

OEHHA received formal comments on the proposed emergency regulations from the following groups and individuals:

1.	Agricultural Council of California (Ag Council)
2.	California Automatic Vendors Council (CAVC)
3.	Can Manufacturers Institute (CMI)
4.	Just Transitions Alliance Clean Water Action As You Sow Physicians for Social Responsibility – Los Angeles Environmental Law Foundation and Black Women for Wellness Center for Environmental Health (CEH)
5.	Natural Resources Defense Fund and Breast Cancer Fund (NRDC)
6.	Northern American Metal Packaging Alliance (NAMPA)
7.	Michele Reniche

CEH Coalition and NRDC/Breast Cancer Fund

Comment: CEH and NRDC state that the regulation should not be approved because OEHHA did not sufficiently justify that there is an emergency that calls for immediate action.

Response: The commenters cite Government Code 11342.545, which defines an emergency as a “situation that calls for immediate action to avoid serious harm to the public peace, health, safety or general welfare.” This proposed temporary regulation addresses an emergency meeting this definition. In the absence of this regulation, businesses will take inconsistent approaches to compliance, ranging from no warnings to ubiquitous warnings. Inconsistent warnings on similar or even identical products would confuse citizens on a topic of vital importance to them—food.

Contrary to the commenters’ arguments, consumers would not have clear choices between food and beverage products in BPA-containing and BPA-free packaging. Variations in language and interpretation of the warning requirement from one retailer or manufacturer to the next will cause more confusion than there would be if retailers and

manufacturers were permitted to temporarily employ a uniform point of sale warning to meet the new Proposition 65 requirements.

The temporary regulation is needed to avert a unique situation stemming from the fact that the BPA warning requirement will apply to a high percentage of the canned and bottled food and beverage supply in California. There is evidence that between 66 and 90% of canned foods contain varying levels of BPA.¹ Given the long shelf life of these types of products, some of them were likely manufactured prior to the listing of BPA in 2015. There is a real concern that variations in warnings on a vast array of canned and bottled foods in grocery stores throughout the state will create consumer confusion. And while there is always this risk when a new chemical gets listed, this situation is unique because of the volume of products that will be affected.

The only viable way to provide warnings for these products, absent the emergency regulation, is with shelf signs. Once these older products are no longer in the stream of commerce, OEHHA expects many newer products requiring warnings will have them on the label. The end of the emergency regulation and/or sunset of a temporary regulation will once again make canned and bottled foods and beverages subject to general Proposition 65 warning requirements. OEHHA is not aware of any instance in the history of Proposition 65 where the effective date of a warning requirement has resulted in a similar profusion of Proposition 65 warnings.

Comment: The proposed regulation does not address the emergency.

Response: The commenters state that “there is no evidence that signs at cash registers using OEHHA’s proposed generic and confusing language will in any way provide a clearer message to consumers than a straightforward warning label on or near products. To the contrary, to the extent they are even read by consumers, the proposed signs are likely to generate more confusion.” This statement is untrue.

In the absence of the proposed regulation, retailers would likely post dozens or hundreds of safe-harbor warning signs throughout their stores that would say:

“WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.”

¹ Study by FDA researchers published in 2011 found BPA in 91% of the canned foods sampled (Noonan GO, Ackerman LK, Begley TH. Concentration of bisphenol A in highly consumed canned foods on the U.S. market. *J Agric Food Chem.* 2011 Jul 13;59(13):7178-85. More recently, the BPA Buyer Aware reported BPA in about two-thirds of the cans sampled. (A Report by: Breast Cancer Fund, Campaign for Healthier Solutions, Clean Production Action, Ecology Center, Mind the Store Campaign, published March 2016. Available online at: <http://www.breastcancerfund.org/assets/pdfs/publications/buyer-beware-report.pdf> Similarly, a sampling of canned food conducted in 2010 in Dallas, Texas found 73 percent of canned foods contained BPA. The study was funded by the National Cancer Institute and Pfeiffer Research Foundation. Reference: Lorber, M., Schechter, A., Paepke, O., Shropshire, W., Christensen, K., and Birnbaum, L. (2015). Exposure assessment of adult intake of bisphenol A (BPA) with emphasis on canned food dietary exposures. *Environment International*, 77, 55–62. <http://doi.org/10.1016/j.envint.2015.01.008>

In comparison, the proposed regulation would provide for the following warnings to appear at the point-of-sale:

“WARNING: Many food and beverage cans have linings containing bisphenol A (BPA), a chemical known to the State of California to cause harm to the female reproductive system. Jar lids and bottle caps may also contain BPA. You can be exposed to BPA when you consume foods or beverages packaged in these containers. For more information go to: www.P65Warnings.ca.gov/BPA.”

