



## Council for Responsible Nutrition

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April 8, 2015

Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
P. O. Box 4010  
1001 I Street  
Sacramento, CA 95814  
Via Email: [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov)

### ***RE: Clear and Reasonable Warning Regulations and Lead Agency Website Regulation***

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 proposed changes to Proposition 65 (Prop 65) regulations, which would repeal the current Article 6 regulations and adopt new Clear and Reasonable Warning regulations in Article 6, Title 27 of the California Code of Regulations. Our comments also address the proposed adoption of Article 2, Section 25205 in Title 27, which would establish a website operated by OEHHA to provide more detailed information to the public about exposures to listed chemicals.

CRN, founded in 1973 and based in Washington, DC, is the leading trade association representing the manufacturers and marketers of dietary supplements, functional foods, and their nutritional ingredients. Providing safe, beneficial, and affordable products with the highest quality ingredients is of paramount importance to CRN and its members. Our members comply with a host of federal and state requirements, including those imposed by Prop 65. CRN also joins the comment letter submitted by the California Chamber of Commerce (CalChamber) and the Prop 65 Coalition, and we urge OEHHA to carefully consider the comments and recommendations included in that letter.

In the Initial Statement of Reasons (ISOR) for the Clear and Reasonable Warning Regulations, OEHHA states that the proposed regulations are intended to improve “the quality of the warnings being given while providing compliance assistance to businesses subject to the warning requirements” of Prop 65. (ISOR, p. 4) CRN, along with many in the business community, contend that the proposed changes will not achieve either of these goals. First, how the public is warned about listed chemicals and the content of the warnings are not the areas of Prop 65 most in need of reform. Issues such as how to test for compliance, what tests to apply and when, and how to interpret those results would provide greater certainty for businesses seeking to comply with Prop 65. The economic impact analysis provided by CalChamber underscores this point and demonstrates that currently, content-based litigation is very rare, with the overwhelming majority (99%) of Prop 65 litigation focused on compliance issues (see page 16 of the analysis). However, content-based litigation may increase under the proposed regulations. Even more concerning to CRN is the lack of scientific basis for the proposed changes. OEHHA states that the changes will “better serve the public by requiring more detailed information” in Prop 65 warnings and “further promote public health and safety.” (ISOR, p. 41) However, CRN is not aware of any scientific basis or research to support these propositions, and we also believe the new warning language is likely to cause

unnecessary alarm and confusion regarding listed chemicals. Thus, we again call for OEHHA to provide clear guidance on compliance matters, rather than leaving these issues to be debated in litigation, and avoid changes to the content of the warnings.

Second, the proposals provide little clarity for businesses seeking to comply with Prop 65, and will only lead to greater uncertainty and impose even more burdens from a compliance perspective. As an industry already subject to countless frivolous lawsuits based on Prop 65, CRN has a significant interest in the outcome of any proposed reforms to Prop 65. However, the proposed changes will not reduce litigation or facilitate compliance with Prop 65. The new, “non-mandatory guidance” and “voluntary safe harbor process” appear to provide the only avenue to avoid private enforcement action regarding what is a “clear and reasonable” warning. Further, businesses will be required to update, maintain, and monitor a significant amount of information about their products, despite OEHHA’s claim that it is only requiring existing information for the lead agency website.

Third, CRN firmly disagrees with OEHHA’s conclusion that the proposals will have “no significant economic impact.” (ISOR, p. 43) We direct the agency to CalChamber’s economic impact analysis, which details the significant cost to businesses which would occur if OEHHA adopts the regulations as currently written. Despite numerous stakeholder meetings and repeated calls for revisions to OEHHA’s proposals since the agency initially announced its intention to “reform” Prop 65, the resulting proposed rulemaking does not address the concerns of businesses in the state and will only make compliance with Prop 65 more onerous and costly, without any demonstrated benefit to the public. Our concerns regarding specific areas of the proposed rulemaking are outlined below.

