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Re: GMA Comments on Food Warning Proposal

Dear Ms. Kammerer:

These comments are submitted on behalf of the Grocery Manufacturers Association ("GMA"), a trade association whose members are companies that produce, process, and prepare foods consumed by virtually all Californians, and the American Beverage Association, a trade association whose members produce and distribute beverages (referred to collectively as "Manufacturers"). As clearly demonstrated by its contributions of time and resources throughout this long rulemaking process, the Manufacturers continue to support the Office of Environmental Health Hazard Assessment ("OEHHA") in its efforts to develop new regulations governing safe harbor options for foods sold in retail settings.

It is appropriate for OEHHA to be considering a warning program for food because, as we have previously explained and as summarized briefly in these comments, food is fundamentally different from virtually all other consumer products. Because of these differences, a different type of warning program would better serve consumers than the options currently available.

For a food warning system to work, however, it must set forth a clear, realistic, and workable statement of actions that food producers/manufacturers on the one hand and retailers on the other can take to satisfy their obligations and further the intent of the voters and the interests of consumers. The current proposal does not do so.

Given the level of commitment and effort devoted by all participants to this process, the Manufacturers and the retailers were extremely disappointed with OEHHA's published proposal. The proposal describes a system that cannot work and, therefore, will not be used by manufacturers and retailers. As such, it will have no impact and effect no change other

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than the number of words in the OEHHA regulations.¹ Thus, the Manufacturers would oppose adoption of the proposal in its current form.

We are encouraged, however, by the fact that the proposal does provide a framework which can be made to work. With only a few modifications—each of which is important—we believe that the OEHHA proposal can produce an effective warning system. We describe the changes we believe are needed below. Our emphasis is on the issues of most concern to manufacturers and producers. We understand that retailers will separately be filing comments elaborating on the issue of most concern to them.

A. Revisions Needed

As a threshold matter, we reiterate two important points:

- *Each of the principles discussed below is essential to creating a workable system.*
- *For a system to improve the status quo as OEHHA contemplates, it must be workable and achievable by both manufacturers and retailers.* The manufacturers are the ones who must build and fund the web site on which the system rests. If the regulation does not work for them, the backbone of the system simply will not be built. The retailers must download the information and communicate it to consumers. Without the participation of each, the system will not work.

1. **Manufacturer and retailer actions for satisfying safe harbor obligations must be independent.**

The food warning safe harbor will not work if manufacturer liability turns on individual retailer participation—a factor outside of the manufacturer’s control. Nor will it work if retailers’ liability turns on individual manufacturer participation. In the August 28 proposal, the availability of the safe harbor to a “Food Provider” depends on foods being “sold by Food Retailers that participate in the Retail Food Warning Program.” Making each player’s role dependent on the actions of another serves no statutory or regulatory purpose, and substantially eliminates the benefit of the system. The proposed regulation needs to be changed so that manufacturers that fully participate get the benefit of safe harbor, and the same should be true of retailers.

¹ The Manufacturers and the retail groups who have participated in this process provided a draft regulation that sought to reflect the views of all participants while effecting real reform.

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2. The requirement for identifying the specific chemical content of each food should be dropped.

The requirement (under section 25603.4 (b)(1)(ii) of the draft) that the manufacturer identify each specific chemical present in the food, and do so by its CAS number, is unworkable, unnecessary, and infeasible. It should be deleted. Such chemical-specific identification is not required by the existing safe harbor regulations. Putting this additional burden on food warnings would make manufacturers reluctant to use the safe harbor option.

Information as to the trace levels of all chemicals unintentionally in foods is not only difficult to obtain but, even when available, is uncertain at best. As explained in more detail below, virtually all foods contain one or more Proposition 65 chemicals in trace amounts either because they are naturally occurring or because they are created when food is heated. As a result, identifying particular Proposition 65 chemicals in foods is not a straightforward task. Doing so also would require a prohibitively expensive chemical testing regime for each food offered to people in California.²

There is no justification for foods to identify specific chemicals in warnings when no other consumer product is required to do so.