The proposed regulation provides for a more informative and meaningful warning that identifies BPA by name, indicates it is present in can linings, jar lids and bottle caps, informs the consumer that they can be exposed to BPA when they consume the food or beverage, and provides the address for OEHHA’s website that has additional information on BPA.

The regulation addresses the emergency by providing consumers with a BPA warning that is clearer, more informative and more meaningful than would otherwise result.

Moreover, the commenters overlook the fact that there won’t be consistent and straightforward warning labels on or near the products under their scenario. The requirement goes into effect in about four weeks in thousands of stores across the state. Each business must determine for itself how to comply with the law, which gives them numerous options, as discussed in OEHHA’s notice. The record supports the obvious fact that they will, in fact, take inconsistent approaches. The commenters offer no explanation, and no factual support, for the notion that somehow consumers will see clear and consistent labels starting May 12.

Comment: CEH and NRDC also argue that OEHHA took too long to start this rulemaking process.

Response: The commenters argue that OEHHA has had almost one year since listing of BPA to develop a non-emergency regulation to address any special warning issues involving the chemical, and that therefore OEHHA lacks the justification for promulgating an emergency regulation. OEHHA disagrees with this comment.

As explained in its Notice of Emergency, OEHHA attempted to develop a Maximum Allowable Dose Level (MADL) for oral exposure to BPA. A MADL, identifies the level of exposure to a listed chemical that does not require a warning. Businesses often rely on safe harbor levels in making decisions whether they need to warn. OEHHA typically uses its safe harbor levels to gauge the possible impact of the warning requirement for newly listed chemicals.

OEHHA determined that it could not develop a safe harbor level for oral exposures to BPA because of complex scientific issues that may be resolved by current research expected to be completed in the next one to two years.

Once it became clear that it could not develop an oral MADL, OEHHA immediately began work on this regulation. In order for the provisions of the regulation to become effective in time for the May 11, 2016 warning requirement, the regulation must be

enacted through the emergency rulemaking process. OEHHA intends to follow with a regular rulemaking process to adopt a regulation for approximately a one-year period which should be sufficient for an orderly transition to more traditional warning methods and for the food industry to transition away from use of BPA where possible.

Comment: CEH and NRDC claim the proposed warning is not “clear and reasonable” because it would allow for placement at the point of sale, rather than on or near each of the canned food and beverage products that require a warning.

Response: The commenters appear to suggest that because the existing law and regulations *allow* product manufacturers to provide warnings on products or at the point of display of the product that these are the *only* clear and reasonable methods for providing a warning in this case. While both are common ways to provide the required warnings and are sanctioned by the regulations, neither of these methods is required by the law. Moreover, OEHHA concluded that in this case, the use of either of those warning methods is infeasible, due to the volume of products covered by the warning requirement, and the fact that so many unlabeled products are already in the stream of commerce. Given the wide prevalence of the use of BPA in the epoxy of can liners and bottle lids, thousands of individual products will be affected by the warning requirement. In order to relabel the canned and bottled foods at issue, the manufacturer would likely have to recall each item, relabel it and redistribute it to retailers. The most feasible approach to warning is for retailers to post dozens or hundreds of Proposition 65 warning signs on shelves where canned and bottled foods and beverages are displayed. As stated earlier, this profusion of warning signs would likely confuse and frustrate most consumers, defeating the very purpose of the warnings.

CEH’s reliance on the *Ingredient Communication*² case as authority for challenging this action is also misplaced. In that case, the Grocery Manufacturers Association developed a 1-800 telephone warning system. Consumers were not given *any* warning information until they called the number and asked about a specific product. The court in that case found that the warning system did not provide clear and reasonable warnings. The court instead found that the system, as applied, delivered less than 500 warnings to consumers over the course of a year, even though over 7,000 products were registered with the service. The court of Appeal stated:

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. An invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product.” (2 Cal.App.4th 1480, 1494).

