CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)

NOTICE TO INTERESTED PARTIES

August 1, 2003

PROPOSED ACRYLAMIDE WORK PLAN

Acrylamide is listed under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65; Health and Safety Code Section 25249.5 et seq.) as a chemical that is known to the state to cause cancer. A No Significant Risk Level (NSRL) for acrylamide of 0.2 micrograms/day was established in regulation (Title 22, California Code of Regulations (CCR), Section 12705(c)) in 1990. Recent research has shown that acrylamide can form during the cooking of certain foods at high temperatures. Accordingly, interested parties have asked the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA), as the lead agency for the implementation of Proposition 65, to interpret the applicability of Proposition 65 regulations to acrylamide in foods.

On May 12, 2003, OEHHA held a public workshop to explore appropriate Proposition 65 regulatory options regarding acrylamide created by cooking foods. Subsequent to the workshop, OEHHA developed this draft work plan, which reflects input received at the workshop, public health considerations, and the need for clear guidance to facilitate Proposition 65 compliance concerning acrylamide in foods.

Consultation With the Carcinogen Identification Committee (CIC)

The evaluation of acrylamide risks in foods is uniquely challenging due to the chemical's pervasiveness and the degree of exposure to it in the diet. Therefore, OEHHA has assigned a consultative role to the CIC in this draft work plan. This is consistent with the CIC's role as the State's Qualified Experts and its general powers and duties as set forth in Title 22, CCR, Section 12305(a)(5), and noted in Title 22, CCR, Section 12302(e). At the next CIC meeting, scheduled for October 17, 2003, OEHHA will seek input from the CIC on this work plan. In addition, with regard to item one of the proposed work plan, OEHHA will ask the CIC for its opinion on updating the NSRL. Opportunity for public comment on the proposed work plan will be provided at the October 17, 2003, meeting of the CIC.

Proposed Acrylamide Work Plan

Because acrylamide is found in a variety of foods and food groups, this proposed work plan outlines four different actions that will provide guidance on the applicability of Proposition 65 to foods. OEHHA proposes to promulgate regulations as follows:

1. Update the NSRL for Acrylamide and Review Data on Foods Causing Exposures Below the Updated NSRL (Regulation). As stated previously, the NSRL for acrylamide (0.2 micrograms per day) was adopted in regulation in 1990. Since its adoption, additional scientific data have been published regarding the cancer dose-response assessment. Pursuant to Title 22, CCR, Section 12705, OEHHA proposes to review these data and adopt an updated NSRL into regulation. OEHHA also proposes to receive and review exposure data in order to identify foods for which normal exposures fall below the revised NSRL, based on exposure scenarios specified in Title 22, CCR, Section 12721.

   At this time, OEHHA is asking the CIC to provide a recommendation whether OEHHA should update the existing NSRL for acrylamide, and, if so, the kinds of factors that OEHHA should consider. Information the CIC may take into account in making its recommendation includes: the availability of additional data and analyses on acrylamide cancer risks in humans published in the scientific literature since 1990; carcinogenesis studies in animals; information regarding the effect of different routes of acrylamide exposure on cancer health effects; the role or importance of the chemical matrix in which acrylamide is found; and other data related to the carcinogenicity of acrylamide. The public is also requested at this time to provide comment to OEHHA on these issues in writing and at the October 17, 2003, CIC meeting.

2. Identify Acrylamide Levels in Foods Below the Limit of Detection (Regulation). Certain exposures are considered not to cause an "exposure" for purposes of Proposition 65 unless a listed chemical is detected using the appropriate method of analysis as specified in Title 22, CCR, Section 12901. While a given exposure may appear to exceed the NSRL, it may not constitute an "exposure" for purposes of Proposition 65 unless the method used to detect the chemical complies with the provisions of Section 12901. OEHHA proposes to develop a regulation that specifies the methods of analysis for acrylamide in food that conform with Section 12901, and the associated food concentrations of acrylamide below the limits of detection for methods of analysis that comply with Section 12901. OEHHA also proposes to receive and review exposure data in order to identify foods for which normal exposures fall below the specified limits of detection, based on exposure scenarios specified in Title 22, CCR, Section 12721.

3. Identify Alternative Acrylamide Exposure Levels for Certain Foods Based on Public Health Considerations (Regulation). For some foods, sound considerations of public health may support alternative regulatory levels for acrylamide exposures that exceed the revised NSRL and the specified limits of detection. For such foods, pursuant to Title 22 CCR, Section 12703(b), OEHHA proposes to develop alternative regulatory levels and develop a regulation listing acrylamide concentrations in such foods deemed to meet the exemption requirements of Proposition 65. In developing such alternative regulatory levels, OEHHA is authorized to take into account public health considerations as prescribed in Section 12703(b).

4. Identify Appropriate Form and Content for Proposition 65 Warnings Required for Foods Due to Acrylamide (Regulation). Some foods may cause acrylamide exposures at levels

high enough to require Proposition 65 warnings. OEHHA proposes to develop a regulation identifying "safe harbor" form and content for such warnings similar to other "safe harbor" language specified in Title 22, CCR, Section 12601(b). The goal of any such regulation would be to clarify the appropriate communication in the appropriate context for warning consumers concerning the presence of acrylamide in the food in compliance with Proposition 65 and to forestall the dissemination of indiscriminate, misleading, confusing, or inappropriately alarming warnings.

Public Comment

Written comments on this work plan should be provided in triplicate and submitted to:

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Proposition 65 Implementation
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In order to be forwarded to the CIC, written comments must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered or sent by fax) by 5:00 p.m. **Friday, September 26, 2003**. The CIC meeting on October 17, 2003, will provide an opportunity for interested parties to present oral comments on this draft work plan. The meeting will begin at 10:00 a.m. in the Sierra Hearing Room, California Environmental Protection Agency Building, 1001 I Street, 2nd Floor, Sacramento, California and will last until all business has been conducted or 5:00 p.m.