



## Council for Responsible Nutrition

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Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, CA 95814  
*Via Email:* [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov)

Dear Ms. Vela:

On behalf of the Council for Responsible Nutrition (CRN), thank you for the opportunity to provide comments to the California Office of Environmental Health Hazard Assessment (OEHHA) regarding a proposed regulation that will address Proposition 65 (Prop 65) warnings. CRN, founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers, marketers, and ingredient suppliers. We represent more than 100 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Providing safe, beneficial, and affordable products with the highest quality ingredients is of paramount importance to CRN and its members. And since the approval of Prop 65 in 1986, our members continue to work diligently to comply with applicable safety levels and labeling requirements imposed by Prop 65.

CRN is encouraged by Governor Jerry Brown's announcement<sup>1</sup> regarding reforms to Prop 65, and we understand that the revised warnings are one area that OEHHA will address to carry out these reforms. OEHHA has stated that its proposed regulation aims to provide more informative and meaningful warnings, providing a variety of means of warnings including alternative methods, and providing businesses with greater certainty that their warnings comply with Prop 65. However, we urge OEHHA to seriously consider what changes will achieve meaningful reform of Prop 65 in a way that benefits consumers and improves the business climate in the state, and in particular, limit the frivolous, meritless lawsuits that continue to drive businesses out of the state. Further, any regulatory changes must be grounded in sound science, with a full understanding of the actual risk and level of harm of exposure from a listed chemical.

Based on the concepts described during OEHHA's July 30<sup>th</sup> pre-regulatory workshop and the list of elements that OEHHA believes should be included in the regulation, CRN offers the following comments regarding: 1) the warning content, including minimum information that must be included in all warnings and any additional information concerning exposures to listed chemicals; 2) warning methods for use by product manufacturers and retailers; and, 3) reasonable transition times for businesses, and the status of existing, approved warnings.

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<sup>1</sup> Governor Brown Proposes to Reform Proposition 65, <http://gov.ca.gov/news.php?id=18026>.

## **Warning Content**

In the pre-regulatory workshop notice<sup>2</sup>, OEHHA states that it believes that warnings should “inform an individual that he or she *will be exposed* to a listed chemical” (emphasis added). CRN recommends revising the phrase “will be exposed” because it does not accurately represent all warnings. As OEHHA is aware, many businesses simply provide a warning without assessing actual exposure in order to reduce liability risk caused by aggressive private enforcers of Prop 65. Therefore, the inclusion of a warning may not mean that a consumer will actually be exposed to a Prop 65 listed chemical. We recommend that OEHHA maintain the language used in the current safe harbor warning: “This product *contains* a chemical known...” (emphasis added) which more accurately reflects the true nature of these warnings. In addition, during the workshop a participant noted that “known to California to cause...” should be part of the minimum information to represent that Prop 65 warnings are not federal in nature but are a requirement unique to California. CRN agrees with this suggestion and encourages OEHHA to retain this language in the regulation.

OEHHA also believes that the regulation should include “minimum information that must be included in all warnings, including the health effect (cancer, male reproductive toxicity, female reproductive toxicity, developmental toxicity) for which the chemical(s) involved in the exposure was listed; information on how a person will be exposed; and, where applicable, simple information (such as washing hands) on how to avoid or reduce an exposure.” During the pre-regulatory workshop, OEHHA reiterated that this information should be among the minimum elements of a warning, and also added that a source for more information should be included. The workshop included some discussion about whether these elements are necessary, but left out crucial pieces of information: to what extent the current safe harbor warnings do not adequately inform or are “vague”, and what research or empirical evidence exists to demonstrate that more specific warnings will actually inform or resonate with consumers. One workshop participant also noted that principles of risk communication should be fully understood before making any changes, but it is unclear whether OEHHA has taken this into consideration or plans to address this in some way. Mandating additional chemical, health effect, and exposure information— which comes with significant increased threat of litigation and burden to businesses, and potential increased costs for consumers – without any fact-based evidence of benefit to consumers and without a solid understanding of risk communication would neither serve the public nor the business community in the state.

