Proposed Sections 25603.3(f) and (g) Should Be Amended Before Being Adopted

Comments of

American Beverage Association

Beer Institute

Distilled Spirits Council

and

Wine Institute

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The American Beverage Association, Beer Institute, Distilled Spirits Council, and Wine Institute (collectively "Beverage Associations" or "we") appreciate the opportunity to comment on proposed changes in the Proposition 65 safe harbor warning for bisphenol A ("BPA").

The American Beverage Association (ABA) is the trade association that represents America's non-alcoholic beverage industry. ABA represents hundreds of beverage producers, distributors, franchise companies and support industries. The non-alcoholic beverage industry has a direct economic impact of more than $17 billion in California, and provides nearly 24,000 jobs in California; our industry pays $1.9 billion annually in California state taxes. The Beer Institute is a 154 year old trade association representing U.S. brewers, beer importers, and industry suppliers, large and small. The beer industry has a direct economic impact of more than $11 billion in California, and provides nearly 107,000 brewing, wholesaling and retailing jobs in California; it pays $3.5 billion annually in state taxes. The Distilled Spirits Council is a national trade association representing producers and marketers of distilled spirits and importers of wines sold in the United States. Wine Institute is the public policy advocacy group of 1,000 California wineries and affiliated businesses that initiates and advocates state, federal and international public policy to enhance the environment to responsibly produce, promote and enjoy wine. The Wine Institute membership represents 85 percent of U.S. wine production and 90 percent of U.S. wine exports.

I. Introduction

The Beverage Associations appreciate the Office of Environmental Health Hazard Assessment's ("OEHHA") desire to avoid significant confusion among people in California concerning the presence of BPA in food. We agree with OEHHA that a safe harbor regulation providing for a point of sale warning is necessary to avoid significant confusion. We respectfully disagree, however, with important aspects of OEHHA's proposed safe harbor regulation. The proposed regulation would mislead people in California into thinking that beverages contain significant amounts of BPA, when they do not. The proposed regulation also would mislead people in California into thinking that there is a readily available and proven effective alternative lining technology that the beverage industry may use for the canned beverages it sells, when there is not. It also would lead to significant over warning. These effects of the proposed regulation undermine rather than advance the purposes of Proposition 65.

OEHHA should adopt the current safe harbor warning for BPA in food, originally adopted as an emergency regulation, as the non-emergency safe harbor warning until such time as OEHHA adopts a Maximum Allowable Dose Level ("MADL") for BPA by the oral route of exposure and allows food companies some time to respond to the MADL.

II. OEHHA Should Adopt the BPA Emergency Regulation as a Non-Emergency Regulation

As a policy matter and for a variety of practical reasons described elsewhere in these comments, we request that OEHHA adopt the existing emergency regulation providing for a BPA safe harbor warning as a non-emergency regulation and advise all parties of its intent to revise the regulation within six months of the adoption of a MADL for BPA by the oral route of exposure. OEHHA has said that it hopes the CLARITY study, sponsored by the federal government, will clarify some issues that currently are making it difficult for OEHHA to adopt an oral MADL. Until such a MADL is adopted, and California thereby identifies which products it believes warrant and do not warrant a warning, a general warning at the point of sale is appropriate.

III. OEHHA Should Not Condition Safe Harbor Protection Upon Participation in a List of Which Companies "Intentionally Used" BPA in Producing Linings

The Beverage Associations oppose OEHHA's proposal to condition availability of the BPA warning safe harbor upon a company's submission of information concerning whether BPA "was intentionally used in the manufacture of the can lining or jar or bottle seals" so that OEHHA may post that information for public review on its web site. (Proposed section 25603.3(f)(1)(A)1.a.) This approach should not be adopted because it is misleading rather than informative and it would result in substantial over warning. Misleading consumers runs directly counter to a core purpose of Proposition 65, and over warning has also been noted by OEHHA as undermining the entire Proposition 65 program.

Having a government health agency communicate "intentionally used" information to the public is misleading in several important respects. A public communication that product manufacturers "intentionally used" BPA in the making of their can linings or jar or bottle seals[1] implies that there is a readily available, viable alternative to BPA for all impacted cans and other food containers, and that is not true. It also incorrectly implies that "intentionally used" BPA is more concerning than other sources of BPA; BPA is the same regardless of the source. It also suggests that all amounts of BPA for which there is litigation risk in light of OEHHA's MADL uncertainty are toxicologically important to consumers. Finally, we are concerned that consumers will overemphasize what they see on the list the first time they review the list, because many consumers may only check the list once, rather than periodically, and many others may down load copies of the initial list and may not update what they have downloaded.

