

Fact Sheet on California's Proposition 65

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Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted by voter initiative in California on November 4, 1986. The law has had a significant impact on companies doing business in California. Indeed, courts have interpreted the law broadly, and it applies to virtually every product sold in California. Proposition 65 enforcement proceedings have involved products such as footwear, jewelry, food, beverages, exercise equipment, sporting goods, apparel, handbags, luggage, dietary supplements, automotive accessories, tools, art supplies, candles, other home accessories, office supplies, paint, and many others.

I. Overview of Proposition 65

Proposition 65 has two primary requirements. First, there is a warning requirement that states: "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 clear and reasonable warning to such individual." Health & Saf. Code¹ § 25249.6. Second, there is a discharge prohibition, which prohibits companies from discharging a chemical "into water or onto or into land where such chemical passes or probably will pass into any source of drinking water." Id. § 25249.5.2

A. Listed Chemicals

Proposition 65 requires that, at least once per year, the Governor shall cause to be published "a list of those chemicals known to the state to cause cancer or reproductive toxicity...." Id. § 25249.8(a). The law also provides that the Governor "shall designate a lead agency" that is responsible for implementing Proposition 65. Id. § 25249.12(a). The Office of Environmental Health Hazard Assessment ("OEHHA") is the designated agency. It has been the lead agency since 1991 (before that, it was the California Health and Welfare Agency).

There are over 850 chemicals on the state's list of chemicals "known to cause cancer or reproductive toxicity." The list is ever-expanding, as OEHHA continues to add chemicals to the list on a relatively frequent basis. The listing process is discussed in greater detail below. A current Proposition 65 list of chemicals is available at OEHHA's website: <http://oehha.ca.gov>.

¹ All statutes referred to herein are California statutes, unless otherwise indicated.

² This summary and outline of Proposition 65 and related issues will focus on the warning requirement in the statute, not the discharge prohibition.

B. Warning Requirement

Proposition 65 requires a “clear and reasonable” warning that is provided before exposure. Health & Saf. Code § 25249.6. The implementing regulations provide: “Whenever a clear and reasonable warning is required under Section 25249.6 of the Act, the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure.” Cal. Code Regs., tit. 27, § 25601. Under the regulations, the warning message must clearly communicate that the chemical in question is known to the state to cause cancer or reproductive toxicity. The regulations state that the warnings may be provided by using one or more methods, including product labeling, point-of-sale signs, or public advertising. Id. § 25603.1(a)-(d).

The regulations also describe “safe harbor” warnings, which are deemed to meet the “clear and reasonable” standard. *Physicians Comm. for Responsible Med. v. McDonald’s Corp.*, 187 Cal. App. 4th 554, 567-69 (2010). For consumer exposures, the safe harbor warnings are:

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Additionally, many court-approved consent judgments, including some settlements with the Attorney General’s office or other private plaintiffs have allowed combined warning language, such as:

WARNING: This product contains chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm.

A company that uses the safe-harbor warning where consumers will likely see it before exposure can argue that the warning was “clear and reasonable,” and thus, that the company is in compliance with Proposition 65. See *id.* at 571 (citing *Env’tl. Law Found. v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 66 (2005)).

Before deviating from the safe harbor language for Proposition 65 warnings, companies should consult with experienced counsel to assess whether the proposed modification to the safe harbor warning language is appropriate or advisable.

C. Regulation by Litigation

A critical and unique aspect of Proposition 65 is that most of the cases are filed by private parties acting “in the public interest,” and not on behalf of any individual harmed by the defendant’s conduct. This distinguishes the law from other consumer product regulations because enforcement is not limited to a governmental agency, but instead can be pursued by private individuals. To be sure, the Attorney General’s office can file Proposition 65 enforcement actions and does so. But the vast majority of the

Proposition 65 lawsuits filed in California each year are by private parties. These private plaintiffs have a financial incentive to pursue Proposition 65 litigation because they can recover a portion of the penalties that are ultimately assessed as well as their litigation costs and attorneys' fees.

Another aspect of Proposition 65 that makes it an easy target for private plaintiffs is that the burden of proof for establishing a prima facie case is relatively easy for the plaintiff. Indeed, courts have ruled that the burden of proof shifts to the defendant if the product in question contains a trace amount of one of the chemicals on the state's list of chemicals known to cause cancer or reproductive toxicity. Accordingly, for these reasons, Proposition 65 is "enforced" primarily through lawsuits brought by private individuals.

