

**INITIAL STATEMENT OF REASONS**  
**TITLE 27, CALIFORNIA CODE OF REGULATIONS**  
**PROPOSED AMENDMENTS TO TITLE 27, CALIFORNIA CODE OF**  
**REGULATIONS SECTION 25603.3, WARNINGS FOR SPECIFIC CONSUMER**  
**PRODUCTS EXPOSURE**

**Adding Subsections**

**(f) Responsibility to Provide Warnings for Exposure to Bisphenol A from  
Canned and Bottled Foods and Beverages**

**and**

**(g) Warnings for Exposure to Bisphenol A from Canned and Bottled Foods  
and Beverages**

**July 29, 2016**

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

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## Summary

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65<sup>1</sup> and has the authority to promulgate and amend regulations to implement and further the purposes of the Act. OEHHA is proposing to amend Title 27, of the California Code of Regulations, section 25306.3<sup>2</sup>, to add an interim regulation to provide safe harbor warning methods and content for exposures to bisphenol A (BPA) released from linings in canned and bottled foods and beverages sold at the retail level.

## Background/Problem to be Addressed by the Proposed Rulemaking

### A. Proposition 65

Proposition 65 was a ballot measure that Californians approved in November 1986 with 63 percent of the popular vote. In part, the statute says:

“No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning...”<sup>3</sup>

Proposition 65 is a right-to-know law based on the concept that members of the public have a right to know when they are being exposed to listed carcinogens or reproductive toxicants. A Proposition 65 warning is not a regulatory decision that a product is safe or unsafe.

### B. The warning requirement for BPA began on May 11, 2016

On May 11, 2015, BPA was added to the Proposition 65 list of chemicals known to the state to cause reproductive toxicity based on the female reproductive endpoint.<sup>4</sup> Female reproductive toxicity occurs when a chemical damages any aspect of the female reproductive system. BPA is commonly used in linings of metal cans and lids of glass bottles and jars containing food and beverages. Under Proposition 65, beginning May 11, 2016 (one year after the listing), warnings have been required for all intentional exposures to BPA unless the business causing the exposure can show that the exposure when multiplied by 1,000 times has no observable effect.<sup>5</sup>

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<sup>1</sup> Health and Safety Code Section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as “Proposition 65”. Hereafter referred to as “Proposition 65” or “the Act”.

<sup>2</sup> All further references are to sections of Title 27, Cal. Code of Regs., unless indicated otherwise.

<sup>3</sup> Health and Safety Code, section 25249.6

<sup>4</sup> [http://oehha.ca.gov/prop65/CRNR\\_notices/list\\_changes/051115listBPA.html](http://oehha.ca.gov/prop65/CRNR_notices/list_changes/051115listBPA.html)

<sup>5</sup> Health and Safety Code sections 25249.10(b), 25249.10(c)

As a guide for regulatory compliance, OEHHA develops Maximum Allowable Dose Levels (MADLs). OEHHA attempted to develop a 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 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.

C. Many canned and bottled foods and beverages sold throughout California will likely require a warning

BPA is used to make epoxy resins, which act as a protective lining on the inside of many (though not all) metal-based food and beverage cans and on lids for glass jars and bottles.<sup>6</sup> It is approved by the US Food and Drug Administration (FDA) for use in food-contact applications 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.<sup>8</sup>

OEHHA understands that some canned food and beverage manufacturers plan to reduce or eliminate the use of BPA, or have recently done so, and the need for warnings for these products will likely decrease over time. Any changes made by manufacturers take time to have effect as inventories of canned foods and bottled beverages manufactured with BPA linings sell through; many canned foods and beverages have a shelf life of up to three years. Thus, although businesses have had more than a year to remove or reduce BPA from their products, many products produced prior to or immediately after the May 2015 listing of BPA are still in the stream of commerce and currently require warnings.

D. An emergency regulation currently provides a temporary process for providing a warning for these products but it will only remain in effect until October 17, 2016.

