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March 28, 2008

Via Email and U.S. Mail

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

Re: Proposition 65 Regulatory Changes Relevant to Food Warnings

Dear Ms. Kammerer:

On behalf of the American Beverage Association ("ABA"), we wish to thank OEHHA for soliciting comments on possible revisions to the Proposition 65 regulations concerning "the method and content for warnings for exposures to listed chemicals in foods." As you know, and as we discussed on March 14, existing regulations reflect the need to craft different warning methods and warning content for foods. Beverages provide nutrients and refreshment and are an important subset of the foods covered by OEHHA's notice on this subject. The ABA strongly supports OEHHA's efforts to provide greater guidance concerning warnings that are clear and reasonable for foods. We understand that OEHHA may convene a task force to work in detail on possible regulations, and we reiterate our request to serve on that task force.

We would like to work with OEHHA to explore the possibility of regulations that (1) establish one or more paths for warnings that do not require product labels or shelf signs for a variety of important reasons noted below, (2) avoid referring to "birth defects" in warnings for reproductive toxicants that do not cause birth defects, and (3) establish a prompt procedure for review and approval of specific warning language and methods proposed for a given food-warning situation.

The ABA is the national trade organization representing the broad spectrum of companies that manufacture and distribute non-alcoholic beverages in the United States. Our members are producers, marketers and distributors of virtually every non-alcoholic refreshment beverage, including bottled waters, ready-to-drink teas and coffees, sports drinks, energy drinks, fruit juices, fruit drinks, milk-based beverages, and carbonated soft drinks. ABA's members employ more than 211,000 people who produce U.S. sales in excess of $105 billion per year.

Warning methods

Product labels and shelf signs have several important limitations. Product labels have very limited space and do not allow for warnings that can provide critical context. Shelf signs also have very limited space, and further have the drawback of being so expensive and difficult to monitor as to be unreasonable in many contexts. For some chemicals, consumers face significant exposure from natural sources that are exempt from the warning requirement pursuant to section 12501; this situation also limits the effectiveness of product labels and shelf signs because those warning methods do not allow customers to place exposures that may require a warning in the proper context with natural exposures that do not require a warning.

These limitations strongly warrant exploring warning pathways that provide accurate, useful information to consumers other than through labels or shelf signs. This approach is supported by Proposition 65, which states that a "warning" "need not be provided separately to each exposed individual and may be provided by general methods." Cal. Health & Safety Code § 25249.11(f). These general methods could include warning pathways that not only provide a clear and reasonable warning, but also permit the communication of additional accurate information that can help consumers better understand the unique issues relating to the presence of listed substances in food.

As OEHHA's predecessor, the Health and Welfare Agency ("H&W"), noted in 1988 "reasonable" means "not excessive or extreme, fair." Final Statement of Reasons for Section 12601 ("FSR") at 3 (quoting the American Heritage Dictionary). "Fair" warnings today often require more context and balance than is available through labels or shelf signs. Product labels often are "excessive" because the channels of distribution for beverages require companies to place labels on products distributed to states surrounding California as well as to California in order to ensure that products in California have a warning.

Increasingly sophisticated methods of detection for chemicals, the increasing size of the Proposition 65 list (now containing approximately 800 chemical listings), and the increasing prevalence of litigation concerning Proposition 65 chemicals in food make this an appropriate time for California to provide greater guidance concerning Proposition 65 warnings for foods.

Avoiding proliferation of "birth defects" warnings

As currently phrased, section 12601(a) may be interpreted to require that the phrase "birth defects" appear on warnings for chemicals that do not cause birth defects. This ambiguity arises because the second sentence in section 12601 contains one comma rather than two, and the word "or" appears twice: "The [warning] message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." It is possible to interpret the existing language to mean that reproductive toxicity warnings "must

communicate" that the chemical in question is "known to the state to cause . . . birth defects or other reproductive harm."

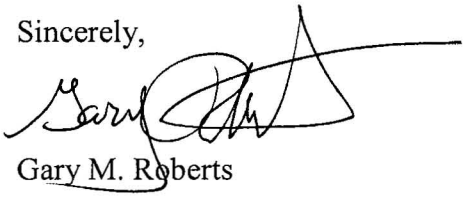
It would be more accurate for the warnings to communicate either that the chemical in question causes birth defects or that it causes reproductive harm, rather than say that it causes "birth defects or reproductive harm" for chemicals that do not cause birth defects. This also would be more consistent with the statute itself, which refers to "reproductive toxicity" but not birth defects. Indeed, the one mention of "birth defects" in the preamble of Proposition 65 clearly separates that phrase from two other distinct concerns: "cancer, birth defects, or other reproductive harm." Proposition 65, Sec. 1(a) (Preamble).

The objective of avoiding over warning, which California has recognized as a concern in the food setting on several occasions, such as when it adopted section 12501, and the objective of promoting informed choices pursuant to "fair" warnings, also recognized by California as noted above, would be promoted by this revision to the regulations.

Expedited approval for proposed warnings

We are interested in exploring further with OEHHA the possibility of a procedure whereby OEHHA or another state agency may be asked to approve a particular proposal to satisfy the statute's clear and reasonable warning requirement. This could benefit all interested parties by providing greater certainty concerning warning compliance issues.

Sincerely,



Gary M. Roberts

cc: Ms. Linda Adams
Dr. Joan Denton
Ms. Carol Monahan-Cummings
Ms. Patricia Magee Vaughan