



April 26, 2016

Via email (PDF) Only (P65Public.Commens@oehha.ca.gov)

Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Re: Clear and Reasonable Warnings Regulation

Dear Ms. Vela,

The Grocery Manufacturers Association (“GMA”) appreciates the opportunity to provide comments to the Office of Environmental Health Hazard Assessment (“OEHHA”) regarding its March 25, 2016 Notice of Modification to Text of Proposed Regulation -- Title 27, California Code of Regulations, Proposed Repeal of Article 6 and Adoption of New Article 6, Proposition 65 Clear and Reasonable Warnings. GMA is simultaneously submitting more general comments on the proposed regulations as part of the California Chamber of Commerce coalition.

GMA is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. The food, beverage and consumer packaged goods industry in the United States generates sales of \$2.1 trillion annually, employs 14 million workers and contributes \$1 trillion in added value to the economy every year.

On January 25, 2016, GMA submitted extensive comments (copy enclosed) on the November 27, 2015 proposed regulations. GMA was disappointed to see that OEHHA did not address any of GMA’s comments in the March 25, 2016 revised version of the proposed regulations. GMA therefore reiterates each of its prior comments and requests that OEHHA consider and respond to these comments.

GMA and its members would appreciate the opportunity to discuss these critical issues with OEHHA staff before the proposed regulations are finalized.

Sincerely,

A handwritten signature in blue ink that reads "John Hewitt".

John Hewitt
Grocery Manufacturers Association



January 25, 2016

Via email (PDF) Only (P65Public.Comments@oehha.ca.gov)

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Re: Proposed Revisions to Proposition 65 Regulations on Clear and Reasonable Warnings

Dear Ms. Vela:

On behalf of the Grocery Manufacturers Association¹ (“GMA”), we incorporate by reference the comments of the California Chamber of Commerce Coalition and the American Beverage Association regarding the November 27, 2015 Notice of Proposed Rulemaking and proposed repeal and replacement of the Proposition 65 regulations on Clear and Reasonable Warnings found in Title 27, Article 6 of the California Code of Regulations. We also write separately, however, to provide GMA’s specific comments on the proposed regulations and to remind the Office of Environmental Health Hazard Assessment (“OEHHA”) that this regulatory proposal has always been intended to be a relatively small part of a broader set of reforms to Proposition 65 and its implementing regulations.

Specific Comments on the Proposed Warning Regulations

Transition Period

GMA appreciates the proposed transition period in Section 25600(b). We believe its intent is to apply to all consumer products, including food, as does the provision defining “consumer product exposure” at Section 25600.1(i). GMA requests that the provision state that intent more clearly and also make clear that it applies to products that are not necessarily “manufactured” in the traditional sense but may simply be packaged for retail sale with little if any processing.

¹ Based in Washington, D.C., the Grocery Manufacturers Association is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. The food, beverage and consumer packaged goods industry in the United States generates sales of \$2.1 trillion annually, employs 14 million workers and contributes \$1 trillion in added value to the economy every year.

GMA believes the following revisions would make the transition provision more clear with respect to foods:

A warning for a consumer product, including a food, manufactured or packaged prior to the effective date of this article is deemed to be clear and reasonable if it complies with the September 2008 revision of this article.

Electronic Methods

Proposed section 25602(a)(2) establishes a safe harbor method for “any electronic device or process that automatically provides the warning . . . , without requiring the purchaser to seek out the warning.” GMA appreciates the agency’s willingness to permit these more modern methods of communication, which the agency describes as including “electronic shopping carts, smart phone applications, barcode scanners, self-checkout registers, pop-ups on Internet websites and any other electronic device that can immediately provide the consumer with the required warning.” ISOR at 25. Nevertheless, we are concerned about the possible misinterpretation of the requirement that the purchaser not be required “to seek out the warning,” and we believe that without modification to or further clarification of this requirement, manufacturers and retailers will be discouraged from providing warnings via electronic means.

