February 11, 2003

Ms. Michele B. Corash
Morrison & Foerster
425 Market Street
San Francisco, California 94105-2482

Dear Ms. Corash:

This letter is in follow-up to my letter of October 15, 2002, concerning the applicability of Proposition 65 to acrylamide in food. As I indicated in that letter, I would be more specifically responding to several issues raised in your letter regarding the regulatory status of acrylamide in food. I also stated that we would be announcing appropriate regulatory steps we would undertake to bring greater clarification and certainty regarding the regulatory status under Proposition 65 of acrylamide in food.

Your letter of July 1 contained two principal assertions regarding the regulatory status of acrylamide in food. The first was that Title 22, California Code of Regulations, Section 12703(b)(1) created an exemption or exclusion from the warning requirements from Proposition 65 for chemicals produced during cooking. This interpretation is inconsistent with the existing regulation. Section 12703(b) authorizes the use of "alternative risk levels" (other than the generally controlling 1 in 100,000 risk level) under certain circumstances. This provision creates some flexibility to depart from the usual risk level based on competing health considerations related to acrylamide exposure in cooked foods. The second was your suggestion that Title 22, California Code of Regulations, Section 12501, Exposure to a Naturally Occurring Chemical in a Food, be applied to acrylamide created by the cooking of various foods. As you know, the regulation is quite explicit that this section applies to situations only to the extent that the chemical did not result from *any known human activity*. (Section 12501(a)(3), italics added.) By definition, cooking is a known human activity. To include acrylamide formed by cooking in the definition of exposure to a naturally occurring chemical in a food would be incompatible with the existing regulation.

While these exemptions do not apply, there are other actions that OEHHA can undertake that will bring greater clarity and certainty to the regulatory status of acrylamide in food. More specifically, OEHHA intends to explore all appropriate regulatory options regarding this matter, including the adoption of alternative risk levels for acrylamide created by cooking foods. Our intention is to issue a public notice this month initiating a data call-in period in conjunction with a public workshop. The data call-in would be "open-ended." That is, we would seek all relevant information regarding this issue as opposed to focusing on a particular regulatory approach.

The public workshop would occur prior to the commencement of the formal rulemaking procedures specified in the Administrative Procedure Act (APA) and would further explore these issues and their relationship to how acrylamide in food is most appropriately addressed within the context of Proposition 65. We expect to initiate the formal APA process shortly after the public workshop.

As you are aware, California is facing an unprecedented budget deficit. Given the potential impact on OEHHA, I can only commit to you that we will move with all possible speed to begin the process of addressing the issue of acrylamide in foods. We will need your participation and input since the food industry will most likely have, or be in the best position to acquire, the data as we go forward.

We look forward to working with you and the other interested parties to address this issue and please call me at (916) 322-6325 if you have any questions or comments.

Sincerely,

Joan E. Denton, Ph.D.
Director