



Council for Responsible Nutrition

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January 25, 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

RE: Article 6 - Clear and Reasonable Warning Regulations

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 November 27, 2015 Notice of Proposed Rulemaking 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 manufacturers and marketers of dietary supplements, functional foods, and their nutritional ingredients. CRN represents more than 150 companies that manufacture dietary 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 dietary supplements and food in the areas of manufacturing, marketing, quality control, and safety. Because nearly all of CRN's members conduct business in California, the proposed changes to the Proposition 65 regulations will have a significant impact on our members.

In addition to the comments provided herein, CRN joins the coalition of organizations (Proposition 65 Coalition) in supporting comments submitted by the California Chamber of Commerce. We urge OEHHA to carefully consider the comments and recommendations included in that letter. Although CRN appreciates OEHHA's attempt to address concerns previously raised by CRN and the Proposition 65 Coalition, the current proposal suffers from many of the same issues as OEHHA's January 2015 proposal. As a result, some of the language contained within CRN's previous comment letter dated April 8, 2015 is repeated herein. A copy of those comments is attached to ensure they are part of the administrative record for the current proposal.

In summary, CRN remains concerned that the proposed regulations lack sufficient clarity and guidance for businesses, making compliance more difficult and increasing the risk of litigation without improving public health. The dietary supplement industry is a frequent target of meritless lawsuits and CRN has repeatedly asked OEHHA to focus its reform efforts on issues related to determining when a warning is required, as these issues represent the vast majority of Proposition 65 lawsuits. We maintain that changes to the content or methods of warning are not necessary and we again ask OEHHA to focus on areas of the regulation that are the source of most frivolous litigation.

In addition to creating more opportunities for private enforcers to pursue frivolous litigation, CRN also questions whether California consumers will actually benefit from the proposed changes. As described in further detail in our comments, the new and unnecessary changes to the warning language are inconsistent with the U.S. Food and Drug Administration's (FDA) labeling and safety provisions for dietary supplements and functional food, and are likely to cause confusion among consumers. As noted in CRN's previous comments, OEHHA's process for determining this new warning language appears to be arbitrary and not grounded in sound science, further eroding the scientific basis for the Proposition 65 framework. Our specific concerns are outlined below in accordance the proposed regulations.

Section 25600: General

Subdivision (b) provides an effective date of two years, whereby businesses will have two years following adoption of the regulations to come into compliance. While CRN appreciates that the regulations allow use of the old safe harbor warning for products manufactured prior to the effective date, we ask OEHHA to extend this implementation period to three years. Based on our members' knowledge and experience with dietary supplement packaging and labeling matters, we believe two years will 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. A three-year phase-in period will be conducive to the existing trade practices of California retailers for selling supplement products and reflect federal requirements for dietary supplement labeling. Many supplement products are labeled with an expiration date allowing a two-year shelf life; however, some supplement products, such as iron mineral supplements, are relatively stable and have longer expiration dates, or no expiration dating at all. The Codex Alimentarius' Guidelines for Vitamin and Mineral Supplements do not require expiration dating in labeling,¹ and FDA does not require expiration dating on dietary supplement packaging.² Considering the "sell through" practices of retailers a two-year effective date is not sufficient and could impose significant costs on both retailers, especially small retailers, and the supplement industry. Therefore, in addition to extending the effective date to three years, CRN requests that OEHHA provide specific guidance in grandfathering dietary supplement product labeling to assure effective implementation of the proposed regulation and avoid unnecessary compliance costs on the industry.

Subdivision (d) of this section permits businesses to provide supplemental information about a listed chemical in a warning as long as such information does not "contradict" the warning. We appreciate that OEHHA has removed the terms "dilute" and "diminish" contained in the January 2015 proposal. However, the scope of this provision remains broad, creating an additional source of litigation for private enforcers, and could easily be interpreted to include many types of lawful and truthful information that accompany a warning. For example, the fact that the warnings required by Proposition 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. However, such information could either be prohibited under this proposal, or challenged by private enforcers as potentially contradicting a warning. Further, existing state and federal laws adequately protect consumers from false and misleading statements in both labeling and advertising (discussed in greater detail in Section 25607.2 below), and therefore we

¹ CAC/GL 55-2005.

² 21 CFR § 111.

question whether this restriction is necessary. We therefore echo the First Amendment concerns raised in the Proposition 65 Coalition comment letter and urge OEHHA to remove this provision, which is unnecessary and will chill commercially protected speech. CRN requests this provision be revised as follows:

(d) A person may provide information to the exposed individual that is supplemental to the warning required by Section 25249.6 of the Act. ~~In order to comply with this article, supplemental information may not contradict the warning.~~ Supplemental information may not be substituted for the warning required by Section 25249.6 of the Act.