[1] The term "cans" is used below as an abbreviation to cover all materials covered by the proposed regulations, including jar or bottle seals.

The presence of BPA in a food depends on much more than whether BPA has been intentionally used in the manufacture of the lining or seal. OEHHA has acknowledged that there are food products where BPA has been intentionally used in the manufacture of the lining or seal and has not been detected in the food itself. Thus, it would be misleading to emphasize to the public the characteristic of intentionally utilized BPA when that characteristic does not always lead to an exposure. Furthermore, some cans and seals, such as aluminum beverage cans that intentionally use BPA, only result in truly small, part per billion exposures to BPA. It is not reasonable for OEHHA to simultaneously take the position that it cannot determine the NOEL for BPA and to require products that result in only low part per billion exposures to participate in a disclosure system purportedly intended to "weed out" less meaningful low exposures.

If OEHHA considers it essential that there be additional information in the marketplace, we request that any "intentionally used" information requirement be one that companies may satisfy on the existing web site - - www.Prop65bpa.org -- rather than on a new web site.

IV. If OEHHA Adopts an "Intentionally Used" Safe Harbor Condition, It Should Exempt Products with BPA Levels Below Commercially Reasonable Detection Limits

BPA is ubiquitous. OEHHA's proposed regulation does not yet adequately account for this reality. A limit of detection exemption from the "intentionally used" disclosure requirement would be an appropriate step in light of the ubiquity of BPA. In the absence of such a step, certain food exposures to BPA would be emphasized more heavily in OEHHA communications when compared with non-food dermal exposures below the MADL. This disparity is all the more confusing and misleading because the dermal route of exposure leads to a higher internal dose of free BPA. OEHHA has on numerous occasions expressed concerns about over warning -- too many Proposition 65 warnings for trivial or no exposure circumstances. Over warning most certainly is a concern for trace amounts of BPA in food. Trace amounts of BPA in food also present important, significant, practical compliance problems because trace amounts of BPA are not easy to detect. For these reasons, the Beverage Associations request that OEHHA exclude from any "intentionally used" list those food or beverage products where BPA is only present at or below an established value in the range of 5 to 2 parts per billion.

Depending on the equipment one uses and the skill of people operating the equipment, one might find that it is not possible to detect BPA at or below 5 parts per billion ("ppb"), 2 ppb, or, in the case of highly specialized circumstances, below 2 ppb. Beverages in cans that utilize BPA in the manufacture of their linings can sometimes be evaluated and no BPA will be detected, and other times BPA might be detected in very small amounts.

A major ABA member spent over $350,000 during the past year to acquire a state-of-the-art Ultra High Pressure Liquid Chromatograph coupled to a Time of Flight Mass Spectrometer in order to test for the presence of BPA. Even with a well-trained technician, the limit of detection for this equipment is greater than 5 ppb. Accordingly, the Beverage Associations submit that OEHHA should only require that products testing at or above 5 ppb of BPA in the food or beverage be required to be placed in an "intentionally used" BPA list as a condition for safe harbor coverage.

In making beverages, most large manufacturers utilize at least 80 materials that warrant testing, in light of present circumstances, and for some manufacturers even more when considering possible multiple suppliers. Regular testing of these materials for BPA at a commercial laboratory would not be economically feasible because commercial laboratories charge in the neighborhood of $200 to $600 per sample, depending on the response time required and the laboratory. Moreover, commercial laboratories do not have sufficient capacity to process the number of samples a major food company needs to analyze.

The US Food and Drug Administration ("FDA") uses a liquid chromatography-mass spectrometry method to identify BPA in food. The FDA method has a limit of detection ("LOD") of 2 ppb to identify BPA in a wide variety of food products. Noonan et al. (2011) and other scientists from FDA's Center for Food Safety and Applied Nutrition ("CFSAN") employed this method to measure BPA concentrations in 78 "highly consumed canned foods."[2] The limit of quantitation ("LOQ") for this method is more than twice the LOD (2 ppb of BPA). While Noonan et al. (2011) did not specifically identify the LOQ in their study, they stated that food samples containing 2.6 and 4 ppb of BPA were below the LOQ. Thus, the LOQ for the method used by FDA must be at least 5 ppb.

Proposition 65 voters were told in the Official Ballot Pamphlet that the law would not take businesses by surprise. Imposing legal requirements at levels that cannot be detected by expensive, newly-purchased analytical equipment and that could not be quantified according to the method used by the FDA certainly would take businesses by surprise.

