

MEMORANDUM

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Re: California's OEHHA Proposed Dermal Safe Harbor Level for BPA and a Temporary Point-of-Sale Warning Message for Canned and Bottled Foods and Beverages

We previously reported that beginning May 11, 2016, California's Office of Environmental Health Hazard Assessment (OEHHA) will start requiring warnings for consumer products containing BPA under the Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65). 1/ On March 17, 2016, OEHHA published two notices related to the BPA warning requirements. In the first notice, OEHHA proposes to establish a Proposition 65 Maximum Allowable Dose Level (MADL) or safe harbor level for BPA of 3 micrograms (μg) per day for dermal exposure from solid materials. 2/ Comments on the dermal safe harbor level are due on May 16, 2016. 3/ Separately, OEHHA proposes an emergency regulation to allow the temporary use of a standard point-of-sale warning message for BPA exposures from canned and bottled foods and beverages. 4/ This would relieve manufacturers of the duty to provide warnings on product packaging for those products that must be labeled by May 11th. While a deadline for comments on the proposed warning message was not provided, under California's Government Code section 11349.6, interested persons only have five calendar days to submit comments. 5/ As such, comments on the point-of-sale warning

1/ See Hogan Lovells Memorandum titled "California's Proposition 65 Warning Requirements for BPA Become Effective Soon" (February 25, 2016).

2/ See "Notice of Proposed Rulemaking Title 27, California Code of Regulations Maximum Allowable Dose Level for Bisphenol A (Dermal Exposure from Solid Materials)" *available at* http://www.oehha.ca.gov/prop65/CRNR_notices/NPR_BPA_MADL031716.html.

3/ See *id.*

4/ See "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" *available at* http://www.oehha.ca.gov/prop65/CRNR_notices/031716EmergencyAction_BPA.html.

5/ See California's Government Code section 11349.6(b) "Emergency regulations adopted pursuant to subdivision (b) of Section 11346.1 shall be reviewed by the office within 10 calendar days after their submittal to the office. After posting a notice of the filing of a proposed emergency regulation on its Internet Web site, the office shall allow interested persons five calendar days to submit comments on the proposed emergency regulations unless the emergency situation clearly poses such an immediate serious harm that delaying action to allow public comment would be inconsistent with the public interest . . ."

message are due on March 22, 2016. This memorandum summarizes the key components of the two notices.

Dermal Safe Harbor for BPA

By way of background, under Proposition 65, businesses are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone in California to a listed chemical on the Proposition 65 list. 6/ However, if the company can establish that the level of the listed chemical in a given product would result in a dietary intake level that is within a "safe harbor," such a product is exempt from the warning requirement. 7/ OEHHA has not yet established a "safe harbor" for BPA. In its March 17 notice, OEHHA proposed a safe harbor of 3 µg per day for BPA dermal exposure from solid materials (e.g., paper and plastic). Businesses that manufacture or market consumer products that can expose California consumers to BPA through dermal exposure may want to determine whether the surface of these materials could present a BPA exposure that exceeds the 3 µg proposed safe harbor level.

We would encourage companies to review carefully the process used by OEHHA to establish the 3 µg/day dermal safe harbor, which is magnitudes lower than the 290 µg/day oral safe harbor contemplated by OEHHA in its 2013 assessment. 8/ In determining the proposed 3 µg/day dermal safe harbor, OEHHA relied on a 2014 study by Veiga-Lopez et al. on reproductive toxicity conducted in female sheep. This study provides a subcutaneous LOEL of 0.05 milligrams BPA per kilogram body weight per day (mg/kg bw/day) in sheep for female reproductive toxicity. 9/ We would encourage companies to work closely with toxicologists to determine whether the following OEHHA "assumptions" are scientifically justifiable: (1) the use of a subcutaneous injection as an appropriate indicator for dermal exposure; (2) the determination that the amount of BPA absorbed trans-dermally is toxicologically equivalent to the same amount injected subcutaneously; and (3) the extrapolation from subcutaneous doses to dermal exposure by relying on findings by the European Food Safety Authority (EFSA) that the dermal absorption fraction for solid BPA from the thermal paper was 0.1 (10%). We would encourage the industry to review carefully the methodology used by OEHHA and submit comments on the scientific validity of the agency's approach.

No OEHHA Oral Safe Harbor for BPA

At this time, OEHHA has not developed a "safe harbor" for oral BPA exposure because the issue is "technically complex." 10/ OEHHA explains in the notice for the proposed dermal MADL that some of the federally funded studies on BPA will not be completed until 2017 or 2018, and the findings of these studies could form the basis of an oral MADL. 11/ These statements indicate that OEHHA may not propose an oral "safe harbor" for BPA until 2017.

In the absence of an OEHHA oral "safe harbor" level, we encourage companies to work closely with their legal counsel to determine whether it is appropriate for a company to determine its own "safe harbor" level based on sound toxicology principles. 12/ While OEHHA explicitly states the dermal safe harbor is inapplicable to the oral exposures from canned and bottled foods and beverages, we

6/ Cal. Health & Safety Code § 25249.6.

7/ Cal. Health & Safety Code § 25249.10.

8/ See "Amendment to Section 25805 Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity – BPA" available at: http://oehha.ca.gov/prop65/law/012513BPA_MADL.html.

