Proposition 65 - California Proposes Regulations for Exposures to Bisphenol A (BPA)

Summary

The Proposition 65 warning requirement for exposures to BPA, listed as a reproductive toxicant, is effective on May 11, 2016. California’s Office of Environmental Health Hazard Assessment (OEHHA) has issued two proposed regulations -- an emergency regulation for exposure to BPA through ingestion, which permits temporary point of sale warning signage for canned and bottled food and beverages, and a proposed regulation which sets a safe harbor level of 3 mcg/day for dermal absorption of BPA from solid materials.

Proposition 65 Background

The Safe Drinking Water and Toxic Enforcement Act of 1986 (California Health and Safety Code §25249.5, et seq.) -- Proposition 65 -- requires the State of California to publish a list of chemicals “known to the state to cause cancer or reproductive toxicity,” and establishes two prohibitions regarding these chemicals. One prohibition is that no person may knowingly and intentionally expose any individual in California to a significant amount of a listed chemical without first providing a “clear and reasonable warning” to such individual (for consumer product, occupational and environmental exposures). The other prohibition is that no person may knowingly discharge or release a significant amount of a listed chemical into drinking water or into or onto land where it will pass into a source of drinking water. More than 900 chemicals have been listed under Proposition 65 by OEHHA.

Warnings are not required and the discharge prohibition does not apply, when exposures are “insignificant.” For warnings, an exposure is insignificant if the person responsible can show that it poses no significant risk assuming lifetime exposure at the level in question for listed carcinogens (the “no significant risk level” or “NSRL”), or that it will have no observable effect assuming exposure at 1,000 times the level in question for listed reproductive toxicants (“maximum allowable dose level” or “MADL”). The exposure assessment must be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis of the listing. California has established NSRLs and MADLs (safe harbor levels) for a number of listed carcinogens and reproductive toxicants. The use of OEHHA safe harbors is voluntary, and the regulations allow a business to calculate its own NSRL or MADL, but those levels may be challenged in an enforcement action.

The law’s discharge prohibition and warning requirement may be enforced by actions for injunctive relief and for civil penalties of up to $2,500 per day for each violation. In addition to enforcement by public prosecutors, Proposition 65 contains a bounty hunter provision that permits private enforcers to bring a lawsuit if a public prosecutor does not act within 60 days after notification (“60-Day Notice”) from a bounty hunter of an alleged violation.

The majority of enforcement actions are brought by private enforcers, who are entitled to 25% of any civil penalty assessed by the courts; they can also seek attorneys’ fees under California’s private attorney general statute. Most Proposition 65 matters settle. In 2014, there were 663 private settlements under Proposition 65, totaling $29.5 million (over 70% of that amount was paid to private enforcers as attorneys’ fees).
Previous Proposition 65 Actions Regarding BPA

OEHHA’s Developmental and Reproductive Toxicant Identification Committee (DARTIC) considered listing BPA in 2009 but voted unanimously against doing so, on the ground that the experimental animal data cited in support of the listing were insufficient.

In January 2013, OEHHA sought to list BPA as a reproductive toxicant under the Proposition 65 authoritative bodies’ listing mechanism, based on a 2008 report by the National Toxicology Program (NTP), which found “clear evidence” of developmental toxicity at high doses of BPA. The American Chemistry Council (ACC) brought a lawsuit in March 2013 challenging the listing. The court issued a preliminary injunction in April 2013, ordering that BPA be removed from the Proposition 65 list pending a final resolution of the ACC lawsuit (American Chemistry Council v Office of Environmental Health Hazard Assessment et al.). The trial court denied ACC’s petition, finding that OEHHA did not abuse its discretion in listing BPA under the authoritative bodies’ mechanism, and the ACC case is on appeal. The outcome of the ACC appeal will not, however, affect the latest listing of BPA because that was based on a DARTIC vote, which is a different mechanism for listing.

Current Listing of BPA

On May 11, 2015, BPA was listed under Proposition 65 as a reproductive toxicant, for the female reproductive toxicity endpoint, after DARTIC reviewed epidemiological and toxicological data on BPA and female reproductive toxicity that had become available since 2009. The effective date of the warning requirement is May 11, 2016. Recently, however, OEHHA indicated that it was not going to propose a MADL for exposure to BPA from ingestion due to concerns regarding the sufficiency of data. In the absence of a proposed safe harbor level, industry faced a difficult compliance situation given OEHHA’s position on existing data. Last week, OEHHA announced proposed regulations for BPA compliance, with respect to both ingestion and dermal absorption, as follows:

1. Exposure -- Ingestion

   • OEHHA posted a proposed emergency regulation to permit temporary point of sale warning signage for canned and bottled food and beverages. The emergency safe harbor language, which is inoperative one year after the date of adoption (unless reenacted by OEHHA) is: 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 please click here.

   • “Point-of-sale” means the area within a retail facility where customers pay for foods and beverages, such as the cash register or check-out line where the warning sign is likely to be seen and understood prior to the consumer purchasing the canned or bottled food or beverage. Point-of-sale also includes the product display page or electronic check-out functions for products sold over the internet. The warning signs must be no smaller than 5 by 5 inches, and the location must be conspicuous. For more information, please click here.

   • The current regulations do not expressly permit standard point-of-sale warnings for consumer products that cause exposures to listed chemicals, and OEHHA hopes to set a proposed MADL for exposures through ingestion during the period covered by the proposed emergency regulation. OEHHA concluded that the situation qualified as
an emergency because if there was no regulation in place by May 11, 2016, manufacturers and retailers might remove canned and bottled food and beverage items from store shelves, or might place multiple and inconsistent warnings on products and on signage throughout a retail facility, resulting in confusion and unnecessary adverse impacts on public access to nutritious food, particularly for California's most vulnerable communities.

- After submission of the proposed emergency regulation to the Office of Administrative Law, interested persons have five calendar days to submit comments.

2. Exposure -- Dermal Absorption

- OEHHA also posted a notice of proposed rulemaking to establish a MADL of 3 mcg/day for dermal absorption of BPA from solid materials. Comments are due by May 16.

For more information on this article or any Proposition 65 matter please contact prop65@khlaw.com.