hach) is writing the Office of Environmental Health Hazard Assessment (OEHHA) to provide comments on the modified proposed amendments to Article 6 concerning clear and reasonable short-form warnings of California Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop 65), as published on Dec. 13, 2021: <https://oehha.ca.gov/media/downloads/crn/shortformmodifiedregtext121321.pdf>.

Hach manufactures and sells water quality analysis instruments and related chemical reagents. These essential products are for industrial, laboratory, and workplace applications and are used by Californian municipalities, beverage manufacturers, consumers, chemical manufacturers, scientific institutions, and other various industries. Realizing that water is the world's most precious resource, our mission is ensuring water quality for people around the world. Our Vision is to make water analysis better—faster, simpler, greener, and more informative.

Hach's Recommendations for Modified Amendment

- A. Retain the current short-form warning format and require disclosure of the carcinogen and/or reproductive toxicant when OEHHA is asked by the consumer or downstream user.
- B. Lengthen the transition period from one year to three years.
- C. Expressly allow an unlimited sell-through period for the products manufactured before the enforcement date under §25602(e).
- D. Enlarge the total maximum surface area for a short-form warning from 12 square inches to at least 20 square inches.

- E. Eliminate the new safe harbor wording options under §25603(b)(2)(A)2, (B)2, (C)2, and (D)2.
- F. Clarify and provide guidance for applying Prop 65 warning labels on irregular packaging or product shapes to conform to the proposed provision and to improve compliance.
- G. Eliminate the option of “CA WARNING”, which causes confusion with the two-letter country code for Canada.

Hach recommends these changes because:

1. We disagree with the claim that there will be little to no significant impact to businesses.
2. The addition of words and chemical identification to the short form is problematic because it increases the amount of space needed for the warning and, more importantly, requires changing every affected label.
3. The transition period of one year is not feasible.
4. The choice of 12 square inch maximum area for short-form warnings still is arbitrary.
5. The new wording options raise the industrial speech First Amendment rights concerns.

Hach also requests OEHHA to clarify:

- Safe harbor standards for round products, bagged products, and other irregularly shaped packaging where labels are required but may wrap around the product and limit visibility.

Main Reasons for Hach’s Recommendations

The proposed amendments with the latest small modifications will not eliminate “over-warning,” and may not significantly decrease the use of such warnings. Most companies will not remove a Prop 65 warning unless they are certain that there are no subject chemicals in their product and there is no Prop 65 litigation risk. The primary driver for the high use of Prop 65 warnings is citizen enforcement, and companies risk litigation from citizen-enforcers if they do not provide safe-harbor warnings. The current short-form warning minimizes risks stemming from the civil enforcement provisions.

If the proposed changes are finalized as written, businesses would lose their safe harbor and be exposed to a heightened risk of private enforcement. Rather than changing the content of warning labels, especially within such a short time (in less than four years) after the last major changes in 2018, OEHHA should instead focus on providing stronger defense measures when companies make reasonable determinations not to warn based on a sound scientific approach. To decrease reliance on the use of safe harbor warnings, OEHHA should reevaluate the burden of proof for civil enforcement instead.

The proposed amendments will cause substantial burdens to companies. With the nearly 1,000 chemicals on the Prop 65 list, many products marketed in California are potentially in scope and require resources to assess and test. In addition to the testing costs, IT (information technology)

and ERP (enterprise resource planning) systems would require updates to accommodate a myriad of custom labels for various chemicals that would need to be disclosed on the warning.

For many companies, due diligence for complying with the proposed changes will become significantly more burdensome in today's complex supply chain. For instance, Hach has numerous suppliers for various parts and accessories that go into our products. The amendment would force Hach to audit numerous replacement or service parts coming from different vendors for Prop 65 short-form warning compliance.

The proposed amendments would fundamentally change how the short-form warnings should look and be applied. Because the proposed amendments would require companies to identify one or more chemicals, the incurred cost in relabeling products may equal or surpass the expenses from the 2018 revision. Additional costs include analyses to identify chemicals, the creation of multiple labels in place of a single short-form label, adapting systems to ensure each product receives the correct label, and scrapping of existing short-form labels. Along with economic costs to scrap existing short-form labels, discarding the labels is environmentally extremely wasteful.

If companies incur increased costs to sell products into California because of the resulting label changes, these companies will likely choose to pass these costs onto end users. As a result, Californian consumers will be at a disadvantage compared to similarly situated consumers in other states.