9/ See "Initial Statement of Reasons: Maximum Allowable Dose Level (MADL) for Bisphenol A (BPA)" available at: http://www.oehha.ca.gov/prop65/CRNR_notices/pdf_zip/03172016DermalBPA_MADL_ISOR.pdf.

10/ See *supra* note 4.

11/ See *id.*

12/ 27 CCR § 25801.

are concerned a safe harbor of 3 µg for dermal exposure could be viewed as a starting point for setting the safe harbor for oral exposures. One of the issues that must be explored is the relevance of the proposed 3 µg safe harbor for dermal exposures from solid materials to the much higher safe harbor levels for oral intake previously established by the U.S. Food and Drug Administration (FDA) and EFSA. ^{13/}

A company that determines oral exposures from its products are within a “safe harbor” can take the view that its products are not subject to Proposition 65 warnings. A company that takes such a position on a food that has detectable levels of BPA, however, does so with the risk that the state or the courts could interpret Proposition 65 differently. As discussed below, companies can avoid putting warning labels on foods with detectable levels of BPA on an interim basis by utilizing the emergency warning provision. Companies relying on the emergency regulation, however, should explore with their legal counsel the impact of that decision on Proposition 65 warnings once the emergency regulation sunsets.

Point-of-Sale Warning Message for Canned and Bottled Foods and Beverages

According to the second notice, OEHHA proposes the emergency regulation for a uniform point-of-sale warning message for BPA exposures mainly to avoid consumer confusion and to keep canned foods and beverages on store shelves after May 11, 2016. ^{14/} OEHHA also notes that some canned food and beverage manufactures are already moving toward reducing or eliminating the use of BPA and the emergency regulation is a temporary measure.

Specifically, under the proposed regulation Section 25603.3(f), Proposition 65 warning requirements are deemed to be met if the “manufacturer, producer, packager, importer or distributor of the canned and bottled food or beverage either affixes a label to the product bearing a warning” or “[p]rovides written notice directly or through an authorized agent or trade association to the retailer or its authorized agent.” ^{15/} Under the regulation, the written notice must include the following: (1) a statement that a warning is required; (2) the exact name or description of each canned or bottled food or beverage that requires a warning; and (3) an offer to provide (or actually provide) a sufficient number of point-of-sale warning signs to the retailers. ^{16/} The proposed Section 25603.3(f) further provides that the “placement and maintenance of warning signs is the responsibility of the retailer seller of the affected products.” ^{17/}

Under the proposed regulation Section 25603.3(g), the point-of-sale warning signs must be no smaller than 5 by 5 inches for products sold at a physical location. For products sold over the

^{13/} See “FDA’s Current Perspective on BPA in Food Contact Applications,” *available at*: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm#summary>. Notably, in a 2014 study commissioned by FDA, the authors found no evidence of adverse health effects arising from low dose exposure to BPA. See, Delclos, K. Barry, et al. “Toxicity evaluation of bisphenol A administered by gavage to Sprague Dawley rats from gestation day 6 through postnatal day 90.” *Toxicological Sciences* 139.1 (2014): 174-197. See also EFSA Scientific Opinion on Bisphenol A (2015) noting that “[b]ased on new data and methodologies, EFSA has lowered the estimated safe level, known as the tolerable daily intake (TDI), to 4 micrograms per kilogram of body weight per day.”

^{14/} See *supra* note 4.

^{15/} See “Proposed Regulatory Language” *available at*: http://www.oehha.ca.gov/prop65/CRNR_notices/pdf_zip/03172016BPA_EmergencyRegLanguage.pdf.

^{16/} See *id.*

^{17/} See *id.*

Internet, the warning must be provided either on the product display page or otherwise be prominently displayed to the purchaser. The Warning Sign shall contain the following: 18/

“WARNING. Many cans containing foods and beverages sold here have epoxy linings used to avoid microbial contamination and extend shelf life. Lids on jars and caps on bottles may also have epoxy linings. Some of these linings can leach small amounts of bisphenol A (BPA) into the food or beverage. BPA is a chemical known to the State of California to cause harm to the female reproductive system. For more information go to: www.P65Warnings.ca.gov/BPA.”

Taken together, OEHHA takes the view that food manufacturers can comply with the Proposition 65 BPA warning requirements by placing the warning on their product or notifying the retailers that their product contains BPA, in which case the manufacturers will be deemed in compliance and it is then the retailers’ responsibility to provide the warning. While a company would not be required to provide the notice if it concludes its product is below its calculated safe harbor level for oral exposure, the regulation presumably would create an incentive for companies to provide the notification regardless of the BPA levels in their products to avoid any liability in the interim. Any company adopting that approach should consider the precedent they are establishing and whether providing notice now would complicate their ability to later argue their products are within a safe harbor.

The emergency regulation will expire after 180 days. During this period, OEHHA plans to commence a regular rulemaking process to adopt the regulation as an interim measure for a one-year period from the date of adoption. OEHHA states that it believes the one-year period should be sufficient to ensure an orderly transition to provide warnings for BPA exposures, and for manufacturers to reduce or eliminate exposures to BPA by switching to safer alternatives where feasible.

The emergency regulation should be reviewed carefully. We encourage the submission of comments in the very short time that has been allowed.

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We will continue to closely monitor all developments related to California’s Prop 65 requirements for BPA. If you have any questions, or if we can be of any assistance, please do not hesitate to contact us.

18/ See *id.*