If OEHHA conditions the point of sale safe harbor warning for BPA upon the disclosure of "intentionally used" BPA in the product lining, OEHHA should at least exempt from that requirement products where BPA is not present in the food above the 5 to 2 ppb range.

OEHHA, as the lead agency to implement Proposition 65, has the authority to implement the law through regulations that further the purposes of the law. Cal. H&S § 25249.12(a). OEHHA has said in its Initial Statement of Reasons that inconsistent decisions by food companies concerning whether or not to provide a warning undermine the purposes of

[2] Noonan GO, et al. (2011) Concentration of bisphenol A in highly consumed canned food on the U.S. market. J Agric Food Chem 59:7178-7185.

Proposition 65. (ISOR at 11). One important potential inconsistency is the inconsistency that different companies may encounter in their efforts to determine whether BPA is present in their products. Another important inconsistency is what may arise if OEHHA implements this regulation in the low ppb exposure range where the presence of unintentional BPA in some foods likely is at roughly the same amount as low ppb BPA in foods where it was intentionally used in formulating the can lining. These inconsistencies may lead to different decisions concerning the provision of warnings. Exempting products where BPA only is present at or below the 5 ppb level, or some value close to that, would serve OEHHA's desire for consistent information in the marketplace in light of varying methods of detection and varying abilities to detect BPA.

Such inconsistencies will result in inaccurate and incomplete information being provided to California consumers, thereby undermining the purpose of Proposition 65. Avoiding such consumer confusion and uncertainty were some of the goals addressed by the creation of Section 12901, the former Proposition 65 method of detection regulation. As explained in the Final Statement of Reasons, that method of detection regulation was implemented to "facilitate compliance," "minimiz[e] confusion," allow businesses to “limit changes in their business activities to those necessary to comply,” and “minimize the possibility of different and conflicting interpretations of the Act. . . .” Section 12901 Final Statement of Reasons at p. 5 (Oct. 1989). Such goals still apply today. OEHHA should exercise its authority to implement a similar method of detection provision as an exemption to its proposed "intentionally used" requirement to similarly avoid such issues.

Moreover, exempting products with 5 ppb or less BPA, or some value close to that, presents no public health concern and is not in a range where a warning should be required. For example, 5 ppb of BPA in twelve ounces of a beverage would result in an exposure slightly less than 2 mcg of BPA. 2 mcg of BPA is well below an oral MADL extrapolated from OEHHA's dermal MADL of 3 mcg per day and adjusted for the internal dose resulting from ingestion rather than injection, taking into account the rapid conjugation of BPA following oral administration and the fact that only 1% of the BPA in human blood is unconjugated (free) following an oral dose.[3] That 2 mcg exposure also would be well below an oral MADL based on the Zhang HQ, et al. (2012) study,[4] if one were to consider that study of sufficient quality for risk assessment, which the Beverage Associations do not.

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[3] Thayer KA, et al. (2015) Pharmacokinetics of bisphenol A in humans following a single oral administration. Environ Int 83:107-15; Veiga-Lopez A, et al. (2014) Developmental programming: prenatal BPA treatment disrupts timing of LH surge and ovarian follicular wave dynamics in adult sheep. Toxicol Appl Pharmacol. 2014 Sep 1;279(2):119-28.
[4] Zhang HQ, et al., "Fetal exposure to bisphenol A affects the primordial follicle formation by inhibiting the meiotic progression of oocytes," (Mol Biol Rep. 2012 May;39(5):5651-7).

This approach to any "intentionally added" list would also promote public health by avoiding unnecessary alarm about the presence of trace BPA amounts in this range, which may also be found from the unintentional presence of BPA, and by making any "intentionally added" list more understandable, more manageable, and less unwieldy. Although the Beverage Associations strongly believe that the FDA has properly advised that the presence of BPA in US foods is not a reason for concern, certainly concern in the 5 ppb and below range is unwarranted. Exempting food in this range from the proposed "intentionally used" list also will advance public health because it will reduce undue pressure to substitute away from aluminum cans to other containers. Aluminum has the least impactful carbon footprint and waste disposal profile of available alternatives. CalRecycle reports that aluminum cans have about a 15% greater recycling rate than other containers, contain more than double the recycled content of those containers, and aluminum cans weigh considerably less, reducing fuel to transport.[5]

V. If OEHHA Adopts an "Intentionally Used" Safe Harbor Requirement, Several Changes Should Be Made

As explained above, we oppose the entire concept of differentiating "intentionally used" BPA from other sources of BPA; BPA is the same regardless of the source. If OEHHA does not accept the Beverage Associations' request that the "intentionally used" requirement be removed, we offer a few additional concerns regarding this requirement. First, we are concerned that the concept of what is and is not "intentionally used in the manufacture of the can lining" is not sufficiently clear and could be subject to litigation. We assume that OEHHA does not intend this requirement to capture can linings that are manufactured at a facility that uses containers lined with BPA to store ingredients, but where BPA is not an intended ingredient in the manufacture of the epoxy resin that forms the can lining. Yet, as presently drafted, we could envision that issue being raised by a plaintiff. Accordingly, we request that "in which bisphenol A was intentionally used in the manufacture of the can lining" be revised to read "in which bisphenol A was intentionally used as a monomer in the formulation of the can lining."

