

**Final Statement of Reasons  
Title 27, California Code of Regulations**

**Proposed Amendment to Section 25603.3 Warnings for  
Exposures to Bisphenol A from Canned and Bottled Foods  
and Beverages**



**California Environmental Protection Agency  
Office of Environmental Health Hazard Assessment**

## General Background and Information

On May 11, 2015, bisphenol A (BPA) was added to the Proposition 65<sup>1</sup> list of chemicals known to cause reproductive toxicity. Effective May 11, 2016, warnings are required for exposures to BPA unless the person causing the exposure can show that an exposure 1,000 times the level in question has no observable effect<sup>2</sup>. Because canned and bottled foods and beverages have a longer shelf life and products manufactured before BPA was listed are still in the market, OEHHA promulgated an emergency regulation to allow temporary use of a standard point-of-sale warning message for BPA exposures from canned and bottled foods and beverages until warnings can be placed on newly manufactured cans and/or BPA is removed from the linings. This amendment to the regulations will continue this temporary safe harbor method for providing the warning at the point-of-sale until December 30, 2017, with certain changes.

OEHHA held a public hearing on this proposal on September 12, 2016. Fourteen oral comments were received. The written comment period closed on September 26, 2016. Nineteen written comments were received, some of which had numerous signatories. Several written and oral comments received during the regulatory process included objections to the listing of BPA, the proposed re-adoption of the emergency regulation related to exposures to BPA from canned and bottled foods, and observations about these regulatory amendments and other laws and regulations that do not constitute an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action. Also, many parties offered their interpretation of these regulations or other laws and regulations, sometimes in connection with their support of, or decision not to object to the regulations, which again does not constitute an objection or recommendation directed at changing the proposed action or the procedures followed in this rulemaking action. Accordingly, OEHHA is not required under the Administrative Procedure Act (APA) to respond to such remarks in this Final Statement of Reasons (FSOR). Since OEHHA is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, OEHHA does not provide responses to all of these remarks in this FSOR. However, the absence of responses to such remarks should not be construed to mean that OEHHA in any way agrees with them.

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<sup>1</sup> The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., commonly known as Proposition 65.

<sup>2</sup> Health and Safety Code section 25249.9 (c)

## Summary of comments and responses

Organizations and individuals providing comments are listed below.

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<b><i>Organizations</i></b>	
1	Agricultural Council et al
2	Beverage Associations
3	Breast Cancer Fund
4	Breast Cancer Fund – Katerina Robinson – Hearing comments
5	CALPIRG
6	CALPIRG – Jason Pfeifle – Hearing comment
7	Center for Environmental Health (CEH) et al.
8	Center for Environmental Health only
9	CEH– Corinne Smith Hearing comments
10	CEH – Emily Boone – Hearing comments – Reading statement from CEO of Bi-Rite Markets.
11	CEH – Lilly MacIver – Hearing comments
12	CEH – Isa Gaillard – Hearing comments – Reading statement of José Bravo, executive director of Just Transition Alliance.
13	CEH– Wynn timer Young – Hearing Comments
14	Californians for a Healthy and Green Economy (CHANGE) – Kathryn Alcantar – Hearing Comments
15	Can Manufacturers Institute (CMI)
16	Clean Water Action (CWA)
17	Clean Water Action – Adria Ventura – Hearing comments
18	Environmental Working Group (EWG)

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19	EWG letter with 3,300 signatures
20	EWG - Bill Allayaud – Hearing comment
21	EWG - Samara Geller – Hearing comment
22	Grocery Manufacturers Association (GMA)
23	GMA – John Hewitt – Hearing comments
24	North American Metal Packaging Alliance, Inc. (NAMPA)
25	NAMPA and CMI – Greg Hurner – Hearing comments
26	NRDC – Miriam Rotkin-Ellman – Hearing comment
27	Oriental Food Association
28	CA Legislators
<b><i>Individuals</i></b>	
29	Emily Boone
30	Raymond Chan
31	Honorable Senator Diane Feinstein
32	Alexis Gossage (The Food Mill, Inc.) Letter to Governor Brown
33	Chris Lish
34	July Neidich, Pediatrician and Geneticist (from EWG signature page)
35	Christine Szymanski (from EWG signature page)
36	Laura McLinn (from EWG signature page)
37	Natural Resources Defense Council and Breast Cancer Fund – this letter was sent with the subject line indicating the comments related to the extension of emergency regulation. However, the comments also address this rulemaking.

OEHHA has reviewed and carefully considered all of the comments in light of the statutory requirements, case law and regulations applicable to this rulemaking.

Comments are summarized and grouped and the responses follow. Commenters are identified by the corresponding number in the table above. Many commenters make the

same or similar comments and an exhaustive accounting of all commenters addressing the same point is not provided.

**1. Comment:** Commenters generally opposed the proposed regulation. (3, 7, 8, 10, 18, 19, 27,28, 29, 31, 32, 33) Commenter states that OEHHA should not adopt the proposed regulation and should repeal the emergency regulation. Commenters state proposed regulation does not accomplish Proposition 65's requirement of clear and reasonable warning about public health risks. (3, 5, 8, 9, 16, 18, 21, 28) Although OEHHA states that this situation is "unique", it is unlikely to prevent companies from trying to rely on this regulation in other situations. OEHHA admits that its purported justifications essentially apply to all chemicals in products at least for newly listed chemicals. (8) The proposed regulation does not address its original justification of avoiding consumer confusion. There is no evidence that signs at the cash register provide a clearer message to consumers than a warning label on or near the product. (8, 9). The 5x5 warning referencing "many cans" is not clear and reasonable. (7, 8, 10, 18) The intent and meaning of these signs has been lost. (5, 26) Commenters state that this regulation undermines consumer's right to know. (3, 5, 7, 8, 9, 17, 32) OEHHA has no authority to promulgate regulations that contradict the statute. By permitting vague warnings as proposed, OEHHA is exempting whole business sectors from Proposition 65. (8)

**Response:** The safe harbor point-of-sale warning sign set out in the proposed regulation provides significantly more information to consumers than the existing safe harbor Proposition 65 warning. It specifies the type of products that can cause an exposure, the chemical that triggers the warning and provides a link to a website where more specifics can be found such as fact sheets about the chemical and where a database of products where BPA was used intentionally in the manufacture of can linings and seals will be available once the regulation is effective.

OEHHA is not aware that the listing of that chemical caused a logistical problem on the scale of BPA. OEHHA concluded that with regard to BPA, the relabeling of existing stock is likely 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, many of which likely were manufactured prior to the listing of BPA in May 2015. While a warning placed directly on a food product might be preferred by the commenters, it is not required under Proposition 65. It is simply one option for conveying the required information. Absent this regulation, the most likely approach to warning would be for retail sellers to post dozens or hundreds of Proposition 65 warning signs on shelves where canned and bottled foods and beverages are displayed. As stated in the ISOR, this profusion of warning signs would likely confuse and frustrate

most consumers, defeating the purpose of the warnings and providing less information than is provided in the point-of-sale warning. No change to the regulations were made based on these comments.

