founded 1881

January 12, 2009

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

Dear Ms. Kammerer:

The Consumer Healthcare Products Association[1] (CHPA) appreciates the opportunity to provide comments on the Office of Environmental Health Hazard Assessment's (OEHHA) redrafted "Regulatory Concepts for Exposures to Human and Plant Nutrients in Human Food" (proposed Nov. 3, 2008).[2] CHPA submitted comments in April 2008 on the original proposed concept. We thank OEHHA for its consideration of our previous comments and incorporation of our suggestion to avoid reliance on Recommended Daily Allowance (RDA) and 20 percent of the Tolerable Upper Intake Level benchmarks for determining exposures; however, as discussed in more detail below, we do not believe that the new case-by-case method for determining maximum daily exposure is an appropriate alternative as it is inadequately described in the redrafted proposal.

As noted in our prior comments, CHPA does not believe that the Beneficial Nutrients Regulatory Concept is necessary or supportive of the intent of the Safe Drinking Water and Toxic Enforcement Act of 1986. OEHHA's proposal is designed to prevent Proposition 65 warnings for safe levels of human nutrients in foods by exempting exposures if: (1) the listed nutrients are "naturally occurring in the food" or (2) "the reasonably anticipated level of exposure to the nutrient from consumption of a food" is below a "maximum daily exposure" level set by OEHHA.[3] Under the proposal, plant nutrients in foods are exempted from the warning requirement if: (1) the nutrient is "naturally occurring" or was added "in an amount necessary for healthy plant development" and (2) the "reasonably anticipated level of exposure" is less than a to-be-determined maximum exposure level.[4] For the reasons described below, the redrafted proposal will not assist OEHHA achieve its goal.

"Naturally Occurring" Exemption is Ineffective

The proposed exemptions for exposures to human and plant nutrients in a food which refer to the existing "naturally occurring" exemption, fail to appropriately protect foods, including dietary

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[1] Founded in 1881, CHPA is a national trade association representing manufacturers and distributors of over-the-counter (OTC) drug products and dietary supplements.
[2] California Office of Environmental Health Hazard Assessment, *Proposition 65 Regulatory Update Project Regulatory Concepts for Exposures to Human and Plant Nutrients in Human Food-Possible Regulatory Language* (proposed Nov. 3, 2008), http://www.oehha.org/prop65/public_meetings/Regupdate110308.html (last visited Jan. 9. 2009) [hereinafter *Possible Regulatory Language*].
[3] *Id.*
[4] *Id.*

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supplements. The "naturally occurring" exemption is an existing affirmative defense that requires the defendant to prove that the exposure "did not result from any known human activity" and that it "was not avoidable by good agricultural or good manufacturing processes."[5] Proving these facts in court is an ineffective and unreliable process that encourages bounty-hunters to bring meritless actions. For example, as recently as October 2008, many vitamin manufacturers received Proposition 65 violation notices from a plaintiff's attorney related to the presence of lead in vitamins despite the fact that the lead naturally occurs in the calcium included in these supplements.[6] These manufacturers must now needlessly engage in expensive litigation to demonstrate that the "naturally occurring" exemption is applicable.

Concerns Regarding Development and Effectiveness of Maximum Exposure Levels

Under the proposal, if the "naturally occurring" exemption is not available, listed human nutrients do not require warnings if the manufacturer can show that the "reasonably anticipated level of exposure" is less than a to-be-determined maximum exposure level.[7] As noted above, for plant nutrients the burden is even higher as two affirmative defenses are required. If the "naturally occurring" exemption is not available, manufacturers using listed plant nutrients must prove that the chemical "was added to the soil or other growing media in an amount necessary for healthy plant development" <u>and</u> that the "reasonably anticipated level of exposure" is less than a to-be-determined maximum exposure level.[8] Even if the "naturally occurring" threshold is met for a plant nutrient, the "reasonably anticipated level of exposure" must still be less than a to-be-determined maximum exposure level.