3. The obligation that manufacturers determine when a Proposition 65 warning is “required” should be removed.

Contrary to the normal operation of Proposition 65, the August 28 draft language establishes a system to address “required” warnings rather than permitted warnings. A warning is not “required” until it has been established that the exposure is not naturally occurring and is “significant.”³ The food industry, including both manufacturers and retailers, has been burdened with enormously expensive litigation concerning when food warnings are “required.” In order to work, a food warning safe harbor must not require the expensive and uncertain examination of what exposures are naturally occurring and what exposures are “significant,” which is what the current proposal does.

² We also note that this unexplained departure from the current safe harbor warnings was not discussed by the working group and the late addition of this significant change is a surprise to those who have worked diligently for more than a year on building a food warning program.

³ Cal. Code Regs., tit. 27 § 25501; Cal. Health & Safety Code § 25249.10(c).

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Section 25603.4(a) of the proposal states that the safe harbor may be used “concerning the content of warnings that are *required* for exposures to listed chemicals.” A food provider is only covered by the safe harbor if it evaluates “all of its foods that require a warning under the Act.” Proposed section 25603.4(b)(1)(ii). Indeed, required warnings are referenced in numerous places in the proposal. In contrast, the current safe harbor provision for consumer products warnings, sections 25603 to 25603.3, does not reference “required” warnings at all.

Proposition 65 offers companies in California the choice of providing warnings rather than facing the burdens of complicated risk assessments that grapple with naturally occurring and “significant” exposure issues. That option must be part of a workable safe harbor system for food warnings.

4. Regulations should distinguish between warnings that must be provided by large grocery chains in which virtually all Californians shop and small or individual grocers.

This distinction is supported by evidence in the record. The comments filed concurrently by trade associations representing retailers include data demonstrating that 99.3% of Californians do grocery shopping at one or more of 15 large grocery chains (“Large Grocers”). We believe the regulations should distinguish between the warnings required of the Large Grocers and the warnings required by all other grocers. Specifically, individual product warnings should be available in the Large Grocers. In the others, a more general warning would be provided directing consumers to the OEHHA web site or other electronic sources for obtaining more product-specific information. No retailer would be excused or exempted from a warning obligation. The nature of that warning obligation would simply reflect consumers’ shopping habits.

This system ensures that consumers will be warned. Not only do more than ninety-nine percent of households (99.3%) shop at one or more of the Large Grocers but, more importantly, these retailers take in seventy-one percent (71%) of all dollars spent on food in the State. So consumers are not just buying a few, select items at the Large Grocers, they are doing the majority of their shopping at these stores. If *only* the fifteen biggest players participated in the system proposed by manufacturers, then warnings would be available to all but less than 1% of consumers and for over 70 percent of total food purchases.

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This system is consistent with prior application of Proposition 65. One example is the settlement with Wendy's, Burger King, McDonalds, and others regarding acrylamide warnings. None of the various warnings allowed by the settlement requires that a consumer be given a warning on food wrappers—a warning posted in the store is sufficient. Furthermore, none of the warning methods requires that consumers receive a warning when they purchase food at a drive-through window. What the settlement does ensure is that *over time* nearly every single consumer of fried potatoes will receive a warning regarding acrylamide.

- *This system is consistent with the text of the law.* A general warning regarding foods sold by retailers that are not Large Grocers is entirely consistent with three existing provisions of existing Proposition 65 regulations.
- Section 25603.3(a) allows the following generic warning for foods sold at Food Establishments:

“WARNING: Chemicals known to the State of California to cause cancer or birth defects or other reproductive harm may be present in foods or beverages sold or served here.”
- Section 25603.3(b) allows the following generic warning for fresh fruits, nuts, and vegetables:

“WARNING: This product may contain a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.”
- Section 25603.3(e)(1) allows the following warning for alcoholic beverages, broadly defined:

“WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine or other Alcoholic Beverages may Increase Cancer Risk and, During Pregnancy, Can Cause Birth Defects.”

Finally, and most importantly, the warning system proposed is consistent with the language of the statute as well as its implementing regulations, both of which state that a warning need not be provided separately to each exposed individual. Cal. Health & Safety Code § 25249.11(f), 22 C.C.R. § 25601.

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5. The system must create incentives for all participants.

