June 13, 2014

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

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 potential amendments to Article 6, Clear and Reasonable Warnings as required by Proposition 65 (Prop 65). 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 was initially encouraged by Governor Jerry Brown’s announcement in May 2013, where he outlined his intention to reform Prop 65 with the goals of “ending frivolous ‘shake-down’ lawsuits, improving how the public is warned about dangerous chemicals and strengthening the scientific basis for warning levels.” However, the current pre-regulatory draft developed by OEHHA will not achieve these objectives, but instead will undermine efforts at meaningful reform. CRN’s comments express general concerns about the current proposal; specific concerns about certain elements of the proposal and its impact on the dietary supplement and food industry; and finally, recommendations to OEHHA for improving the current Prop 65 framework. We also support the comments submitted by the California Chamber of Commerce on behalf of numerous organizations, including CRN, in its coalition letter (“Prop 65 Coalition Letter”) to OEHHA regarding the proposal.

General Concerns with OEHHA’s Proposal

OEHHA has stated that the proposed changes are “intended to implement the Administration’s visions concerning improving the quality of warnings and providing certainty for businesses subject to” Prop 65. CRN appreciates OEHHA’s intent and agrees that certain aspects of Prop 65 must be reformed in order to provide consumers with more useful information about listed chemicals and to improve the business climate in the state. Unfortunately, the proposal as currently written will not benefit consumers and will do nothing to address the abuses of Prop 65. Instead, the proposed changes will only serve to

---

confuse consumers and create more opportunities for litigation – thus in direct opposition to OEHHA’s intent and the Governor’s stated goals for reform.

First, the proposed changes are focused solely on the warning language, i.e., how to warn consumers about exposures to listed chemicals. However, this focus ignores a fundamental issue with Prop 65 and the primary basis for the vast majority of Prop 65 litigation – when a warning is required. Issues such as how to test for compliance, what tests to apply and when, and how to interpret those results should be resolved at the regulatory level and would provide greater certainty for businesses seeking to comply fully with Prop 65. Both businesses and consumers would be better served if OEHHA provided clear guidance on these matters, rather than leaving these issues to be debated in litigation.

Second, the elimination of general “safe harbor” warnings and the imposition of new, detailed warning language is very problematic, exposing businesses to an even greater risk of litigation and creating uncertainty regarding the adequacy of warnings. In addition, OEHHA now proposes that businesses must demonstrate that a warning is in fact required, in order to discourage unnecessary warnings. Under the current framework, businesses are permitted to provide general safe harbor warnings on consumer products based on potential exposure to a listed chemical, without assessing the actual amount a consumer may be exposed to. Determining the level of exposure from a given product is difficult and costly, especially in the case of food products with varying levels of naturally-occurring chemicals. Businesses also choose this option to reduce the threat of litigation from aggressive private enforcers of Prop 65, who often challenge a business’s decision not to provide a warning. By taking away this protective mechanism, and also 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.

These proposed changes will also require a business to test for each chemical exposure in a product to determine if a warning is warranted, and then submit additional exposure information to OEHHA for each of these chemicals. Testing for multiple chemicals, measuring exposure, and gathering this additional exposure information is costly and time-consuming, and even if a business fully complies with the proposed regulation, plaintiffs can still challenge its compliance, based on whether the appropriate test method was performed and the level of risk adequately characterized, and the sufficiency of information provided to OEHHA (discussed in more detail in the next section).

Finally, CRN has concerns about the lack of objective, scientific basis for the proposed regulatory changes throughout the current proposal. As noted in our previous comments to OEHHA regarding potential changes to Prop 65, the agency has not provided any consumer research or empirical evidence to demonstrate that more specific, detailed warnings will actually inform or resonate with consumers, and it appears that OEHHA has no plans to do so. During the workshop held on April 14, 2014, OEHHA indicated that the current changes are based, in part, on phone calls to the agency. However, mandating additional chemical, health effect, and exposure information – which comes with significant increased threat of litigation, substantial compliance costs for businesses, and potential increased costs for consumers – without any fact-based evidence of benefit to consumers or expert analysis of consumer perception is of serious concern to CRN. Similarly, OEHHA’s proposal is based on the assumption that all exposures to listed chemicals warrant avoidance, without any evidence to support this broad proposition. We also

question the process used by OEHHA to determine the twelve chemicals that must be expressly identified in warnings, as required by proposed Section 25605. OEHHA has not provided its scientific or policy basis for this requirement, but only indicates that these chemicals are “commonly found in consumer products, including foods” and are “commonly understood.” However, the agency has not provided any substantiation to support this statement.

CRN once again urges OEHHA to seriously consider what changes will achieve meaningful reform and pursue only those regulatory changes that are clearly grounded in sound science and fact-based evidence, rather than assumptions and anecdotal evidence. As written, the proposal weakens rather than improves the current Prop 65 framework, without any benefit to consumers or businesses. Our concerns about specific aspects of the proposal are addressed below. We also encourage OEHHA to closely review the detailed comments provided in the Prop 65 Coalition Letter, which outlines common concerns among numerous industry stakeholders, including CRN, and offers suggestions for meaningful reform of Prop 65.

**Website and Additional Information Requirement**

Proposed Section 25604(a) would require businesses to submit eleven items of information to OEHHA for each chemical exposure requiring a Prop 65 warning, such as the anticipated route(s) or pathway(s) of exposure, the anticipated level of human exposure (if known), and actions a person can take to mitigate or eliminate exposure to the chemical, unless the requirement information is already provided in a warning. OEHHA would then make this information publicly available on its website.