Another issue discussed during the workshop concerns the potential requirement to list or provide additional information about multiple chemicals. There are currently hundreds of chemicals on the Prop 65 list, each requiring its own risk assessment to determine safe exposure levels. With foods such as dietary supplements, levels of naturally occurring contaminants (e.g., lead) may be difficult to assess, quantify, and differentiate from what is not naturally occurring. Any proposal that requires a warning to include each chemical that may be present in the product will create an enormous burden on businesses, as they would need to conduct multiple tests to determine exposure and perform a risk assessment for each chemical. This type of testing is extremely costly and time-consuming, and will almost certainly lead to increased litigation regarding how to comply the regulation, e.g., whether the appropriate test method was performed and the level of risk adequately characterized. Even if a specific limit on the number of chemicals is included, there is still the

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<sup>2</sup> Notice of Public Workshop on Concept for Regulation Addressing Proposition 65 Warnings [07/09/13], [http://oehha.ca.gov/prop65/public\\_meetings/wrkshop070913.html](http://oehha.ca.gov/prop65/public_meetings/wrkshop070913.html).

possibility that plaintiffs will challenge how a business chose certain chemicals or prioritized the list. And even if safe harbors are provided for chemicals, plaintiffs may continue to allege that a chemical is present at a higher level, based on a different testing assay, and should be included in the warning – which is currently the case with many Prop 65 lawsuits. Thus, the outcome of listing multiple chemicals results in businesses being faced with the same challenges but with an even greater risk of litigation.

In addition, consumer products with small packaging, such as dietary supplements, simply do not have the label space to accommodate a lengthy warning that lists multiple chemicals with multiple health effects, how to avoid or reduce exposure, etc. It is also questionable whether consumers would actually benefit from lengthy, potentially confusing warnings, given the lack of empirical research in this area. An alternative warning method, such as a website where consumers could go to obtain more detailed information, is one possibility. However, the risk of litigation and potential increased burden will depend on the amount of information that must be provided, i.e., all chemicals or some, and any other contextual information OEHHA deems necessary.

If OEHHA determines that more specific information should be provided to consumers, CRN echoes the recommendations of participants in workshop and requests that OEHHA maintain the current safe harbor warning, but also give businesses options for providing further chemical-specific information in the warning via a website maintained by OEHHA. For example, businesses could add the following statement to the current safe harbor warning: “For more information: [OEHHA website].” CRN would consider supporting this method of providing additional information to consumers, if in fact OEHHA determines that consumers would benefit from this additional information. This approach would serve the public interest by providing more information to those who wish to access it and lessen concerns about label space. However, as noted in the workshop, there are many details that must be analyzed, discussed, and also explicitly described in the regulation regarding operation of the website, e.g., how the information will be maintained, updated, and protected. OEHHA should ensure that it works closely with stakeholders regarding how such a website would be structured and the amount of information that should be included. As another option, businesses could work directly with OEHHA to develop their own warnings that provide additional information about a listed chemical or chemicals that may be present in a product. These specific warnings, if approved by OEHHA, would be deemed to be “clear and reasonable” and possibly available to other businesses that have similar products and chemical exposures. However, business would need some assurances in the regulation, including parameters on OEHHA’s or other governmental entities’ ability to revise or reject these approved warnings at a later date, thereby providing business with certainty and protection from future liability.

Finally, we note that Prop 65 is intended to put consumers on notice, and CRN has serious concerns that a regulation requiring specific, detailed information about listed chemicals goes well beyond that intent. OEHHA should consider whether its proposed revisions conform to the overall purpose of Prop 65, and also keep in mind the many existing federal requirements for food products, and specifically the very detailed, robust federal regulatory framework for dietary supplements that addresses all aspects of safety including labeling and ingredient testing.<sup>3</sup> We encourage OEHHA to ensure that any proposed changes to the current warning system recognize and comply with those existing mandates.

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<sup>3</sup>These FDA mandates include regulations related to Good Manufacturing Practices, New Dietary Ingredients, and Food Safety Modernization Act requirements, among others.