Section 25600.1: Definitions

CRN supports the definition of “food” in subdivision (d), which has the same meaning as defined in Health and Safety Code Section 109935 and expressly includes “dietary supplements” as defined in California Code of Regulations, Title 17, Section 10200. This definition is consistent with federal law and affirms that dietary supplements are considered food under Proposition 65.

Subdivision (i) defines “consumer product exposure” as “an exposure that results from a person’s acquisition, purchase, storage, consumption, or any reasonably foreseeable use of a product, including consumption of a food.” CRN requests that OEHHA further clarify this definition and remove the phrase “any reasonably foreseeable use.” As written, the definition is vague, overly broad, and a likely target for litigation. Further, with respect to the use of dietary supplements and other food, it is unclear whether a consumer product exposure would extend to exposures beyond what is provided in the directions for use listed on the product label. By not defining “consumer product exposure” according to the use of a particular product, such as a dietary supplement that has specific directions for use or customary (ordinary) uses, the definition may be interpreted to require manufacturers to assess all potential types of exposures to a listed chemical beyond oral use of product. Thus, CRN also asks OEHHA to further clarify that a “consumer product exposure” means use of a product in accordance with the product labeling recommendations or ordinary conditions of use, which is consistent with the FDA’s safety provisions related to the use of dietary supplements.³

Section 25601: Safe Harbor Clear and Reasonable Warnings – Methods and Content

In this section, OEHHA again fails to provide necessary guidance to businesses as to what is considered a “clear and reasonable warning” for purposes of compliance with Proposition 65. Despite the language in subdivision (b) stating that businesses are permitted to use alternative warning content or methods other than those provided in the regulations, businesses cannot rely on alternative warnings with certainty unless OEHHA provides a definition or further guidance. As drafted, the only way to provide a “clear and reasonable warning”, and therefore mitigate the threat of private enforcement action, is to use the warning language provided in the proposed regulations. In order to make alternative warning language a meaningful, defensible option for businesses, OEHHA should maintain the existing description of “clear and reasonable warning” or provide additional guidance for businesses seeking to use a fully compliant alternative warning.

³ Under 21 USC § 342(f), a dietary supplement is considered adulterated if it “presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.”

Second, CRN has grave concerns about the chemical specification requirement in subdivision (c). While OEHHA appropriately removed previous language that required businesses to include the names of certain listed chemicals in a warning, the newly proposed language is equally problematic and will create uncertainty from a compliance standpoint. The language is vague and lacks clarity regarding how a business should select the “one or more of the listed chemicals for which the warning is being provided” and will undoubtedly be the subject of litigation. In addition, it will lead to arbitrary decisions by manufacturers regarding chemical selection.

Some CRN members market products that contain many ingredients, including herbal ingredients derived from natural sources, many of which contain multiple chemical constituents that in the future may become subject to the Proposition 65 warning requirements. Due to the lack of guidance regarding the maximum number of chemicals that must be listed in the proposed warning language, it is unclear whether supplement and functional food manufacturers must specify all of the chemicals for which a warning is being provided (if the manufacturer determines a warning is necessary for exposures to multiple listed chemicals) and further, how the manufacturer should select the chemical(s) to be included in the Proposition 65 warning.

In addition to the product label information required by federal law,⁴ many dietary supplement products are sold in small packages, for which little if any label space is available for listing multiple chemicals in a Proposition 65 warning. Using larger containers in order to accommodate larger product labels is restricted by federal and state slack-fill requirements (including those in California), and larger packaging unnecessarily adds to environmental waste streams and may increase consumer cost. For example, excess packaging is considered misbranding under federal law and could subject dietary supplement and food companies to enforcement action.⁵

Moreover, as written this requirement clearly provides an opportunity for private enforcers to challenge a business’s decision to list a given chemical, or to list only one chemical. It is also unclear how businesses should make this determination when an exposure involves both listed carcinogens and reproductive toxicants. For example, a supplement or functional food manufacturer that chooses to specify only one chemical may be targeted by a private enforcer and be required to defend its decision in court at significant expense. We strongly urge OEHHA to consider the revisions suggested by the Proposition 65 Coalition to improve this section and more importantly, specify that businesses have sole discretion to determine which chemical and how many chemicals to list in the warning to avoid unnecessary litigation regarding this issue. OEHHA should also consider providing detailed guidance as to the criteria for selecting one or more chemicals and then seek public comment on these criteria. These selection criteria should be based on sound scientific reasoning and labeling considerations, as well as on the basis of consumer safety.

Finally, subdivision (c) also requires that a warning specify a chemical “to the extent that an exposure to that chemical or chemicals is at a level that requires a warning,” suggesting that businesses will now have the burden to prove that a warning is required. This requirement creates an unlawful burden because Proposition 65 only requires defendants to prove that no warning is required; it has never been interpreted to require defendants to justify a decision to warn. In doing this, OEHHA also creates a new source of litigation for private enforcers to challenge the existence of a warning, in addition to its content

⁴ 21 CFR § 101 et seq., Food Labeling.

