



May 2, 2008

Fran Kammerer
Staff Counsel
California Environmental Protection Agency
Office of Environmental Health Hazard Assessment (OEHHA)
via email: fkammerer@oehha.ca.gov

Re: OEHHA's Regulatory Concept on Exposure to Beneficial Nutrients in Food

Dear Ms. Kammerer,

This letter serves to provide comments of the American Herbal Products Association (AHPA) in the matter of OEHHA's March 21, 2008 announcement that it is requesting input on possible regulatory language that OEHHA has developed, with regard to the necessity for providing Proposition 65 warnings for exposures to listed chemicals in foods, to address the issue of exposure to chemicals that both (1) are "beneficial to human health" (referred to in the March 21 announcement as "beneficial nutrients") and (2) "can cause cancer or adverse reproductive effects."

Although the comments that follow question both the need for and the content of the possible regulatory language, AHPA appreciates the effort expressed by the issuance of this language to provide greater clarity on compliance with California's Proposition 65. AHPA also appreciates the opportunity to provide comments on this matter.

The possible regulatory language that OEHHA has developed is as follows:

Section 1250X. Exposure to Beneficial Nutrients in a Food

(a) Human consumption of a food shall not constitute an "exposure" for purposes of Section 25249.6 of the Act to a listed chemical in a food if the person causing the exposure to the chemical can show that the chemical is a nutrient that is beneficial to human health and that the total amount of the chemical consumed in a food, whether naturally occurring, intentionally added to the food, or otherwise present, does not exceed the level established in subsection (c).

(b) For purposes of this section, a chemical is beneficial to human health if a daily value or allowance has been established for the chemical or compound by the Food and Nutrition Board of the Institute of Medicine, National Academies.

(c) This section applies only to exposures that do not exceed the Recommended Daily Allowance (RDA) established in the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine,

National Academies, current edition, if one is established. If no RDA is established, this section applies only to exposures that do not exceed 20 percent (20%) of the Tolerable Upper Intake Level established in the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine, National Academies, current edition.

It is AHPA's view that the possible regulatory language identified by OEHHA is unnecessary and probably irrelevant, or nearly so, and AHPA requests that OEHHA cease its regulatory process in this matter and withdraw its possible regulatory language. AHPA believes that other mechanisms that are already in place are more effective for addressing provision of Proposition 65 warnings for exposure to chemicals that are beneficial to human health and that are listed, or that may come to be listed, as chemicals known to the state of California to cause cancer or reproductive toxicity.

In addition, should OEHHA choose not to accept AHPA's request to terminate its work on this matter, AHPA believes that significant changes would be needed to address the issue of Proposition 65 warnings for exposures to beneficial nutrients that can cause cancer or adverse reproductive effects. AHPA believes, for example, that the description of "a nutrient that is beneficial to human health" in the possible regulatory language is far too narrow; that quantities established as Recommended Daily Allowances in the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine have no relevance to evaluating the effect of a chemical on its potential carcinogenicity or reproductive harm; and that OEHHA's proposal to set 20 percent of the Tolerable Upper Intake Level established in the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine as a calculator for determining when warnings would or would not be required is arbitrary.

The relevance of the possible regulatory language is very narrow

OEHHA maintains a list of chemicals known to the state of California to cause cancer or reproductive toxicity, and revises that list from time to time. It is only chemicals that are included on this list that would be affected by the possible

regulatory language, because it is only such listed chemicals that could possibly constitute an exposure, as identified in proposed Section 1250X (a).

It was reported by OEHHA staff at a public workshop hosted by OEHHA on April 18, 2008 to gather input on the issues raised by its March 21 announcement that there are only two chemicals that are included on both OEHHA's list and the Food and Nutrition Board's Dietary Reference Intake (DRI) tables. One of these was reported to be "chromium." AHPA notes, however, that "chromium," as addressed by the Food and Nutrition Board, is not, in fact, the same chemical as "chromium (hexavalent compounds)," which is the chemical listed by OEHHA as a carcinogen.

The only other chemical identified by OEHHA staff at its April 18 workshop as found on both lists is Vitamin A. The Food and Nutrition Board provides recommended intakes for individuals and estimated average requirements for groups for Vitamin A, both expressed in retinol activity equivalents, while OEHHA lists "retinol/retinyl esters, when in daily dosages in excess of 10,000 IU, or 3,000 retinol equivalents," as a developmental toxin. This OEHHA listing also records the following: "NOTE: Retinol/retinyl esters are required and essential for maintenance of normal reproductive function. The recommended daily level during pregnancy is 8,000 IU."

Thus, of the many hundred chemicals currently listed by OEHHA as known to the state of California to cause cancer or reproductive toxicity, only one has been identified by OEHHA staff that can be acknowledged as meeting the very narrow terms addressed in the possible regulatory language. AHPA does not support the establishment of new regulatory language for this single instance, especially since the listing for retinol/retinyl esters already includes in its listing a quantitative limit below which no warnings are required. The establishment of a new calculator for determining a level at which warnings would be required for this chemical is at best redundant (if the calculated level under the possible regulatory language is the same as that included in the listing), and at worst confusing and contradictory (if the calculated level under the possible regulatory language is different than that included in the listing).

