

September 26, 2016

Ms. Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 I Street Sacramento, CA 95812
Via e-mail to P65Public.Comments@oehha.ca.gov

**RE: Proposed Amendments to Title 27, California Code of Regulations Section 25603.3
Warnings for Specific Consumer Products Exposure (Bisphenol A from Canned
and Bottled Foods and Beverages)**

Dear Ms. Vela:

On behalf of the Grocery Manufacturers Association¹ (“GMA”) and its members, we are submitting these comments regarding the Office of Environmental Health Hazard Assessment’s (“OEHHA”) above-referenced proposed regulation (“Proposed Regulation”).

We appreciate OEHHA’s efforts to adopt a workable and uniform warning program for bisphenol-A (“BPA”) used in food and beverage containers. We believe that OEHHA’s actions in adopting the April 19, 2016 emergency regulation (“Emergency Regulation”) on which this Proposed Regulation is based have to date achieved the agency’s goals. The signage program that GMA and other trade associations have coordinated has avoided a plethora of shelf signs and other warning labels at retail, provided useful information to consumers, communicated a consistent, clear, and reasonable message, and avoided unnecessary litigation expenses and burdens on the courts. GMA continues to believe that OEHHA should not have listed BPA, agrees with the U.S. Food & Drug Administration (“FDA”) that its use in food and beverage packaging is safe for consumers, and believes that the level of exposure from foods and beverages does not require a warning under Proposition 65. GMA nevertheless supports the proposed extension of the signage program and believes it is necessary and appropriate for the same reasons.

¹ Headquartered in Washington, D.C., with a representative based in Sacramento, California, 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. Based on data from the United States Department of Agriculture, American households spend more than five percent of their disposable personal income on food products intended for consumption at home. <http://www.ers.usda.gov/data-products/food-expenditures.aspx>.

That said, GMA objects to the one significant change to the emergency regulation that OEHHA has included in the Proposed Regulations, and GMA has several recommendations it believes are also due consideration, as detailed below.

The Emergency Regulation Is Providing Clear and Reasonable Warnings

GMA supports the reasonable retail-based warning program that OEHHA included in the Emergency Regulation, and welcomes OEHHA's inclusion of those features in the Proposed Regulation.

First, under the Emergency Regulation, manufacturers are required to provide notices and warning materials to retailers, and retailers are responsible for posting warnings as instructed.² It is appropriate for OEHHA to delineate responsibilities as between retailers and manufacturers. Indeed, a number of recent court-approved settlements with manufacturers have included retail-based warning programs allocating manufacturer and retailer obligations.³ Second, retailers that are in substantial compliance have the opportunity to cure a minor deviation from the warnings.⁴ This cure provision addresses the realities of posted warnings in retail settings: for example, cash register areas may change or warnings may inadvertently be displaced for a short period of time.

Even if certain retailers do not post the warnings as instructed by the manufacturers, or if there are minor deficiencies in a retailer's warning program, the fact that each consumer does not see a BPA warning on each separate shopping visit does not invalidate the warning program. Retailers have posted the warnings such that they have become widespread in California, and so consumers are receiving the warning many, many times as they shop for food.⁵ On average,

² 27 Cal. Code Regs. § 25603.3(f)(2).

³ For example, the court approved over a dozen settlements incorporating retail-based warning programs in the Attorney General's case against multivitamin manufacturers. *See, e.g., People v. 21st Century Healthcare, Inc., et al.*, Alameda County Superior Court No. RG08426937. A retail-based warning program was also incorporated in 2014 court-approved settlement involving over a dozen alcoholic beverage manufacturers in *Bonilla, et al. v. Anheuser-Busch, LLC, et al.*, Los Angeles Superior Court No. BC537188.

⁴ 27 Cal. Code Regs. § 25603.3(f)(2)(A).

⁵ For example, during a hearing to approve a settlement in a case brought by the Attorney General concerning acrylamide in french fries, the Deputy Attorney General in the case explained that a Proposition 65 warning need not be posted at a restaurant's drive-thru in addition to the interior of a restaurant because drive-thru customers would be expected to go into the restaurant during other visits. *People v. Frito-Lay, Inc.*, Los Angeles County Superior Court No. BC 338956.

consumers make 1.5 trips to a supermarket per week.⁶ Indeed, the statute recognizes that warnings “need not be provided separately to each exposed individual and may be provided by general methods”⁷ This signage program is far more specific than a “general method,” and as such fully satisfies the statute’s requirement for a clear and reasonable warning.