Second, if OEHHA rejects our primary comment and moves forward with the "intentionally used" list, proposed subsection (f)(1)(A)1.a.iv. should be revised. As currently drafted this proposed subsection assumes that the transition from BPA-based liners to BPA-NI liners (i.e., liners where BPA was not intentionally used as a monomer in the formulation of the can lining) will be a one-time flip of a switch for a particular product, but that is not how we

[5] CalRecycle, *Biannual Report of Beverage Container Sales, Returns, Redemption, and Recycling Rates* (May 9, 2016); CalRecycle, *Life Cycle Assessment of Polyethylene Terephthalate (PET) Beverage Bottles Consumed in the State of California* (Feb. 14, 2011); The Aluminum Association, *The Aluminum Can Advantage Key Sustainability Performance Indicates* (June 2016).

would expect the marketplace to work in certain important instances. Cans and other seals and liners for the California market are made in different facilities. One UPC of a beverage might be produced at any of five or more manufacturing facilities. Different facilities may acquire the capability to produce BPA-NI cans at different times. Different bottling companies have responsibility for cans in different regions of California. These variations, as well as current uncertainties in the long-term functionality of BPA-NI liners, mean that just one UPC for one particular type of beverage might have thirty or more production runs available for sale in California that alternately have some BPA-NI liners and some BPA-based liners. This is especially likely over the next several years as companies test and implement various BPA-NI linings. Thus, proposed subsection (f)(1)(A)1.a.iv should be revised to accommodate this marketplace reality.

This need to modify proposed subsection (f)(1)(A)1.a.iv to accommodate thirty or more entries for a single UPC, however, further underscores that OEHHA should not adopt the "intentionally used" requirement at all, or should at the very least exempt products with less than 5 ppb or so of BPA from the requirement. To do otherwise would generate an unwieldy list of products that easily could balloon to thirty thousand (30,000) or more entries just for the three largest members of the American Beverage Association alone. This reality reinforces an additional significant concern of the Associations, that OEHHA will not have the resources to properly maintain the list in a fair and up-to-date way. Even if OEHHA were to dedicate adequate resources to maintain this database, it is difficult to see how those resources would be justified, particularly for products with less than 5 ppb or so of BPA. The realistic prospect of 30,000 or more line entries just for three ABA members also highlights that the OEHHA proposed "intentionally used" list could become inherently misleading because it could well have substantially more entries from companies that have very low amounts of BPA in their products, leading some consumers to incorrectly believe that the products listed most frequently present the most significant concern. Ironically and misleadingly, the OEHHA "intentionally used" list could wind up being dominated or grossly overpopulated by the products that contain the lowest BPA levels and that are actively making substantial efforts to move away from BPA-based linings.

VI. OEHHA Should Revise the Proposed Regulation to Clarify that It Intends No Retroactive Application and to Create an Implementation Period

The current wording of the proposed new section 25603.3(f)(1) might be argued by some to impose retroactive requirements for warnings given between May 10, 2016 and the effective date of the proposed new section. The proposed new section purports to apply to all canned and bottled foods and beverages causing a BPA exposure and offered for sale after May 10, 2016, rather than only to exposures after some date on or after the effective date of the new, non-emergency regulation.

This appears to be a drafting issue rather than a substantive issue; we would be surprised if it were OEHHA's intent to change the rules retroactively for product sales that occur before this proposed non-emergency regulation takes effect. In order for OEHHA to correct this apparent drafting error, we request that OEHHA adopt the existing "emergency" version of section 25603.3(f) as part of the new non-emergency regulation and have it cover the time period from after May 10 to 60 days after the effective date of the newly adopted non-emergency regulation. We believe sixty days for companies to gather the necessary information to submit to OEHHA and to avoid a crunch over the holidays and at the end of the year would be more appropriate than implementation on or about January 1, for both impacted companies and for OEHHA.