But the warning proposed by OEHHA here is different than the system proposed by the Grocery Manufacturers Association in that case. It identifies two specific types of products (foods packed in hermetically sealed metallic or glass containers), identifies

² *Ingredient Communication Council, Inc. v Lungren*, (2009) 2 Cal.App.4th, 1480

the listed chemical (BPA), and explains the route of exposure (ingestion of food). Further, the warning would be placed at the point of sale where it is likely to be seen and understood prior to purchase of the products and, therefore, prior to exposure without requiring any action or effort on the part of the consumer. Unlike the situation in the *Ingredient Communication* case, the consumer here would not have to take any extra steps to be informed about the risk of exposure.

It should be noted that the other case cited by CEH, *American Meat Institute v. Leeman* (2009) 180 Cal.App.4th 728, was a case in which the court addressed whether a Proposition 65 point of sale warning was preempted by federal law. It did not address the question whether such a warning would be clear and reasonable for purposes of the act. Instead, the court compared a proposed warning to the federal statutory scheme to determine if it met the federal definition of “labeling” and was, therefore preempted. The court did not address the validity of providing warnings via this method under Proposition 65. In context, the court held that:

Thus, because (1) point of sale warnings are “labeling” within the meaning of the FMIA, and (2) there is no dispute that the warnings required by Proposition 65 are “in addition to, or different than” the labeling required by the FMIA (21 U.S.C. § 678), we conclude that the trial court properly ruled that Proposition 65’s point of sale warning requirements with respect to meat are preempted by the FMIA. “

Thus, the court assumed in this case that a point of sale warning was a valid method for providing the required warning and then compared the theoretical warning to the definition of “labeling”, finding that a point of sale warning was “labeling” for purposes of the federal law at issue. The case does not support CEH’s challenge to the proposed regulation.

Placing point-of-display signs throughout a facility at each location where an affected product is displayed would be unworkable given the number of products affected. Canned foods and beverages are located in many locations throughout a facility and their point of display may change frequently. For example, products currently on sale are often grouped together on endcaps or in other locations away from the normal canned food aisle. Refrigerated foods and beverages are similarly located in different locations from the canned food aisles. Placing and maintaining adequate signage at every point of display of a vast array of food product is infeasible. Further, if the regulation is not enacted, each food manufacturer, distributors and retailers would be responsible for providing a clear and reasonable warning for their products. If each business in the supply chain develops its own warning method and message content, there is a high likelihood that they will differ substantially from each other. As noted in OEHHA’s Notice, the sudden appearance of a multitude of different warnings for food products throughout a store would likely confuse consumers and cause them unnecessary concern. Clearly, the situation calls for a *temporary solution* that will provide the required warning in a manner that complies with Proposition 65, but that allows for an orderly and reasonable transition to the more typical Proposition 65 warning regimen.

The law requires that a business provide a “clear and reasonable” warning prior to exposure. In this case, the warning message proposed by OEHHA specifically identifies the types of products that are causing the exposure, names the chemical at issue, explains how the exposure occurs and provides a link to OEHHA’s website for more information. OEHHA has already posted 3 fact sheets related to BPA exposures to help consumers make informed decisions (attach copies). The warning is being provided to consumers prior to exposure to the listed chemical. This level of specificity meets the requirement of the law and is not, as CEH claims, an “invitation to inquire about a warning” in violation of existing case law. While a warning placed directly on a food product might be preferred by CEH, it is not required. It is simply one option for conveying the required information. In this case, as noted above, providing a uniform warning message at each point of sale is a clear, reasonable and feasible method for providing the required warning during the period in which manufacturer either move toward providing on-product labels, remove BPA from their products, or reduce exposures to BPA to levels that do not require a warning.

Comment: CEH and NRDC state that the proposed regulation lacks clarity.

Response: The commenters dismiss the regulation’s proposed safe harbor BPA warning as unclear when, as discussed above, it is actually demonstrably clearer and more informative than the conventional Proposition 65 warning. The commenters also argue that the proposed warning “provides consumers absolutely no information as to which products in any particular store could expose them to BPA.” While the proposed warning is general in nature, OEHHA disagrees that a plethora of BPA warnings all over retail stores if the regulation were not adopted would enable most consumers to determine which canned or bottled products may expose them to BPA, and which would not. Diligent consumers would have to search shelves to locate products that do not appear to be associated with any of the warning signs. It might be difficult to tell if there is truly no warning for a particular product or if a shelf sign somehow shifted or was moved away from that product. OEHHA believes that the proposed warning, while more general in nature, is clearer and more reasonable.