Lastly, the proposed changes impose additional compliance burden of re-registering certain Food and Drug Administration (FDA)-approved or Environmental Protection Agency (EPA)-approved pesticidal products, as well as certain drinking water standard related products because changes in labeling trigger such actions to conform to the relevant regulations or standards.

Discussion of Hach's Recommendations

A. Retain the current short-form warning and disclose the relevant carcinogen and/or reproductive toxicant upon consumer request

This current approach from 2018 adequately warns California consumers about potential health risks, which sufficiently conforms to the regulation's original intent and eliminates the need for burdensome changes to the warnings on products and packaging. It is more practical to inform California consumers of the relevant carcinogen and/or reproductive toxicant on an as-needed basis or after OEHHA receives such inquiries.

B. Lengthen the transition period to three years

If OEHHA proceeds with the overwhelming proposed changes to the short-form warning, Hach believes it is infeasible for businesses to comply in the allotted one-year timeframe. Products will

have to be tested extensively to identify chemicals to disclose in the warnings. IT and ERP systems will have to be updated to provide the applicable long-form warning for every affected SKU (stock keeping unit) or part number. Companies will be forced to create new labels, relabel products. Many have to change from short form to the regular form, and these are not changes that can happen in a short period.

Changes made to comply with the last amendment, which only became effective less than four years ago, were expensive and burdensome. Without a generic short-form warning, it will be even more burdensome and time-consuming to adapt to a new process to comply with the proposed changes than it was in 2018. For example, Hach sells thousands of different products into California that require a Prop 65 warning. The proposed regulation will potentially require testing thousands of products to identify specific Prop 65 chemicals. We will then have to generate a different process for multiple labels and match them to the specific products.

Additionally, we would need more time to work with our suppliers to determine which Prop 65 listed chemicals may be present in many components. We estimate that these steps alone may take more than two years to implement. Due diligence for accessories and replacement parts from external vendors will be similarly time and cost-intensive.

Also, to minimize unnecessary product recalls and costly relabeling, Hach requests an unlimited sell-through period for the products manufactured and labeled with the current Prop 65 short-form warning before the final rule's enforcement date. The current text of the amendment is not explicitly clear on such accommodation in §25602(e).

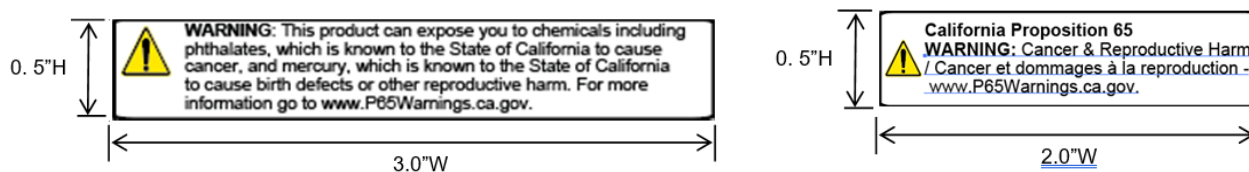
C. Enlarge the total maximum surface area for a short-form warning to at least 20 square inches

Hach also recommends expanding the maximum label space from 12 square inches to twenty (20) square inches. We welcome the modification of 5 square inches to 12 square inches of label space, but it is still inadequate. 20 square inches is still a small label space considering other required labeling elements, such as other warnings (e.g. federally mandated safety warnings or precautions), directions for use, content information, and net quantity or volume.

Again, OEHHA has failed to provide a detailed explanation in the modification notice or the modified text of the proposed amendment as to why 12 square inches of label space was deemed sufficient. Such determination only appears arbitrary to the regulated community.

