Council for Responsible Nutrition
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November 12, 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

Re: Pre-Regulatory Proposal - Naturally Occurring Concentrations of Listed Chemicals in Unprocessed Foods

Dear Ms. Vela:

On behalf of the Council for Responsible Nutrition (CRN), thank you for the opportunity to provide comments regarding the California Office of Environmental Health Hazard Assessment's (OEHHA) pre-regulatory proposal to establish naturally occurring background levels for lead and arsenic found in certain unprocessed foods. 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 concept of amending 27 Cal. Code Regs. § 25501 to provide safe harbor values for naturally occurring background levels of chemicals in food. With regard to food products such as dietary supplements and their ingredients, trace levels of naturally occurring chemicals are found in many of these products. Prop 65 regulations currently provide that naturally occurring levels of listed chemicals in food are not considered an exposure under Prop 65; however, the exemption under § 25501 only applies to the extent that a person can meet a set of strict requirements to prove that a listed chemical is naturally occurring. In practice, the exemption as currently written is unworkable and ineffective. Background levels of these chemicals are difficult to assess, quantify, and differentiate from what is not naturally occurring, particularly with natural-sourced products like botanical dietary supplements. The levels can also vary from batch to batch, even among the same product. For example, lead is known to be a naturally occurring element in soil and is taken up by plants, such botanicals, which are then used in dietary supplements. For the supplement industry, where ingredients come from different growers in different regions, the global supply chain makes the naturally occurring exemption impractical and therefore additional guidance from OEHHA is needed to address these issues.

We appreciate OEHHA's proposal as a first step toward improving the naturally occurring exemption. However, we share the same concerns outlined by the California Chamber of Commerce in its Coalition letter to OEHHA on this proposal. As a member of the Coalition, we urge OEHHA to consider the suggestions provided in that letter and we offer the following additional comments below. We also encourage OEHHA to consider adopting additional levels for other chemicals and types of foods, which would improve the current framework and also help reduce litigation in this area.

First, we agree with the Coalition's suggestion to increase the proposed allowances and address variability of lead levels in foods. CRN also questions OEHHA's basis for deriving the naturally occurring allowances for non-leafy and leafy vegetables using the limits of detection in the U.S. Food and Drug Administration's (FDA) Total Dietary Survey (TDS). According to FDA, an estimated 15 percent of the U.S. food supply is imported, *including 60 percent of fresh fruits and vegetables*.[1] OEHHA should use an approach that reflects the complex supply chain realities in the food and dietary supplement industries, whereby the lead levels in ingredients (many plant-based) vary depending on the region and factors that impact the climatic and soil factors (e.g., pH, clay content and organic matter), and agronomic management. We also note that in the TDS, the Market Baskets are from four different regions of the U.S. However, this collection method does not necessarily guarantee that the samples collected are indeed from varied croplands to reflect current supply chain. In order to consider using TDS limits of detection, one must determine the various origins (cropland) for the 24 samples gathered for cabbage. If most of these 24 samples are from two or three states in the U.S., the average number may not be representative of what is actually consumed and TDS data may not be meaningful.

Further, given these supply chain realities, the correction factor (0.88) used for the proposed allowances is not appropriate because OEHHA based this number on data from croplands within a single state (California). Rather, it should not only include soil data from as many U.S. states as possible, but also soil data from other countries. Like many other industries, the dietary supplement industry relies on a global supply chain and therefore, the background levels of lead and arsenic in food-based dietary ingredients used in both dietary supplements and other foods will vary depending on the source.

Second, OEHHA's proposal should include naturally occurring allowances for lead in other food ingredients, as previously established in several court-approved consent judgments. The Coalition letter includes a detailed list of these consent judgments, along with the maximum allowances for lead in various ingredients used in many dietary supplements and foods. CRN requests that OEHHA review these consent judgments and adopt these levels in the regulation so that all businesses, not only the individual parties to the consent judgments, can rely on them with certainty. In particular, the modified consent judgment in *People v. Warner-Lambert Co., et al.* (Warner-Lambert) provides allowances for lead for several minerals commonly found in a wide variety of dietary supplements.[2] These allowances have also been incorporated into numerous consent judgments, as noted in the Coalition letter, and many dietary supplement companies rely on these allowances. Thus, CRN strongly urges OEHHA to adopt the 2011 Warner-Lambert allowances into the proposal and in addition, permit all companies to use these allowances.

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[1] http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm301708.htm.
[2] *People v. Warner-Lambert Co., et al.*, San Francisco Superior Court No. 984503.

In summary, while CRN believes that OEHHA has taken a positive step by acknowledging that certain chemicals are naturally occurring in foods and setting background levels for these chemicals, we also encourage OEHHA to consider the Coalition's and CRN's suggestions to improve its proposal. We also urge OEHHA to adopt into the regulation all court-approved consent judgments noted in the Coalition's letter, but at a minimum include the allowances established by the modified Warner-Lambert consent judgment which is relied upon widely and will provide certainty for many in the dietary supplement industry.

Again, thank you for the opportunity to submit comments on this pre-regulatory proposal. 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