On April 18, 2016, OEHHA adopted an emergency regulation to address the issues discussed above<sup>9</sup>. The emergency regulation was developed to further the purposes of the Act by providing interim guidance on the methods for

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<sup>6</sup> <http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm064437.htm>

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

<sup>8</sup> See, e.g., and 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> and *Journal of Agriculture and Food Chemistry* article “Concentration of Bisphenol A in Highly Consumed Canned Foods on the U.S. Market” *J. Agric. Food Chem.*, 2011, 59, 7178-7185

<sup>9</sup> Title 27 Cal. Code of Regs., subsections 25603.3 (f) and (g).

providing warnings and a standard warning message for BPA exposures from canned and bottled foods and beverages that can be posted at the point of sale.

The emergency regulation will expire on October 17, 2016. For the reasons described below, OEHHA is initiating this regular rulemaking process to maintain the point-of-sale safe harbor warnings until December 30, 2017, as was contemplated in the emergency rulemaking.

## **Purpose**

Each substantive provision of the proposed regulation and its specific purpose is discussed below.

### **Subsection 25603.3(f) Responsibility to Provide Warnings for Exposure to Bisphenol A from Canned and Bottled Foods and Beverages**

Subsection 25603.3(f)(1) allows a food manufacturer, producer, importer or distributor of a canned or bottled food that causes an exposure to BPA, to either provide a warning on the product label that complies with the existing safe harbor language, or provide the required warning at the point of sale for the product using the language specified in subsection(g).

The temporary regulation is needed to address a unique situation stemming from the fact that the BPA warning requirement applies to a high percentage of the canned and bottled food and beverage supply in California. Recent studies found between 66 and 90 percent of canned foods contain varying levels of BPA.<sup>10</sup> Given the long shelf life (as long as three years) 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 the proposed temporary regulation (or the emergency regulation currently in effect), the most viable way to provide warnings 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,

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<sup>10</sup> 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, 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>

along with variations in warnings on a vast array of canned and bottled foods in grocery stores throughout the state, would create consumer confusion.

Variations in warnings could also occur because some manufacturers might conclude that BPA exposures from their products are not high enough to require a warning, while other businesses making comparable products that result in comparable exposures might choose to provide warnings. And while there is always this risk when a new chemical is added to the list, this situation is unique because of the volume of products that are affected. Furthermore, most businesses would likely use the wording provided in the general Proposition 65 warning regulation<sup>11</sup>, which would not identify BPA or provide consumers any information about its presence in food containers.

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. Once older products are no longer in the stream of commerce, OEHHA expects many newer products requiring warnings will have them on the label. The sunset of this temporary regulation will once again make canned and bottled foods and beverages subject to general Proposition 65 warning requirements.

A point-of-sale warning process would not be effective without the cooperation of all businesses in the chain of commerce. Therefore, this regulation establishes a temporary process whereby a manufacturer, producer, packager, importer or distributor of the canned and bottled food or beverage may provide a warning for exposures to BPA from their products by following the procedure established in the regulation.

Under subsection 25603.3(f), in order to take advantage of the point-of-sale safe harbor warning for BPA in canned foods and beverages, the manufacturer, producer, packager, importer or distributor of the canned and bottled food or beverage must do several things. Specifically, pursuant to subsection 25603.3(f)(1)(A), a manufacturer, producer, packager, importer or distributor of the canned and bottled food or beverage who chooses not to affix a warning label for BPA exposures on its products must:

- Provide the lead agency (OEHHA) with a list of all products in which BPA is intentionally used in the manufacture of the can lining, jar lid or bottle cap, including the brand name, product description, and specific identifying information including the date of manufacture or “sell by” date. The list is to be provided in a searchable, electronic format to facilitate

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<sup>11</sup> “WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.” 27 CCR §25603.2

posting the information on the Lead Agency website (Subsection 25603.3(f)(1)(A)2.); and

- Provide a written notice to product retail sellers stating that the product can cause an exposure to BPA, and provide sufficient information for the retailer to identify the affected products. The Notice must include or offer to provide sufficient point-of-sale signage to the retailer that complies with the requirements of subsection 25603.3(g). (Section 25603.3(f)(1)(A)3.).