OEHHA has not described specific methods for determining acceptable maximum daily exposures for these human and plant nutrients. Deferring these decisions until after the regulation is implemented does not provide stakeholders an adequate opportunity to evaluate a key element of the redrafted proposal. These methods should be clearly defined prior to moving forward with this proposal.

Researchers and government regulators have spent decades developing methods for determining "safe" intake levels of potentially hazardous substances in foods. Policies and regulations based on these values are subject to intense public review prior to their implementation. Most regulatory limits employ safety factors and assessments of other exposure sources, both of which can drastically affect the final values. These parameters are especially important in the present discussion since, as OEHHA correctly points out, for essential nutrients, standard safety calculations could lead to a conclusion that exposures far below the recommended daily allowances are hazardous.[9] Defining maximum exposure levels for essential nutrients is a complex process that is outside of OEHHA's current scope of work.

Even if OEHHA is able to accurately and effectively establish maximum exposure levels, like the "naturally occurring" regulation, the numeric limit will be an affirmative defense and will require the

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[5] Cal. Code Regs. tit. 27, § 25501(a)(3)-(4) (2008).
[6] *See* California Office of the Attorney General, 60-Day Notice database, http://proposition65.doj.ca.gov/default.asp (search Plaintiff- "Hamilton" and Source/Product -"vitamin") (last visited Jan, 9, 2009).
[7] *Possible Regulatory Language*, *supra* note 2.
[8] *Id.*
[9] *See* California Office of Environmental Health Hazard Assessment, *Draft Initial Statement of Reasons Title 27, California Code of Regulations: Proposed New Sections 25506 and 25507 Exposures to Human and Plant Nutrients in Human Food,* page 3, http://www.oehha.org/prop65/public_meetings/pdf/draftisor111908.pdf (last visited Jan. 9, 2009) [hereinafter *Draft Initial Statement of Reasons*].

defendant to prove, using expert testimony, that the "reasonably anticipated level of exposure to the chemical from consumption of a food" is below the numeric limit. Similar to the naturally occurring defense, this provides an opportunity for costly challenges by plaintiffs.

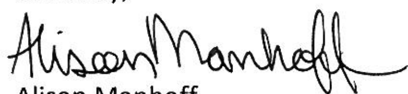
Furthermore, it is not clear that OEHHA has the authority, particularly with regard to reproductive toxicants, to set a numeric limit. While Proposition 65 omits a numeric definition for the "no significant risk level" of a carcinogen, it sets a specific 1000-fold safety factor below the no-observable-effect level (NOEL) for exposures to reproductive toxicants.[10] Therefore, even after OEHHA sets a maximum exposure level, it is possible that this level will be successfully challenged in court by plaintiffs, and a manufacturer in compliance with the level set by OEHHA will still be exposed to costly litigation.

Potential Unintended Public Health Consequences

As OEHHA notes in its "Draft Initial Statement of Reasons," "it is not in the interest of public health to warn the public away from foods that are beneficial to their health and safe to consume."[11] As discussed above, the safeguards OEHHA has proposed would not prevent unnecessary warnings on products containing the essential nutrients. Labeling food products, specifically dietary supplements such as multi-vitamins and mineral products, with Proposition 65 warnings due to inclusion of human and plant nutrients could potentially have unintended public health consequences by discouraging consumption of these nutrients. If consumers reduce or cease intake of foods and/or dietary supplements containing these essential nutrients due to unnecessary warnings, it is possible they may no longer consume levels of the nutrients needed for general health and wellness and/or disease prevention.

CHPA members thank OEHHA for the opportunity to provide our comments. We understand that this proposal is still in a concept stage and we look forward to continuing to work closely with the Agency on this matter if the proposal moves forward. If you have any questions or if CHPA can be of any assistance, please let me know.

Sincerely,



Alison Manhoff
Associate General Counsel

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[10] Cal. Health & Safety Code § 25249.10 (2008).
[11] *Draft Initial Statement of Reasons, supra* note 9, page 2.