**2. Comment:** Commenters request that this rulemaking treat BPA like cocamide DEA. Manufacturers should reformulate their products to remove the chemical, print warning on new products and provide stickers for products already in stock. (28, 14)

**Response:** OEHHA did not establish any specific warning requirements for cocamide DEA when it was listed. OEHHA is not aware that the listing of that chemical caused a logistical problem on the scale of BPA. OEHHA concluded that with regard to BPA, the relabeling of existing stock is likely 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, many of which likely were manufactured prior to the listing of BPA in May 2015. While a warning placed directly on a food product might be preferred by the commenters, it is not required under Proposition 65. It is simply one option for conveying the required information. Absent this regulation, the most likely approach to warning would be for retail sellers to post dozens or hundreds of Proposition 65 warning signs on shelves where canned and bottled foods and beverages are displayed. As stated in the ISOR, this profusion of warning signs would likely confuse and frustrate most consumers, defeating the purpose of the warnings and providing less information than is provided in the point-of-sale warning. No change to the regulations were made based on these comments.

**3. Comment:** Commenter states that BPA is linked with increased risk of breast cancer, even minuscule exposures can increase risks for breast cancer, prostate cancer, infertility, early puberty, metabolic disorders and type-2 diabetes. Some lab studies indicate BPA may interfere with breast cancer treatment drugs. (3, 4, 19, 29, 33). BPA is a known endocrine disruptive toxin. (11, 14) BPA's effects appear to be irreversible and may be transgenerational, that is, lead to epigenetic alteration in the germ line, impacting subsequent generations. (14) Three years ago there were about 225 studies that showed harmful effects of BPA and 25 almost all-industry studies that showed there was no harm. (20) BPA has been demonstrated to damage the early development of mouse fetuses. Should not allow pregnant women to be exposed unknowingly to BPA. (34)

**Response:** OEHHA appreciates the information provided by the commenter, however, this comment is not relevant to the proposed rulemaking. BPA has already been listed under Proposition 65 based on findings of female reproductive toxicity. This rulemaking

provides a safe harbor warning method and content for products that cause exposures to BPA.

**4. Comment:** Commenter states that a Stanford study shows a link between consumption of canned food and urinary BPA levels. (18) Changes in dietary intake can lower levels of BPA in humans by 60%. (3) Commenters state that packaging with BPA-based epoxy linings are likely the greatest source of human exposure to BPA. A 2007 EWG analysis showed Americans are exposed to BPA at higher levels than levels causing harm in animal studies. (18, 20)

**Response:** OEHHA appreciates the information provided by the commenter about the levels of exposure to BPA from canned foods, however, this comment is not relevant to the proposed rulemaking. BPA has already been listed under Proposition 65. This rulemaking provides a safe harbor warning method and content for products that cause exposures to BPA.

**5. Comment:** Commenters state that 67% of cans still have BPA, including 100% of Campbell's cans. (3, 4)

**Response:** OEHHA appreciates the information provided by the commenters concerning the prevalence of BPA, however, this comment is not relevant to the proposed rulemaking. BPA has already been listed under Proposition 65. This rulemaking provides a safe harbor warning method and content for products that cause exposures to BPA.

**6. Comment:** Commenters argue that information should be available to the public while comparing items on a shelf and should be product specific. (3, 4, 5, 8, 10, 11, 12, 16, 18, 20, 21, 29, 33, 37) Commenters state the new Article 6 regulations that become effective in 2018 will require product-specific warnings, this regulation should as well. (8, 16) Product-specific warnings are essential to protect consumers, especially pregnant women and children in critical windows of development. (20) There are too many distractions (candy, magazines) at the register and people should not have to leave products on the conveyor belt to find non-BPA ones. (35) Commenter states that even if companies put many signs on shelf, having to read through many labels for BPA is no different than living with food allergies and having to read all the ingredients in a product in order to avoid allergy triggers. (17)

**Response:** The law requires that a business provide a "clear and reasonable" warning prior to exposure to a listed chemical. In this case, the point-of-sale warning message provided in the regulation 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. While a warning placed directly on a food product might be preferred by commenters, it is not required by the law and would not be workable in this situation.

Placing shelf 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 provides the required warning in a manner that complies with Proposition 65, and that allows for an orderly and reasonable transition to the more typical Proposition 65 warning regimen. No change to the regulations was made based on these comments.

**7. Comment:** Commenters argue that the opportunity to cure provision gives unequal treatment to retailers and does not incentivize regulatory compliance. OEHHA provided no reason for this opportunity to cure. Commenters oppose it. (3, 7, 8, 9, 26, 37)

**Response:** OEHHA disagrees with the commenters. Providing a retailer with a 24-hour period to post a sign that has been lost or damaged is necessary and reasonable in this situation as it is foreseeable that warnings posted 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 point-of-sale will not likely result in the complete absence of signage at a given facility. OEHHA provided the reasons for this opportunity to cure in the ISOR, where it states that providing an opportunity for a retailer who is substantially complying with the regulation to correct an inadvertent error will curtail filing of frivolous lawsuits for a brief absence of the required signage. No change to the regulations was made based on these comments.

**8. Comment:** Commenters oppose the emergency readoption process. (5, 6, 16, 19, 26, 30, 31, 32) Alternatively, the commenter proposed that the emergency regulation sunset in October 2016; that amendments should be made to Proposition 65 and the DARTIC review practices to make the law and practices reasonable; and the oral exposure to BPA from food and beverages should be exempted from the warning requirement until an oral MADL can be established, or when there is sufficient evidence to support that food containers containing BPA are unsafe. In the meantime, OEHHA should issue a statement supporting the FDA position on BPA in food containers; thereby exempting the warning requirement for those containers. (30)

**Response:** OEHHA acknowledges receipt of these comments, and notes they are not relevant to this proposed action and as such require no response as part of this rulemaking.

**9. Comment:** Commenter states that the database of products where BPA is intentionally used in the manufacture of the can lining or seals makes information far more difficult for the public to access (5). The proposed database shifts the burden from manufacturers to the public. (21)

**Response:** The proposed database of products where BPA is intentionally used in the manufacture of the can lining or seals is simpler, clearer and more specific than having a multitude of signs posted throughout a retail facility. As was explained in the ISOR, it also addresses the fact that under the emergency regulation, manufacturers have provided retail sellers with exhaustive lists of products where BPA may or may not be present that are intended to be covered by the point-of-sale warning. Focusing consumers on products where BPA is intentionally used in the can linings or seals will help them identify those products that could cause significant BPA exposures. OEHHA believes that providing the public with a narrower list of products where BPA is intentionally used will provide consumers with more meaningful choices about potential exposures to this chemical. The database does not shift the burden from manufactures to the public. Manufacturers are still responsible for providing the point-of-sale signs to retailers and for providing the information to the retailers concerning the products for which the warning is provided. They must also provide information to OEHHA regarding cans and bottles where the linings or seals were manufactured with BPA for posting on the OEHHA website, if they intend to take advantage of the temporary safe harbor point-of sale-warning provided by this regulation. No change to the regulations was made based on these comments.

**10. Comment:** Commenters state that vague warnings contribute to criticisms of Proposition 65 itself, weakening the underpinnings of the law. (5, 7, 21) In the last 4

years, commenters have had to repeatedly defend Proposition 65 from legislative proposals that would weaken it. (7)

**Response:** OEHHA disagrees with the implication that the point-of-sale warning is vague. The point-of-sale warning 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. This is more informative than the current safe harbor. The second part of the comment is not relevant to this rulemaking and requires no response. No change to the regulations was made based on these comments.