### ***Section 25600 – General***

CRN shares the concerns noted in the Prop 65 Coalition Letter. This section fails to adequately define the scope of warning content and methods that would be considered “clear and reasonable” under the Act, which will lead to uncertainty as to what alternative warnings, if any, satisfy the requirement. OEHHA asserts that the proposed regulation gives businesses the “option to use warning methods adopted by the lead agency.” (ISOR, p. 41) However, it is unclear what type of warning language would be considered “clear and reasonable”, other than the newly proposed “safe harbor” warning. By failing to define what constitutes a “clear and reasonable” warning, the proposal creates a new source of litigation related to the content of the warning – in addition to the existing threat of litigation caused by the lack of clear guidance regarding when a business must provide a Prop 65 warning. Therefore, businesses seeking to avoid additional litigation risk have no option other than to use the “non-mandatory” safe harbor warning provided in the proposed regulations, because they are unable to rely on alternative language or prior approved warnings.

CRN also has concerns about the two-year effective date provided in subdivision (b). Based on our knowledge and experience with dietary supplement packaging and labeling matters, we believe two years may not provide businesses with adequate time to comply with the new warning requirements. Some dietary supplements, such as vitamin or mineral tablets, have a long shelf-life and may remain in the stream of commerce longer than two years. Although these products may be compliant with the existing regulations, businesses may nonetheless be subject to legal challenges simply because their products were purchased after the new regulations came into effect. In addition, due to the supply chain complexities involving manufacturers, distributors, and retailers, it is likely that some retail stores will have products with non-compliant labels that were not “sold through” prior to the effective date of the proposed

regulation. Therefore, CRN recommends that OEHHA include a provision that grandfathers in products with a warning compliant with existing law, unless the plaintiff can prove the product was manufactured after the effective date of the new regulations. Such language would help reduce the risk of frivolous litigation and provide certainty for businesses.

Finally, subdivision (d) of this section permits businesses to provide supplemental information about a listed chemical in a warning. However, this provision also states that such information “may not contradict, dilute, or diminish the warning” – even if the information is lawful and truthful. As noted in the Prop 65 Coalition Letter, this prohibition not only raises First Amendment and commercial free speech concerns, but its scope is so broad and could easily be interpreted to include nearly all contextual or additional information that accompanies a warning. The fact that the warnings required under Prop 65 are unique to California and do not reflect federal food safety standards, or that animal studies, rather than human studies, are the basis for listing a certain chemical are just two examples of information that is truthful, not misleading, and may provide useful context for consumers. In addition, many dietary supplements and functional foods include label claims about the general health benefits of these products and their ingredients, or other benefits specific to the brand or type of product. However, such information could either be prohibited under this proposal, or challenged by private enforcers as potentially diluting or diminishing a warning. In addition, existing state and federal laws already prohibit false and misleading statements in both labeling and advertising, and therefore we question whether this restriction is necessary.

### ***Court Approved Settlements***

In a pre-regulatory draft of these regulations, OEHHA included a provision stating that the new requirements would not apply to warnings already in use, including those resulting from prior court-approved settlements. However, this “grandfathering” provision was not incorporated in the current formal regulatory proposal. OEHHA reasons that such a provision is unnecessary because the proposed regulations include a “non-mandatory, safe harbor approach” and that “businesses who are parties to a settlement or judgment must comply with the provisions of the court’s order, regardless of whether this regulation states that fact.” (ISOR, p. 13) OEHHA further states businesses can petition the agency to adopt warning content or methods specific to a product, chemical or type of exposure, including court-approved warnings. This approach dismisses the legitimate concerns of businesses that have relied on these approved warnings and would require them to go through a lengthy and unnecessary rulemaking process in order to use these warnings again. Instead, CRN urges OEHHA to restore language that grandfathers existing warning language in judgments or settlements approved by a court, and makes it clear that these warnings are deemed “clear and reasonable.” We request inclusion of the following language in the regulation: “Nothing in this Article shall affect warnings for specific exposures that are approved by courts as compliant with the Act or require that such warnings be revised.”