Existing mechanisms are already in place to address the described issue

As noted above in the discussion of Vitamin A and the chemical retinol/retinyl esters, OEHHA already has a mechanism that has been in place at least since this chemical was listed in 1989, which is to include in the listing itself a level at which the chemical is identified as a carcinogen or reproductive toxin. AHPA encourages OEHHA to utilize this same mechanism in the future, and notes that, if this mechanism is utilized for any future listings of chemicals that may be identified as beneficial nutrients, there would be no need for the possible regulatory language.

OEHHA's description of beneficial nutrients is too narrow

In the possible regulatory language, OEHHA limits the number of nutrients that are described as "beneficial to human health" as just those that are addressed by the Food and Nutrition Board. But there are numerous other substances that have been identified as providing health benefits.

For example, the Food and Drug Administration has a process whereby it authorizes health claims and qualified health claims for foods and food components. Although most of the currently approved health claims are, in fact, for nutrients that are included in the Food and Nutrition Board's DRI tables, health claims have also been established for other ingredients. Two such examples are soy protein and plant sterol/stanol esters. FDA has acknowledged that there is significant scientific agreement that the addition of soy protein to a diet that is low in saturated fat and cholesterol may help to reduce the risk of coronary heart disease (see 21 CFR 101.82: Health claims; soy protein and risk of coronary heart disease); and that diets that include plant sterol/stanol esters may reduce the risk of coronary heart disease (see 21 CFR 101.83: Health claims; plant sterol/stanol esters and risk of coronary heart disease). Similarly, many of the qualified health claims which FDA has subjected to enforcement discretion are for DRI-listed nutrients, but qualified health claims are also recorded for many other substances, such as tomatoes and tomato sauce; green tea; walnuts; corn oil; omega-3 fatty acids; etc.

AHPA cannot know whether any of the foods and food components identified in the above paragraph as the subject of a health claim or qualified health claim will

ever come to be listed as a chemical known by the state of California as a carcinogen or reproductive toxin. But AHPA believes that this is neither more nor less likely than for such listings to come about for any of the nutrients in the Food and Nutrition Board's DRI tables. Yet the possible regulatory language, since it has limited its description of nutrients that are beneficial to human health to just those for which the Food and Nutrition Board has established a daily value or allowance, would treat that narrow set of beneficial nutrients differently than any other beneficial nutrients. AHPA does not believe that such an approach would be appropriate.

As noted above, AHPA believes that the best outcome for the possible regulatory language would be for it to be withdrawn. If, however, OEHHA determines to go forward with this process, it is AHPA's strong belief that the description of nutrients that are beneficial to human health must be significantly expanded. AHPA's identification of the ingredients that have already been addressed by FDA in relation to health claims and qualified health claims, however, is not intended to be exhaustive, and efforts should be made, if this process goes forward, to identify all beneficial nutrients.

The Food and Nutrition Board's RDAs are not relevant to safety evaluations

The possible regulatory language would establish, in the unlikely event that any of the nutrients for which the Food and Nutrition Board has established a daily value or allowance comes to be listed by OEHHA as a carcinogen or reproductive toxin, that the presence of such nutrient would not constitute an exposure under Proposition 65 so long as below certain levels. For nutrients for which a Recommended Daily Allowance (RDA) is established, the level below which the envisioned exemption would occur would be the actual RDA level.

AHPA believes that such an approach has no scientific basis. RDAs do not, in any manner, constitute evidence of or even commentary upon the safety of an ingredient or its risk of carcinogenicity or reproductive toxicity. Rather, an RDA is, according to the Food and Nutrition Board, "the average daily dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in

a particular life stage and gender group.”¹ AHPA is aware of no rationale to support the use of these levels in determining whether or not clear and reasonable warning should be provided for any nutrient for which there is an RDA and which comes to be listed by OEHHA as a chemical known to cause cancer or reproductive harm.

AHPA repeats here its request that OEHHA cease its regulatory process in this matter and withdraw its possible regulatory language. If OEHHA nonetheless determines to go forward with this process, AHPA does not believe that information on the average daily intake of a nutrient should be used to determine whether or not an exposure to a listed chemical occurs.

Arbitrary calculations from ULs are not scientific

In the above discussed process for determining levels below which the presence of certain beneficial nutrients would not constitute an exposure under Proposition 65, the other mechanism for determination of such an exempt level would be by calculating 20 percent of any established Tolerable Upper Intake Level (UL). But AHPA is again unaware of any scientific rationale to support this apparently arbitrary proposed mechanism, and believes that it would be neither more nor less accurate to choose any other percentage of a nutrient’s UL in making such a determination.

AHPA suggests that if OEHHA proceeds with further development of the possible regulatory language, contrary to AHPA’s request, it consider a non-arbitrary mechanism for identifying levels below which any nutrient for which a UL is established would not constitute an exposure under Proposition 65.

Summary

AHPA has requested herein that OEHHA withdraw the possible regulatory language issued on March 12, 2008 in relation to beneficial nutrients, and has made numerous suggestions for consideration, should OEHHA determine, contrary to AHPA’s request, to go forward with this process.

¹ Accessed May 1, 2008 at <http://ific.org/publications/other/driupdateom.cfm?renderforprint=1>.

AHPA notes that, in providing these comments, there was no clear understanding of the regulatory problem or problems that were meant to be addressed by the possible regulatory language. If OEHHA issues any other possible regulatory language in relation to this or related matters, identification of the specific problem or problems that are intended to be addressed by any such further activity should be communicated.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'M. McGuffin', written in a cursive style.

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