Council for Responsible Nutrition
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October 28, 2015

Ms. Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812
Via Email: monet.vela@oehha.ca.gov

Re: Pre-Regulatory Proposal in Response to Petition by Center for Environmental Health Requesting Repeal or Amendment of Safe Harbor for Lead

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 August 28, 2015 pre-regulatory proposal in response to an administrative petition by the Center for Environmental Health (CEH) to repeal or amend the safe harbor level for lead. CRN, founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. We represent more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our members comply with a host of federal and state requirements, including those imposed by Proposition 65 (Prop 65).

CRN supports the comments submitted to OEHHA by the California Chamber of Commerce (CalChamber) on behalf of the Prop 65 Coalition. As a coalition member and signatory to this comment letter, we urge OEHHA to carefully consider the far-reaching and substantial impact of this proposal on the consumer products industry broadly. CRN's comments reiterate many of the same issues outlined in CalChamber's comments. With regard to dietary supplements and functional foods, the pre-regulatory proposal poses significant challenges to our members. Naturally occurring lead is found in many of these products, making our members an easy and frequent target for private enforcers of Prop 65 despite good faith efforts to comply with the regulations. Further, this proposal also goes far beyond answering the issues addressed in the CEH petition, without explanation or rationale, and will create a great deal of uncertainty for the dietary supplement and food industry and make the industry more vulnerable to meritless litigation.

The August 28th proposal would amend 27 Cal. Code Regs. Section 25805(b) to make two changes: 1) significantly reduce the current Maximum Allowable Dosage Level (MADL) for lead and, 2) require the existing safe harbor MADLs for all other reproductive toxicants to be based on single day exposures. If adopted, this proposal would substantially increase the amount of Prop 65 warnings, increase frivolous lawsuits, and weaken the scientific basis for warning levels – directly undermining Governor Brown's calls for Prop 65 reform in May 2013.[1] And although OEHHA states that these are "pre-regulatory" proposals

[1] https://www.gov.ca.gov/news.php?id=18026.

intended as a "starting point for discussion,"[2] CRN has grave concerns about the direction of this proposal, especially when considered with the additional pre-regulatory proposals recently issued by OEHHA.[3] We also note OEHHA has not provided sufficient time for stakeholders to assess the impact of the proposal, given the highly technical nature of the issues and the many valid questions from stakeholders regarding the underlying science for the proposed MADLs. The fact that pending litigation[4] addresses the very same issues outlined in the proposal and may be impacted does not justify an expedited timeline; both industry stakeholders and consumers deserve a framework based on sound science and that provides a demonstrable public health benefit.

- ***Increase in Warnings and Litigation Risk***

OEHHA proposes to reduce the safe harbor level for lead by 60% - from the current MADL of 0.5 mcg/day to 0.2 mcg for a single day. This change will have a significant impact on the dietary supplement and functional food industries, as lead is a natural component of many essential food ingredients in these products. Even if firms reformulate their products in attempt to meet the new MADL, this level is unjustifiably low. Reformulation may not be possible or economically feasible, in which case firms will then be forced to place unwarranted warnings on their products. Although OEHHA appropriately permits higher levels for intermittent exposures, the proposed chart of duration periods for higher exposures add an unnecessary layer of complexity and more opportunities for abusive, meritless litigation. Any business that relies on these higher levels is likely to be targeted by private enforcers who will challenge the exposure calculations.

The current 0.5 mcg/day MADL has been in place for over 25 years, with businesses able to rely on a single number and a single calculation. Rather than be forced to perform expensive testing in response to private enforcers, many firms will instead rely upon the single-day MADL even if the exposure occurs less frequently than every day. As a result, firms – including many dietary supplement companies that have been the frequent target of private enforcers – will place a warning on a product even when a warning is not required to avoid the threat of litigation. Private enforcers are well aware that naturally occurring lead is ubiquitous in many food and supplement products. And although not added intentionally to these products, defendants face substantial challenges, both legal and financial, when defending against private enforcement actions especially when coupled with the difficulty of using the naturally occurring exemption. Not surprisingly, the vast majority of these lawsuits involve lead and this proposal will add an even greater number as private enforcers target not only the product manufacturers and distributors, but also the retailers selling these products. Thus, the proposal contravenes two of the Governor's goals by increasing Prop 65 litigation and exacerbating the "overwarning" problem.

In the proposal, OEHHA also fails to address how court-approved settlements will be impacted by the reduced lead MADL and the single-day requirement for exposures to other reproductive toxicants. Dietary supplement companies that are parties to these settlements have already expended significant

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[2] OEHHA Pre-Regulatory Draft Discussion (August 2015), page1: http://oehha.ca.gov/Prop65/CRNR_notices/pdf_zip/082815DraftPreRegulatoryLead.pdf.