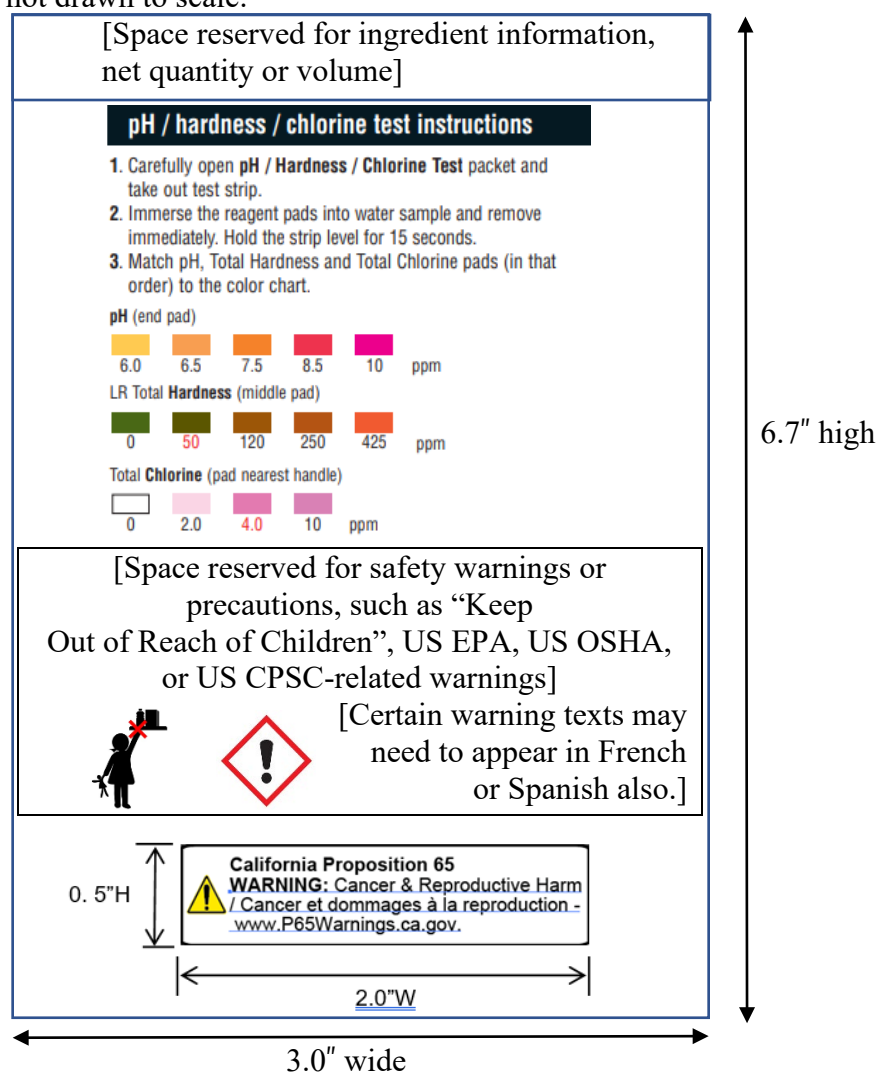
12 square inches is simply impractical to include all the mentioned labeling elements and also display the proposed short-form warning in a 6-point font size. To illustrate the impracticality, let's consider the current Prop 65 requirements. The minimum short-form label size is an inch

square, and the minimum long-form label must be an inch and a half square. These dimensions do not account for other required label content:



Displaying all the other label elements in 10.5 to 11 square inches of remaining space is extremely difficult if not infeasible. Compliance with the proposed changes becomes even more difficult if other languages must appear on the labels, notably French and Spanish because a Prop 65 warning must appear in those languages as well. Based on our estimated calculations, the minimum surface area for a short-form warning should be at least 20 square inches to be reasonable.

For illustration purposes, here is Hach's mock-up of 20 square inch label with the current short-form warning. Please note that the indicated measurements are approximations, and the label is not drawn to scale:



Based on our calculations and review, displaying all the information above in a 12-inch square space would render the label illegible, while 20-inch square space was barely sufficient.

D. The content issue regarding forced inaccurate statements for carcinogens and reproductive toxicants

We request removing the new requirement of disclosing the “name of one or more chemicals” listed as Prop 65 carcinogen or reproductive toxicant on the short-form safe harbor warning. Hach believes that the 2018 short-form warning adequately warns of the dangers associated with suspected carcinogenic and reproductively toxic products.

If OEHHA decides to require the chemical name included in the short form warning, however, then Hach suggests OEHHA eliminate the second alternative warning phrases in §25603(b)(2)(A)2, (B)2, (C)2, and (D)2, which remove the risk qualifiers to a product’s carcinogenicity and reproductive toxicity.

The proposed text of §25603(b)(2) creates the warning phrase “Exposes you to ... a carcinogen, and ... a reproductive toxicant,” which removes the qualifier “cancer risk” or “risk of reproductive harm”. This qualifier makes it clear that consumers are at risk of cancer or reproductive harm, rather than being affirmatively exposed to cancerous or harmful chemicals. The warning phrase as currently written may result in companies making inaccurate statements, which goes against the intent of the “clear and reasonable warning” Prop 65 regulation and raises industrial speech First Amendment rights concerns under the US Constitution.

Hach requests that OEHHA remove this alternative warning phrase for three reasons:

- 1) The proposed content option possibly compels industry speech by encouraging companies to warn about carcinogenicity and reproductive toxicity for specific chemicals that have not necessarily been agreed to be cancerous or harmful by the scientific community;
- 2) the text of the Prop 65 regulation does not align with the proposed new short-form warning options; and
- 3) the proposed alternative warning does not save space or more effectively protect California consumers.