The emergency regulation did not contain the requirement that specific information be provided to OEHHA for posting on the website. OEHHA is adding this provision to this regular rulemaking proposal so interested consumers can visit OEHHA's website to learn where BPA is intentionally used in can linings, jar lids or bottle caps for food products. This is intended to address concerns that the emergency regulation did not provide a convenient way for consumers to access this information.

Additionally, it is important to distinguish between products where BPA is intentionally added, and products where BPA may be present, but is not intentionally used. BPA has been found in foods packaged in materials that did not have BPA intentionally added by the manufacturer of the lining or seal. The reasons for this are still unclear, although it may be due to BPA cross-contamination issues in laboratories analyzing the foods. 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. 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 their exposures to this chemical.

The purpose of the subsection requiring written notice to the retailer is to ensure that the product retail seller has adequate notice about products it is selling that can cause exposures to BPA and that the retail sellers are provided with the appropriate point-of-sale signage by the manufacturer, producer, distributor or importer of the food. Proposition 65 specifically provides that:

“[i]n order to minimize the burden on retail sellers of consumer products including foods, regulations implementing section 25249.6 shall to the extent practicable, place the obligation to provide any warning materials such as labels on the producer or packager rather than the retail seller...”<sup>12</sup>.

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<sup>12</sup> Health and Safety Code section 25249.11(f)

Therefore, OEHHA has included this provision in the regulation to clearly allocate to the product manufacturer, or similarly situated parties in the chain of commerce, the responsibility for providing notice to the retail seller of the need to provide a warning and ensures that the costs for providing the warning signs are born by those parties rather than the retail seller.

As noted above, 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<sup>13</sup> issues. However, not all test protocols suffer from these issues.<sup>14</sup> Therefore, OEHHA believes that the current lists of products being provided to retail sellers may be overinclusive.

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 added to the packaging 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.

Subsection 25603.3(f)(2) of the regulation sets out the retail sellers' responsibilities in regard to providing warnings for BPA exposures from canned foods and beverages, which are to post and maintain the warning signs at each point of sale for the affected products. This interim approach appears to be working well under the existing emergency regulation and allows food manufacturers, packagers, importers, producers and distributors to provide warning materials in a single format to all retail sellers. This is primarily being accomplished through manufacturer, distributor or producer trade organizations to reduce costs and ensure timely and uniform compliance. Retail sellers can simply post the compliant warning signs provided by the manufacturer, packager, importer, distributor or producer at each point-of-sale for their facility.

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<sup>13</sup> National Research Council (1999), *Hormonally Active Agents in the Environment*, National Academy of Sciences, National Academies Press, Washington DC. Available online at:

<http://www.nap.edu/download/6029>

<sup>14</sup> Watabe Y, Kondo T, Imai H, Morita M, Tanaka N, Haginaka J, Hosoya K (2004). Improved detectability with a polymer-based trapping device in rapid HPLC analysis for ultra-low levels of bisphenol A (BPA) in environmental samples. *Anal Sci.* 20(1):133-7.



Subsection 25603.3(f)(2)(A) provides product retail sellers with an opportunity to cure in situations where a warning sign is absent if such absence is not due to neglect or disregard of the regulation and is not avoidable using normal and customary quality control and maintenance. A retail seller who satisfies these provisions will have the opportunity to cure this absence of a required sign by posting the appropriate signage within 24 hours of discovery or notification. Given that the point-of-sale signs are being posted in a high traffic area within a retail facility, it is possible they may become damaged or inadvertently be removed 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. A brief opportunity to cure such inadvertent temporary absences of the warning sign in order to avoid unnecessary litigation against an otherwise compliant retailer is thus provided.

