NATIONAL HEALTH FEDERATION

A NOT-FOR-PROFIT HEALTH-FREEDOM ORGANIZATION

May 2, 2008

VIA E-MAIL TO FKAMMERER@OEHHA.CA.GOV

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

Re: Proposition 65 Regulatory Update Project – Beneficial Nutrients

Dear Ms. Kammerer:

On behalf of the National Health Federation and its many thousands of consumer members, I thank you again for having had the opportunity to attend, participate, and speak out at your recent public workshop held on April 18th in your Sacramento, California offices concerning the above-referenced matter. In furtherance of our spoken comments at that meeting, we ask OEHHA to take the following comments into account in deciding whether or not to proceed with its beneficial nutrients regulatory concept within Proposition 65 and, if it does proceed, then in what form.

1. **Mischaracterization of Beneficial Nutrients Risk.** In your request for public participation, you have stated that "Certain chemicals or compounds such as vitamins and minerals are necessary to promote human health or to ensure the healthy growth of food crops." You then continue by mischaracterizing these nutrients with "Excessive exposure to these same chemicals or compounds can cause cancer or adverse reproductive effects." With only one or two well-known exceptions (such as iron), this is incorrect, misleading, and does a great disservice to those consumers who will be led to forgo taking nutrients in such quantities as will be beneficial to them in the prevention of cancer.

In fact, numerous studies demonstrate that only large doses of natural Vitamin E, Vitamin D, selenium, fish oils, resveratrol, and other such beneficial nutrients will prevent cancer or ameliorate it when present. Synthetic nutrients and those either at or below RDI levels rarely show benefit. A major review of studies on the relationships between vitamin intake and various diseases published between 1966 and 2002 demonstrated that suboptimal levels of vitamin intake are associated with increased risk of contracting a variety of chronic diseases, including cancer, heart disease and osteoporosis. The authors of this study concluded that many physicians may be unaware of common food sources of vitamins or may be unsure which vitamins they should recommend for their patients, and that given the current status of scientific knowledge, it may be prudent for most adults to supplement their diet with a daily multivitamin.

In a very large study of 88,756 women from the Nurses' Health Study who were free of cancer in 1980 and who provided updated assessments of diet, including multivitamin supplement use, from 1980 to 1994, the researchers followed their subjects for colon cancer. The researchers found that their subjects' long-term use (i.e., over 15 years' use), but not short-term use (less than 4 years' use), of multivitamins containing folic acid markedly reduced by some five-fold the frequency of colon cancer.

To obtain these benefits, however, one must take more than simply RDI-levels of beneficial nutrients. Indeed, what may seem "excessive" to some individuals are actually the ***minimal*** amounts needed by others. Therefore, OEHHA does an enormous disservice mischaracterizing the cancer-preventative effects of large dose vitamin-and-mineral dietary supplements. How many people will die because this myth is carried forward and restated time and again by institutions that should know better?

2. **"RDAs" are the Wrong Standard Here.** The proposed regulatory concept states, in part, that "[t]his section [1250X] applies only to exposures that do not exceed the Recommended Daily Allowance (RDA) established in the Dietary Reference Tables of the Food and Nutrition Board of the Institute of Medicine, National Academies, current edition, if one is established." Leaving aside the fact that the term of art has been revised to RDI, this standard – whether RDA or RDI – is not and never has been a ***safety*** standard. Rather, it is a ***nutrition*** standard that constitutes more of a floor than a ceiling for appropriate nutrient intake levels. Setting an exemption from the definition of "exposure" at or below the RDI levels would dramatically exclude nutrient levels that would actually help prevent cancer and reproductive harm.

3. **Alternative Suggestions.** The Federation agrees that there should be no warning requirement for any below- or at-RDI level nutrients that might fall within the ambit of Proposition 65, but suggests that OEHHA look at other, more expansive ways of accomplishing this goal of protecting beneficial nutrients from over-regulation. Therefore, we propose to OEHHA the following two options:

(a) Option 1 – Full Exemption from the Definition. The draft Section 1250X would be revised as follows: "Human consumption of a food or food supplement shall not constitute an "exposure" for purposes of Section 25249.6 of the Act to a listed chemical in a food or food supplement where the listed chemical is a nutrient that is historically naturally occurring in the human diet and has been shown to have beneficial effects upon human health beyond any alleged risk of cancer or reproductive harm arising from its consumption at reasonable levels." This, or similar wording, would be the Federation's preferred option as it takes into account the benefit portion of a risk-assessment analysis. In addition, it acknowledges the historic, millennia-long role of such beneficial nutrients in the human diet.

(b) Option 2 – Expanded Exemption within the Definition. The second, and lesser, option would be to expand the envelope of exemption by reference to the upper-limit standards set forth by other authoritative agencies and organizations in this field, such as the Council for Responsible Nutrition. While the Federation disagrees with the establishment of such upper limits, other entities are investigating, setting, and recommending upper limits that would at least establish a more reasonable standard of reference, which in turn would result in fewer overly-broad Proposition 65 warnings that would scare consumers away from beneficial nutrients.

4. **Other Concerns.** The Federation's other concerns are that this regulatory concept does not address any current issues since, as OEHHA has told us, there are only two beneficial nutrients – retinol and chromium – even on the Proposition 65 list of carcinogens and reproductive toxins. Therefore, the question occurred to many at the April 18th public meeting, does OEHHA anticipate listing other beneficial nutrients later, after this "concept" becomes a regulation. The Federation is suspicious that this might be the case. We would appreciate it if OEHHA would specifically address this concern.

In short, the Federation appreciates this opportunity to address OEHHA with the issues raised by this particular regulatory concept. As a consumer health-freedom organization, our mission is to ensure a maximum of health freedom, and in this case a maximum of consumer access to beneficial nutrients. We were encouraged to learn from you at the April 18th public meeting that your stated goal was not to restrict access but to minimize the warnings on otherwise beneficial nutrients. Unfortunately, even with the best of intentions, these laudable goals can easily be high-jacked and/or misdirected to another, less-beneficial goal if vigilance is not maintained.

We look forward to your response to all comments.

Sincerely yours,

Scott C. Tips
President & General Counsel

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