

May 27, 2005

Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
Proposition 65 Implementation Program  
P.O. Box 4010  
Sacramento, CA 95812-4010

Dear Ms. Oshita:

Enclosed please find comments prepared by the California League of Food Processors regarding Proposition 65 regulations proposed by the Office of Environmental Health Hazard Assessment (OEHHA) with reference to acrylamide. If you have any questions regarding this submission please contact me.

Sincerely,

Rob Neenan  
Director of Regulatory Affairs

*California Office of Environmental Health Hazard Assessment proposed regulations that would exempt chemicals that form from natural constituents in foods during cooking from the California Proposition 65 warning requirements.*

Comments Submitted by:  
**California League of Food Processors**  
**Sacramento, CA**  
**May 26, 2005**

The California League of Food Processors is a statewide non-profit association that represents food processors with production facilities in California. The membership includes firms involved with canning, freezing, or drying a wide array of fruit and vegetable products. The League appreciates the opportunity to provide its views on this important issue related to acrylamide and Proposition 65 regulations.

Recommendations:

The League has two principal recommendations for the Office of Environmental Health Hazard Assessment (OEHHA) in reference to this issue:

1. **Exempt Natural Constituents in Foods that Result From Cooking.** Traditional cooking methods employed by food processors, restaurants, or in home kitchens can create a number of chemicals from naturally occurring constituents in foods. The presence of a chemical in foods should not constitute an exposure under Proposition 65 if the chemical is the unintended byproduct of cooking. Thus, a specific exemption should be established for acrylamide and other natural constituents in foods that result from cooking or heat processing.
2. **Promulgate Clear and Specific Regulations.** Any new regulations regarding an exemption for acrylamide developed by OEHHA must be crafted to be readily and clearly interpreted by consumers and the regulated community. This will ensure that OEHHA satisfies its obligation to inform the public and will also minimize the potential for subsequent litigation of this matter.

Background:

Recent research indicates that acrylamide and other Proposition 65 chemicals can be formed as natural byproducts of the cooking process. Although these findings are relatively new, cooking food at higher temperatures is not. In the view of the California League of Food Processors and a coalition of organizations that grow, process, sell, prepare, and serve the foods consumed by Californians, chemicals that are by-products of cooking or heating foods should not be regulated under Proposition 65. We strongly support a regulation recognizing that a food that would not be subject to Proposition 65 in its raw form should not be regulated by the statute solely because

it is cooked or heated. Anything else would be contrary to public health, the policy of the statute, sound science, and common sense.

Proposition 65 already recognizes that naturally occurring chemicals in food should not be regulated under this statute. There is no toxicological, health, or policy difference between a chemical formed as a byproduct of cooking, and the chemical as a natural product of the cultivation process. The presence of a chemical in food should not constitute an exposure under Proposition 65 if the chemical is the unintended byproduct of the cooking or heating processes. The statute also recognizes that some human activities normally associated with food production (such as irrigation, plowing and preparation of soil) do not, on their own, make a food subject to Proposition 65 requirements. There is no reason for treating cooking differently.

Our paramount concern remains the best interests of consumers and assuring that they have a safe food supply. The U.S. Food and Drug Administration (FDA) and other food health agencies conduct research and adopt regulations to provide that assurance. The food industry has worked with FDA to understand the effects of acrylamide on food safety. Currently, there is no evidence supporting that acrylamide's presence results in significant harm to humans. In fact, there are studies supporting an absence of harm to people consuming food containing naturally formed acrylamide. The limited amount of research available on this topic, the apparent divergence in opinion within the scientific community, and the ongoing efforts to help clarify this issue should be sufficient rational for the proposed exemption.

Acrylamide and other by-products of cooking have been present in a wide variety of foods for centuries, including common items such as coffee, bread, and meat. Analysts have estimated that as much as 40 percent of the food sold in grocery stores may contain acrylamide. These foods are part of a healthy diet, and the FDA has warned that inappropriate warnings and actions could lead to unintended adverse health consequences. If the public responds to new warnings by cooking foods less, they may be increasing the fat content of some foods and increasing their exposure to dangerous food-borne pathogens. Alternatively, consumer avoidance of these foods could lead to significant changes in the consumption of important macro- and micro-nutrients. There is a tangible risk that consumers may be overwhelmed by the number of generic warnings and ignore them altogether. This would greatly undermine the effect of warnings about real hazards, subverting the intent of Proposition 65.

While efforts to reduce the levels of acrylamide in foods are important, the total elimination of acrylamide is likely impossible, as it is a common and unintentional consequence of processing activities. However, this alone should not trigger action by consumers or regulators. FDA and other leading health and food safety agencies around the world have studied the potential health effects of acrylamide and have uniformly concluded that no change in diet is warranted. The League would like to stress that California consumers need and desire to receive clear, concise, consistent, and balanced information regarding sound nutrition and any potential public health

issues. The proposed cooking exemption will further that goal and will be a logical and scientifically sound extension of the existing “naturally occurring” exclusion in the statute.

#### May 9 OEHHA Workshop

The League would also like to respond to two questions raised by Dr. Denton at the workshop conducted by OEHHA on May 9 regarding acrylamide:

- *How can OEHHA establish incentives for industry to reduce the level of acrylamide to the lowest possible levels?* It is the view of the California League of Food Processors that sufficient incentives current exist for food processing companies to ensure the safety of their products. The industry is monitored by the U.S. Food and Drug Administration (FDA) and must comply with a wide range of food safety regulations and good manufacturing practices as defined by the Federal Food, Drug, and Cosmetics Act. If FDA were to revise its opinion with respect to impact of consumption of acrylamide as part of a normal diet, then industry would make adjustments in manufacturing practices as required or recommended by FDA.
- *If a regulation is proposed, how would stakeholders want “cooking” to be defined?* Food preparation encompasses a vast array of processes, technologies, and products that are used by commercial processors, food service establishments, and home cooks. Establishing a strict definition of “cooking” that covers all of the potential options may prove problematic. The League suggests that cooking be simply defined as any thermal food preparation process that is used to preserve food for future use, render food safe for consumption, or make the product more palatable for human consumption.

#### Summary:

As indicated by the scientists that testified during OEHHA’s May 24, 2005 hearing on this topic, there remains a significant difference of opinion about the cancer risk posed to humans from consumption of minute amounts of acrylamide as an unintended by product of cooked foods. Requiring Proposition 65 warnings for food products that contain acrylamide solely due to the cooking process may not be consistent with the true health risks and may send a confusing message to consumers. The League believes that a cooking exemption for naturally occurring chemical in processed food products is in the best interest of California consumers and public health policy, and is consistent with the goals of Proposition 65. The League strongly urges OEHHA to enact such an exemption.