### **Warning Methods**

During the pre-regulatory workshop, OEHHA noted that new technologies offer several possibilities for providing warnings, such as wireless warnings, smart phone scanners, and point-of-sale receipts. OEHHA also stated that one method alone may not be sufficient, e.g., a colored flag or sticker at retail, which could also direct the consumer to additional information about the chemical or chemicals that are the basis for the warning, such as a website. CRN supports exploration of alternative methods given the variety of consumer products, as one method may not be suitable for all products. As noted above, one suggestion is a website maintained by OEHHA for further information about a specific chemical or product. Subject to learning additional details about how such a website would be maintained and how much information would be required, CRN may consider this concept of providing chemical information through a website versus the product label, which would be especially helpful for dietary supplements and other consumer products with limited label space. We note that the website should also include information about the level of risk and the hazard associated with the likely exposure. Further, because Prop 65 is intended to put consumer on notice, we believe such an approach would fulfill the intent of Prop 65. However, any proposal must explain in detail how OEHHA would obtain, organize, and maintain the information, as well as the scientific basis and factual support for requiring this information.

### **Transition Times for Businesses and Existing Warnings**

CRN supports OEHHA's goal of "reasonable transition times" for businesses to come into compliance with this regulation, especially if product labeling changes are required. We urge OEHHA to consult with industry stakeholders to fully understand the impact on businesses and reduce any undue economic burden. In general, relabeling is an extremely complex undertaking, entailing multiple steps, and typically requiring at least 18 months. Many relabeled products will have different universal product codes and possibly different prices. With such changes, a product cannot simply be stocked in place of the former product it is to replace; instead shelf tags must be changed and retailers must work within their systems for an orderly inventory transition. Retailers change their planogram<sup>4</sup> at most twice a year, and the timing of the change is different for each retailer. Thus, any abrupt changes may cause companies to be faced with costly returns. OEHHA should allow for reasonable "sell-through dates" to avoid unnecessary product returns and allow those products with older labels to continue to be sold until the inventory is exhausted. The transition times should also take into account: the cost of any labeling changes; the cost of any new or additional testing that may be necessary to comply with additional information requirements for warnings; company size, allowing smaller companies additional time to come into compliance; and other labeling compliance dates, such as the Globally Harmonization System of Classification and Labeling of Chemicals compliance date of December 1, 2015.<sup>5</sup>

We also strongly support the protection of existing, approved warnings, specifically those approved prior to any regulatory changes made by OEHHA. Language must be included that codifies or grandfathers existing warning language in judgments or settlements approved by a court, the California Attorney General, or OEHHA. We recommend that OEHHA adopt in regulation these

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<sup>4</sup> A planogram is diagram of a retail store that specifies, in detail, how and where every product should be placed, i.e., which aisle, which shelf, how many facings are allocated to each SKU.

<sup>5</sup> <https://www.osha.gov/dsg/hazcom/hazcom-faq.html>.

existing warnings to provide clarity and bring certainty as to what warnings are “clear and reasonable”, which would help reduce future liability concerns for businesses.

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In summary, OEHHA should carefully consider the need for detailed warning requirements, whether on a consumer product label, retail signage or website, and CRN cautions against requiring specifics given the questionable benefit to consumers and the almost certain possibility of increased litigation that would follow. It is not clear that the potential benefits of providing consumers with additional information about a product outweigh the risk of increased liability, contra to Governor’s Brown stated goal of reducing liability risks for businesses in the state. Any changes made by OEHHA must be understood in this context, making the need for meaningful litigation reform all the more urgent. Further, the intent of Prop 65 is to put consumers on *notice* rather than provide specific details about listed chemicals. OEHHA’s suggestion for minimum information for a warning goes well beyond that intent.

We appreciate OEHHA’s willingness to hold forums with stakeholders to further address these issues and consider the needs of all those impacted by Prop 65. As representatives of the dietary supplement industry, we recognize the importance of complying with Prop 65 and will continue to ensure that our products are of the highest quality and meet all applicable safety standards.

Again, thank you for the opportunity to submit comments and we appreciate your consideration. Should you have questions, please do not hesitate to contact me at [ralmondhiry@crnusa.org](mailto:ralmondhiry@crnusa.org) or (202) 204-7672.

Sincerely,



Rend Al-Mondhiry, Esq.  
Regulatory Counsel