**11. Comment:** Commenters state that the proposed regulation will delay industry's transition to safer products. Industry has had sufficient time to transition, for example, Eden Foods has transitioned. No BPA was found in Eden's cans when tested. By the end of the emergency regulation, the food industry will have had 6 months more to transition than others have ever been given under Proposition 65. (7, 16, 18, 19, 21) The 6-month extension undermines the compliance with the warning requirements and should be removed. (26) Companies have been selling BPA-free products for a long time. (20)

**Response:** Although some manufacturers have transitioned to BPA-free products, as was stated in the ISOR, recent studies found that between 66 and 90 percent of canned foods contain varying levels of BPA. Given the long shelf life of these types of products, some products that are currently on store shelves were likely manufactured prior to the listing of BPA in May 2015. Without this temporary regulation (or the emergency regulation currently in effect), the most probable way warnings would be provided would be for retail sellers to post a shelf sign for each food and beverage product requiring a warning. For a typical supermarket, this would involve hundreds of shelf warning signs throughout the store where canned and bottled products are on display. The sheer number of warnings, along with variations in warnings on a vast array of canned and bottled foods in supermarkets throughout the state, would create consumer confusion.

Further, OEHHA believes that the new requirement that manufacturers provide information about products where BPA was intentionally used in the manufacture of the can linings or seals will incentivize the industry to move away from the use of BPA in their products more quickly than they would do otherwise in order to avoid having the products identified on the OEHHA website. No change to the regulations was made based on these comments.

**12. Comment:** Commenters state that this regulation sets a bad precedent for innovation under Proposition 65 and the Green Chemistry Initiative. (7, 18, 19, 21)

**Response:** OEHHA disagrees. This regulation provides a temporary solution to an unprecedented problem. As was stated in the ISOR, once older products are no longer in the stream of commerce, OEHHA expects many newer products requiring warnings will have them on the label. At the same time, OEHHA is aware that many food manufacturers are working towards substituting away from BPA in can linings and seals. The sunset of this temporary regulation in January 2017 will once again make canned and bottled foods and beverages subject to general Proposition 65 warning requirements. No change to the regulations was made based on these comments.

**13. Comment:** Commenter states warning should be provided in languages spoken by California communities. (7, 16)

**Response:** OEHHA acknowledges the comment. However, due to the temporary nature of this regulation, adding a requirement to provide warnings in several languages could be difficult to accomplish in the short period of time in which the regulation is effect. OEHHA has encouraged the voluntary use of alternative language warnings by providing warnings on its website in 9 languages. Requirements for warnings to be provided in alternative languages is addressed in the new Article 6 warning regulations that will become fully effective in 2018. No change to the regulations was made based on these comments.

**14. Comment:** Commenter states the proposed regulation undermines CalEPA's commitment to Environmental Justice, resulting in the disproportionate burden of harm on low income communities. The Supplemental Nutrition Assistance Program (SNAP) demonstrated that higher BPA body burdens are negatively associated with lower income. The vague warnings could cause low income families to avoid all canned foods because of not knowing which have BPA. (7, 12, 16, 18) Not everyone has access to smartphones and the internet, there is a digital divide. (7, 8, 9, 13, 16, 17, 18, 21) OEHHA's proposed regulation disregards Environmental Justice requirements [Government Code] section 65040.12, fair treatment code [sic], and federal Executive Order 12898. Over 30% of all fruit consumed by SNAP and WIC programs is canned, compared to 25% for other households. Almost 40% of vegetables as opposed to 31% of other households. BPA body burdens are higher in lower income people. (7, 12)

**Response:** Proposition 65 does not limit or ban the sale of products containing BPA in canned food products. OEHHA cannot do so by regulation. Instead, the regulation allows food manufacturers to provide the required warning to consumers, regardless of

income, at the point-of-sale of the products. The additional information available on the OEHHA website is supplemental to the warning. It is available to anyone with access to a computer or smart phone. Reduction of exposures to a listed chemical is not required in order to comply with Proposition 65, though it is a laudable goal and a common result of the law. This regulation does not treat low income individuals differently than others. All consumers receive the same warnings. No change to the regulations was made based on these comments.

**15. Comment:** Commenters state that CEH's survey found that in 6 retail locations, 67% of shoppers who might not have access to a smartphone stated a BPA warning on a can would be an important factor in their decision to purchase. Consumers should have access to information before purchase, not at home on the internet. (7, 9, 37) Any information provided online should be in addition to, not in place of, product specific warnings. If OEHHA develops a database of food and beverage products that contain BPA, recommend that any information on the website should have requirements for accuracy and should be updated. (7, 16) Busy consumers won't have time to consult the OEHHA website in store. (9)

**Response:** While a warning placed directly on a food product might be preferred by the commenters, it is not required. It is simply one option for conveying the required information. 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, the most likely approach to warning would be for retail sellers to post dozens or hundreds of Proposition 65 warning signs on shelves where canned and bottled foods and beverages are displayed. As stated in the ISOR, this profusion of warning signs may confuse and frustrate consumers, defeating the purpose of the warnings. The additional information available on the OEHHA website is supplemental to the warning. It is available to anyone with access to a computer or smart phone. No change to the regulations was made based on these comments.

**16. Comment:** Commenters argue that there is minimal cost to labeling specific canned products. (7, 17) Confusion regarding older versus newer products and a sea of shelf tags can be avoided with updating labels. A study commissioned by Just Label It shows label updates are carried out without a rise in food prices. Permanent, adhesive, peel-and-stick warning labels can be placed directly on the product and are available for retailers. Labels could be printed with pack date, sell-by, or other date system as is required for OEHHA's database. (18) Commenter states that if product information is available to give to OEHHA, then it could easily be used to create product-specific warnings. (8) Commenter supports on-product label. (31, 37)

**Response:** Given the wide prevalence of the use of BPA in can liners and bottle seals, thousands of individual products are affected by the warning requirement. Proposition 65 does not require on-product labels; it is simply one option for providing a warning. Absent this temporary regulation, the most likely approach to providing the warning would be for retail sellers 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 may confuse and frustrate consumers, defeating the purpose of the warnings. No change to the regulations was made based on these comments.

**17. Comment:** Commenters state this regulation shields industry. (8, 9, 12, 16, 18, 26, 37) OEHHA is trying to justify the proposed regulation on the grounds that it will reduce the burden of compliance for industry. (8) OEHHA is clearly protecting industry in violation of the intent of Proposition 65. (8) Commenter states the proposed regulation places manufacturers need for more time to comply above the needs and wants of citizens to protect themselves. (18, 21)

**Response:** OEHHA disagrees. This regulation provides a temporary safe harbor for food manufacturers to provide a point-of-sale warning for exposures to BPA from canned and bottled foods. It does not allow businesses to avoid providing a warning. In addition, this regulation requires the industry to provide more information to consumers than would normally be provided using the existing safe harbor Proposition 65 warnings, namely, the type of product that could cause an exposure, the chemical that triggers the warning and a link to the OEHHA website where more specific information can be found such as fact sheets and a future database containing a list of products where BPA was used intentionally in seals and can linings. OEHHA believes this regulation furthers the purposes of Proposition 65 by providing consumers with this information. No change to the regulations was made based on these comments.