### ***Section 25602 – Chemicals Included in the Text of the Warning***

CRN shares the concerns of the Prop 65 Coalition with regard to the increased risk of litigation and the economic burden on businesses created by this section, especially given the questionable benefit to consumers. We also question the process used by OEHHA to determine the twelve chemicals that must be expressly identified in warnings, as the agency has not provided a scientific or sound policy basis for this requirement. In the ISOR, OEHHA states that these chemicals are “commonplace” and widely prevalent, and that the agency also considered criteria such as “the potential for significant exposure to the listed chemical through human interaction with products” and the “recognizability of the chemical name among

the general public.” (ISOR, p. 14) These criteria are not based in science and therefore do not validate the agency’s determination that the public should be alerted to the presence of these twelve chemicals specifically. Further, as noted in CRN’s August 2013 comments to OEHHA and again in our June 2014 comments,<sup>1</sup> the agency has yet to produce any consumer research or empirical evidence to demonstrate that more specific or detailed warnings will actually be informative or meaningful to consumers. And although OEHHA may not intend “to imply that any or all of these chemicals pose greater health risks to the public than other listed chemicals” (ISOR, p. 15), it is difficult to conclude that the public will not regard these chemicals as more harmful – even though, as OEHHA is aware, the amount of a listed chemical in a given product is often well below that which poses an actual risk of harm to consumers. The ISOR also notes that businesses have the option of using the “short form” warning, which does not require chemical names, petitioning OEHHA to adopt a product-specific warning, or using their own “clear and reasonable warning.” (ISOR, p. 23) However, these are not acceptable alternatives for businesses, especially given the lack of clarity regarding “clear and reasonable” warnings.

### ***Section 25608.2 – Food Exposure Warnings – Content***

OEHHA appropriately recognizes that warnings for food products present a unique set of considerations.<sup>2</sup> The composition of food, including dietary supplements, is complex and inherently variable, making it difficult to measure exposure to potential chemicals with any certainty. The current framework permits use of the term “may contain”, which recognizes the inherent variability of the presence and levels of certain chemicals that are naturally found in food products. The proposed regulations would require the phrase “consuming this product *can expose* you to...” (emphasis added), which is an improvement from an earlier pre-regulatory draft which required the phrase “consuming this product *will expose* you to...” Although CRN appreciates this revision, we maintain that changes to the content of warnings are unnecessary, because *when* to warn is more frequently the cause of Prop 65-related litigation versus *how* to warn. CRN recommends that OEHHA maintain the current safe harbor warning language and permit use of the term “may contain”, which will allow flexibility and more accurately describe the potential chemical content in a food product.

The ISOR also references regulations concerning naturally-occurring chemicals in foods. (ISOR, p. 29) However, as noted by CRN in previous comments, the scope is extremely narrow and the process for establishing the amount of a chemical for purposes of this exception is time-consuming, expensive, and often the subject of litigation. With foods such as dietary supplements, levels of naturally occurring substances may be difficult to assess, quantify, and differentiate from what is not naturally occurring. Rather than revising the content of the warning for foods, we renew our request for OEHHA to focus its efforts on clarifying the naturally occurring exception and expanding its applicability, which would improve the current warning system and reduce litigation in this area.

This section also permits food products to include a “short form” warning, which uses the term “WARNING” along with “Cancer Hazard”, “Reproductive Hazard”, or both, which must be enclosed in a box. Although we appreciate OEHHA’s attempt to address labeling space concerns, the text of the shorter warning is likely to alarm and confuse consumers. As noted above, in many cases the amount of a listed

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<sup>1</sup> CRN Comments to OEHHA, submitted on August 30, 2013, [http://www.oehha.org/prop65/public\\_meetings/pdf/070913CRNcomments.pdf](http://www.oehha.org/prop65/public_meetings/pdf/070913CRNcomments.pdf); CRN Comments to OEHHA, submitted on June 13, 2014, <http://oehha.ca.gov/prop65/warnings/pdf/commentsJune2014/CouncilResponsibleNutrition.pdf>.