As OEHHA recognizes, consumers often have to take certain minimal steps in order to seek out and obtain a warning. Even when a warning sign is posted “in plain sight,” a consumer must look for it amidst all the other objects or signage that may be present, for instance in a restaurant or at a retail store. If the warning is on the exterior labeling of the product itself, a consumer often must pick up the product from the store shelf and turn it over or otherwise review the wording on the label in order to obtain the warning. When shopping online, the consumer often must enlarge the images of the product, or read through the sometimes quick extensive product description, in order to obtain the warning. Even if the warning is automatically printed on a receipt that is handed to the consumer, the consumer may need to review the receipt carefully to find the warning. And it is common knowledge that warnings may be provided in plain sight on shelf tags or signs that are prominent and visible but that go unnoticed by consumers who are not looking for them, i.e., consumers who are not “seeking out” the warnings. Since there is no practical way for a product manufacturer or retailer to transmit the warning to every consumer without *any* effort on the part of the consumer to seek out the warning, the question is the degree of effort required by consumers and not the mere fact that *some* effort to seek out the warning is required.

Because conventional means of warning all require the purchaser to seek out the warning in some manner, it is simply too broad for the proposed section 25602(a)(2) to require that the electronic device or process provide the warning “without requiring the purchaser to seek out the warning.” GMA does not disagree with the agency’s examples of warnings provided via electronic means that would not comply with this provision, i.e., a “general reference to a website.” But GMA believes the agency needs to better describe means that are permissible.

Based on the ISOR, this proposed requirement on methods that “requir[e] the purchaser to seek out the warning” appears to have its origin in OEHHA’s reading of the 1992 Court of Appeal decision in *Ingredient Communication Council, Inc. v. Lungren*. As OEHHA correctly notes, that decision disapproved of a warning program involving store signage and newspaper advertisements that invited consumers to phone a toll-free number in order to learn whether a Proposition 65 warning applied to individual products. This case of course predates the widespread use of mobile telephones, much less smart phones, as well as the Internet and

other forms of electronic communication. The trial court and Court of Appeal noted the relative difficulties of calling a toll-free number (from a landline) in advance, taking approximately one minute for every product the consumer intended to purchase, particularly when expert testimony showed that many consumers make their purchase decisions at the store and not in advance.

The Court of Appeal noted, "An invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product." *Ingredient Communication Council, Inc. v. Lungren*, 2 Cal. App. 4th 1480, 1494 (1992). But this statement belongs in the context of the preceding sentences:

Any meaningful definition of "availability" prior to exposure must similarly consider the probability of the prospective consumer seeing or hearing the warning message. Availability of the warning message, to be consistent with the Act, must mean more than the possibility a consumer would be apprised of the specific warning message **only through considerable effort**.

Id., at 1494 (emphasis added). Based on this decision, the relevant criterion therefore is whether the warning method requires "considerable effort" by the purchaser, and not whether it requires the purchaser to "seek out" the warning.

GMA therefore urges OEHHA to revise proposed section 25602(a)(2) to read as follows:

A product-specific warning provided via any electronic device or process that makes the warning available to the purchaser, without considerable effort on the part of the purchaser, prior to or during the purchase of the consumer product.

Set Off and Box Requirement

Proposed section 25607.1(b) would require that warnings provided on the label of food products be "set off from other surrounding information" and "enclosed in a box" in order to qualify for safe harbor treatment. The ISOR states that the "box" requirement is proposed "because food product labeling does not generally include warning symbols." GMA does not understand this logic or believe that either the "set off" or "box" requirements are necessary or appropriate in order for consumers to see or read the warning.

First, there is no precedent for requiring Proposition 65 warnings to be set off or enclosed in a box. Safe harbor regulations in effect for more than two decades have not called for warnings to meet such requirements in any context. Furthermore, no broad-scale court approved consent judgments or out-of-court settlements require any such boxed warnings on the label of products. GMA is not aware of any such boxed warnings under Proposition 65 that any business routinely provides on the exterior label of any category of product. Said differently, warnings that are not set off and not enclosed in boxes have been approved by dozens of courts, as well as the Attorney General and other public enforcers of Proposition 65, as "clear and reasonable" warnings under Proposition 65.