For purposes of clarity, subsections 25603.3(f)(3) and (4) provide definitions for key terms used in this proposed regulation, including “canned foods and beverages” and “point of sale”. These definitions are based on generally available definitions for these terms which can be found in most dictionaries or other authoritative sources.<sup>15</sup>

Subsection 25603.3(f)(5) provides a sunset for the regulation on December 30, 2017. This regulation will become inoperative on that date. As stated above, OEHHA’s intent in providing this safe harbor warning process for BPA in canned foods and beverages is to provide a transition or sell-through period for products that were manufactured and distributed prior to or shortly after the May 2015 listing of BPA. It is not intended to allow for an on-going point-of-sale warning for these products. It is anticipated that, going forward, manufacturers will continue to reduce or eliminate exposures to BPA from canned and bottled foods and beverages. It is therefore anticipated that 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.

Subsection (f)(5) has been slightly modified from the existing emergency regulation, which provides that the BPA warning provision will remain in effect for one year after date of adoption. The emergency regulation went into effect on April 18, 2016, which was nearly a month before the warning requirement went into effect for this chemical. For clarity, this proposed regulation would specifically establish the inoperative date for this section as December 30, 2017, approximately one year after the regulation is expected to take effect.

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<sup>15</sup> [http://www.yourdictionary.com/point of sale](http://www.yourdictionary.com/point-of-sale),  
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/acidifiedlact/default.htm> ;<http://www.yourdictionary.com/canned#websters>,

### **Subsection 25603.3(g) Warnings for Exposure to Bisphenol A from Canned and Bottled Foods and Beverages.**

Subsection 25603.3(g) provides the requirements for point-of-sale warnings for BPA exposures from canned and bottled foods and beverages. The law requires that a business provide a “clear and reasonable” warning prior to exposure. 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.

The warning is being provided to consumers prior to exposure to the listed chemical. In this case, under the unique circumstances described 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 foods manufactured prior to the warning requirement cycle through the stream of commerce and manufacturers move toward compliance in other ways (i.e., providing on-product labels, removing BPA from their products, or reducing exposures to BPA to levels that do not require a warning). Providing a consistent, understandable warning message at the point of sale for these products ensures that consumers see and understand the warning prior to purchasing the products. In addition to providing the required elements of a Proposition 65 warning, the point-of-sale warning message content explains why BPA is present in the food and beverage cans and how a person might be exposed, and gives information on the endpoint/effect of concern (female reproductive toxicity). The warning also provides a way to access additional information about the exposures through a link to OEHHA’s website.

OEHHA has posted three fact sheets related to BPA exposures on its website to help consumers make informed purchasing decisions<sup>16</sup>. In addition, providing the public with information on OEHHA’s website about the range of products and exposures to BPA from its intentional use in canned foods and beverages will assist consumers in making informed choices<sup>17</sup>. Those consumers with smart phones will be able to access the information while at the store, while others may be able to access the information via their computer at home.

OEHHA believes the information in the point-of-sale warning and the supplemental information on its website will further the purposes of Proposition 65 by allowing consumers to make more informed choices about BPA exposures from canned and bottled foods and beverages during this interim period than they otherwise could if this regulation were not promulgated.

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<sup>16</sup> <https://www.p65warnings.ca.gov/chemicals/bisphenol-bpa>

<sup>17</sup> <https://www.p65warnings.ca.gov/fact-sheets/bisphenol-bpa-canned-and-bottled-foods-and-beverages>

Lastly, Subsection (g)(3) has been modified to establish a sunset date of December 30, 2017, consistent with the provision in Subsection (f)(5). As explained above, OEHHA's intent in proposing this safe harbor warning process for BPA in canned and bottled foods and beverages is to provide a transition period for products that were manufactured and distributed prior to the effective date of the warning requirement for BPA. It is not intended to allow for an on-going point-of-sale warning for these products. It is anticipated that, going forward, manufacturers will reduce or eliminate exposures to BPA from canned and bottled foods, so fewer 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.

## Necessity

Proposition 65 was enacted to provide the public with information about exposures to chemicals that cause cancer, birth defects, or reproductive harm. This proposed emergency regulation is necessary to avoid potential consumer confusion and dilution of the effectiveness of Proposition 65 warnings that would result from a plethora or inconsistent messages being provided throughout a retail facility.