**18. Comment:** Commenter cites *American Meat Institute v. Leeman* – stating “case law has discussed the importance of designing warnings to identify the specific consumer product that is the subject of the warning” and “point-of-sale warnings must be designed to effectively communicate to consumers that the specific product targeted by the warning is a carcinogen or a reproductive toxin”. (8)

**Response:** *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. No change to the regulations was made based on these comments.

**19. Comment:** Commenter points to statements in the ISOR for the new Article 6 Warning regulations that go into effect in 2018, to support their opinion that providing information to OEHHA for the website is not a substitute for a clear and reasonable warning. The commenter cites *ICC v. Lungren* and states that this regulation contradicts that statement by OEHHA. (8, 9, 37)

**Response:** In *Ingredient Communication*<sup>3</sup>, 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).

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<sup>3</sup> *Ingredient Communication Council, Inc. v Lungren*, (2009) 2 Cal.App.4th, 1480.

The warning being provided through this temporary regulation 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 the listed chemical (BPA), and explains the route of exposure (ingestion of food). Further, the warning is being 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. OEHHA believes the regulations fully comply with the provisions of Proposition 65. No change to the regulations was made based on these comments.

**20. Comment:** Commenter states that OEHHA's "consumer confusion" justification is invalid because the same situation exists for every chemical subject to Proposition 65. (8)

**Response:** OEHHA believes that this situation is unprecedented because of the sheer volume of products involved. Given the wide prevalence of the use of BPA in can liners and bottle lids, and the long shelf life of these products, thousands of individual products are affected by the warning requirement. The most likely approach to warning is for retail sellers to post dozens or hundreds of Proposition 65 warning signs on shelves where canned and bottled foods and beverages are displayed. It is this profusion of warning signs that would likely confuse and frustrate most consumers, defeating the purpose of the warnings. No change to the regulations was made based on these comments.

**21. Comment:** Commenter states that the absence of a MADL is not justification for the proposed regulation since OEHHA has only established MADLs for 2 dozen chemicals out of 300 listed. Proposition 65 does not discuss regulatory safe harbor levels; it puts the burden on businesses to determine one. (8)

**Response:** While it is true that many listed chemicals do not have safe harbor numbers adopted by OEHHA, the unavailability of a safe harbor at this time means that a large number of products that contain BPA in the packaging at measurable levels are already in the stream of commerce and will be on the shelves for a significant period of time and likely require a warning. Therefore, OEHHA believes a temporary approach to providing warnings at the point-of-sale is appropriate in this circumstance. No change to the regulations was made based on these comments.

**22. Comment:** Commenter states that the three regulations [emergency regulation, new Article 6 warning regulations, and this regulatory proposal] presented in the hearing [on October 12, 2016] adds too much confusion to the regulated community. (14)

**Response:** OEHHA acknowledges the comment and notes that there is only one regulation being proposed in this regulatory action. Separate comment periods and responses to those comments were provided for the other actions.

**23. Comment:** Commenter supports the continuation of the warning sign program in 2017. (15, 24)

**Response:** OEHHA acknowledges receipt of the comment.

**24. Comment:** Commenter looked for warnings in stores but could not easily find them. General warnings are not being enforced as well as they need to be. (17)

**Response:** OEHHA does not have the authority to enforce Proposition 65<sup>4</sup>. In the event stores are not providing a point-of-sale warning or otherwise complying with the warning requirements of Proposition 65 and are causing exposures to BPA from their products, the law can be enforced by members of the public or the Attorney General, county prosecutors, and some city attorneys. This comment is beyond the scope of the rulemaking. No change to the regulations was made based on these comments.

**25. Comment:** Commenter states that the comments on EWG's Facebook page since EWG's *BPA Bombshell* report was published show that most people are disheartened, confused and misinformed; they want explicit information. (18) The warning desensitizes the public. (21)

**Response:** OEHHA believes that the point-of-sale method provides a clear and reasonable warning for exposures from the wide variety of canned and bottled foods that can cause exposures to BPA. OEHHA believes the public is less likely to be confused or desensitized by the point-of-sale warning than they would be if a plethora of signs were to be posted all over the stores. No change to the regulations was made based on these comments.

**26. Comment:** Commenters state that the proposed regulation penalizes manufacturers that have made transitions. (18, 21, 32)

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<sup>4</sup> Health and Safety Code section 25249.7(c)

**Response:** This regulation provides a voluntary safe harbor approach for warnings for exposures to BPA from canned and bottled foods. It only applies where a manufacturer has decided to provide a warning. It does not prevent companies from letting consumers know that their products are packaged without BPA. No change to the regulations was made based on these comments.

**27. Comment:** Commenter asks if it will be clear on the website what term is used on product – use-by, sell-by, etc.? (21)

**Response:** OEHHA will post the product specific information received from manufacturers. Where the manufacturer has discontinued use of BPA, it can provide a “sell-by” or “use by” date for inclusion in the database so consumers will know when the chemical is no longer used in the food packaging. This will be explained on the website. No change to the regulations was made based on these comments.

**28. Comment:** Commenter states that alluding to jar lids and bottle caps is insufficient. There are other containers that have BPA. (21) OEHHA should clarify the scope of products covered. Make it clear that it also covers containers of any material that use metal lids or sidewalls. OEHHA should clarify in the statement of reasons that “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. (22)

**Response:** The regulation expressly applies only to “foods and beverages packaged in hermetically sealed, durable metal or glass containers, including, but not limited to, those containing fruits, vegetables, soups, pasta products, milk, soda, and alcoholic beverages.” (Section 25603.3 (f)(3)) OEHHA declines to expand the scope of the regulation as suggested by the commenter.

**29. Comment:** Commenter states that the information generated by the proposed provision for identification of those products canned with BPA containing linings and the planned database could potentially be very useful in helping some consumers – those able to access or use the technology – make more informed choices by improving their ability to search for information. (37)

**Response:** The comment is noted. The intent of the OEHHA website database is to provide consumers with access to information that can help them make informed choices.

**30. Comment:** Commenter states the proposed regulation is bad for businesses who put customers first because it does not give businesses appropriate tools to be fully transparent with customers. Without labels on products, consumers and staff cannot know which cans may or may not contain chemical. Staff has been “commonly” questioned on this. (10, 32)

**Response:** This regulation requires food manufacturers to provide information to retailers about the products intended to be covered by the point-of-sale warnings. The point-of-sale warning provides more information than is provided in the current Proposition 65 warning. Further, under the new provisions of this regulation, information will be available through the OEHHA database of products where BPA was intentionally used in the manufacture of the can linings or seals. No change to the regulations was made based on these comments.

**31. Comment:** Commenter states that not only is BPA linked to the breast cancer epidemic, its replacement, BPS, has been approved as a replacement using a special breed of rats with immunity to estrogenic effects. Both BPA and BPS are dangerous. (36)

**Response:** This comment is beyond the scope of this rulemaking and requires no response. OEHHA is aware that manufacturers are investigating a number of different materials for potential use as a replacement for BPA.

**32. Comment:** Commenters support Food and Drug Administration (FDA) statement that BPA is safe in packaging. (22, 30)

**Response:** OEHHA acknowledges the comments. As was stated in the ISOR, OEHHA acknowledges that BPA is approved by the FDA for use in food-contact application including food and beverage can linings and seals, except for baby formula.<sup>5</sup> Nevertheless, BPA can migrate from the can lining into the food or beverage, resulting in exposures to varying amounts of BPA. Such exposures may still be subject to the warning requirements of Proposition 65 even where use of the chemical in food packaging is approved by FDA. No change to the regulations was made based on these comments.