⁵ 21 CFR § 100.100, Misleading Containers.

due to the proposed chemical specification requirement. If OEHHA is intending to reduce “overwarning” we suggest it focus on improving the scientific basis for Proposition 65 overall, rather than adding an additional burden on defendants. Thus, CRN urges OEHHA to remove this phrase in its entirety.

Section 25602: Consumer Product Exposure Warnings – Methods of Transmission

CRN has concerns that the language in subsection (a) stating that a warning can be provided using “one or more of the following methods” may be misinterpreted by a private enforcer who claims that multiple warning methods must be used. Therefore, we suggest the language be modified to state that a warning complies if it meets the content requirements and “is provided using at least one of the following methods” and further, that businesses have sole discretion when determining which warning method to use.

CRN agrees with the comments in the Proposition 65 Coalition letter regarding “labeling” and the need for further clarification in subsection (a). Although OEHHA has defined the term “labeling” in the proposed regulations to include materials (written or otherwise) that accompany a product, it is unclear whether a warning transmitted through “labeling” is compliant, as currently permitted under the existing regulations. CRN recommends that OEHHA revise Section 25602(a)(4) to include the term “other labeling” so that the regulations continue to allow for warnings in package inserts and related methods that may contain other health and safety information or warnings for consumers.

CRN also shares the Coalition’s concerns regarding the “prior to or during the purchase” provisions found throughout this section. Existing regulations state that warnings should be provided “prior to exposure,” which provides needed flexibility for businesses when providing a warning in various circumstances. OEHHA has not provided any justification or reasoning for this significant departure from the current requirements. CRN also questions OEHHA’s authority to make this change, as this change is inconsistent with the Act. Implementing this new requirement will also be impractical and burdensome, and the benefit to consumers questionable. Moreover, it calls into question whether a warning in labeling such as a package insert would comply with the regulations, as a consumer would not have access to this information until after purchase.

Finally, CRN’s concerns regarding the foreign language requirement in subsection (d) are provided in our comments to Section 25607.1. In brief, this requirement is impractical, ambiguous, and as described in further detail below, potentially in conflict with federal dietary supplement and food labeling requirements.

Section 25607: Specific Product, Chemical and Area Exposure Warnings

Subsection (b) states “if a person does not cause an exposure to a listed chemical required to be identified in a warning set out in this section, the name of that listed chemical need not be included in the warning” to be considered “clear and reasonable.” However, it further states that “the name of at least one chemical requiring a warning must be included in all warnings.” As written, this subsection is confusing and seems to suggest, similar to the language in Section 25601(c), that businesses have the burden of proving that a warning is in fact required. CRN recommends that OEHHA revise the language in accordance with the suggestions provided in the Proposition 65 Coalition letter to improve the clarity of this subsection and avoid unnecessary confusion.

Section 25607.1: Food Exposure Warnings – Methods of Transmission

The foreign language requirement in subsection (c) is problematic for several reasons. First, it is impractical for a product manufacturer, producer, packer, or distributor to know in advance all of the languages a retailer may use on signs, especially given the number of retailers that may be selling its products. And because the term “consumer information” is not defined, private enforcers will interpret this term as broadly as possible, leaving businesses vulnerable to litigation. Second, the FDA’s labeling regulations for both dietary supplements and food are highly detailed and have strict requirements regarding font, content, and placement, in addition to foreign language requirements for product labeling.⁶ For example, if any foreign language is used on the label, companies must translate everything into that language. Therefore, if a dietary supplement label uses three languages (e.g., English, French, and Spanish), the Proposition 65 warning statement must also be in three languages. Even if OEHHA were to give businesses flexibility, dietary supplement companies must follow the federal labeling laws without exception and place all legally-required information on the label in the format provided therein.

Due to multiple federal labeling requirements and the small packaging of many dietary supplement and food products, companies have significant space limitations and the label cannot accommodate additional warnings in other languages, especially if OEHHA intends to maintain the chemical specification requirement as written. As noted above, slack-fill requirements restrict the ability to use larger containers or packaging, and there are environmental waste concerns as well. CRN questions whether OEHHA has carefully reviewed the relevant federal mandates for dietary supplements and food to avoid potential conflicts, as dietary supplement and food labeling are subject to stringent labeling regulations that do not allow for state-specific exemptions. For these reasons, CRN strongly urges OEHHA to reconsider Section 25607.1 in its entirety until OEHHA has conducted a thorough review of relevant federal labeling requirements for dietary supplement and food products and expressly identifies potential conflicts, and also explains to stakeholders how its proposed regulations should be reconciled with the federal requirements. Otherwise, dietary supplement and functional food companies may be subject either to private enforcement action or federal enforcement action for failing to comply with the respective requirements under Proposition 65 and federal law.