<sup>2</sup> CRN also recognizes that “food” is appropriately defined in proposed Section 25600.1(c) to include “dietary supplements,” which is necessary and consistent with federal law.

chemical in a given product is well below that which poses an actual risk of harm to consumers. Therefore, the proposed warning can mislead consumers by elevating the level of risk to consumers, as they may easily conclude that the product does in fact cause cancer or reproductive harm. CRN also notes that existing federal Food and Drug Administration (FDA) requirements for food products, which includes a very detailed, robust federal regulatory framework for dietary supplements, address all aspects of safety including labeling and ingredient testing.<sup>3</sup> Federal laws also address food products and dietary supplements that are adulterated (unsafe); therefore, OEHHA's proposed language for the short form warning presents a conflicting message about the safety of these products and may be misinterpreted by consumers. Although additional contextual information could help to remedy any confusion, label space is limited and the proposal's restrictions on supplemental information, as noted above, present an additional challenge.

### ***Article 2, Section 25205 – Lead Agency Website***

CRN echoes the comments and concerns noted in the Prop 65 Coalition Letter regarding this separate but related proposal. The regulation would establish the framework for a website maintained by OEHHA to provide supplemental information to the public about listed chemicals. Although OEHHA appears to have primary responsibility for collecting this information, subsection (b) would require businesses to provide this information to OEHHA upon its request, along with "any other related information that the lead agency deems necessary." This requirement goes well beyond merely determining whether a listed chemical is present and would require the submission of complex and highly technical information, such as the concentrations of listed chemicals and estimated levels of exposure. As noted in the Prop 65 Coalition Letter, CRN also questions the statutory authority to demand such information from businesses. While OEHHA maintains that Prop 65 is a "right-to-know" law, it only requires that businesses provide notice to the public about potential exposures to listed chemicals in a clear and reasonable manner. We disagree with OEHHA's statement in its ISOR for the Lead Agency Website that this additional information is "inextricably linked to the right of the people of California to be informed about exposures to listed chemicals," and therefore the agency has a "statutory responsibility" to require it. (Lead Agency Website ISOR, p. 8)

CRN also has additional concerns about this proposal from a compliance perspective. OEHHA's brief economic impact assessment concludes that the proposed regulation will not impose significant costs. (Lead Agency Website ISOR, p. 12-13) On the contrary, not only will businesses be required to produce information to OEHHA on demand, but they must also monitor the website to ensure that the information regarding their products is accurate and correct any erroneous information. In addition, subsection (c) may not provide adequate protection for trade secrets and other confidential business information (CBI). The regulation appears to provide OEHHA with sole discretion in determining whether information is CBI, with only a limited timeframe to challenge such determinations by the agency.

### ***Conclusion***

As outlined above, CRN has serious concerns about the proposed regulations and urges OEHHA to withdraw these proposals. These proposals provide questionable benefit to consumers while increasing uncertainty and litigation risk for businesses. We once again ask OEHHA to seriously reconsider its approach and pursue only those regulatory changes that are clearly grounded in sound science and fact-based evidence, rather than assumptions and anecdotal evidence. The agency should also focus its efforts

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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.

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on the most litigated areas of Prop 65: when to provide a warning, and how to determine and calculate exposure to listed chemicals. We also urge OEHHA to clarify the naturally occurring exception and expand its applicability. Clarifying these issues and assuring that any changes are based on sound science would provide the greatest benefit for consumers and businesses alike and help reduce the amount of Prop 65-related litigation.

Again, thank you for the opportunity to submit comments. As representatives of the dietary supplement and functional food industries, CRN recognizes the importance of complying with Prop 65 and we will continue to ensure that our products are of the highest quality and meet all applicable safety standards. Should you have questions, please do not hesitate to contact me at [ral-mondhiry@crnusa.org](mailto:ral-mondhiry@crnusa.org) or (202) 204-7672.

Sincerely,

A handwritten signature in black ink, appearing to read "Rend Al-Mondhiry". The signature is fluid and cursive, with a long horizontal stroke at the end.

Rend Al-Mondhiry, Esq.  
Regulatory Counsel