The system must be feasible and workable for the retailers. If it is not, retailers will not participate. A retailer's obligation should be to **pass along the information, and/or not interfere with the warnings provided to the retailer by the manufacturer.** Retailers have said that for many retailers the best—perhaps the only feasible—way to do that is to allow them to download a **compendium** of information that has been uploaded to OEHHA's web site by manufacturers. Manufacturers believe a paper compendium or a web site are the two best ways to transmit the information because both can be a vehicle for nuanced information and for providing context that explains the warning. Placing this compendium within the largest/most frequented food retail locations will ensure that it is available to 99.3% of consumers at some time during each year. Because of the market saturation of the Large Grocers and the availability of the internet to many consumers (not to mention a preference for internet research by many consumers), the compendium need not be provided in every gas station and little corner market.

6. Details matter.

The final version of the regulation must correct details that create unnecessary and inadvertent obstacles:

- Section 25603.4 (c) 2 should be eliminated. While we do not believe this to be the intent, the effect of this provision appears to create an end-run around the entire system by putting the burden of creating and delivering a warning on the retailer if the manufacturer simply sends one fax. This provision seems to be addressed to a wholly theoretical scenario while serving no useful purpose.
- Because this will be a new system, there should be an opportunity to correct minor violations without penalty within a certain number of days of their being identified.
- Food providers should enjoy safe harbor protection for all of the foods they enter into the food warning program. The safe harbor protection should not depend on an "all or nothing" participation requirement. The proposal does not protect any foods entered into the food warning system by a food provider unless that provider identifies "all" of its foods and "each" of its foods that "require" a warning. *See, e.g.*, Proposed Section 25603.4(b)(1)(ii) and 25603.4(b)(1)(v). Under this proposal, if a plaintiff

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contended that a food provider should have provided a warning for one food, that argument would threaten the safe harbor status of all that provider's other food products that were included in the food warning system. This makes the system unworkable and unattractive to Manufacturers.

- Proposed Section 25603.4(b)(1)(vi) calls for an unnecessary blizzard of paper and creates potential confusion about warning mechanisms that should be avoided.
- The proposal should be focused on the obligation to make warnings available, not the more confusing and less practical obligation of "providing" a warning.

B. The Regulation Must Serve the Fundamental Purposes of the Food Warning Project.

We have often stated a principle fundamental to this project: Food is different. In order for the proposed regulation to further the purposes of Proposition 65 and to be workable, it must reflect a number of unique characteristics of food:

- o ***Proposition 65 chemicals are ubiquitous in the food supply in amounts and through processes that are often unknown and unpredictable.*** Virtually every food contains some minute quantity of one, or in many cases, several Proposition 65 chemicals.⁴ Some chemicals in foods may be partly or completely naturally occurring. With rare exceptions, these chemicals are not added to the food. Unlike other consumer products, analyzing any given food to determine whether a warning is required is a complex process fraught with uncertainties for retailers *and* manufacturers. Many chemicals that are present in foods are created through cooking and are subject to different risk assessment rules.⁵ Some chemicals in foods may be partly or completely naturally occurring.⁶ As previously stated, these chemicals can change without the knowledge or the intent of those who process, serve, or sell it. Determining the existence and extent of naturally occurring chemicals is often a difficult, complicated, and costly process requiring the assistance of experts. In fact, because the chemicals are present in food for

⁴ Final Statement of Reasons for Cal. Code Regs., tit. 27 § 25501 (hereinafter, "25501 FSOR"), at 3; *Nicolle-Wagner v. Deukmejian*, 213 Cal. App. 3d 652, 660 ("We all presume, to some extent, that foods that have been eaten for thousands of years are healthful, despite the presence of small amounts of naturally occurring toxins.")

⁵ Cal. Code Regs., tit. 27 § 25703(b)(1).

⁶ Cal. Code Regs., tit. 27 § 25501.