Section 25607.2: Food Exposure Warnings – Content

CRN appreciates OEHHA’s recognition that dietary supplements are a category food, and that food products should have unique, tailored warnings. However, CRN again urges OEHHA to reconsider its proposed warning language for food exposures for two key reasons.

First, the language does not reflect the nature of food products. The composition of food and dietary supplements is complex and inherently variable, often containing a number of naturally occurring chemicals which make 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*

⁶ 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.

expose you to...” As noted above, this change to the content of warnings is unnecessary, because *when* to warn is more frequently the cause of Proposition 65-related litigation versus *how* to warn.

CRN also notes that 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 (i.e., to what extent levels are naturally inherent versus what levels are inadvertently “added”). As an example, lead ions are known to mimic calcium ions, both of which are naturally assimilated from soils during growth and become bound to the tissues of plants (i.e., crops) that are part of the human diet.⁷ It has been long-recognized that these plant-bound lead ions can exhibit lower bioavailability,⁸ and many dietary supplement ingredients are derived from plant material. Rather than revising the content of the warning for food exposures, CRN also renews its request for OEHHA to focus its efforts on clarifying the naturally occurring exception and expanding its applicability for dietary supplements and other complex food products, which would improve the current warning system and reduce litigation in this area.

Further, the use of “may contain” is more appropriate for dietary supplement and food products in the context of the total daily diet. The ingestion of chemicals from these products as part of the diet does not guarantee absorption from the gastrointestinal lumen into systemic circulation. It is well recognized that dietary components, particularly for dietary fiber and fats, alter the bioavailability of naturally occurring and other chemical substances into the human system, where reproductive toxicants and carcinogens typically exert their effect.⁹ Continued use of the term “may contain” will allow flexibility and more accurately describe the potential exposure of dietary chemicals in dietary supplement and food products.

Second, the language is unnecessarily alarming and inconsistent with the federal regulation of dietary supplements and food, which includes detailed labeling provisions and requirements for assessing contaminant levels, among other things. The fact that Proposition 65 is not consistent with the FDA’s regulation of dietary supplements and other foods is not a new issue. However, given the alarming language required for food products proposed by OEHHA, California consumers are likely to be confused by the new warnings, as 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.

As OEHHA is aware, 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. Therefore, the proposed warning may mislead consumers by elevating the level of risk, as they may erroneously conclude that the product presents an undue risk of cancer or reproductive harm. Existing FDA requirements include a robust federal regulatory framework for dietary supplements that addresses all aspects of safety including good manufacturing practices (GMPs), ingredient testing, adverse event reporting requirements, and detailed requirements to ensure consumers receive accurate and informative labeling. Federal law also provides FDA with authority to declare a dietary supplement adulterated (unsafe), if the agency determines that it poses an unreasonable

⁷ Centers for Disease Control, Toxicological Profile for Lead, Agency for Toxic Substances and Disease Registry (2007), pp. 582.

⁸ U.S. Environmental Protection Agency, Symposium on the Bioavailability and Dietary Exposure of Lead (September 24-27, 1990), Chapel Hill, North Carolina, pp. 279.

⁹ National Research Council, Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Institute of Medicine, National Academy of Sciences (2005), pp. 1,359; National Research Council, Carcinogens and Anticarcinogens in the Diet, National Academy of Sciences, National Academy Press (1996), pp. 417.

Ms. Monet Vela
January 25, 2016
Page 8

risk of injury or illness.¹⁰ Functional food products are subject to similar laws and regulations, including GMPs, adulteration provisions, and labeling and ingredient requirements. Given the existence of these laws that help ensure the safety of dietary supplements and food on a national level, OEHHA's proposed language presents a conflicting message about product safety that may be misinterpreted by consumers. Although additional contextual information could help to remedy any confusion, label space on many dietary supplements and functional foods is limited. Further, the proposed regulation's restriction on supplemental information, as noted above in Section 25600, presents an additional labeling challenge for companies.

Therefore, given the complex nature of dietary supplements and other food products, as well as the comprehensive federal regulatory structure in place to address possible contaminants and overall safety concerns, CRN requests that OEHHA reconsider its proposed warning language for food exposures and maintain the current safe harbor language.

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 ralmondhiry@crnusa.org or (202) 204-7672.

Sincerely,



Rend Al-Mondhiry
Associate General Counsel

Enclosure: CRN Comments to OEHHA (April 8, 2015)

¹⁰ 21 USC § 342(f).



Council for Responsible Nutrition

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April 8, 2015

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Via Email: 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,¹ 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.² 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

¹ CRN Comments to OEHHA, submitted on August 30, 2013, 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>.

² 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.³ 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

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

Ms. Monet Vela
April 8, 2015
Page 6

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 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