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May 2, 2008

Fran Kammerer  
Staff Counsel  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, CA 95812

**RE: Possible Regulatory Concept: Section 1250X. Exposure to Beneficial Nutrients in a Food**

Dear Mrs. Kammerer;

I hope this finds you well. It was a pleasure to meet you in person at the public workshop on the 18<sup>th</sup>. The Natural Products Association, formerly the National Nutritional Foods Association (NNFA), is submitting this letter as general comment, for the possible regulatory concept offered by the Office of Environmental Health Hazard Assessment (OEHHA) titled **Exposure to Beneficial Nutrients in a Food**. The Natural Products Association was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. The Natural Products Association is a nonprofit 501(c) (6) association whose mission is to unite a diverse membership, from the smallest health food store to the largest natural products supplier. We champion consumers' freedom of choice in our marketplace. We strengthen and safeguard retailers and suppliers and we build strong markets to fuel industry growth. We are the oldest and largest trade association in the Natural Products industry representing over 10,000 members. Thank you very much for the opportunity to comment.

First and foremost, we appreciate and recognize that the OEHHA staff set the proposed regulatory scheme in motion with the intended purpose to exempt and/or protect foods from being wrongfully maligned under the current Proposition 65 regulatory framework. As was discussed at the meeting held on April 18<sup>th</sup> the current text as put forth by OEHHA will not provide such exemption or protection, and may possibly have the opposite effect. While the current text would be difficult to justify from an administrative legal perspective of how it is different than that which the current Prop. 65 regulations offer, we would welcome additional discussions and public workshops on how to develop a regulatory scheme that would appropriately meet OEHHA's intended purpose to exempt and/or protect foods including dietary supplements, which are a subcategory of foods, whether this would involve developing an entirely new scheme or through expanding the naturally occurring exemption in Prop. 65 to dietary supplements and fortified foods.

With moving forward towards a scheme that would exempt or protect foods and dietary supplements it is important to identify the items as they appeared in the proposed concept which would not be appropriate in moving forward:

**1) Endpoint Criteria**

The proposed concept assumed that exposure at some level of beneficial nutrients ultimately results in the onset of Cancer (CAT) or Developmental and Reproductive Toxicity (DART). This assumption could not be further from what research shows which is that most nutrients, even at supraphysiological levels have no evidence of yielding either a CAT or a DART effect. Thus to base this scheme for Proposition 65 warning label levels on Recommended Dietary Allowances (RDA) & Tolerable Upper Levels (TUL) from the Institute of Medicine (IOM) would in no way be appropriate, because those RDA's and TUL's were not established for a CAT or DART effect.

**2) Beneficial Nutrients**

By definition, a nutrient is beneficial, without the appropriate risk assessment tools in place to demonstrate otherwise, the scheme in essence equating nutrients with a toxic effect via requirement of a warning label could potentially adversely effect public health discouraging people from taking amounts of nutrients (e.g. folic acid) deemed essential by the Federal Government. Without scientific justification of either 20% of the TUL or the 1/1000<sup>th</sup> safety ratio - both of which would discourage consumers from taking minimally beneficial Recommended Dietary Allowances (RDAs) and Dietary Reference Intakes (DRIs). This is significant when we consider that incidence rates of classical nutrient deficiency diseases like rickets are currently on the rise. In addition, there are a number of other nutrients that do not have an RDA or TUL that are indeed beneficial. These nutrients like fish oil/omega-3 fatty acids would need to be included in any scientifically based regulatory scheme.

**3) Food "Exposure" needs to be Considered Differently than Air & Water Exposure**

The legality of the regulation is questionable in relation to the definition of exposure for food, per Prop. 65 does the 1/1,000<sup>th</sup> level typical for air/water contamination, which is involuntary exposure, need a different standard for individual food and/or supplement intake which is a voluntary exposure where a consumer is aware of the nutrient content profile of the product? This is a question that must be asked repeatedly with regards to the intent of Prop. 65 was to provide cleaner air and water for Californians by reducing toxic materials that the residents were unaware that they were being exposed to. "Exposure" to nutrients occurs on a conscious informed level as maintained by the Federal Food, Drug and Cosmetic Act and related Acts that have allowed Americans access to nutritional information to make informed choices on what they eat are quite different circumstances and need to be addressed as such.

**4) Validated and Proper Risk Assessment Tools must be used**

The RDA/DRI/TUL as put forth by the IOM were primarily developed to prevent nutritional insufficiency not as risk exposure tools. When OEHHA ruled on retinol, it investigated on an ingredient specific basis to reach a final ruling. Any science based risk assessment must account for both specific nutrient forms and population groups, and not just nutrient names or general populations. Risk assessment tools like the ones used in the Codex process consider these measures as

well as provide for procedures for scientists to work together to come to consensus on data, which would also be critical for any such framework to move forward.

In closing we would like to reiterate that the current text in the proposal would not accomplish the protection or exemption OEHHA is looking to provide for foods, nutrients and/or dietary supplements. We ask that in its current format the proposal not be moved ahead by OEHHA for a number of regulatory, scientific and technical flaws that were discussed in depth at the hearing on the 18<sup>th</sup>. The predominating issue for this proposal to be withdrawn is that its current text is a "solution in search of a problem" and under administrative law it would not demonstrate an improvement to the public welfare where current regulations fail to do so. In moving ahead we would like OEHHA to consider the points within this letter at any time in the future where the agency proposes regulation intent on exempting/protecting food, nutrients and/or dietary supplements from unnecessary and potentially harmful Prop. 65 label warnings. In addition we would like to be a part Food Exposure Regulatory Language workgroup. Thank you again for the workshop and the opportunity to comment.

Best regards,

A handwritten signature in blue ink that reads "Daniel Fabricant". The signature is written in a cursive, flowing style.

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