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

Re: Proposition 65 Regulatory Update Project, Beneficial Nutrients Regulatory Concept

Dear Ms. Kammerer:

These comments are submitted on behalf of the Grocery Manufacturers Association ("GMA"), a trade association whose members are companies that produce, process, and prepare foods consumed by virtually all Californians, in response to the above-related proposed regulatory action.[1] The Office of Environmental Health Hazard Assessment ("OEHHA" or the "Agency") has proposed a "conceptual" regulation under Article 5 of Proposition 65's implementing regulations to exempt listed chemicals that are also beneficial nutrients in food (the "Proposal").

As a threshold matter, GMA wishes to reiterate its strong support for OEHHA's efforts to update Proposition 65's implementing regulations.[2] However, GMA cannot support the Proposal for the following reasons:

There is no current need for such a regulation. In fact, it appears that there are no chemicals currently on the Proposition 65 list that would actually be exempted under the Proposal. At the April 18, 2008 workshop held to discuss the Proposal, OEHHA identified

[1] OEHHA, *Request for Public Participation, Notice of Public Workshop – Proposition 65 Regulatory Update Project, Beneficial Nutrients Regulatory Concept* (March 21, 2008), available at http://www.oehha.ca.gov/prop65/law/regs032108.html

[2] OEHHA, *Proposition 65 Regulatory Update Project, 2008 Project List* (Jan. 22, 2008), available at http://www.oehha.org/Prop65/law/regs012208.html; Letter from Michèle B. Corash to Dr. Joan Denton (November 17, 2007) ("GMA Update Comment Letter"), available at http://www.oehha.org/Prop65/public_meetings/pdf/GMAcomments111607.pdf.

two listed chemicals—chromium and vitamin A—as beneficial nutrients.[3] However, as several commentors pointed out during the workshop, neither chemical would fall within the proposed exemption.[4] Chromium hexavalent, the only form of chromium on the list, is not a nutrient.[5] And vitamin A is listed with a qualification that would place it beyond the scope of the Proposal.[6] Adoption of the Proposal would serve no purpose and provide no benefit to the citizens of California.

The Proposal As Written is Flawed. Even if there were a current need for a provision dealing with beneficial nutrients, the Proposal would not effectively address that need. As OEHHA has recognized in past rulemakings, food is different from other consumer products for the very simple reason that human beings cannot do without it: "Food is a basic daily necessity of life on a par with the water that we drink and the air that we breathe."[7] Therefore, regulations that affect foods – especially those directly targeted at nutrients that are vital to the functioning of the body's systems – implicate important public health issues.[8] To further the purpose of the statute (thereby fitting within the Agency's authority), such regulatory provisions must be carefully crafted to provide meaningful information to consumers while avoiding a proliferation of warnings that would confuse, rather than enlighten.[9] The Proposal does not accomplish this goal.

As numerous workshop participants pointed out, the Proposal contains cut-off levels based on faulty assumptions about the use of the Institute of Medicine's Dietary Reference Intake

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[3] OEHHA, Slideshow Presentation by OEHHA staff, at slide 5, available at (April 18, 2008)http://www.oehha.ca.gov/prop65/law/pdf_zip/041808wkshpslides.pdf.

[4] No transcript was prepared for the April 18, 2008 workshop. However, an audio recording of the proceedings is available at http://www.oehha.ca.gov/prop65/law/regs032108.html

[5] Cal. Code Regs., tit. 22, § 12705; OEHHA, *Safe Drinking Water and Toxic Enforcement Act of 1986, Chemicals known to the State to Cause Cancer or Reproductive Toxicity* (hereinafter, the "List"), at 4 (March 21, 2008), available at http://www.oehha.ca.gov/prop65/prop65_list/files/032108list.pdf.

[6] List, at 18.

[7] Final Statement of Reasons, 22 California Code of Regulations Section 12501, at 5.