- 1) The proposed warning statements without risk qualifiers raises First Amendment industry speech concerns:

Prop 65 short-form warnings affect speech and thus implicate the First Amendment. Court cases have well established that businesses have free speech rights and that compelling speech (in the form of mandated notices or warnings) must meet the First Amendment standards. Such scrutiny is applied to prohibiting speech also.

Although the federal and state governments have wide discretion to issue various types of warnings, they generally cannot force businesses to make certain warnings on behalf of the government. As held in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), the regulatory authority can only compel speech in the form of a warning or disclosure so long as it is purely factual and uncontroversial, and the requirements are not unjustified or unduly burdensome.

These governmental restrictions regarding free speech similarly apply to California and, by extension, OEHHA. There are numerous chemicals listed in Prop 65, which are the subject of conflicting or controversial scientific studies and tests, but by removing the qualifier “cancer risk,” OEHHA may be compelling speech from industry by affirmatively stating that any given chemical in a product “exposes you to” a carcinogen or reproductive harm based on scientific evidence that is both “factual and uncontroversial.”

Since there is evidence for numerous chemicals listed on Prop 65 for which evidence of cancer risk or reproductive harm is controversial, the proposed alternative short-form warning, “exposes you to,” raises serious First Amendment concerns without the qualifiers in other options. A similar argument was made in the recent case of *National Association of Wheat Growers, et al. v. Xavier Becerra*, Case No. 17 Civ. 2401, 2020 WL 3412732 (E.D. Cal. June 22, 2020), in which the U.S. District Court for the Eastern District of California ruled against OEHHA’s position. For this reason, the alternative warning should be removed.

2) The proposed changes do not align with the text or purpose of Prop 65

Section 25249.6 of the regulation states that “no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual.” This text places a clear emphasis on warning customers about risks of exposure, not about disclosing the carcinogenicity or reproductive toxicity of the particular chemicals themselves.

The warning phrase “exposes you to” affirmatively states that consumers are exposed to a carcinogen or reproductive toxicant without any mention of the risk associated with this exposure. This is in clear contention with the regulatory goal of Prop 65, which is to provide a clear and reasonable warning about **risk** of exposure.

The short-form warning promulgated in 2018 more closely aligns with the Prop 65 regulatory intent of warning California consumers about risks of cancer or reproductive harm, and OEHHA should not encourage an alternate warning phrase that conflicts with the purpose of the regulation.

3) The proposed changes do not save space or more effectively protect California consumers

The main purpose of the Prop 65 short-form warning is to save space on products that cannot accommodate the long-form or regular warning. The modified alternative short-form warning phrases do not save space or provide increased protection to California consumers. The qualifier “cancer risk” or “risk of reproductive harm” takes up approximately the same amount of space as the proposed “exposes you to.” There is little or no benefit to the alternative short-form warning, and the preceding option, “cancer risk” or “risk of reproductive harm” does not create compelled speech or raise the First Amendment concerns.

E. Clarify warning labels on irregular packaging or product shapes to improve compliance

In addition, Hach requests that OEHHA clarify the standards being applied to round products, bagged products, and other irregularly shaped packaging when determining label space to properly guide businesses on how to apply Prop 65 safe harbor warnings. Such products have unique labeling needs, including wrap-around labels. Hach specifically requests OEHHA’s guidance on how the revised short-form warnings can be applied to irregularly shaped packaging or products. We also ask that OEHHA provide a visibility standard for products that are multi-dimensional or irregularly shaped.

F. Hach supports the proposed change allowing “CALIFORNIA WARNING” but not “CA WARNING”

Hach welcomes the modified change that would allow businesses to use the additional warning text option of “CALIFORNIA WARNING.” This change will allow companies to more accurately inform customers about the scope of the Prop 65 warning.

However, we oppose the use of “CA WARNING” because it potentially causes confusion with the two-letter country code, CA, for Canada. The intent of Prop 65 regulation is to provide a clear warning to affected consumers. Therefore, we ask OEHHA to avoid creating consumer confusion when possible and omit the words “CA Warning” under §25603(a)(2).

Hach appreciates the opportunity to provide input to this important process. Hach strongly supports OEHHA’s efforts to protect health and safety of Californians. Should you have any questions or require any additional information, please contact me at jalee@hach.com or the phone number listed above.

With kind regards,



James Lee