

NOTE: THIS NOTICE SUPERSEDES THE NOTICE POSTED ON MARCH 17, 2016

**For information concerning the Emergency Rulemaking Process and how to comment on this proposal, please go to:
http://www.oal.ca.gov/Emergency_Regulation_Process.htm**

**NOTICE OF EMERGENCY ACTION
TO AMEND SECTION 25603.3 TITLE 27, CALIFORNIA
CODE OF REGULATIONS WARNINGS FOR EXPOSURES
TO BISPHENOL A
FROM CANNED AND BOTTLED FOODS AND BEVERAGES**

April 1, 2016

I. INTRODUCTION

The Office of Environmental Health Hazard Assessment (OEHHA) is the state entity responsible for the implementation of Proposition 65.¹ OEHHA has the authority to adopt and amend regulations to implement and further the purposes of Proposition 65. OEHHA maintains a list of chemicals known to cause reproductive toxicity or cancer. Proposition 65 requires businesses to provide a warning when they knowingly and intentionally cause an exposure to a listed chemical, and prohibits the discharge of listed chemicals into sources of drinking water.

The current safe harbor warning regulations adopted by OEHHA in Title 27 of the California Code of Regulations, section 25601, provide general guidance concerning the types of warning methods and content that are deemed “clear and reasonable” for purposes of the Act.

On May 11, 2015, bisphenol A (BPA) was added to the Proposition 65² list of chemicals known to cause reproductive toxicity. Effective May 11, 2016, warnings are required for

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq.*, commonly referred to as “Proposition 65”.

² http://oehha.ca.gov/prop65/CRNR_notices/list_changes/051115listBPA.html

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.³ OEHHA is proposing to promulgate 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.⁴

II. BACKGROUND

A. Proposition 65

Proposition 65 passed by citizen initiative 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...”⁵

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. Rather, the law is designed to help consumers decide whether to assume the risks of purchasing particular products that result in exposures to listed chemicals.

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

On May 11, 2015, bisphenol A (BPA) was added to the Proposition 65 list of chemicals known to the state to cause reproductive toxicity based on the female reproductive endpoint.⁶ Female reproductive toxicity occurs when a chemical damages any aspect of the female reproductive system. BPA is commonly used in certain linings of metal cans and lids of glass bottles containing food and beverages. Under Proposition 65, one year after the listing, beginning May 11, 2016, warnings are required for all exposures to BPA unless the person causing the exposure can show that the exposure when multiplied by 1,000 times has no observable effect.⁷

C. Businesses make the decision whether to provide a warning and have options for the content of the warnings.

³ Health and Safety Code, sections 25249.10(b), 25249.10(c)

⁴ In a separate rulemaking process, OEHHA is proposing a Maximum Allowable Dose Level (MADL) that establishes a level of dermal exposure to BPA that does not require a warning. The MADL is unrelated to this rulemaking package because exposures from canned and bottled foods and beverages are not dermal exposures.

⁵ Health and Safety Code, section 25249.6

⁶ http://oehha.ca.gov/prop65/CRNR_notices/list_changes/051115listBPA.html

⁷ Health and Safety Code sections 25249.10(b), 25249.10(c)

A product does not require a warning simply because it contains a chemical that is listed under Proposition 65. A warning is required only when a business knowingly and intentionally causes an exposure to a listed chemical. The business that is responsible for the product must make several decisions:

First, the business should determine whether its products are likely to expose individuals to any listed chemicals.

Second, if the product causes an exposure to a listed chemical, the business should determine whether OEHHA has identified a regulatory safe harbor level for the chemical. An exposure below a safe harbor level (for reproductive toxicants, also known as a Maximum Allowable Dose Level, or MADL) is exempt from the warning requirement.⁸

Third, if there is no regulatory safe harbor level for a listed reproductive toxicant, a business that knowingly exposes individuals to that chemical is generally required to provide a Proposition 65 warning, unless the business can show that the exposure to the chemical, when multiplied by 1,000, has no observable effect⁹. Determining this threshold level for the chemical and the exposure caused by the product can be complex.

Fourth, if a business decides that a warning is required, OEHHA's safe harbor regulations on warnings allow the business several options.¹⁰ A business may provide the warning on a product's label, shelf tags, shelf signs, menus or any combination thereof as long as the warning is prominent and conspicuous.¹¹ OEHHA regulations also provide for a general safe harbor warning for consumer products, including food, that states: "This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."¹² Thus, there is currently no statutory or regulatory requirement for a Proposition 65 warning to actually identify the chemical at issue. Also, the current regulation does not expressly allow for point-of-sale warnings for consumer products that cause exposures to listed chemicals.

