Major New Wave of California Proposition 65 Lawsuits About to B(PA)reak

Joseph J. Green

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May 11, 2016. A day that may live in California Proposition 65 infamy. The date marks the one – year anniversary of the listing of Bisphenol A (BPA) as a reproductive toxicant under Proposition 65, and the expiration of the grace period for enforcing the regulatory program's consumer warning requirements. Businesses selling consumer goods in or to California, particularly those made from polycarbonate plastic, will now face compliance obligations including assessing the need for a BPA-related warning, and, if so, implementing a program for providing the appropriate warning system to consumers.

Polycarbonate is a common polymer widely used in plastics for its durability, impact resistance, temperature resistance, and optical transparency. These features make polycarbonate highly desirable for a wide range of products, from sunglasses and eyeglass lenses to drinking bottles and food containers to sports equipment and safety visors. Food and beverage can linings also commonly include polycarbonate. BPA is a precursor monomer used in the manufacture of polycarbonate and, accordingly, may be found in polycarbonate products.

Companies that sell polycarbonate products will be high profile targets for Proposition 65 enforcement actions, particularly from one of the prominent and highly active citizen enforcement plaintiff groups in the state, and should be examining their compliance without delay.

What To Do If Your Product May Contain BPA?

Polycarbonate consumer goods manufacturers, distributors, and retailers, among others who do business in California, should promptly assess (a) whether their product contains BPA, and (b) if so, how much BPA is released from the product (*i.e.,* potential consumer exposure) during foreseeable use (and abuse). Testing of representative samples is recommended to provide the company with concrete data that can be used to refute potential future claims under Proposition 65.

In theory, to determine if a warning is required, businesses should compare data on potential BPA exposure levels to a "safe harbor" threshold established under the regulations. California has proposed a safe harbor level of 3 micrograms per day for dermal exposure to BPA, but this standard has yet to be finalized and does not address other exposure pathways such as hand-to-mouth contact. Companies are advised to seek counsel regarding the development of an appropriate safe harbor level for their product.

In practice, due to the cost and difficulty to establish a safe harbor level for a listed chemical, companies often default to providing prophylactic warnings if they have reason to believe that a listed chemical may be present in their product (regardless of the potential for consumer exposure).

Such “over-warning” is rational given the alternative, including the potential for a citizen enforcer to challenge a company’s independent “safe harbor” determination.

If a warning is required, companies must then determine how best to deliver the warning in a manner that fits their business model while providing the requisite information to consumers in a clear and reasonable manner.

Ostensibly to ease compliance for food and beverage retailers, California adopted an emergency regulation requiring the posting of point-of-sale warning signs that read as follows:

WARNING: Many food and beverage cans have linings containing bisphenol A (BPA), a chemical known to the State of California to cause harm to the female reproductive system. Jar lids and bottle caps may also contain BPA. You can be exposed to BPA when you consume foods or beverages packaged in these containers. For more information, go to: www.P65Warnings.ca.gov/BPA.

Similar provisions have not been adopted for other consumer goods.

Kelley Drye has extensive experience with Proposition 65, including BPA, and can help your business navigate compliance options.

Background On Proposition 65

Proposition 65 was adopted by voter referendum in 1986 as the Safe Drinking Water and Toxic Enforcement Act. The law requires businesses who expose individuals in California to substances deemed by the state to cause cancer or reproductive harm to provide a clear and reasonable warning before exposure. The Office of Environmental Health Hazard Assessment (OEHHA) implements Proposition 65 and maintains a list of chemicals, over 900 currently, identified as carcinogens and reproductive toxins for which warnings may be required.

If a warning is required, business must provide one that is “reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individuals prior to exposure.” The warning “message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm.” The regulations provide that if certain specific text is used, the warning is deemed to be *per se* compliant (“WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.”). Most commonly, warnings are provided either on direct product labels or through point-of-sale signs posted with the product, though numerous other options are available (including electronic delivery). On-line purchases also may require a warning.[1]

The failure to provide a warning can subject violators to penalties of up to $2,500 per day and per exposure. The state Attorney General may bring a lawsuit to enforce the law’s requirements, and many of the most high profile cases are handled in this manner. However, most cases are brought under the law’s “bounty hunter” provision, which allows private plaintiffs to bring an action seeking penalties for alleged violations. Each month, scores of new cases are filed mostly by approximately a dozen highly active private plaintiff groups alleging failure to warn due to the presence of listed substances. Thus, the law leaves businesses vulnerable not only to scrutiny from state regulators, but from private citizens as well.[2]

Products containing lead and phthalates have been cited most frequently in 60-day notices and complaints filed over the last several years, as have exposures to tobacco smoke and diesel exhaust.

BPA-related actions are expected to vault to the top of the list in the very near future.

Several important, though somewhat limited, exemptions are provided. For example, a warning is not required for "naturally occurring" substances in a food product, and businesses with less than 10 employees are not subject to the requirements. Most significantly, a warning is not required if an exposure is so low as to create no significant risk of cancer or reproductive harm (per stringent standards specified under the regulations). While the exemption provides entities with some relief from liability, the burden rests on the business to demonstrate that a particular exposure level poses no significant risk. This task often is prohibitively expensive, as it can require extensive testing and technical analysis.

To facilitate compliance, OEHHA has adopted "safe harbor" warning threshold levels for approximately 300 substances that helps eliminate some of the uncertainty in determining what exposure level requires a warning. However, these "safe harbor" levels generally are very low, in accordance with highly conservative and non-scientific risk assumptions. It is important to note that "safe harbor" thresholds identify the level of *exposure* to, and not the product content of, a substance that is deemed not to pose a risk or require a warning.

Ultimately, Proposition 65 is the source of lawsuits against many businesses for failure to provide a warning. These cases often are brought against companies that are unaware that low levels of listed chemicals (such as lead and phthalates, or, now, BPA) are present in their products. When confronted with a lawsuit from a plaintiffs group, these businesses often rationally decide to settle the case by agreeing to provide a warning and paying a penalty, typically in the range of $20,000-$150,000 or more, instead of facing the costs during litigation of establishing that an exposure is exempt from warning requirements. Hence, historically, the statute has encouraged over-warning, as businesses may provide warnings even where an exemption may apply simply to avoid costs.

Kelley Drye has extensive experience providing counsel to consumer good and manufacturing clients on compliance with Proposition 65, including with respect to BPA. We would be happy to assist your company in assessing your Proposition 65 obligations and developing an appropriate compliance program. For more information about this client advisory or Proposition 65 in general, please contact:

Joseph J. Green
(202) 342-8849
jgreen@kelleydrye.com

Kelley Drye's Environmental Law Practice Group specializes in providing comprehensive solutions to complex problems. We provide both advice and representation for clients participating in rule-making and policy-making activities by federal regulatory agencies, including the U.S. Environmental Protection Agency and the Occupational Safety & Health Administration, and similar state agencies. We have decades of experience advising companies and industry trade organizations with respect to Proposition 65 requirements and related compliance and litigation matters.

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[1] Substantial revisions to the Proposition 65 warning requirements have been proposed and may be adopted by the end of the year. Please see our previous advisories for further details.
[2] Before bringing a lawsuit, private groups must take certain preliminary steps, including providing the alleged violator and the Attorney General's office with a notice of the alleged violation 60 days before commencing a lawsuit.