December 11, 2008

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

Dear Ms. Kammerer:

The California League of Food Processors (CLFP) appreciates the opportunity to comment on the draft regulations proposed by the Office of Environmental Health Hazard Assessment (OEHHA) regarding Proposition 65 exposures to human and plant nutrients in food. CLFP recognizes that OEHHA developed this proposal to address an important and complicated issue. However, CLFP urges OEHHA to delay the adoption of the proposed regulation until concerns can be fully addressed regarding whether the proposal is practical, enforceable, based on sound science, and whether it may lead to more, rather than less, expensive and frivolous litigation.

Background

The majority of CLFP's members are fruit and vegetable processors. These firms purchase tomatoes, peaches, garlic, raisins, and dozens of other raw products directly from numerous growers located across the state. The growing conditions for these crops vary by location. Soil types can differ widely across a given field. As a result there are numerous controllable and uncontrollable factors that must be balanced by every farmer to produce a quality crop in a cost effective manner. Crop boron requirements and tolerances are among those considerations. Soils may have inherently high or low levels of boron, and the crops may be irrigated with water that contains boron. To promote plant health, fertilizers may be applied that contain essential micronutrients such as boron.

Once the plant material is harvested, it is virtually impossible to determine whether any boron that might detected in a can of tomatoes or bag of frozen spinach came from the soil, fertilizer, irrigation water, or all of the above. Further, products from different fields and growers may be mixed together during the production process, rendering it nearly impossible to trace the source of a specific micronutrient. In many cases the processor will not be aware of all of the decisions made by their growers with respect to crop fertilization and irrigation. Clearly it is very difficult to prove if boron or another micronutrient present in a consumer product is naturally occurring, and whether the

amount added to the soil by the farmer through irrigation or fertilization was "*necessary* for plant health development." In the context of Proposition 65 litigation these types of uncertainties can be quite problematic for food companies.

Key Questions Regarding OEHHA's Proposed Regulations:
CLFP has reviewed OEHHA's proposed regulations and this evaluation has raised a number of questions that should be addressed before the rulemaking proceeds further. Some of the key questions include the following:

Numeric Exposure Limit for Boron

- How will OEHHA determine the numeric limit for boron in foods?
- How will boron numeric limits used by OEHHA compare to the levels established by the National Academy of Science's Food and Nutrition Board?
- How will OEHHA determine the numeric limit for boron in fertilizer?
- How will the numeric limit for boron in fertilizer differ from the numeric limits in foods?
- Since OEHHA has no expertise outside risk assessment, which human and plant nutritional authorities will inform OEHHA's decisions?
- Will OEHHA consider the nutritional benefits of boron and manganese in establishing a numeric limit?
- Will OEHHA be required to use the NOEL (No Observed Effect Level) from the most sensitive animal study to set the numeric limit for boron?
- Will OEHHA be required to apply the 1000-fold factor to the most sensitive NOEL?
- Where is your authority to contradict the statutory thousand-fold factor for warnings?
- Is OEHHA confident that the courts would agree that OEHHA has the authority to contradict the specific statutory language setting Proposition 65 levels for reproductive toxicants?
- What section of the Proposition 65 statute allows OEHHA to consider the nutritional benefits of boron?

Naturally Occurring Exemption

- How does the naturally-occurring exemption in foods protect food companies against Proposition 65 litigation?
- If a plaintiff sends a 60-day enforcement letter, how does a company prove boron or manganese in a food product or fertilizer is naturally-occurring?
- Who has the burden of proving that a listed substance is naturally-occurring in a food product?
- According to Section 25501(a)(3), a chemical is naturally occurring only to the extent that a chemical did not result from any known human activity. How can firms prove that the presence of boron or manganese in a food product did not result from any known human activity?
- According to Section 25501(a)(4), "a chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing

practice." Will this apply to boron and manganese? Who would have the burden of proving that a nutrient is "added to the soil or other growing media in an amount necessary for healthy plant development"? How would we prove this? Wouldn't this vary from crop to crop and from geographic location to location?

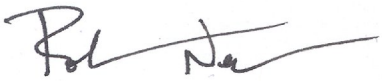
- How many times have defendants successfully used the naturally occurring defense in litigation? How often did the courts agree that the product was exempt from a warning due to the naturally occurring defense?
- Can OEHHA provide an example of when the naturally-occurring exemption stopped a plaintiff from going forward with an enforcement action against a food product?

Potential Impact on Public Health

- What is the benefit of providing a Proposition 65 warning for boron?
- Is anyone in California being harmed by exposure to boron today?
- What is the largest source of exposure to boron?
- Aren't nutritionists concerned that Americans are not getting enough boron in their diet?
- How does dietary consumption of boron in the U.S. compare to other countries of the world?
- Does OEHHA feel it would be beneficial to provide a warning that deters people from consuming fruits and vegetables?

CLFP looks forward to working with OEHHA to address these and other issues and to assess whether the proposed regulatory language must be modified in order to be consistent with statutory requirements and to best promote public health. If you have any questions regarding this letter please contact me.

Sincerely,



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