The potential for penalties is significant: a violator can be subject to a civil penalty of \$2500 per violation per day in addition to "any other penalty established by law." Health & Saf. Code § 25249.7. These penalties can add up to significant amounts even if the company's sales of the product in question were low. Additionally, the cost of litigation and establishing that a defense applies or that no violation occurred can be quite expensive. As a result, most Proposition 65 enforcement actions are resolved via settlement.

II. Safe Harbor Levels

OEHHA has established safe harbor levels for some of the chemicals listed under Proposition 65, which include No Significant Risk Levels for cancer-causing chemicals, and Maximum Allowable Dose Levels for chemicals causing reproductive toxicity. Exposure levels that are below the safe harbor levels are exempt from the requirements of Proposition 65. Safe harbor levels are not provided as content limits, however, and there are no safe harbor levels for the majority of listed chemicals.

III. 60-Day Notice Requirement

A Proposition 65 lawsuit may be filed by "any person in the public interest" if a 60-day notice with a certificate of merit is provided, and if there is no action being pursued by the California Attorney General or any district or city attorney in the state. *Id.* § 25249.7(d).

A. Notice Must Be Filed and Served Appropriately

Private actions require a 60-day notice before the private plaintiff can file a lawsuit in court. *Id.* The notice must be sent to the alleged violator, the California Attorney General, and the City Attorneys for cities with populations of over 750,000 where the violation is alleged to have occurred. *Id.* Note that the typical service requirements for state complaints do not apply here. Frequently, plaintiffs simply mail the 60-day notice to a high-ranking executive at the defendant company.

B. Certificate of Merit

The 60-day notice must include a certificate of merit. The certificate of merit must be signed by the attorney for the noticing party, or by the noticing party, if the noticing party is not represented by an

attorney. It must state that the person executing the certificate has “consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposure to the listed chemical that is the subject of the action, and that, based on that information, the person executing the certificate believes there is a reasonable and meritorious case for the private action.” *Id.* In addition, factual information sufficient to establish the basis of the certificate of merit (such as test results) must be attached to the certificate of merit that is sent to the Attorney General. *Id.*

C. Court-Approval of Settlements Brought in the Public Interest

When there is a settlement of a Proposition 65 lawsuit by a plaintiff acting “in the public interest,” the plaintiff must submit the settlement to the court for approval.³ The plaintiff must file a noticed motion for approval of the settlement, and the court may approve the settlement only if the court makes all of the following findings: (1) any warning that is required by the settlement complies with the statute; (2) any award of attorneys’ fees is reasonable under California law; and (3) any penalty amount is reasonable based on the criteria set forth in the statute. *Id.* § 25249.7(f)(4).

IV. Defenses

A. No Significant Risk/No Observable Effect

The warning requirement under Proposition 65 does not apply if the defendant can show: (1) for cancer, that the alleged exposure poses “no significant risk” assuming lifetime exposure at the level in question; and/or (2) for reproductive toxicity, that the exposure will have “no observable effect” assuming exposure at 1,000 times the level in question. *Id.* § 25249.10(c). The defendant company has the burden of establishing that the alleged exposure meets these criteria and must do so with the use of reliable scientific evidence. *Id.*

B. Fewer Than 10 Employees

Proposition 65 does not apply to companies that have fewer than 10 employees under the terms of the statute. *Id.* § 25249.11(b).

C. Federal Preemption

Proposition 65 does not require a warning for “[a]n exposure for which federal law governs warning in a manner that preempts state authority.” *Id.* § 25249.10(a). Federal preemption can be difficult to establish, and courts have rejected preemption arguments in numerous cases. However, the California Supreme Court upheld the defense in *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004) (holding that Proposition 65 warning requirement regarding smoking cessation products is preempted by the federal Food, Drug and Cosmetic Act and FDA regulations).

³ A voluntary dismissal of the lawsuit, where no consideration is paid by the defendant, does not require court approval. Health & Saf. Code § 25249.7(f)(4).

D. Naturally Occurring

Under Proposition 65, there is an exemption for chemicals that are “naturally occurring” in food. Cal. Code Regs., tit. 27, § 25501. This exemption applies only to naturally occurring chemicals in foods or products made from foods. Id. § 25501(a), (b). Notably, OEHHA drafted this exemption narrowly, and it can be difficult or costly to establish because the defendant company must show that the chemical’s presence “did not result from any known human activity” but only from absorption or accumulation of chemicals “naturally present in the environment in which the food is raised.” Id. § 25501(a)(1), (3). Further, the defendant must show that the chemical in the food is at the “lowest level currently feasible.” Id. § 25501(a)(4).

This defense was successfully applied in *The People ex. rel. Brown v. Tri-Union Seafoods, LLC*, 171 Cal. App. 4th 1549 (2009), a case involving methylmercury in tuna products.



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