[8] Grocery Manufacturers Association, *Industry Guidance on Making Structure-Function Claims for Food*, available at http://www.fpa-food.org/upload/pdfs/guidance_claims.pdf (essential nutrients provide energy through macronutrients, supplying essential vitamins, minerals, and other micronutrients, providing moisture and hydration, or supplying other physiologically active components).

[9] *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 660-61 (1991).

reports and definitions, principally the Recommended Dietary Allowance (RDA) and the Tolerable Upper Intake Level ("UL" or "upper level").

For nutrients that have no RDA, the Proposal would apply only where the nutrient at issue does not exceed 20% of the UL.[10] However, the UL is defined as "[t]he highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase."[11] This provision is flawed for at least two reasons.

First, the RDA it is not intended to establish a maximum safe value for exposure. It is defined as [t]he average daily dietary nutrient intake level that is sufficient to meet the nutrient requirements of nearly all (9-98 percent) healthy individuals in a particular life stage and gender group."[7] Moreover, while OEHHA's slide presentation at the workshop asserted that "[s]ome beneficial nutrients can cause cancer or reproductive effects at levels higher than the recommended dose," neither RDA nor the UL is designed to address either Proposition 65 endpoint.[12]

Second, setting a cut-off level based on 20% of the UL appears to be aimed at taking other sources of the nutrient into account, an approach that runs counter to past Agency actions. For example, the Agency has long been of the view that levels of a chemical in one product should not be combined with those caused by other products for purposes of ascertaining liability under the statute.[13] Further, ULs are more often than not based on endpoints that have nothing to do with carcinogenicity, or reproductive or developmental toxicity.

Finally, as written, the Proposal does little more than create another complicated scheme shifting the burden of proof to defendants on whether there is an "exposure," which involves factual issues that (1) cannot be resolved without resort to litigation, and (2) are assigned by statute to plaintiff.[14]

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[10] OEHHA, *Request for Public Participation, Notice of Public Workshop – Proposition 65 Regulatory Update Project, Beneficial Nutrients Regulatory Concept* (March 21, 2008), available at http://www.oehha.ca.gov/prop65/law/regs032108.html

[11] Institute of Medicine. Dietary Reference Intake definitions, available at http://www.iom.edu/CMS/3788/4574/45105.aspx.

[12] OEHHA, Slideshow Presentation by OEHHA staff, at slide 5, available at (April 18, 2008), available at http://www.oehha.ca.gov/prop65/law/pdf_zip/041808wkshpslides.pdf.

[13] Final Statement of Reasons for Cal. Code Regs., tit. 22, § 12721, at 56.

[14] Cal. Health & Saf. Code § 25249.6.

For each of these reasons, the Proposal would hinder, rather than further, the purposes of Proposition 65.

The Agency Must Focus Scarce Resources Where They Will Count the Most. If the regulatory update project is to yield any useful outcome, GMA believes that the Agency must focus its resources on regulatory actions that will address the most pressing needs and offer the most promising solutions. In its comments on OEHHA's November 2, 2007 workshop to discuss its regulatory update project, GMA identified several such priorities—all aimed at serving the purposes of Proposition 65 while avoiding the crush of unnecessary litigation that results from ambiguous and difficult-to-implement provisions.

The most promising of these projects is already underway. OEHHA has held two workshops to develop proposed regulatory amendments aimed at establishing a clearer and more reasonable warning regime for exposures in foods sold in a retail setting.[15] Successful completion of this project will provide more useful information to consumers, implement the statutory and regulatory balance in burdens between manufacturers and retailers, and provide a mechanism that could prevent or aid in the resolution of numerous lawsuits.

In order to achieve these and other goals outlined by OEHHA at the November 2, 2008 workshop on the regulatory update project, OEHHA must retain its focus and not be distracted by activities that address no current problem. GMA recommends that the Agency stay focused on these more fruitful pursuits and abandon the Proposal.

Sincerely,

Michèle B. Corash

[15] OEHHA, *Proposition 65 Regulatory Update Project, Warnings for Exposures to Listed Chemicals in Foods* (Feb. 15, 2008), available at http://www.oehha.ca.gov/prop65/law/regproc021508.html.