GMA is aware of objections that the BPA warning program does not provide consumers with information on the labels of foods or beverages or on signs at the point of display of foods and beverages, but GMA agrees with OEHHA that to require warnings to be provided in this manner will be both impractical and confusing to consumers and will likely result in over-warning for all canned foods and beverages. OEHHA cites data showing that between 66 and 90 percent of all canned foods and beverages, many of which have a shelf life of up to three years, contain BPA, a figure that shows how impractical it would be to provide warnings on the labels of these products or on shelf signs at the point of display.⁸

Instead, OEHHA has adopted, in its Emergency Regulation, and should adopt in its Proposed Regulation, the technologically-advanced form of warning that involves a reference to a website where more information is available to consumers -- far more information than could ever be provided on a store sign, much less on a food label. President Obama recently signed Public Law 114-216 (S. 764) into law recognizing digital disclosure as on par with text or a symbol on a label. Today’s consumer has turned “Google” into a verb. More than 300 million people in the U.S. have access to and use the internet and 89% of consumers use search engines for purchase decisions. Smartphone ownership is projected to reach 80% by 2018 bringing all this information to consumers’ fingertips.

GMA therefore supports the overall structure of the Proposed Regulation and believes it provides an appropriate, clear and reasonable warning to consumers, with the food and beverage manufacturers identifying for retailers the specific products for which the warning is being provided. This is consistent with Proposition 65 and reflects a careful balancing of policy and technical considerations that is within OEHHA’s discretion as the lead agency for implementation of the Proposition 65 statute.

OEHHA Should Not and Cannot Require the Data for a “BPA Intent” List

GMA’s primary objection to the Proposed Regulation is the requirement in proposed section 25603.3(f)(1)(A)(2) that each manufacturer of food or beverage products provide information to

⁶ Food Marketing Institute, “Supermarket Facts,” 2015, available at: <http://www.fmi.org/research-resources/supermarket-facts>.

⁷ Cal. Health & Safety Code § 25249.11(f).

⁸ Initial Statement of Reasons, Proposed Amendment to 27 Cal. Code Regs. § 25603.3, at pp. 4-5 (July 29, 2016).

OEHHA concerning those “products for which a warning is being provided” and” in which BPA was intentionally used in the manufacture of the can lining or jar or bottle seals.” This list is in addition to the list required under proposed section 25603.3(f)(1)(A)(3), and which has already been compiled by GMA on behalf of food and beverage producers, in order to provide information to retailers identifying the products for which the manufacturers are providing warnings.

GMA believes this new, second database of “BPA-intent” products will create complexity for food companies intending to comply with the regulation and provide the safe harbor warning while also creating confusion for consumers. The list of products for which the BPA warning is being provided includes products in which BPA was intentionally used as well as products in which BPA was not intentionally used. This list is publicly available and indeed the link to this list has been provided directly to every retailer of these products in the state of California. This is the operative list that relates to the warning. It reflects those products for which the manufacturer intends to provide the warning. And it is the list of products that a public or private enforcer of Proposition 65 would need to consult in order to determine whether an appropriate warning has been provided for a given food or beverage product. The responsibility to warn is primarily on the manufacturer of the products, and the manufacturers therefore are entitled to, and do, decide whether to provide a warning for each of their products, taking into consideration the variety of factors that the law makes relevant.

The second database proposed by OEHHA would, by contrast, include only a subset of the products for which a warning is being provided -- those in which BPA was intentionally used in the can lining. The food in these products does not necessarily contain BPA in higher concentrations; as OEHHA acknowledges, for example, BPA can be present in cans with no BPA used in the lining. Furthermore, because consumers’ exposure levels relate to the rate at which the food is consumed, those cans in which BPA was intentionally used may or may not cause any greater exposures to BPA. Notably, when OEHHA adopted the Emergency Regulation, it focused on a warning program for businesses to identify “which canned and bottled food products cause exposures to BPA” rather than which products contain intentionally added BPA in the lining.⁹ As such, there is no legitimate public health goal to be served by requiring information from manufacturers, and publicizing it to consumers, concerning which cans use BPA intentionally in their linings.

Any warning program for foods raises unique issues, which OEHHA has recognized in adopting the Emergency Regulation and in adopting new safe harbor warnings for foods in 27 Cal. Code Regs. § 25607.2.¹⁰ Food and beverage products are an integral part of Americans’ daily lives.