We request that OEHHA have any changes to the current emergency regulation appear in a new section 25603.3(g) so that the safe harbor for 2016 product sales is maintained and any new standards are articulated in a new subsection (g) that would be clearly presented as only prospective. The existing proposed subsection (g) could then be re-lettered as proposed subsection (h).

VII. OEHHA Should Revise the Proposed Regulation to Clarify that It Does Not Intend To Exclude Other Clear and Reasonable Warnings

We request that OEHHA clarify that proposed regulation 25603.3(f)(1)(A) does not eliminate a person's right to provide a warning not described in the safe harbor section that otherwise complies with Section 25249.6 of the Act. As currently drafted, Section 25603.3(f)(1)(A) could be read by some to imply that the *only* permissible forms of Proposition 65 BPA warnings are the two warning mechanisms specifically provided for, namely, an on-product label or a notice at the point-of-sale (with the corresponding OEHHA "intentionally added" website), thereby eliminating the existing "clear and reasonable" warning mechanism provided for by statute. *See also* ISOR at p. 6 ("a manufacturer . . . who chooses not to affix a warning label for BPA exposures on its products must: provide the lead agency [] with a list of products . . . .").

OEHHA should clarify that nothing in the proposed regulations is intended to deny a person the right to avail themselves of the warning mechanisms that normally exist. Such a denial of a statutorily permitted warning mechanism would be inconsistent with the statute, inappropriate, and unjustified. Further, depriving a person of their statutory right to provide a "clear and reasonable" warning in whatever manner they chose and *requiring* them to use an agency-imposed safe harbor method would be a substantial departure from the existing warning process and from nearly thirty years of Proposition 65 precedent. Indeed, such a requirement would represent the first time the agency has attempted to dictate that there are only two possible "clear and reasonable" warnings and anything other than those warnings fails to meet Proposition 65 requirements. There is

no justification in the ISOR or in the relevant facts and circumstances at play for a conclusion that there are *only* two possible clear and reasonable warnings.

Therefore, in order to avoid confusion and a potential conflict with the statutory language of Proposition 65, we request the following addition to Section 25603.3(f):

> (6) Nothing in this Section shall be construed to preclude a person from providing a warning using content or methods other than those specified in Subsection (1) above that nevertheless complies with Section 25249.6 of the Act.

VIII. OEHHA Should Extend The BPA Safe Harbor Program by At Least Six Months and Should Remove or Revise the "Become Inoperative" Provision

Despite substantial efforts by major beverage companies and their suppliers to identify alternatives to BPA, members of the beverage industry have not yet identified a reliable BPA-NI lining that has been fully tested and that properly performs in all relevant respects. Thus, in order to avoid confusion and too many warnings, OEHHA should extend the point of sale warning program either at least six months further, to June 30, 2018 or until six months after the determination of a MADL. This extension also would better allow for sell through of most foods canned before or essentially at the same time as the May 2015 listing decision. OEHHA has stated in the Initial Statement of Reasons that many canned foods have shelf lives of up to three years and during the hearing on this proposed regulation that some canned foods have shelf lives even longer than three years.

Proposed section 25603.3(f)(5) states "This subsection shall become inoperative on December 30, 2017." The adoption of this language would not achieve what we perceive as OEHHA's intent. We are concerned that if this subsection is rendered inoperative on December 30, 2017, enforcement actions after December 30, 2017 will be able to argue that the safe harbor no longer exists to protect conduct that occurred prior to December 30, 2017. The safe harbor that OEHHA is proposing should not "become inoperative" until after all relevant limitation periods have expired.

IX. Significant Transition Efforts

During the September 12 public hearing on this proposed regulation, one speaker asserted that companies have been offering BPA free products for a long time, so there was no need to accommodate a marketplace transition away from the use of BPA technologies in can linings. That comment most certainly does not apply to the beverage industry. Important companies in the beverage industry have been working aggressively to pursue viable BPA-NI alternatives, including all of ABA's major members. ABA members have tested many different BPA-NI options in many different products, invested

significant internal resources and capital, and engaged all possible lining suppliers and can manufacturers concerning BPA-NI options that will not impact flavor and can integrity.

X. Conclusion

For the reasons stated above, the Beverage Associations respectfully request that OEHHA adopt the current emergency regulation as the non-emergency regulation, with the intent of revising the regulation when greater clarity on the MADL emerges. If OEHHA determines that it cannot implement this primary request, the Beverage Associations request that OEHHA at least adopt a commercially feasible method of detection exemption to the "intentionally used" requirement, permit such disclosures on the existing website that already is in place, and make the technical changes we suggest.

Respectfully submitted,

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