Second, boxed warnings are not common under other laws that apply to products sold in the United States but when they are used, they are used for the most significant of hazards. In fact, the federal Food & Drug Administration reserves boxed warnings, also known as "black box" warnings, on prescription drug labeling for "serious or life-threatening risks". See, e.g., A Guide to Drug Safety Terms at FDA (Nov. 2012), at 1 (available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM107976.pdf>). For

example, FDA requires the prescription blood thinner warfarin to display on its labeling a boxed warning about the risk of bleeding to death. Proposition 65 warnings, particularly on foods and beverages, do not merit this degree of attention and, if required to be set off in boxes, will unnecessarily alarm and confuse consumers.

Third, consumers read food labels, often quite closely, and this is the basis for significant regulatory programs administered by the U.S. Department of Agriculture and the FDA. It is not necessary to set off a Proposition 65 warning for consumers to notice it.

And finally, federal regulators require a great deal of information to be provided on food labels in order to assist consumers in making their eating and nutrition decisions. GMA and others in the food and beverage industries have worked for years to improve the relevant information provided to consumers. Food labels can be quite small and have little space for conveying information other than the required nutrition and other labeling information as well as differentiating brand information. Therefore, there often may not be space to set off a Proposition 65 warning from other surrounding information without sacrificing other information that consumers find relevant and useful.

GMA therefore urges OEHHA to remove the requirements for set off and boxed warnings on food labels.

Broader Proposition 65 Reform

GMA urges OEHHA to devote its resources to longstanding and more pressing Proposition 65 issues that continue to weaken the state's business climate.

As you know, the origin of the subject regulatory proposal is Governor Brown's call to reform Proposition 65 almost two years ago. The Governor called on his administration, stakeholders, and the Legislature to discuss the following reforms:

- Cap or limit attorney's fees in Proposition 65 cases.
- Require stronger demonstration by plaintiffs that they have information to support claims before litigation begins.
- Require greater disclosure of plaintiff's information.
- Set limits on the amount of money in an enforcement case that can go into settlement funds in lieu of penalties.
- Provide the State with the ability to adjust the level at which Proposition 65 warnings are needed for chemicals that cause reproductive harm.
- Require more useful information to the public on what they are being exposed to and how they can protect themselves.

These issues were set out as part of an overall effort to "pursue regulatory changes to improve the state's business climate," as noted in the Governor's May 7, 2013 press release.

The Governor's office convened intensive discussions among stakeholders in the summer and fall of 2013, during which these and other proposals were discussed in great detail. The one concrete regulatory action resulting from these discussions to date is the subject proposal to overhaul OEHHA's regulations concerning clear and reasonable warnings. Although GMA appreciates the effort that OEHHA has put into this proposal, including the time that OEHHA staff have spent with GMA and other interested stakeholders, we must reiterate that the issues addressed by this proposal are not among our members' priorities for reform of Proposition 65.

On the contrary, there are many aspects of Proposition 65 and its implementing regulations that GMA and its members, among others, have been asking OEHHA to address for many years -in some cases more than a decade. OEHHA took a useful step toward identifying these issues with its September 16, 2014 Request for Public Participation on Potential Regulatory Actions, which requested ideas on the following concepts, among others:

- Alternative risk levels for chemicals in foods (25703(b))
- Update the Naturally Occurring regulation (25501)
- Update and streamline the Safe Use Determination process (25104)
- Where Interpretive Guidance is needed

GMA and dozens of other members of the business community submitted extensive comments to OEHHA as part of the California Chamber of Commerce Coalition in November 2014. Other than a pre-regulatory draft proposal to set naturally occurring concentration levels of lead and arsenic in certain foods, to date there has been little evidence of activity by OEHHA to respond to these submissions or otherwise engage on efforts to reform these aspects of Proposition 65 and its implementing regulations. We urge OEHHA to devote its resources toward these issues, and we stand ready to work with OEHHA to develop and refine proposals in these areas that will address the pressing problems of Proposition 65 that our members and the entire California business community would like addressed as part of the Governor's reform efforts. Thank you for considering these comments. GMA and its members appreciate the opportunity to continue this dialog with OEHHA and look forward to progress on these core issues of Proposition 65 reform.

Sincerely,



John Hewitt
Grocery Manufacturers Association