CALIFORNIA'S PROPOSITION 65

Sarah Esmaili, Arnold & Porter LLP

California's Safe Drinking Water and Toxic Enforcement Act – commonly referred to as Proposition 65 – applies to almost everyone doing business in California, including companies that ship products into California.[1] Proposition 65 can be enforced by public enforcers as well as private plaintiffs through civil lawsuits, and plaintiffs do not need to show any actual injury. Plaintiffs can seek civil penalties of up to a maximum of $2,500 per violation, injunctive relief, and attorneys' fees. In enforcement actions, Proposition 65 places the greater burden of proof on businesses rather than plaintiffs.

Proposition 65 is often more stringent than federal law, and Proposition 65 cases involving a wide variety of products – such as (among others) children's products, jewelry, cosmetics, decorated glassware, dietary supplements, and plumbing fixtures – have set reformulation standards that go beyond federal requirements. Proposition 65 cases have also acted as a trigger leading to recalls, CPSC and other federal agency review, and federal and state regulations. A few examples of this are cases concerning Mexican candy, children's toys, and jewelry.

Not only is Proposition 65 wide-ranging in its impact on businesses, it is complex. Even some very sophisticated companies have found themselves facing enforcement issues. Because of its scope and impact, an understanding of Proposition 65's unique requirements is essential to developing an effective compliance strategy.

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[1] Cal. Health & Safety Code §§ 25249.5 *et seq.*

There are over 800 chemicals currently listed under Proposition 65. Listed chemicals are classified either as carcinogens or reproductive toxicants (or both).

Proposition 65 prohibits businesses with 10 or more employees from knowingly and intentionally exposing any individual in California to a listed chemical without first giving a clear and reasonable warning. The warning requirement applies separately and independently to each covered business in the chain of distribution such as manufacturers, distributors, and retailers.

When a warning is required. An exposure to any amount of a listed chemical requires a warning unless the exposure is specifically exempted. Therefore, a plaintiff bringing a Proposition 65 lawsuit only needs to show detection of any amount of a listed chemical – no matter how minimal – and that no warning was provided.

Once the plaintiff makes this showing, the burden shifts to the business to prove an exemption. One key exemption is that exposures will not exceed specified health risk thresholds, which are extremely conservative. For carcinogens, this is the "No Significant Risk Level" (NSRL), which is the level calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming a lifetime of exposure. For reproductive toxicants, it is the "No Observable Effect Level" (NOEL), which is the level at which there is no observable reproductive effect, divided by a 1000-fold safety factor. To avoid liability, a business must demonstrate, usually through a complex risk assessment, that exposures will not exceed the NSRL or NOEL. The lead agency implementing Proposition 65 (OEHHA) has set regulatory "safe harbor" NSRL and NOEL exposure levels for only a subset of chemicals.

Proposition 65 regulates exposures, not concentration. Therefore, in a compliance setting, many businesses refer to other Proposition 65 settlements for guidance on concentration levels that may be present in products without the need to provide warnings. Although these settlements technically only apply to the settling parties, they are a useful reference for other companies.

How to provide warnings. Proposition 65 requires "clear and reasonable" warnings. The method used to transmit the warning must be reasonably calculated to make the warning available to an individual before exposure. The message must clearly communicate that the chemical in question is known to the State to cause cancer, on the one hand, or birth defects or other reproductive harm, on the other hand (or both).

OEHHA has developed "safe harbor" warnings that are presumptively clear and reasonable. Depending on the type of exposure, there are different safe harbor warning methods and messages that may apply. In providing warnings, a business may rely on the safe harbor warning methods and messages, but is not required to do so.

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An effective compliance strategy is necessary to meet the complex requirements of Proposition 65. Although there is no "one-size-fits-all" approach to compliance, every affected business must take steps to ensure that it meets the law's unusual requirements.

Sarah Esmaili is with Arnold & Porter's San Francisco, California office. Sarah.Esmaili@aporter.com.