⁹ OEHHA’s Response to Comments on Emergency Regulation, at p. 9 (April 19, 2016), available at: <http://oehha.ca.gov/media/downloads/crn/responsecmtsbpaemerg041916.pdf>

¹⁰ The new safe harbor warning requirements in Section 25602.7 for food products differ in key respects from safe harbor warnings for other consumer products in Section 25603. For example,

The need for consistent and clear messages to consumers is critical as a matter of public health. Yet the distinction that OEHHA proposes for exposures from BPA-intent products and other types of products which nonetheless may contain BPA will result in conflicting and confusing messages to consumers about BPA exposures. Simply put, there is no rational relationship between the statute's requirement that manufacturers warn consumers about exposures to listed chemicals above threshold levels and OEHHA's requirement that manufacturers provide it with a list of food and beverage products in whose packaging BPA is used.

Indeed, GMA believes that OEHHA lacks authority to require food companies to submit this information. Not only does this new database of "BPA-intent" products provide no useful information to consumers; it is unrelated to Proposition 65's requirement to provide "clear and reasonable" warning of exposures to listed chemicals above threshold levels. While OEHHA may have some authority to condition a voluntary safe harbor warning on other actions by a business, those other actions must relate logically to the purposes of Proposition 65 and the warning to be provided to consumers. For the reasons noted, OEHHA's proposal for a "BPA intent" database does not meet this standard.

GMA also questions whether it is consistent with OEHHA's role, priorities, and budget authority to compile and maintain such a database. There will be obvious costs for collecting and maintaining this internet-based information, for correcting errors, and for responding to the inevitable requests for information, if not subpoenas, from private enforcers seeking access to this data and prior iterations of this data. We doubt that OEHHA is willingly seeking a role for itself as a third-party provider of information in litigation.

OEHHA's "BPA Intent" database proposal also suffers from a number of practical issues:

- First, it is not clear when the data must be provided to OEHHA. This cannot happen instantaneously the day the Proposed Regulation is adopted, but instead food companies must be provided adequate time to submit this information, if indeed OEHHA is going to require its submission.
- Second, it is not at all clear what the Proposed Regulation means by the term "Product description, including the [FDA] product category for the food." The description might be quite short (e.g., "green beans") or it might be quite long (e.g., "French-style green beans with ham, 12 ounces, select, packed in water"). OEHHA at the least needs to provide specificity as to what is required lest this ambiguity become fodder for litigation by bounty-hunters.

the warning symbol specified for consumer products under Section 25603 is not required for foods under Section 25607.2(a).

- Third, the reference to a Universal Product Code, even with the option for “other specific identifying designation” will create logistical nightmares because UPC codes frequently are changed, even on products that do not change in any appreciable manner, and so the database will need to regularly updated. It is also not clear what value consumers will find in a 14-digit number that may well apply to multiple product variants in a similar category, some of which are included in the warning program and some of which are not.
- Finally on this point, OEHHA’s proposal to require the “last expiration or ‘use by’ date for the product” where BPA is no longer intentionally used in its packaging is unworkable. Many products do not carry expiration, “use by,” or “best by” date. These are not required by law, and they are used in different ways on different products by different manufacturers. In just this past legislative session, the California legislature considered but did not enact a bill¹¹ that would have regulated such statements, in part due to the complexity of the issue, concerns about national uniformity, and the possibility of increasing consumer confusion.

Most fundamentally, GMA objects to the implication -- and indeed the statements -- in OEHHA’s proposal for the “BPA Intent” database and in comments of OEHHA staff that reformulation of canned foods and beverages to avoid BPA is the agency’s goal or even a legitimate public health goal. As GMA and others have emphasized in prior comments, BPA is a safe and useful chemical, fully approved by FDA decades ago for contact with food, that has been a major component in the unprecedented safety and availability of nutritious and refreshing products for many decades. Indeed, FDA has continued to find BPA to be safe.¹²

While many food manufacturers and their suppliers have for several years considered alternatives to BPA, and many have implemented some alternatives in response to public opinion and consumer preferences, GMA believes strongly in the safety of BPA as it has been and is being used in food and beverage products sold and served in California. OEHHA has no authority provided by Proposition 65 to promote widespread changes in food packaging, and indeed this is neither OEHHA’s role nor its area of expertise. GMA therefore urges OEHHA to not pursue its proposal for a “BPA intent” database.

¹¹ Cal. Assembly Bill 2725.