The following facts support this finding:

- BPA is commonly found in the linings of cans, jar lids and bottle caps, for food and beverage products that are sold throughout California.
- BPA can move into the food or beverage from the linings and lids of cans and bottles.
- Because canned and bottled foods have shelf lives of up to three years, there are large inventories of canned and bottled food products currently on store shelves.
- Proposition 65 warnings for BPA are not provided on the cans, bottles or jars that were already in commerce prior to and shortly after the May 2015 listing of BPA.
- Consumers determined to navigate through a maze of warnings may identify and buy products that do not have a warning under the mistaken belief that they do not contain BPA. This is because some businesses may choose not to provide warnings because they believe the BPA exposures they are causing are below the level required for Proposition 65 warnings, even though other businesses causing comparable or lower exposures are providing Proposition 65 warnings for their products. These inconsistencies in the marketplace are likely to thwart the informational purposes of Proposition 65.
- A temporary, uniform point-of-sale warning will help avoid public confusion that could result from inconsistent warning messages about these products. The proposed safe harbor warning for BPA in canned and

bottled foods and beverages is intended to provide an orderly transition to consistent, product-specific warnings.

- The proposed regulation will extend the benefit of the existing emergency regulation by providing the public with supplemental information via a link to the OEHHA website, which contains fact sheets and links to materials from other authoritative organizations concerning exposures to BPA from canned and bottled foods and beverages to help consumers make informed decisions.
- The proposed regulation will also allow the public to view on OEHHA's website a searchable list of food and beverage products in cans and bottles where BPA is intentionally used in the epoxy coating or seals. No such list currently exists, but it would be created as a result of this rulemaking, enabling interested members of the public to make better-informed purchasing decisions.
- Under the existing general safe harbor regulations, businesses could lawfully provide general warnings that do not even identify BPA as the chemical of concern and that do not provide a link to the OEHHA website.

### **Economic Impact Assessment Required by Gov. Code section 11346.3(b)**

In compliance with Government Code section 11346.3, OEHHA has assessed all the elements pursuant to sections 11346.3(b)(1)(A) through (D):

#### **Creation or elimination of jobs within the State of California**

This regulatory action will not impact the creation or elimination of jobs within the State of California. The proposed regulation will simply provide an interim method for businesses to comply with the requirements of Proposition 65 while transitioning to new materials for product packaging or to an on-product warning.

#### **Creation of new businesses or elimination of existing businesses within the State of California**

This regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California. The proposed regulation will simply provide an interim method for businesses to comply with the requirements of Proposition 65 while transitioning to new materials for product packaging or to an on-product warning.

#### **Expansion of businesses currently doing business within the State of California**

This regulatory action will not impact the expansion of businesses within the State of California. The proposed regulation will simply provide an interim method for businesses to comply with the requirements of Proposition 65 while transitioning to new materials for product packaging or to an on-product warning.

## **Benefits of the proposed regulation to the health and welfare of California residents, worker safety, and the state's environment**

OEHHA has concluded that both the public and the food and beverage industry would benefit from the clarity that a uniform point-of-sale warning regulation would provide. The proposed regulation would allow sufficient time to ensure an orderly transition period for manufacturers to either provide more product-specific warnings for BPA exposures as older products manufactured and packaged prior to the May 2015 listing of BPA exit the stream of commerce, or to reduce or eliminate exposures to BPA by switching to safer alternatives where feasible. It will also allow additional time for OEHHA to evaluate the emerging science that, if sufficient, would support a MADL for oral exposures to BPA, which would further clarify which products require a warning. This regulatory action will further protect the health and welfare of the California public by assuring that the necessary information is available and minimizing possible consumer confusion concerning exposures to BPA from canned and bottled foods and beverages during this period of transition.