Comment: CEH and NRDC state that the proposed regulation is duplicative of existing law.

Response: OEHHA disagrees with this comment. The proposed regulation is intended to address a unique situation involving BPA warnings for canned foods and beverages. Nothing in statute or OEHHA’s regulations prohibit OEHHA from adopting regulations specific to warnings for specific products.

Comment: CEH, NRDC state that the provision in the proposed regulation allowing a retailer to correct a minor deviation such as the brief absence of a sign at the check-out is unreasonable and beyond OEHHA’s authority.

Response: Providing a limited opportunity to cure a minor violation of the proposed regulation is not beyond OEHHA’s authority. It is foreseeable that warnings in a high-traffic area within a retail facility might be damaged or fall down from time to time. Most facilities will have the sign posted in more than one location, so the absence of the sign

from a single check-out line will not likely result in the complete absence of signage. Providing an opportunity for a retailer who is substantially complying with the regulation to correct an inadvertent error will not encourage blatant violations of law, but will curtail filing of frivolous lawsuits or a brief absence of the required signage.

Michele Reniche of Manhattan Beach

Comment: The commenter objected to “checkout-only” BPA warnings, agreeing with the Center for Environmental Health that such warnings are inadequate, and the reasoning behind them is flawed, and noting that information on BPA’s risk should not be hidden from customers.

Response: The comment is noted and is addressed above in response to the Comments from CEH and NRDC.

North American Metal Packaging Alliance, Inc. (NAMPA)

Comment: NAMPA wrote in support of the emergency regulation, noting that “a point of sale warning is preferable to shelf tags that could result in multiple signs throughout a retail establishment”, and the impending enforcement deadline. NAMPA made no comment about or suggestions for change in the proposed language of the emergency regulation.

Response: OEHHA acknowledges the comment.

Comment: NAMPA expressed its opposition to the listing of BPA under Proposition 65, and urged the development of an oral MADL.

Response: OEHHA acknowledges receipt of these comments, and note they fall outside of the scope of the emergency regulation, and as such require no response.

Agricultural Council of California (Ag Council)

Comment: The Ag Council expressed overall support for the emergency regulation, discussing consequences on the food industry if emergency action is not taken, and referring to some of the discussion of issues in the April 1, 2016 Notice of Emergency Action in support of the regulation. The Ag Council also expressed support for the opportunity to cure “where signs will inadvertently be moved or fall down during regular retail activities”.

Response: OEHHA acknowledges receipt of these comments.

Comment: The Ag Council called for the addition of language to the warning to address other types of packaging besides can linings, jar lids, bottle caps that may contain BPA.

Response: While a large percentage of canned food products contain BPA with the attendant opportunity for confusion over the potential plethora of warnings during this transition period, the same does not appear to be the case for other types of packaging.

One study³ sponsored in part by the National Cancer Institute found in a sample of 204 canned, frozen and fresh foods that only 7% of the non-canned food contained BPA, and at low concentrations, in contrast to 73% of foods in cans. Further, there are a wide variety of food packaging materials available for non-canned foods that do not contain BPA so the prevalence of BPA in these other products is not clear.

Comment: The Ag Council noted that some food companies have moved away from BPA and the general store sign does not indicate that some companies no longer use BPA. This could discourage customers from purchasing healthy foods. It will not be feasible to add a label to products as BPA free for products already in the supply chain, and can be difficult to add labels to other BPA products in a timely fashion. To address this issue, the Ag Council requested the addition of the following language to the warning message:

“Some food and beverage packages no longer use BPA. Consumers are urged to follow up with food and beverage manufacturers to determine which products do not contain BPA.”

Response: First, the proposed language of the safe harbor warning already conveys this message in the first sentence by stating that “many” (not “all”) food and beverage cans contain BPA. Second, the proposed regulation requires that the authorized agent or trade association provide the retailer or its authorized agent the name or description of the canned or bottled foods or beverages for which a warning is being provided, such as a Universal Product Code or other identifying designation. This will enable the consumer to ask the retailer whether specific canned, jarred or bottle product contains BPA. OEHHA plans to commence a regular rulemaking process to adopt a regulation as an interim measure for a one-year period. During this process additions to the warning language or other methods for further addressing this issue will be considered.