⁸ Health and Safety Code sections 25249.10(c), Title 27, Cal. Code of Regs., section 25801, et seq.

⁹ Health and Safety Code sections 25249.10(c)

¹⁰ Title 27, California Code of Regulations, section 25601

¹¹ Title 27, California Code of Regulations, sections 25603 and 25603.1.

¹² Title 27, Code of Regulations, Section 25603.2

D. Maximum Allowable Dose Levels can clarify when a warning is required, but none exists for oral exposure to BPA at this time

Because Proposition 65 requires businesses, rather than OEHHA, to determine when warnings are required, some businesses may make their own determination that the BPA exposures that they are causing are too low to require a warning, even though the BPA exposures from their products may be comparable to, or even greater than, exposures from other products that carry warnings. OEHHA generally tries to avoid such situations by establishing MADLs. Businesses over the years have relied on MADLs and related guidance in determining when they need to provide warnings.

Unfortunately, there is currently no MADL for oral exposure from food and beverages to BPA.¹³ OEHHA is waiting for research sponsored by the federal government that may resolve complicated scientific questions that would enable OEHHA to establish a MADL for BPA oral exposures. The research is expected to be completed in late 2017 or early 2018.

E. The Attorney General, local prosecutors, and private litigants enforce Proposition 65 through litigation, which can result in civil penalties and other sanctions

Proposition 65 is enforced through civil lawsuits brought by the California Attorney General, or by a district attorney or city attorney of a city with a population exceeding 750,000. Private parties may also bring Proposition 65 lawsuits.¹⁴ If a business is found to be in violation of Proposition 65, a court may order the business to stop committing the violation. The business is also subject to civil penalties of up to \$2,500 per day for each violation.

F. Many canned and bottled food and beverages sold throughout California are likely to require warning

The listing of BPA under Proposition 65 will have widespread impacts on food and beverages sold across the state. 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.¹⁵ It is approved by the U.S. Food and Drug Administration (FDA) for use in food-contact applications including food and beverage

¹³ OEHHA is developing a MADL for dermal (skin) exposure. See footnote 2, above.

¹⁴ Health and Safety Code, section 25249.7(d)

¹⁵ <http://www.fda.gov/food/ingredientpackaginglabeling/foodadditivesingredients/ucm064437.htm>

can linings and seals, except for baby formula.¹⁶ Many canned and bottled food and beverages can cause exposures to varying amounts of BPA.¹⁷

Currently, these canned and bottled foods and beverages do not carry Proposition 65 warnings because no warning is required for BPA exposures until May 11, 2016. 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 will not immediately affect existing retail inventories, however, because many canned foods and beverages have a shelf life of up to three years. Thus, although businesses have had 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 will require warnings beginning in May 2016.

G. Emergency action is needed

Given this situation, OEHHA is concerned that businesses will take inconsistent approaches to compliance, particularly in the time period immediately following May 11, when the warning requirement begins. For example:

- *Products that contain relatively high amounts of BPA may have no warning at all.* In the absence of a MADL, businesses must decide on their own whether the BPA exposures their products cause are high enough to trigger the warning requirement. This is a complex decision by individual businesses that involves not only scientific interpretation of the health effects of BPA, but also the use of the business' own information on the frequency that consumers use their products and how much they consume. Some businesses may decide that products causing relatively high exposures to BPA do not require warnings, while others decide to place warnings on products causing lower exposures to BPA. Consumers will have no immediate way of distinguishing between them. Some may incorrectly assume that a product with no warning has no BPA.
- *Some retailers may put warnings on all products with BPA, while others warn selectively.* Consumers could see a warning for a product in one store, and no warning for the same products in another. Ubiquitous warnings may undermine

¹⁶ Title 21, Code of Federal Regulations, section 175.300

¹⁷ 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

the effectiveness of Proposition 65, as some consumers are alarmed by them and others disregard them as meaningless and uninformative.

Under the current Proposition 65 warning regulation, the most likely way for businesses to ensure pre-May 2015 canned and bottled food and beverage products have warnings is for retailers to post shelf signs with warnings *for each individual canned and bottled food product that may require a warning*. Until pre-May 2015 products are no longer in the stream of commerce, it is likely that most retailers would have a plethora of warning signs wherever canned and bottled food and beverage products are displayed in their stores. The relatively sudden appearance of a large number of warning signs referring to a multitude of food and beverage products is likely to confuse and overwhelm consumers. Some consumers might become overly alarmed, while many consumers would dismiss them as uninformative. Neither outcome furthers the purposes of Proposition 65.

