



## Council for Responsible Nutrition

1828 L Street, NW, Suite 510 • Washington, DC 20036-5114  
(202) 204-7700 • fax (202) 204-7701 • [www.crnusa.org](http://www.crnusa.org)

June 6, 2016

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: 15-Day Notice of Modification to Proposed Regulation – Article 6, Clear and Reasonable Warnings***

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 its 15-Day Notice of Modification to Proposed Regulation to repeal Article 6 and adopt a new Article 6 in Title 27 of the California Code of Regulations pursuant to the Safe Drinking Water and Toxic Enforcement Act (Proposition 65).

CRN, founded in 1973 and based in Washington, DC, is the leading trade association representing the dietary supplement and functional food industry. Our membership includes more than 150 companies that manufacture nutritional ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies comply with a host of federal and state regulations governing the manufacturing, quality, and safety of dietary supplements and food, including those imposed by Proposition 65. CRN is also one of the over 200 California-based and national organizations and businesses in the Proposition 65 Coalition (the Coalition) led by the California Chamber of Commerce and we fully support the comments submitted on behalf of the Coalition.

CRN appreciates that OEHHA has made additional changes to the modified proposed regulations published on March 25, 2016. Although these changes fail to address the many concerns described in our comment letters to OEHHA dated January 25, 2016 and April 26, 2016, the comments herein focus on the need for additional clarification regarding warnings for food exposures. In its Final Statement of Reasons (FSOR) for the regulation, OEHHA should clarify that on-product warnings for food exposures, including dietary supplements, may use the shortened warning language provided in proposed Sections 25602(a)(4) and 25603(b).

Proposed Section 25602(a)(4) states that for consumer product exposures, an on-product warning may be provided using the shortened warning language in Section 25603(b). In its Initial Statement of Reasons (ISOR) dated November 27, 2015, OEHHA states that the shortened warning is intended to “accommodate some product manufacturers’ stated concern that a longer warning message will simply not fit on the labeling or packaging of some small products.” (ISOR at p. 31) The ISOR further states that “all methods for transmitting the warning for other consumer products under Section 25602 are equally available to businesses that manufacture or sell foods.” (ISOR at p. 34) Based on these statements in the ISOR, CRN

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initially understood that warnings for dietary supplement products and other food exposure warnings may utilize the shortened warning language provided in Section 25603(b); however, the proposed regulation as currently written is ambiguous regarding this point.

Proposed Section 25607.1(a) states that a warning for food exposures, including dietary supplements, is compliant if it meets the content requirements of Section 25607.2 and uses a method provided in Section 25602. One of those permitted methods, under Section 25602(a)(4), is an on-product label warning that complies with the content requirements of Section 25603(b), which is the shortened warning noted above. However, it is unclear whether food exposures may utilize the shortened warning because the required content for food exposure warnings under Section 25607.2 does not include the shortened warning language.

CRN therefore requests that OEHHA clarify this issue in the FSOR for the regulation by expressly stating that a warning for food exposures, including dietary supplements, may use the shortened warning indicated in Section 25603(b) and that such a warning would be deemed compliant with the regulation. In our previous comments to OEHHA, CRN noted that many dietary supplements have small packaging and labeling that must incorporate federal Food and Drug Administration requirements for content, font size, and placement.<sup>1</sup> Because of this limited label space, dietary supplements should have the option to use this type of warning and we believe OEHHA intended Section 25603(b) to apply to warnings for dietary supplements, given its statements in the ISOR. However, supplement companies cannot do so with certainty unless OEHHA clarifies this issue in the FSOR.

Thank you for considering our comments and providing the opportunity to participate in the regulatory process. 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,



Rend Al-Mondhiry  
Associate General Counsel

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<sup>1</sup> See 21 CFR § 101.15(c)(2) regarding the use of label space for any representation in a foreign language; see also 21 CFR § 101 et seq., Food Labeling.