### **Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon**

Citations to documents relied on for this proposal are provided in this document. Copies of these documents will be included in the regulatory file for this action, and are available from OEHHA upon request. In addition, OEHHA reviewed comments received during the emergency rulemaking process. Those comments and OEHHA's responses to them are available on the OEHHA website and upon request to OEHHA. No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

### **Benefits of the Proposed Regulation**

The health and welfare of California residents will benefit from the proposed regulation because they will receive consistent, understandable warnings for BPA exposures at the point of sale of affected products and will have easy access to additional, detailed information concerning these exposures on the OEHHA website.

The implicit net benefit of Proposition 65 and the proposed regulation is the promotion of openness and transparency in business and government and is based on the stated desire of Californians to be informed of exposures to chemicals that are known to cause cancer or reproductive effects, as evidenced by the passage of Proposition 65 by the voters in 1986 by a significant majority vote.

## Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

During the emergency rulemaking process, OEHHA received several comments. Some comments referenced the actual emergency rulemaking procedure and were not suggestions of alternatives. A summary of the proposed alternatives from the comments submitted on the emergency regulation are provided below together with OEHHA's reasons for rejecting those alternatives.

1. The proposed warnings should be placed on or near each of the canned food and beverage products and not at point of sale.

**Response:** OEHHA concluded that the requirement to place warnings on or near each of the canned food and beverage products would be confusing to consumers and would not further the purposes of Proposition 65, 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 can liners and bottle lids, thousands of individual products are affected by the warning requirement. The most feasible 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. As stated earlier, this profusion of warning signs would likely confuse and frustrate most consumers, defeating the purpose of the warnings.

2. The opportunity to cure should be eliminated from the proposed regulation.

**Response:** Providing a limited opportunity to cure a minor violation of the proposed regulation is necessary because 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 retail seller 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.

3. OEHHA should add 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, the same does not appear to be the case for other types of packaging. The opportunity for confusion over the potential plethora of warnings during this transition period outweighs the benefit of including other types of packaging.

One study<sup>18</sup> 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 is 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.

4. A commenter 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 OEHHA with the names of products with packages where BPA has been intentionally added, and to 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 obtain information on products in cans, jars or bottles containing BPA from either OEHHA’s website or the retailer.

5. Delete the language requiring the manufacturers to provide the retail seller with the name/description of the canned/bottled foods or beverages for which a warning is being provided.

**Response:** It has been over one year since the listing of BPA, which should be sufficient time for businesses to determine which canned and bottled food products cause exposures to BPA. The proposed regulation keeps the emergency regulation in effect for a total of one year from the effective date of the warning requirement. 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 a warning is being given to provide the information to customers upon request and provides a reasonable balance between the cost of relabeling food products

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<sup>18</sup> 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>

and the necessity for providing a clear and reasonable warning to consumers about exposures to BPA from these products.

6. Warning provisions should not be required for vending machines.

**Response:** 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.

OEHHA cannot exempt whole business sectors 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.

OEHHA believes that providing a temporary, interim process that allows point-of-sale warnings for canned and bottled foods and beverages that cause exposures to BPA is the most effective way to address the problem. The most obvious alternative would be to not adopt the regulation, thereby not providing guidance for the affected industries. This is likely to result in a plethora of inconsistent warnings being provided for canned and bottled foods and beverages that cause exposures to BPA that would not help consumers make informed decisions about the purchase of canned foods and beverages.

### **Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency’s Reasons for Rejecting Those Alternatives**

OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the proposed action, or would be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small business. In addition, OEHHA has determined that the proposed regulatory action will not impose any mandatory requirements on small



businesses. Proposition 65 expressly exempts businesses with less than 10 employees<sup>19</sup> from the requirements of the Act.

### **Evidence Supporting Finding of No Significant Adverse Economic Impact on Business**

Because the proposed regulation provides an interim alternative to providing shelf sign or shelf tag warnings at every location where canned foods or beverages that may cause exposures to BPA are displayed throughout a facility, OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

### **Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues**

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulations do not duplicate and will not conflict with federal regulations.

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<sup>19</sup> Health and Safety Code section 25249.11(b).