



January 12, 2009

Fran Kammerer  
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Office of Environmental Health Hazard Assessment (OEHHA)  
via email: [fkammerer@oehha.ca.gov](mailto:fkammerer@oehha.ca.gov)

Re: OEHHA's Regulatory Concept on Human and Plant Nutrients in Human Food

Dear Ms. Kammerer,

This letter serves to provide comments of the American Herbal Products Association (AHPA) on OEHHA's re-drafted regulatory concepts for exposures to human and plant nutrients in human foods, as issued on November 3, 2008, and on the associated Initial Statement of Reasons on proposed new sections 25506 and 25507 of Title 27 of the California Code of Regulations (CCR). AHPA filed comments on May 2, 2008 on OEHHA's initial regulatory proposal in this matter, as issued on March 12, 2008, and AHPA reiterates here its appreciation for the efforts undertaken by OEHHA to provide greater clarity on compliance with California's Proposition 65, and for the opportunity to provide comments. AHPA also notes and appreciates that significant modifications have been made in the interim, such that the re-drafted regulatory concepts have taken into account many of the issues raised by comments to the initial proposal.

Central to AHPA's May 2008 comments on the initial regulatory proposal was the view that the establishment of a new regulation on nutrients is unnecessary to address chemicals that are both beneficial to human health and are listed, or may come to be listed, under California's Proposition 65 as known to the State to cause cancer or adverse reproductive effects. In support of this view, AHPA noted in its May 2008 comments that OEHHA already has a mechanism that has been in place at least since the 1989 listing of vitamin A ("retinol/retinyl esters"). The existing mechanism to which AHPA referred is that of including in any listing itself

the level at which the identified chemical would constitute an exposure under Proposition 65.

AHPA continues to believe that this existing mechanism is preferable to the November 2008 re-drafted regulatory concept to add new sections 25506 and 25507 to 27 CCR. If this existing mechanism is utilized for any future listings of chemicals that may be identified as a human or plant nutrient in human food there would be no need for the proposed new sections 25506 and 25507. AHPA encourages OEHHA to examine the possibility of standardizing the process of including in each chemical listing itself the level at which the identified chemical would constitute an exposure under Proposition 65.

Nonetheless, and assuming that OEHHA goes forward with the addition of proposed sections 25506 and 25507, AHPA offers the following additional comments.

AHPA notes that both sections 25506 and 25507, as currently proposed, would establish regulatory limits on when an exposure occurs. If these sections come to be adopted AHPA believes that this regulatory approach must be maintained so that the sections set limits below which no exposure occurs for chemicals that may come to be identified in those sections.

Should OEHHA go forward with the establishment of these new regulations AHPA also believes that the phrase in each proposed new section that addresses whether a nutrient is naturally occurring should be deleted. To begin with, existing 27 CCR § 25501 already establishes that human consumption of a food does not constitute an exposure under Proposition 65 to a listed chemical in the food – whether or not the chemical is a “nutrient,” as that term would be used under proposed new sections 25506 and 25507 – to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food in compliance with 27 CCR § 25501. Thus, there is no reason to restate this extant regulatory limit on the occurrence of exposures to naturally occurring chemicals. In addition, there is no scientific basis to assign a greater risk to an

added nutrient than to one that is naturally occurring, and no reason to limit the application of sections 25506 and 25507, should they be established, to just naturally occurring chemicals. Also, the language in OEHHA's associated Initial Statement of Reasons seems to imply that the proposed new sections need not address the issue of natural occurrence.<sup>1</sup>

Finally, AHPA also believes, should OEHHA go forward in establishing new section 25506, that the section should be extended to include any constituents and ingredients in food, rather than be limited just to nutrients in food. Under the current listing process, a chemical may be added to Proposition 65 and only at some time in the future is an NSRL (No Significant Risk Level, for carcinogens) or an MADL (Maximum Allowable Dose Level, for chemicals causing reproductive toxicity) established and publicized by OEHHA in regularly issued status reports on these "safe harbors." In the interim, marketers of foods in which a chemical is present, including at a naturally occurring level, have a burden to either provide clear and reasonable warnings or to be prepared to show that any amount of the listed chemical is naturally occurring or is present at a level at which such warning is not required. As an example, caffeic acid was listed as a chemical known to cause cancer on October 1, 1994. As of the date of the most recent issued OEHHA status report (May 2008), there is no NSRL for this chemical and it is identified as a "fourth priority" for NSRL development. Yet caffeic acid is a broadly distributed naturally occurring constituent in many fruits, vegetables, herbs, and other food plants, such as coffee. Every marketer and retailer of such common foods or foods that contain these ingredients (especially, for example, in a concentrated form) must, under the current regulatory process, consider whether it should place a clear and reasonable warning on its marketed foods, as the option is to be prepared to show that the chemical is naturally occurring or is present at a sufficiently low level so that a warning is not required. If such

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<sup>1</sup> For example: "This proposed regulation addresses situations in which the nutrient cannot be shown to be naturally-occurring or is intentionally added to a food product," Initial Statement of Reasons at footnote 1.

marketer or retailer is forced to make such showing in response to a complaint brought under Proposition 65, their legal expenses alone will be some tens of thousands of dollars. AHPA therefore reiterates its belief that, should OEHHA go forward in establishing new section 25506, the section should be extended to include any constituents and ingredients in food, rather than be limited just to nutrients in food. But as also stated above, AHPA believes that OEHHA should consider broader use of a listing process in which the level at which an exposure occurs is identified at the same time that the listing is made, and AHPA notes that such an approach would better address the issue described in this paragraph.

AHPA has reiterated here its belief, as stated in initial comments on this matter, that the existing mechanism of including in any listing itself the level at which an identified chemical would constitute an exposure under Proposition 65 is superior to establishment of a new regulation on nutrients, as envisioned by proposed new sections 25506 and 25507. AHPA has also provided numerous suggestions for consideration should OEHHA determine to go forward with its proposed regulatory process on human and plant nutrients in human foods.

AHPA hopes and assumes that these comments will be seriously considered, and again appreciates the opportunity to provide this input.

Respectfully submitted,



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