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reasons beyond the control of food growers, manufacturers, and sellers, the levels of the chemicals in the food are often unknown or unpredictable.⁷

- ***The safety of the food supply is highly regulated at both the state and federal level.*** Extensive federal, state, and county regulations prohibit the sale of food that could be injurious to health.⁸ Whatever criticisms some may have of that system, there can be no argument that no food that poses an acute risk of cancer or birth defects can legally be sold and, were such food to make it on the market, it would be recalled when discovered.⁹ Moreover, as it did with fish, FDA issues alerts to consumers, advising them of risks associated with consuming foods in quantities that exceed safe levels, and provides information on how to avoid such risks.¹⁰
- ***Proposition 65 litigation over foods is escalating.*** Nevertheless, because it is so easy to detect a Proposition 65 chemical in food, the number of lawsuits and threatened lawsuits against food companies—including retailers—is escalating.¹¹ A vehicle that allows

⁷ Final Statement of Reasons for Cal. Code Regs., tit. 27 § 25703, at 5; Final Statement of Reasons for Cal. Code Regs, tit. 27 § 25601, at 4 (“Situations may exist in which a business cannot know whether in fact there is an exposure from each item sold, as in the case of bulk produce. Those situations may warrant special treatment under these regulations.”)

⁸ See, e.g., Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342 (1938); Federal Meat Inspection Act, 21 U.S.C. § 453; Poultry Products Inspection Act, 21 U.S.C. § 601(m). See also, FDA, *Retail Food Protection: A Cooperative Program*, available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/default.htm> (“More than 3,000 state, local and tribal agencies have primary responsibility to regulate the retail food and foodservice industries in the United States. They are responsible for the inspection and oversight of over 1 million food establishments - restaurants and grocery stores, as well as vending machines, cafeterias, and other outlets in health-care facilities, schools, and correctional facilities.”).

⁹ 21 U.S.C. § 334(a)(1).

¹⁰ FDA, *What You Need to Know About Mercury in Fish and Shellfish* (March 2004), available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm115662.htm>

¹¹ Proposition 65 lawsuits filed over the past several years have affected numerous foods, including tuna, chocolate, vinegar, french fries, potato chips, meat, grilled beef, and grilled chicken. Many of these lawsuits have named retailers.

One of the most glaring examples of the counterproductive consequences of such litigation is the law suit brought against the manufacturer of Wheatena—a toasted whole-grain cereal that has been qualified by FDA to make claims for heart health and cancer prevention. The company was sued by a private Proposition 65 plaintiff over the presence of acrylamide. Faced with the certainty of high litigation costs, the company chose to withdraw from the California market. Result: A product with documented health benefits is no longer available to Californians.

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certainty about how warnings are to be provided and, where appropriate, context for those warnings, is therefore very much needed.

- ***Consumers purchase food frequently and will make multiple purchases of food products before they even approach exposure above the warning threshold.*** Unlike brass keys, faucets, ceramics, handbags, automobiles and garden equipment, barbecue grills and hundreds of other consumer products that have been the subject of Proposition 65 enforcement actions, foods are consumed within a few days – and, typically, hours – of purchase, and repurchased weekly, if not daily. Therefore, a consumer need not receive a Proposition 65 warning before the *first* purchase of a product in order to obtain the benefit the warning. A warning in a grocery store that chemicals in foods may pose certain risks and advice about where to obtain product-specific information gives the consumer ample opportunity to obtain product-specific information long before her purchases reach a point where there is even a remote risk of the harm warned of. The law requires a “clear and *reasonable* warning.” It does not require a *prior* warning, and certainly not a prior warning before each and every purchase. The standard by which to measure a warning system is whether it is “reasonable.” Because a single purchase of legally sold food will not expose consumers to a risk of cancer or birth defects, a warning that assures consumers will have access to warning information in the course their shopping over the course of a period of time will meet the criteria and the objectives of Proposition 65.

CONCLUSION

The Manufacturers began this process believing that OEHHA and the stakeholders to this regulatory update project could craft a useful and pragmatic set of regulations that will provide consumers with the information Proposition 65 assures them. The proposed version of the regulation has fallen far short of this goal and, as it stands, would discourage manufacturers and retailers from participation. While the Manufacturers cannot support the proposal in its current form, we can support the framework proposed and the specific modifications set forth in these comments and those provided by the retailer trade associations. We believe Californians deserve a system that works, and we are prepared to work with OEHHA and other stakeholders to achieve one.

California consumers deserve no less.

Sincerely,



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