**33. Comment:** Commenters expressed concerns with the proposed requirement to provide information to OEHHA identifying products where BPA is intentionally used in the manufacture of the can lining or bottle seals, which will be posted on the OEHHA website. The commenters argue that the requirement would provide no new information

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<sup>5</sup> Title 21, Code of Federal Regulations, section 175.300

that is not already publicly available and may cause confusion. The regulation will sunset in December, 2017 and the OEHHA intentionally added list will become unnecessary and misleading where products no longer contain BPA. (1, 2) Commenter remains opposed to the listing of BPA under Proposition 65 and opposes the warning sign program that requires food and beverage manufacturers to report to OEHHA a list of products in which BPA was used in the manufacture of the can lining, jar or bottle seals. (25)

**Response:** As is stated in ISOR, it is anticipated that manufacturers will continue to reduce or eliminate exposures to BPA from canned and bottled foods and beverages over the next year or begin transitioning to on-product labeling for those products where BPA cannot be substituted out. OEHHA anticipates that fewer and fewer food products will require warnings over time and it will be easier for consumers to differentiate products that cause exposures to BPA since warnings will eventually be provided on the product labels or near the products on shelf tags or signs. OEHHA agrees that once the proposed regulation expires, the list of products where BPA is intentionally used may become unnecessary. OEHHA will discontinue the list at that time. The remaining comments are not relevant to this rulemaking. No change to the regulations was made based on these comments.

**34. Comment:** The proposed regulation would lead to over-warning (2). Posting the information on the OEHHA website implies that viable alternatives exist for the listed products, that intentionally used BPA is more concerning than other exposures to the chemical, suggests that all levels of BPA exposure are of toxicological importance (2), and that consumers may not check it to see if lists have been updated. (2)

**Response:** As is stated in the ISOR, OEHHA is aware that some product manufacturers and distributors, out of an abundance of caution, may be providing potentially overbroad lists of products that may contain BPA to retail sellers under the provisions of the emergency regulation. They may provide these lists without actual knowledge that the products do or do not cause exposures to BPA. OEHHA is also aware that some tests of food products may show false positive results for BPA due to laboratory cross-contamination or analytic interference issues. However, not all test protocols suffer from these issues. Therefore, OEHHA believes that the current lists of products being provided to retail sellers may be over inclusive.

OEHHA encourages businesses to refine the data on which they are relying for providing notice to retailers. Overbroad lists of products that contain BPA can cause confusion and, in some cases, unnecessary concern about BPA exposure. OEHHA therefore encourages the use of more accurate and tailored lists in the future. As stated above, the provision for manufacturers to provide OEHHA with a list of products where

BPA is intentionally used in the manufacture of the can linings or bottle seals is an attempt to address the potentially overbroad list of products provided to retailers and to provide a means to let consumers know which products are more likely to expose them to BPA.

OEHHA has met with a number of businesses over the past several months and is aware that some companies have moved to alternative can linings and bottle seals. While this transition can take time and suitable alternatives may not be available for all types of products, there are alternatives available for many products. OEHHA plans to provide contextual information with the BPA intentionally added list on its website to help consumers understand these issues.

It should be noted that the OEHHA website is not a vehicle for providing warnings for BPA exposures to consumers. The information on the website is supplemental to the Proposition 65 warning which is being provided on the point-of-sale signs posted at retail stores. The website list is supplemental information and will be updated regularly. If consumers do not check it to see if the databases has been updated, the warning is still being provided at the point-of-sale. No change to the regulations was made based on these comments.

**35. Comment:** Commenters state the intentionally added list is inconsistent with the Proposition 65 mandate and claim it imposes unnecessary resource burdens on industry and government. (15, 22, 23, 24, 25)

**Response:** The list of canned and bottled foods where BPA was intentionally used to manufacture the can lining or seals is not inconsistent with Proposition 65 because consumers are not receiving the warning from the OEHHA website. The warning is being provided on the signs posted at the point-of-sale. As is stated in the ISOR, the OEHHA database only provides supplemental information so interested customers can learn where BPA is intentionally used in can linings, jar lids or bottle seals for food products. It is not a substitute for the warning required under Proposition 65.

The proposed regulation is not imposing resource burdens on industry and government. The regulation provides an optional safe harbor for businesses and helps businesses comply with Proposition 65 by providing a reasonable balance between the cost of relabeling food products and the necessity for providing a clear and reasonable warning to consumers about exposures to BPA from these products. The industry has already created lists of products they intend to be covered by the warnings as required by the related emergency regulation. This regular rulemaking simply requires businesses to provide OEHHA with a subset of these lists that identify the products where BPA is

intentionally used in the manufacture of the can linings or bottle seals. Creating and maintaining a database is not a significant resource burden for OEHHA because the information will be provided by industry and will simply be compiled and displayed on the website. The warning website has already been created. Uploading the information required under this regulation into a database for posting on the website does will not require significant new resources or an inordinate amount of time. No change to the regulations was made based on these comments.

**36. Comment:** Commenter states that any information about products where BPA is intentionally used in the can lining or bottle seals should be added to the BPA product website ([www.Prop65bpa.org](http://www.Prop65bpa.org)), which was developed by the GMA and other business organizations to collect information for retailers about the products manufacturers intend to cover with the point-of-sale warning [as required by Section 25603.3(f) of the emergency regulation]. (2) Commenters state that a list is already available and provided to all retailers in California. It's a list of products manufacturers intend to provide a warning for. The new OEHHA database would only be a subset of the existing one. (22, 24) By requiring two lists, OEHHA is violating the law, increasing its workload while demanding industry report the same information to two entities. (24)

**Response:** As was stated in the ISOR and in response to earlier comments, OEHHA believes that the current lists of products on the GMA-sponsored website being provided to retail sellers may be over-inclusive. Manufacturers and distributors, out of an abundance of caution, may be providing overbroad lists of products that may contain BPA to retail sellers without actual knowledge that the products do or do not cause exposures to BPA.

OEHHA encourages businesses to refine the data on which they are relying for providing notice to retailers. Overbroad lists of products that contain BPA can cause confusion and, in some cases, unnecessary concern about BPA exposure. No change to the regulations was made based on these comments.

**37. Comment:** Containers where BPA is intentionally used in the can linings or seals may or may not cause higher exposure to BPA. OEHHA should provide a link to the existing industry database on its website. (22, 24) Existing database should be enough for next 12 months. (23, 24) BPA has been found in food packaged in materials that did not have BPA intentionally added, so products not listed on the OEHHA database could still result in exposure to BPA. Therefore, the database will provide no benefit to the consumer looking for information about potential BPA exposure. (24)

**Response:** Requiring manufacturers to provide OEHHA with information concerning products where BPA is intentionally used in the can linings or bottle seals will help

interested consumers focus on those products where BPA exposures are more likely to occur. This furthers the purposes of Proposition 65 by providing consumers with information they can use to make informed choices about the products they purchase. The two lists are different. The list provided to retailers is a list of products the manufacturers intend to be covered by the point-of-sale warnings which could include products where BPA is an unintentional contaminant or may not even be present. The OEHHA website list is a subset of that information and would only include those products where BPA was intentionally used in the manufacture of the can linings or seals. Products for which BPA is intentionally used but does not cause exposure do not require warnings, and no safe harbor is needed. Manufacturers need only provide OEHHA information for those products to be covered by the safe harbor warning. No change to the regulations was made based on these comments.