- *Currently there is no statutory or regulatory requirement for Proposition 65 warnings to name the chemical of concern or the health effect associated with it.* While some businesses may choose to name BPA and provide supplemental information about it in its warning, OEHHA anticipates that most warnings will simply say the food or beverage product “contains a chemical known to the State of California to cause birth defects or other reproductive harm.” Consumers seeing these warnings will not know what chemical they are being warned about or how they could reduce their exposure to it. While this has been the case with the majority of Proposition 65 warnings over the years, the multitude of warnings for foods and beverages combined with a lack of information creates a uniquely high potential for confusion that does not serve the public interest and should be avoided.

Rather than address these problems, OEHHA could do nothing and simply assume that enforcement actions will eventually resolve uncertainty about what products require warnings and the adequacy of the warnings. But litigation will not provide clear guidance for businesses attempting to prepare for May 11. Nor will it help consumers and businesses faced with these problems in the period immediately following May 11.

The proposed emergency regulation will provide a reasonable transition period to help avoid consumer confusion and at the same time provide consistent, informative, and meaningful warnings to consumers about significant exposures to BPA. The proposed safe harbor warning for canned and bottled foods and beverages will identify BPA by name, and disclose that it causes harm to the female reproductive system. The warnings will also provide the public with supplemental information via a link to OEHHA’s website, which will contain fact sheets and links to informational materials on

BPA from other authoritative organizations. Moreover, because it will be limited in duration, businesses that have not already switched to safe alternatives will have a strong incentive to do so before the regulation expires. At that time, OEHHA will attempt to have completed a MADL so that businesses have guidance on the amount of BPA exposure that does not require a warning under Proposition 65.

OEHHA views this emergency regulation as addressing a unique situation. This emergency regulation should not be used as a precedent for future regulatory actions.

III. FINDING OF AN EMERGENCY

A. Section 48 Statement

Title 1 of the California Code of Regulations, section 48 requires the following statement:

“Government Code section 11346.1 (a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.”

B. Facts Constituting the Need for an Emergency Action

The APA defines an "emergency" to mean "a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare." (Gov. Code section 11342.545.) To make a finding of emergency, the agency must describe the specific facts supported by substantial evidence that demonstrate the existence of an emergency and the need for immediate adoption of the proposed regulation. (Gov. Code section 11346.1(b)(2).) Some factors an agency may consider in determining whether an emergency exists include: (1) the magnitude of the potential harm, (2) the existence of a crisis situation, (3) the immediacy of the need, i.e., whether there is a substantial likelihood that serious harm will be experienced unless immediate action is taken, and (4) whether the anticipation of harm has a basis firmer than simple speculation. Pursuant to these statutes, OEHHA finds that an emergency exists in the present case.

An emergency exists because, if this regulation is not in place by May 11, 2016, consumers will see inconsistent health warnings on canned and bottled food and

beverages throughout the state. This situation would cause widespread confusion and undermine the purpose of Proposition 65.

The following facts support this finding:

- BPA is commonly found in the linings of cans, and jar and bottle lids, 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 are already in commerce. OEHHA anticipates that retailers will post multiple warning signs where canned and bottled foods and beverages are displayed, resulting in a plethora of warnings that will confuse consumers.
- Consumers determined to navigate through the 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.
- OEHHA generally tries to provide MADLs and related guidance to businesses to avoid such situations, but is unable to do so at this time because of complicated scientific questions involved in identifying a No Observable Effect Level for BPA, which is the key step in calculating the MADL.
- A temporary, uniform point-of-sale warning would help avoid public confusion that could result from inconsistent warning messages about these products. OEHHA believes that pending research may inform the development of an oral MADL and other guidance to address inconsistent warnings. 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 provide the public with supplemental information via a link to the OEHHA website, which will contain 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. Under the current 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.

- The short duration of the regulation, and the consumer awareness of BPA that it would promote, would motivate businesses to reduce or eliminate BPA from their products if they have not already done so.
- Action is necessary to ensure an effective transition from the sale of canned and bottled foods without Proposition 65 warnings to providing consistent warnings for significant BPA exposures from these food products and reformulation of products with safe alternatives where feasible.