In addition, OEHHA notes that this proposal came from a trade group representing farmers, rather than food and beverage manufacturers. OEHHA received no comments from food and beverage manufacturers expressing a commitment to provide information directly to consumers on BPA in their food packaging. Without such a commitment, it is not clear that consumers would be able to receive information from food and beverage manufacturers as the requested warning language implies. In its many years of responding to public inquiries about Proposition 65, OEHHA has routinely heard from members of the public who said businesses did not provide them with information they requested about the business’s Proposition 65 warnings.

Can Manufacturers Institute (CMI)

Comment: CMI objects to proposed language in 25603.3(f)(1)(B)(ii) requiring the manufacturers to provide the retailer with the name/description of the canned/bottled

³ Lorber, M., Schecter, A., Paepke, O., Shropshire, W., Christensen, K., and Birnbaum, L. (2015). Exposure assessment of adult intake of bisphenol A (BPA) with emphasis on canned food dietary exposures. *Environment International*, 77, 55–62. <http://doi.org/10.1016/j.envint.2015.01.008>

foods or beverages for which a warning is being provided, indicating it is burdensome and cannot be collected and distributed to retailers by May 11.

Response: By the time the BPA warning requirement takes effect on May 11, it will have been one year since the listing, which should be sufficient time for businesses to determine which canned and bottled food products cause exposures to BPA. The proposed emergency regulation provides a safe harbor method for warnings including affixing the warning to the product or providing a notice to the retailer or its agent about which products require warning, along with signage as needed. The responsible party can use either approach. Providing notice and signage to the retailer should be considerably less burdensome than recalling and individually labeling cans that are already in the supply chain.

This provision will enable retailers selling products for which warning is being given to provide the information to customers upon request.

Comment: CMI argues for the development of a MADL based on a particular study, the Delclos et al. 2014 study and urges the adoption of a MADL by the time the safe harbor warning regulation expires.

Response: Although this comment falls outside the scope of the emergency regulation, OEHHA notes that the discussion by the Developmental and Reproductive Toxicant Identification Committee that formed the basis for the listing of BPA does not support the establishment of the MADL proposed by CMI and others. The Proposition 65 exemption from the warning requirements requires the establishment of the level requiring no warning “based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing.” The CMI proposal is inconsistent with this requirement.

Comment: Many foods have already switched to BPA alternative coatings, but will be penalized by the signage requirements, leading to confusion. This will tarnish those products so long as signage appears at retail counters.

Response: This issue is addressed above in response to similar comments by CEH and NRDC.

California Automatic Vendors Council

Comment: The Council objected to “any requirement that each vending machine in the state display a warning sign about exposure” to BPA. They noted that there are hundreds of thousands of vending machines in California, any additional cost to the operators would “have a devastating effect on their bottom line”.

Response: First, in order for businesses to take advantage of the safe harbor for canned and bottled products containing BPA linings, products would either have to be labeled individually or the vending machine would have a warning sign. The proposed law requires the manufacturer, producer, packager, importer or distributor to provide the warning sign – which could also be printed from OEHHA’s website. Cost of the point of sale warning signs themselves are therefore expected to be minimal and will be borne

by the product manufacturers. The retailer has the obligation to post the sign. Signs can be posted and maintained when the machines are being stocked, at a minimal cost. The regulation provides a relatively seamless and efficient process for complying with Proposition 65.

Second, OEHHA cannot exempt whole sectors of businesses from complying with the law, which requires warnings to be provided when the business exposes a consumer to a listed chemical from a product at significant levels. If the business can show the exposure level falls below this level, warning is not required Health and Safety Code section 25249.10(c)). That option is also available to manufacturers.

Comment: Requiring these warning signs would expose vending businesses to legal action in the event the sign is removed from the machine without the operator's knowledge.

Response: The emergency regulation includes a provision for cure in such a situation as the short-term absence of a required sign, which is not the result of intentional neglect or disregard when it is corrected within 24 hours of discovery or notification. In addition there may be approaches for displaying warning signs from inside the vending machine that minimize such issues.