**38. Comment:** Commenters would support voluntary effort where companies that transitioned to non-BPA linings and seals identify themselves and OEHHA could provide a link so public could see this information, which would be more helpful to consumers. (1, 23, 24, 25)

**Response:** OEHHA has and continues to encourage businesses to provide the public with such lists. However, OEHHA has not received any comprehensive list of such products or links about products where BPA is not used. If sufficiently reliable information becomes available, OEHHA may link to it on its website. However, this regulation is focused on implementing the warning requirements of the Act, not those products that do not require a warning. No change to the regulations was made based on these comments.

**39. Comment:** OEHHA should adopt the existing language in the emergency regulation without modification and advise all parties of its intent to revise the regulation within six months of the adoption of after a MADL for oral exposure is adopted for BPA. (2)

**Response:** This regulation is being proposed as a temporary measure to address a unique situation stemming from the fact that the BPA warning requirements applies to a high percentage of the canned and bottled food and beverage supply that was produced prior to the listing of BPA. This regulation allows for an orderly and reasonable transition to the more typical Proposition 65 warning regimen. The purpose of this regulation is not to provide a safe harbor for warnings for BPA exposure from these products until a MADL for oral exposure is developed. OEHHA is not required to adopt a MADL for oral exposures to BPA. The adoption of a MADL is a separate regulatory process. OEHHA is waiting for additional scientific research to be completed before deciding whether or not to propose a safe harbor level for oral exposures of BPA.

**40. Comment:** Commenter states that BPA is ubiquitous and opposes the entire concept of differentiating “intentionally used” BPA from other sources; BPA is the same regardless of the source. If the “intentionally used” requirement is not removed, the commenter requests 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 2 to 5 parts per billion. The FDA method of detection has a limit of detection (LOD) of 2 ppb. Noonan et al. (2011) stated that food samples containing 2.6 and 4 ppb were below the limit of quantitation. Commenter also states that depending on lab equipment used and the people operating the equipment, it’s not possible to detect BPA below this range.

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 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.” Inconsistent detection by businesses may lead to different decisions by businesses about whether to provide warnings or not. Exempting products where BPA is below 5 ppb would serve OEHHA’s desire for consistent information in the marketplace in light of varying methods of detection and abilities to detect BPA. (2)

**Response:** OEHHA declines to amend the regulation as requested. Methods to detect BPA in a wide range of foods with a limit of quantitation (LOQ) of 0.5 ppb have been available from at least one commercial laboratory, Covance, since 2010. In describing its BPA method, Covance indicated the method was adapted from one used by Health Canada. Covance’s on-line Directory of Services offers analyses of BPA in ‘various food matrices’, and indicates the LOQ is 0.5 ppb for infant formula, and LOQ varies by sample matrix. When contacted by phone, Covance stated that the LOQ for BPA in other foods, including beverages, gravies, tomato sauce, and green beans, was 0.5 ppb.

BPA is not ubiquitous in foods. One study 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 when it was found in non-canned food, it was present at low concentrations. This same study found BPA in 73% of the canned foods. Thus BPA was not detected in more than one quarter of the canned foods tested, and was infrequently detected in non-canned foods. It should be noted that warnings are only required for knowing and intentional exposures to listed chemicals.

OEHHA will separately consider issues related to the limits of detection and quantitation for BPA, but declines to establish a LOQ or LOD in this regulation.

**41. Comment:** Commenter states that exempting products with 5 ppb or less presents no public health concern. For example, 5 ppb of BPA in 12 oz. of a beverage would result in an exposure slightly less than 2 micrograms, which is well below an oral MADL extrapolated from OEHHA's dermal MADL of 3 micrograms 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. That exposure would also be well below an oral MADL based on the study of Zhang HQ et al. (2012). The 5 ppb and below range will avoid the pressure to substitute away aluminum cans which have the lowest carbon footprint and waste disposal profile. (2)

**Response:** As noted in response to the previous comment, OEHHA will separately consider issues related to the limit of detection for BPA, but declines to establish a LOD in this regulation.

OEHHA notes that 5 ppb BPA is an order of magnitude greater than the LOQ for BPA in most foods by a well-known commercial laboratory, using commercially available analytical testing methods.

The level of exposure to BPA from consumption of a particular food or beverage product is a function of both the level of BPA in the product in question, and the amount of the product that is consumed per day. Because the amount of a given food or beverage product consumed per day differs, depending upon the specific product (e.g., soda versus green beans), the commenter's suggestion to exempt products containing up to 5 ppb BPA would result in differing levels of exposure to BPA across different food and beverage products.

Businesses subject to Proposition 65 are required to provide a warning if they cause exposures to chemicals listed as causing birth defects or reproductive harm when those

exposures exceed one one thousandth (1/1000<sup>th</sup>) of the “no observable effect level.” As defined in Cal. Code of Regs. Title 27, section 25801, the “no observable effect level” for a chemical listed under Proposition 65 as causing reproductive toxicity is the maximum level of exposure at which a chemical has no observable reproductive effect.

The commenter refers to Maximum Allowable Dose Levels (MADLs), which are specific regulatory levels OEHHA adopts for chemicals causing reproductive toxicity in Cal. Code of Regs. Title 27, section 25805. OEHHA has adopted a MADL for dermal exposure to BPA from solid materials of 3 micrograms per day based on an assumption that 10% of the BPA would be dermally absorbed. This was calculated from an internal (injected) dose of 0.3 micrograms.

**42. Comment:** Commenter states that dermal route of exposure leads to higher internal dose of free BPA than oral route, yet there is a MADL for dermal – this is confusing and can lead to over warning. (2) OEHHA should adopt a MADL for BPA via ingestion. (22)

**Response:** This comment is not relevant to the current rulemaking and requires no response. OEHHA reviewed studies that presented sufficient evidence to establish a MADL for a dermal exposure to BPA. However, OEHHA determined that it could not develop a safe harbor level for oral exposures to BPA at this time because of complex scientific issues that may be resolved by current research expected to be completed in the next one to two years.

**43. Comment:** Commenter states that testing all products for BPA is not economically feasible (\$200 to \$600 per sample), and that commercial labs do not have sufficient capacity. (2)

**Response:** This regulation does not require any business to test its products for BPA. Instead, it provides a safe harbor method and content for warnings for those exposures where a business has decided to provide a warning. The statute requires warnings for knowing and intentional exposures to listed chemicals, including BPA<sup>6</sup>. It is not necessary to test a product in order to determine whether it was manufactured using BPA in the can lining or bottle seals. The product manufacturer can request such information from the can or bottle cap manufacturer who is in the best position to know what chemicals were used in the linings. OEHHA will separately consider issues related to the limit of detection for BPA, but declines to establish a LOD in this regulation.