OEHHA attempted to address the emergency situation through non-emergency regulations, but encountered technical and practical problems with that approach. As stated above, OEHHA attempted to develop a MADL for oral exposure that would have been enacted through the normal regulatory process. In the course of that process, OEHHA scientists found that the issue was technically complex and additional research is needed. However, the federal government is currently sponsoring a large series of studies intended to clarify the effects of BPA at low doses.¹⁸ Some of these studies, expected to be complete in 2017 or 2018, could inform the development of an oral MADL that will provide clarity for consumers and businesses. As the May 11, 2016 deadline for warnings has approached, OEHHA also became concerned that some manufacturers and retailers will take the kind of inconsistent approaches discussed above. Accordingly, OEHHA developed this temporary regulation to mitigate potential harm and confusion for consumers.

OEHHA has concluded that both the public and the food and beverage businesses would benefit from the clarity that a uniform point-of-sale warning regulation would provide. The proposed emergency regulation would expire after 180 days. During that period, OEHHA will commence a regular rulemaking process to adopt a regulation as an interim measure for a one-year period from date of adoption. This time period should be sufficient to ensure an orderly transition to providing more product-specific warnings for BPA exposures, and for more manufacturers 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.

¹⁸Birnbaum LS, Bucher JR, Collman GW, Zeldin DC, Johnson AF, Schug TT, Heindel JJ (2012). Consortium-based science: the NIEHS's multipronged, collaborative approach to assessing the health effects of bisphenol, *Environmental Health Perspectives*, 120(12):1640-4. Available at: <http://ehp.niehs.nih.gov/1205330/> Heindel JJ, Newbold RR, Bucher JR, Camacho L, Delclos KB, Lewis SM, Vanlandingham M, Churchwell MI, Twaddle NC, McLellen M, Chidambaram M, Bryant M, Woodling K, Gamboa da Costa G, Ferguson SA, Flaws J, Howard PC, Walker NJ, Zoeller RT, Fostel J, Favaro C, Schug TT (2015). NIEHS/FDA CLARITY-BPA research program update. *Reproductive Toxicology*, 58:33-44. See also http://www.niehs.nih.gov/research/programs/endocrine/bpa_initiatives/bpa-related/index.cfm

C. Need for the Proposed Regulation to Effectuate the Statute

Proposition 65 was enacted to protect the public from exposures to chemicals that cause cancer, birth defects, or reproductive harm by informing the public about exposures to these chemicals. As is discussed above, this proposed emergency regulation is necessary to avoid potential consumer confusion and dilution of the effectiveness of Proposition 65 warnings to the public that could result from inconsistent messages.

IV. TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON

Citations to documents relied on for this proposal are provided in this document. No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

V. AUTHORITY

Health and Safety Code section 25249.12(a)

VI. INFORMATIVE DIGEST

A. Background (see Section II, above)

B. Specific Benefits of the Proposed Regulations

This regulatory proposal is intended to further the purposes of Proposition 65 by encouraging the use of a consistent and informative point-of-sale warning message for BPA exposures from canned and bottled foods and beverages. (See Sections II and III, above.)

C. No Inconsistency or Incompatibility with Existing Regulations

OEHHA has conducted an evaluation and has determined that this would be the only regulation concerning Proposition 65 BPA warnings. Therefore, the proposed regulation is neither inconsistent nor incompatible with any other existing state regulations. The proposed regulation does not change the existing mandatory requirements on businesses subject to Proposition 65, state or local agencies and does not address compliance with any other law or regulation.

D. Local Mandate/Fiscal Impact

Because Proposition 65 by its terms¹⁹ does not apply to local agencies or school districts, OEHHA has determined the proposed regulatory action would 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. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action. Also, the proposed action will not create any cost or saving to any state agency, and will not create any cost or savings in federal funding to the state.

E. Costs of Savings to State Agencies

Because Proposition 65 by its terms²⁰ does not apply to any state agency and this regulation is simply a clarification of existing procedures, OEHHA has initially determined that no significant savings or increased costs to any state agency will result from the proposed regulatory action.

F. Efforts to Avoid Unnecessary Duplication of Conflicts with Comparable Federal Regulations

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.

VII. FISCAL IMPACT

A. Costs to Local Agency or School District

Because Proposition 65 by its terms²¹ does not apply to local agencies or school districts, OEHHA has determined the proposed regulatory action would 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. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action. Also, the proposed action will not create any cost or saving to any state agency, and will not create any cost or savings in federal funding to the state.

¹⁹ Health and Safety Code section 25249.11(b).

²⁰ Health and Safety Code section 25249.11(b).

²¹ Health and Safety Code section 25249.11(b).

B. Cost of Savings to State Agencies

Because Proposition 65 by its terms²² does not apply to any state agency and this regulation is simply a clarification of existing procedures, OEHHA has initially determined that no significant savings or increased costs to any state agency will result from the proposed regulatory action.

²² Health and Safety Code section 25249.11(b).