¹² In August 2008, FDA released a draft report finding that BPA remains safe in food contact materials. In 2014, FDA completed a four-year review of more than 300 scientific studies. In an April 6, 2015 letter to OEHHA, FDA informed OEHHA that the assessment that FDA completed in 2014 “reaffirm[s] FDA’s determination that BPA is safe provided it is used in accordance with [FDA’s] regulations.” In that letter, FDA also concluded that the “results from the large extent of reproductive, sperm, and hormone parameters evaluated in the [FDA] study do not support BPA as a reproductive toxicant.”

GMA acknowledges the criticisms of the database that it assembled, under extreme time pressure, to inform retailers of the products for which food manufacturers are providing warnings pursuant to the emergency regulation at section 25603.3(f)(1)(B). GMA intends to make this database more user-friendly by including information in a consistent format. That said, this database was never intended by OEHHA to provide information directly to consumers but was instead intended to inform retailers as to the products for which warnings were being provided via the signage program. GMA could have provided this list in paper form under section 25603.3(f)(1)(B), but went beyond the requirements of the regulation and made this data accessible via the internet. Furthermore, contrary to statements by some commenters, the database is searchable using the familiar “find” or “control-F” feature, found in most internet browsers, on the product lists. GMA also notes that at least one interest group has already used this database to update its own database of products to include information on BPA warnings under Proposition 65. GMA has demonstrated its good faith by making this data publicly accessible, and we are committed to working with OEHHA to consider and address criticisms.

GMA believes the intent of the current BPA warnings would be furthered if OEHHA were to place a link to this database on OEHHA’s website at www.P65Warnings.ca.gov/BPA -- the website to which consumers are directed by the now ubiquitous BPA warning signs at retail locations across California. Consistent with the purposes of Proposition 65 and the warning program, this would provide consumers with a direct link to easily accessed information concerning the products for which the warning is being provided, and it would do so without involving OEHHA in collection of this data or any appreciable expenditure or agency resources. This industry-maintained database will be updated in real time as manufacturers add or revise their own data to add new products.

OEHHA Should Clarify the Scope of Products Covered

OEHHA should make clear in the text of the Proposed Regulation that it applies not only to glass and metal containers but also to containers of any material that use metal lids or sidewalls. Moreover, OEHHA should clarify in the statement of reasons that the Emergency Regulation’s term “hermetically sealed, durable metal or glass containers” applies not only to glass and metal containers but also to hermetically sealed containers of any material that use metal lids or sidewalls. This is consistent with the goal of the Emergency Regulation and just addresses a previously overlooked, albeit very small, category of products.

Furthermore, we understand that OEHHA intends the BPA warning program to apply broadly to all food and beverage containers that contain BPA. A key advantage of this proposal is that it promotes uniformity for warnings concerning BPA in food and beverage containers and thereby reduces the potential for consumer confusion. OEHHA should clarify that the Proposed Regulation, and the Emergency Regulation before it, applies broadly to all foods and beverages that contain BPA, and OEHHA should conform the text of the Proposed Regulation to cover

these additional types of containers. This clarification would avoid consumer confusion arising from different warning practices for various types of food and beverage containers, and it would minimize litigation risk arising from an otherwise overly narrow reading of the scope of the Emergency and Proposed Regulations.

OEHHA Should Adopt an Appropriate MADL for BPA via Ingestion

Finally, GMA notes that much, if not all, of the need for the warning program embodied in the Emergency and Proposed Regulation would be obviated by OEHHA adopting an appropriate maximum allowable dose level (“MADL”) for oral exposure to BPA. GMA therefore reiterates its request that OEHHA develop an appropriate MADL for the ingestion route of exposure that is based on a review of the studies of sufficient quality. Because OEHHA’s warning program for BPA in food and beverage containers will last only a total of approximately eighteen months, manufacturers and retailers in the near future will face tough decisions about whether to reformulate their products, whether to provide warnings in one manner or another, or whether to risk litigation by public and private enforcers of Proposition 65. Without a published MADL for ingestion exposures to BPA, manufacturers and retailers using BPA will face unnecessary litigation risk if they do not either provide warnings or take the risks and incur the expense entailed in reformulation of their products. By failing to adopt an appropriate MADL for oral exposure to BPA -- a very common exposure due to its ubiquity in the food supply -- OEHHA is creating incentives that lead to ongoing warnings for the foreseeable future.

Thank you for considering our comments. We look forward to continuing our participation in this important regulatory effort and our discussions with OEHHA on how to improve the implementation of Proposition 65.

Sincerely,

A handwritten signature in blue ink that reads "John Hewitt". The signature is written in a cursive, slightly slanted style.

John Hewitt
Western Region Director, State Affairs
Grocery Manufacturers Association