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<sup>6</sup> Health and Safety Code section 25249.6

**44. Comment:** Commenter states that the ballot says Proposition 65 would not take businesses by surprise. Legal requirements at levels that can't be detected by expensive, newly-purchased analytical equipment and that could not be quantified according to the method used by the FDA would do so. (2)

**Response:** As was stated in the response above, Proposition 65 does not require businesses to test their products, it requires warnings for knowing and intentional exposures to listed chemicals. The product manufacturer can request such information from the can or bottle cap manufacturer who is in the best position to know what chemicals were used in the manufacture of the can linings or seals.

**45. Comment:** In the implementation of Section 12901, the former Proposition 65 method of detection regulation, OEHHA explained in the Final Statement of Reasons that the method of detection regulation was implemented to facilitate compliance, minimize confusion, allow businesses to limit changes in their businesses activities to those necessary to comply and minimize the possibility of different and conflicting interpretations of the Act. OEHHA should exercise its authority to implement a similar method of detection provision as an exemption to its proposed "intentionally used" requirement. (2)

**Response:** This comment is beyond the scope of this rulemaking. OEHHA will separately consider whether an additional regulation or other guidance is needed concerning limits of detection for BPA.

**46. Comment:** Commenter states that the term "intentionally used" when used relating to containers of ingredients for manufacturing can liners is not clear and could be subject to litigation. Suggests using "in which BPA was intentionally used as a monomer in the formulation of the can lining." (2)

**Response:** The regulation provides, in relevant part, that a business that uses the safe harbor point-of-sale warning must, among other things, provide OEHHA with:

"a. A list of all food products for which a warning is being provided in which bisphenol A was intentionally used in the manufacture of the can lining or jar or bottle seals."

OEHHA believes the provision is sufficiently clear. The regulation applies only in cases where safe harbor protection is desired. In cases where the manufacturing process has been modified so that BPA does not move from the lining into the food or beverage,

such that BPA exposures do not occur, a safe harbor protection is not needed. No change to the regulations was made based on this comment.

**47. Comment:** Commenter claims that variations between container manufacturing facilities acquiring alternative materials can mean that one UPC for one type of beverage might have 30 or more production runs available for sale in California that have both non-intentional BPA or intentional BPA-based liners. Proposed subsection (f)(1)(A)1. a. iv should be revised accordingly or this could result in 30,000 or more entries for the three largest members of the American Beverage Association alone. The “intentionally used” list could become inherently misleading because it could 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. (2)

**Response:** The database being developed by OEHHA can accommodate many thousands of entries. UPC codes would be submitted to OEHHA for those products to be covered by the safe harbor warnings. The database will only be posted and maintained during the effective period of this regulation and will then be removed. OEHHA believes it can accommodate a large data set. Providing product specific information can help consumers make more informed choices which furthers the purposes of Proposition 65. No change to the regulations was made based on this comment.

**48. Comment:** Commenter requests OEHHA to revise the proposed regulation to clarify that it intends no retroactive application and to create an implementation period. The commenter also requests the adoption of existing emergency regulation to cover from after May 10 to 60 days after the effective date of the non-emergency regulation. Sixty days would allow businesses to submit necessary information to OEHHA (considering holidays). (2)

**Response:** The regulation is prospective in nature. OEHHA does not intend for it to have retroactive effect. At the same time, the regulation will sunset on December 30, 2017. At that time, the point-of-sale warning method will no longer be available as a safe harbor method. If businesses choose to continue using this method, they will have to prove it is “clear and reasonable” for purposes of the Act. The regulation will be in effect for approximately one year from the date of adoption. This will provide sufficient time for an orderly transition to other lining materials or to on-label or shelf warnings for these products. No additional implementation periods are needed. No changes to the regulations were made based on this comment.

**49. Comment:** Commenter requests that any changes to the emergency regulation appear in a new section (g) so that the safe harbor for 2016 product sales is maintained and any new standards are articulated in (g) that would be clearly presented as only prospective. Existing (g) could then be re-lettered as (h). (2)

**Response:** OEHHA declines to make the suggested modifications to the regulation. This regulation replaces the provisions of the emergency regulation. There is no need for additional sections or renumbering. Such an approach would be confusing for businesses and would lack clarity.

**50. Comment:** Commenter requests that OEHHA revise the proposed regulation to clarify that OEHHA does not intend to exclude other clear and reasonable warnings. Current language could be read to imply only the described options are available. Request to add: “(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.” (2)

**Response:** This regulation provides safe harbor methods and content for businesses to use to provide warnings for exposures to BPA from canned and bottle foods. The business may either provide a warning on the product’s label or via a point-of-sale sign. One of the purposes of the regulation was to avoid a plethora of shelf signs throughout a retail facility. Therefore, shelf signs and tags are not one of the safe harbor options for providing warnings for these products under this regulation. Businesses may choose to use other warning methods, but would need to show they are clear and reasonable for purposes of the Act.

**51. Comment:** Extend BPA safe harbor program by at least 6 months or until 6 months after the determination of a MADL to avoid confusion and the provision of too many warnings because major beverage companies have not identified an alternative. It would better allow for the sell through of most foods canned prior to the May 2015 listing of BPA. Becoming inoperative in December 2017 would not protect conduct that occurred prior, the safe harbor should not become inoperative until all “relevant limitation periods have expired” (2)

**Response:** The purpose of the regulation is to provide a temporary safe harbor method for providing warnings for products that expose people to BPA that were manufactured prior to the effective date of the warning requirements for BPA. The chemical has been listed since May 2015 and the regulation will be in effect until December 2017. Manufacturers should be either moving away from the use of BPA or where that is not

possible, begin providing compliant warnings on the products. No changes to the regulations were made based on this comment.

**52. Comment:** Commenter states that the beverage industry has invested heavily in alternatives to BPA without finding a solution. (2)

**Response:** OEHHA acknowledges that the process of finding alternative can linings can take time and the investment of resources. However, this regulation addresses the issue of providing warnings, not the question whether alternatives are available for a given application.

**53. Comment:** Commenter supports the emergency regulation and states that even if warnings are not found in every cash register, the public is exposed to many of these signs in different stores. Commenter notes that the emergency regulation addresses the difficulty of providing warnings on product labels or shelf signs because of the high number of products involved. Commenter also notes that 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. 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. (22)

**Response:** OEHHA acknowledges the comment. It is not directly relevant to the proposed regulation and requires no response.

**54. Comment:** Commenters state that OEHHA lacks authority to require businesses to provide information about where BPA is intentionally used in the manufacture of can linings or seals, or to maintain database of this information. Commenter states the database is unrelated to the Proposition 65 requirement of clear and reasonable warnings. OEHHA may have some authority to condition a voluntary safe harbor warning, other actions must relate logically to purposes of Proposition 65. (22, 23)

**Response:** OEHHA has express authority under Health and Safety Code section 25249.12 to enact regulations that implement the provisions of Proposition 65 and further its purposes. The regulation provides a voluntary, safe harbor method for providing warnings for BPA in foods and beverages. OEHHA finds that providing a database where consumers can access more information and learn where BPA is intentionally used in can linings, jar lids or bottle seals for food products furthers the purposes of the statute by allowing consumers to make more informed choices about potential exposures to BPA. No changes to the regulations were made based on this comment.