[3] Draft pre-regulatory language for the possible amendment to Section 25821(c) (August 2015), http://oehha.ca.gov/Prop65/CRNR_notices/pdf_zip/25821ArithmeticmeanDraftLanguage082815.pdf; Pre-Regulatory Draft Language for Section 25821(a) (August 2015), http://oehha.ca.gov/Prop65/CRNR_notices/pdf_zip/082815PreRegdraftText25821a.pdf

[4] *Mateel Environmental Justice Foundation v. California Office of Environmental Health Hazard Assessment, et al.*, No. RG15754547 (California Superior Court, Alameda County).

resources, only to be faced with the possibility of re-negotiating these settlements in order to comply with the new MADL requirements. For example, the Warner-Lambert consent decrees include a provision for naturally occurring lead allowances for eight ingredients (calcium, ferrous fumarate, zinc oxide, magnesium oxide, magnesium carbonate, magnesium hydroxide, zinc gluconate and potassium chloride) found in multivitamins, antacids and calcium supplements. OEHHA should expressly identify such settlements in this or related proposals to ensure they are protected, thereby allowing the industry to have certainty, avoid further litigation, and prevent a proliferation of new warnings. We further request that if OEHHA intends to reduce the lead MADL by any amount, the proposal should provide sufficient compliance time and also expressly allow companies to sell through current inventory to protect against lawsuits filed concurrently with the effective date.

- ***Lack of Scientific Basis and Questionable Public Health Benefit***

CRN agrees with the detailed comments provided by CalChamber, and as a member of the Prop 65 Coalition we echo the concerns about the proposal weakening the scientific basis for warning levels. We also highlight the fact that Prop 65 already has an extremely conservative safety factor built into the statute: warnings are required at *one one-thousandth of the no observed effect level*. Thus, the proposed lead MADL, with such a significant reduction, is unjustified and not necessary to protect public health.

The coalition letter correctly points to deficiencies in OEHHA's analysis of the science on lead and its use of the "Leggett Plus" pharmacokinetic model. CRN agrees that OEHHA has not adequately justified its determination that a target blood lead level (BLL) of 15 mcg per deciliter should be the basis for the proposed lead MADL. A further assessment of the science, using the relevant toxicological endpoints, is warranted. OEHHA's proposal also fails to take into account the frequency of exposures, which is not scientifically valid, and assumes a ten-year exposure period but without providing any substantiation for this approach. We raise additional questions regarding OEHHA's use of the 1,000-fold safety factor in its analysis of the relevant scientific studies. CRN encourages OEHHA to consider the suggestions outlined in the coalition letter and revise its proposal accordingly. Just as our industry is committed to developing products that reflect valid science and promote wellness, we request that OEHHA promote only those policies that do the same.

CRN also notes that the proposal will have a unique and significant impact on our industry. As noted above, naturally occurring lead is found in common dietary supplement and functional food ingredients. These include calcium and other minerals, herbs and botanical ingredients, and ingredients like chocolate which may be added to a functional food or supplement for flavor. Dietary ingredient suppliers, who supply their products to supplement and food companies, are likewise impacted by this proposal. These suppliers are responsible for providing ingredients to their customers that comply with Prop 65 and therefore any significant reduction in the lead MADL is likely to disrupt the supply chain.

We also note that the U.S. Food and Drug Administration (FDA) imposes a comprehensive regulatory framework for dietary supplements and other food products, including regulations that address ingredient safety. Further, the Federal Food, Drug, and Cosmetic Act (FD&CA) already includes sanctions for products that are misbranded or adulterated (unsafe).[5] Our industry has diligently complied with both FDA and Prop 65 regulations for decades, despite notable inconsistencies and conflicts. Once again, OEHHA has singled out a chemical (lead) and seeks to impose requirements that do not reflect FDA policy

[5] 21 U.S.C. § 342; 21 U.S.C. § 343.

and do not benefit public health, which will cause uncertainty for both the industry and consumers. CRN has concerns about the effect of warnings on widely-used products like calcium and multi-vitamins, as these products are well-studied for their ability to promote health and wellness. Consumers are likely to be confused, given that FDA has not found these products to be unsafe due to mere traces of naturally occurring substances such as lead. As noted, Prop 65 already builds in a safety mechanism through its extremely conservative 1,000-fold safety factor. And unlike the FD&CA, Prop 65 is not designed to be a public health statute, but rather to be a framework for providing warnings. Thus, we question how this proposal would enhance product safety or the public health given FDA's regulatory framework and as outlined above, the questionable scientific basis for the proposal.

- ***Unjustified Ban on Averaging for Non-Lead Reproductive Toxicants***

OEHHA also proposes an amendment that prohibits averaging for all reproductive toxicants other than lead under Prop 65. Safe harbor levels for these chemicals would instead be based on single day exposures regardless of whether the exposure occurs daily or intermittently. As noted in the coalition letter, this proposed change is inconsistent with existing law and goes well beyond the scope of the CEH petition, which is specific to the lead MADL. Moreover, OEHHA has not provided any scientific support for this broad limitation which is in fact a significant shift, rather than clarification, of existing policy. This action also sets a troubling precedent and further erodes the scientific basis for warnings.

This proposal also has practical implications. Businesses will need to reassess and reanalyze exposure calculations to preemptively avoid a Prop 65 lawsuit. The proposal also ignores the fact that exposure duration and frequency vary for each reproductive toxicant, and therefore different reproductive toxicants act differently over a given period of time. Thus, it takes away flexibility and forecloses the opportunity for businesses to make these determinations on a case-by-case basis. As a result, many additional products may require warnings even when the science does not support doing so.

In conclusion, we strongly urge OEHHA to reconsider this dramatic and unjustified reduction of the lead MADL and also remove the provision related to other reproductive toxicants, the latter of which is not germane to the CEH petition. This proposal is not scientifically valid and will only benefit private enforcers of Prop 65 rather than consumers, and therefore we urge OEHHA to withdraw this pre-regulatory proposal and reconsider its approach.

Again, thank you for the opportunity to submit comments. 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