This requirement goes well beyond merely determining whether a listed chemical is present, and could significantly increase litigation risks for businesses. Plaintiffs will now have additional opportunities to challenge a business’s compliance with Prop 65 based on the vague and ill-defined language in this section. For example, plaintiffs could challenge the adequacy, type, or accuracy of the information a business provides to OEHHA, including what is considered “reasonably available information” regarding the anticipated level of human exposure to the listed chemical. Thus, it may not be enough that a business provides a warning and information as required under the proposal, because creative enforcers of Prop 65 could now challenge a warning based on their own interpretation of this section. And although OEHHA has stated that the new requirement is not intended to create a new cause of action under Prop 65, this has not been clearly articulated and remains an area of uncertainty. We encourage OEHHA to review the examples provided in the Prop 65 Coalition Letter, which illustrate the various ways this requirement increases the risk of litigation.

Further, proposed Section 25604(c) also requires businesses to update the information submitted under 25604(a) within 30 days after becoming aware of any necessary updates. However, the language fails to specify how a business should determine what updates are needed. Therefore, businesses will not only be required to perform ongoing monitoring, but will also be exposed to yet another litigation risk, as plaintiffs could challenge the adequacy of this new information or allege that a business omitted new information.

As noted in the Prop 65 Coalition Letter, the entirety of Section 25604 suffers from lack of clarity due to ambiguous language and vague requirements, which will result in uncertainty for businesses seeking to comply with Prop 65 along with more opportunities for litigation. Rather than require businesses to submit this additional information, OEHHA should encourage businesses to voluntarily provide this information to the agency for publication on its website, and also make clear that providing such information will not create a cause of action for private enforcers of Prop 65.
Food Exposure Warnings

OEHHA appropriately recognizes that warnings for food products present a unique set of considerations. In addition to practical concerns regarding labeling space, 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 this inherent variability of the presence and levels of certain chemicals that are naturally found in food products. Proposed Section 25607.4, however, would require the phrase “consuming this product will expose you to…” (emphasis added). This terminology assumes that the amount of a chemical in a given food product can be easily determined and measured with precision. 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. These levels can also vary from batch to batch, even among the same product.

Further, by eliminating the ability to voluntarily provide a warning, food and dietary supplement manufacturers could no longer warn about the potential exposure to a chemical, but must instead attempt to measure actual exposure or face increased risk of litigation. While current regulations provide an exception for naturally occurring chemicals under Section 25501, its scope is extremely narrow and the process for establishing the amount of a chemical for purposes of this exception is time-consuming, expensive, and continues to be the subject of litigation. Rather than revising the content of the warning for foods, OEHHA should 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.

CRN also notes that the proposal’s shorter warning for foods, which uses the term “WARNING” along with “Cancer Hazard”, “Reproductive Hazard”, or both, will only serve to alarm and confuse consumers. This language fails to recognize that, in many cases, the amount of a listed chemical in a given product is well below that which poses an actual risk of harm to consumers. Further, existing federal Food and Drug Administration (FDA) requirements for food products, including a very detailed, robust federal regulatory framework for dietary supplements, address all aspects of safety including labeling and ingredient testing. Federal laws also adequately address food products and dietary supplements that are adulterated (unsafe); therefore, OEHHA’s proposed language 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 (described in more detail below) present an additional challenge. Instead, 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 – thereby providing clear, meaningful information for consumers that is also consistent with federal food safety policies.

Restrictions on Supplemental Information

Proposed Section 25607.4(c) also permits businesses to provide supplemental information about a listed chemical in a warning. However, this provision also states that such information shall not “dilute or negate the warning” – even if the information is lawful and truthful. As noted in the Prop 65 Coalition

---

4These FDA mandates include regulations related to Good Manufacturing Practices, New Dietary Ingredients, and Food Safety Modernization Act requirements, among others.
Letter, this prohibition not only raises First Amendment 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, FDA information or advice about certain chemicals in food may be inconsistent or conflict with a Prop 65 warning, because in many cases FDA has not concluded there is a risk to humans when consumed at levels that would require a Prop 65 warning. However, such information would either be prohibited under this proposal, or challenged by private enforcers as potentially diluting or negating a warning. Finally, CRN notes that 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.

**Recommendations**

In summary, CRN has serious concerns about the proposal as currently written and urges OEHHA to withdraw the proposal. The proposed changes to the current warning language are misguided, unnecessary, and are likely to confuse rather than educate consumers. In addition, these changes will only exacerbate the already abusive Prop 65 litigation climate. Thus, we offer the following recommendations for meaningful reform of Prop 65: (1) OEHHA should reconsider the need for detailed warning requirements until it conducts consumer research confirming that the current warning language should be revised and what language is most beneficial for consumers; (2) OEHHA should maintain the current “safe harbor” warning language and continue to allow businesses to use warnings without a scientific demonstration that a warning is required; (3) OEHHA should clarify the naturally occurring exception and expand its applicability; and, (4) most importantly, CRN urges OEHHA to focus its efforts on the most pressing issue regarding Prop 65 – the need for meaningful guidance regarding when to provide a warning, and how to determine and calculate exposure to listed chemicals. Clarifying this issue would provide the greatest benefit for consumers and businesses alike and significantly 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. We also appreciate OEHHA’s willingness to hear perspectives of all stakeholders impacted by Prop 65.

Should you have questions, please do not hesitate to contact me at ral-mondhiry@crnusa.org or (202) 204-7672.

Sincerely,

Rend Al-Mondhiry, Esq.
Regulatory Counsel