**55. Comment:** Commenters state that the proposed database would expand the meaning of “exposure” because the fact that BPA was intentionally added to the epoxy lining does not mean there is a BPA exposure. The responsibility to determine if there is an exposure lies with the manufacturer and this is being addressed with the existing list. (23, 24, 25)

**Response:** By proposing a list of products where BPA is intentionally used in can linings, jar lids or bottle seals, OEHHA is not determining whether there is an exposure when these products are used, or whether a warning is required. The safe harbor regulation is available to businesses if they choose to use it. OEHHA acknowledges that BPA has been found in foods packaged in materials that did not have BPA intentionally added by the manufacture of the lining or seal; conversely a can lining may use BPA in manufacturing in such a way that BPA exposure via consuming the food product do not occur. However, as was explained in the ISOR, without making a distinction between BPA that is and is not intentionally added, some manufacturers have provided retail sellers with exhaustive lists of products where BPA may or may not be present in the packaging or food. Focusing on products where BPA is intentionally used in the can linings or seals will help identify those products that could cause significant BPA exposures. OEHHA believes that providing the public with a narrower list of products where BPA is intentionally used will provide consumers with more meaningful choices about potential exposures to this chemical. No changes to the regulations were made based on this comment.

**56. Comment:** Commenters identify the following concerns with the proposed database: (a) It is not clear when data must be provided to OEHHA. Food companies need adequate time to submit. (b) The term “product description” is not clear. (green beans or French-style green beans with ham, 12 ounces, select, packed in water, etc.) (c) UPC codes are frequently changed requiring the database to be regularly updated (22, 24) and the number may apply to multiple product variants in a similar category, some included in the program, some not. (d) Many products do not carry expiration, “use by”, or “best by” dates. (22)

**Response:** Businesses must provide OEHHA with the list of products for which they are providing a warning where BPA was intentionally used in the manufacture of the can lining or seals by no later than the effective date of the regulation. OEHHA anticipates that the regulation will be adopted effective January 1, 2017 if it is approved by the Office of Administrative Law. OEHHA encourages businesses to provide the information to OEHHA prior to the effective date to ensure it is available on the OEHHA website in a timely manner and to provide timely updates during the approximately one-

year period during which the regulation is effective. Product manufacturers already have collected the information such as “product description” for the lists being provided to the product retailers under the emergency regulation and may use the same descriptions. OEHHA is simply asking for a subset of this information to be provided to it directly for posting on the OEHHA website. OEHHA will provide a process for businesses to upload the information on the OEHHA website and will also accept electronic or hardcopy submissions of the required information. The “use by” date is needed in order to help consumers differentiate those products where BPA is no longer being used in the manufacturer of the can linings or seals. If such information is not available to the manufacturer, they need not provide it to OEHHA. No changes to the regulations were made based on these comments.

**57. Comment:** Commenter objects to staff statement that reformulation of canned foods and beverages to avoid BPA is the agency’s goal or a public health goal. BPA is safe as is confirmed by FDA decades ago for contact with food. (22, 27) OEHHA has no authority to promote widespread changes in food packaging. (22)

**Response:** As was stated in the ISOR, BPA is approved by the FDA for use in food-contact application including food and beverage can linings and seals, except for baby formula.<sup>7</sup> Nevertheless, BPA can migrate from the can lining into the food or beverage, resulting in exposures to varying amounts of BPA. Such exposures may still be subject to the warning requirements of Proposition 65 even where use of the chemical in food packaging is approved by FDA. Proposition 65 does not require a change in the food packaging, but many businesses may choose to move to linings that are not manufactured with BPA in order to avoid the warning requirements of the law. OEHHA believes this is consistent with the purposes of Proposition 65. No change to the regulations was made based on these comments.

**58. Comment:** Commenter objects to the listing of BPA by the DART-IC (27, 30)

**Response:** OEHHA acknowledges receipt of these comments, and notes they are not relevant to the proposed regulation, and as such require no response.

**59. Comment:** Commenter states that OEHHA should clarify that this regulation applies broadly to all foods and beverages that contain BPA. Commenter suggests that OEHHA should change the regulatory text to cover these types of containers to avoid consumer confusion and avoid litigation from overly narrow reading of the scope of these regulations. (22) Commenter states that OEHHA cannot explain why it only

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<sup>7</sup> Title 21, Code of Federal Regulations, section 175.300

targeted canned food in the warning. Commenter also states that some plastic bottles contain BPA and it is in the water, dust, and in the air. (30)

**Response:** As is stated in the ISOR, while a large percentage of canned food and beverage products can cause exposures to BPA, the same does not appear to be the case for other types of packaging. One study 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. The general provisions of the Article 6, Regulations for Clear and Reasonable Warnings regulations apply to warnings for BPA exposures from other sources or products, including other types of foods. No change to the regulations was made based on these comments.

**60. Comment:** Commenter states that the cost to re-label only for California products deprives California Asian communities of the ability to buy products at a competitive cost. (27)

**Response:** OEHHA acknowledges the comment and notes that this proposed regulation makes it possible for businesses to provide a point-of-sale warning for BPA without the necessity to re-label individual cans produced prior to the date of the listing BPA in May 2015. The regulation is intended to provide a transition period for products already in the stream of commerce that were manufactured and distributed prior to the effective date of the warning requirements for BPA. The proposed regulation does not deprive any sector of the community of the ability to buy products at a competitive cost.

**61. Comment:** Commenter states that OEHHA understated the impact of the regulation. Commenter further states that the loss of sales because of the warning, the cost to retailers to post warnings, and the costs incurred to inquire whether BPA is contained in a product were not evaluated. (30)

**Response:** This regulation provides a voluntary safe harbor method and content for warnings for exposures to BPA from canned and bottled foods. The regulation will allow businesses to comply with the warning requirements of Proposition 65 by using a point-of-sale warning until the regulation's sunset date. Any cost impacts that a representative private person or business would necessarily incur in reasonable compliance is very small relative to the typical cost of operating a business. The statute requires warnings for knowing and intentional exposures to listed chemicals, including BPA<sup>8</sup>. That requirement is not established by this regulation and no evaluation of the costs of that requirement need be provided in this regulation.

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<sup>8</sup> Health and Safety Code section 25249.6

**62. Comment:** OEHHA should amend its DARTIC practices to review and approve the exposure quantity at the same time a chemical is tabled for review. (30)

**Response:** OEHHA acknowledges receipt of this comment, and notes it is not relevant to this regulatory action, and as such require no response.

**63. Comment:** Commenter states OEHHA lacks authority to promulgate the provision for cure because Health and Safety Code section 25249.7 provides for penalties and injunctive relief but does not include any provision for cure (8).

**Response:** Providing a limited opportunity to cure a minor violation of the proposed regulation is not beyond OEHHA's authority described in Health and Safety Code section 25249.12 as OEHHA "may adopt and modify regulations, standards, and permits as necessary to conform with and implement this chapter and to further its purposes." 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 for a brief absence of the required signage.

### **Local Mandate Determination**

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65

### **Alternatives Determination**

In accordance with Government Code section 11346.9(a)(4), OEHHA has, throughout the adoption process for this regulation, considered available alternatives to determine whether any alternative would be more cost effective in carrying out the purpose for which the regulation was proposed, or would be as cost effective and less burdensome to affected private persons than the proposed action.

OEHHA has determined that no other reasonable alternative considered by OEHHA or that has otherwise been identified or brought to the attention of OEHHA would either be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons, or would be more cost

effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed regulation.