



## Proposition 65: How does this regulation affect food packaging?

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If you sell products into California, you need to be aware of Proposition 65, commonly known as Prop 65. Prop 65 was enacted as the Safe Drinking Water and Enforcement Act in 1986 to address concerns about consumer exposure to toxic chemicals. Prop 65 requires that the state of California publish a list of chemicals (now over 900) that may cause cancer, birth defects or reproductive harm. The list includes additives, ingredients, or impurities that may be found in common household products, food, drugs, dyes, or solvents. They can also be chemicals used in manufacturing, or byproducts of chemical processing. For businesses selling into California, the Prop 65 regulation requires warnings to be provided to citizens prior to exposure to any chemical found on the list.

The list contains information on the chemical, the type of toxicity, the CAS (Chemical Abstracts Service) Number, and the date it was listed. Further information regarding the chemical use, listing mechanism, and supporting documents associated with the listing may be found on the California OEHHA website for Prop 65. An independent list provides the safe harbor level, if available. A safe harbor level is a daily exposure limit that is expressed as  $\mu\text{g}/\text{day}$ . It is completely different from the chemical total content of a product ( $\text{mg}/\text{kg}$ ). Where it may be demonstrated that typical use of a product results in exposure that falls below the safe harbor levels, the regulation provides a warning exemption. If exposure falls above these levels and the business has 10 or more employees, a warning label is required. In an effort to make warnings more meaningful and useful for

the public, new warning requirements came into effect in August 2018. They require identification of listed chemicals on the warning label and contain updates to notification requirements to retailers. Enforcement begins 12 months after listing any chemical under Prop 65. Companies failing to comply with this rule are liable to civil penalties, especially as active litigation for Prop 65 is increasing.

Estimating exposure to a listed chemical for Prop 65 requires consideration of the handling (skin contact), ingestion, and potential inhalation (volatile compounds) of the product components. For food products, exposure to consumers occurs through consumption of the product where listed chemicals may migrate from the packaging material into the food. In addition, handling of food packaging may expose skin to compounds occurring on product labels, such as in inks, plastics, or paperboard coatings. Compounds such as bisphenol A, benzophenone, phthalates, vinyl chloride, vinylidene chloride, styrene and other listed chemicals may be present in packaging materials.

Bisphenol A is on the Prop 65 list because it can harm the female reproductive system, including effects on ovaries and eggs. The source could include some linings in metal food and drink cans, jar lids and bottle caps. Bisphenol A can also be present in polycarbonate plastic items such as some water bottles and water cooler bottles.

Benzophenone is on the list because it can cause cancer. Benzophenone is present in inks used on some food packaging materials that can migrate from food packaging materials into food or result in exposure through handling.

Six phthalates are on the list because they can cause birth defects or other reproductive harm and/or cancer. Some plastic food packaging materials can contain phthalates.

Questions to ask to determine if your package is affected by Prop 65 are:

- » Are any listed chemicals used in the production of the packaging material present as byproducts of the manufacturing process or impurities or residuals of unreacted starting materials?
- » If any of the listed chemicals are in the finished package, will exposure under typical use conditions exceed the safe harbor levels? This analysis considers the residual levels of the listed chemical in the package, the average use of the package (single or repeated use), and the manner in which the package is used. An appropriate consumption factor can be used to estimate ingestion exposure. The “consumption factor” is the fraction of an individual’s diet that is likely to contact a specific material.

It is the responsibility of the manufacturer of the finished consumer product to determine whether its products can reasonably be expected to result in a significant exposure. One should consider the impact of packaging for chemical migration. It is important for companies to understand their Proposition 65 liability, how to assess that liability, and how to interpret the regulations. ●

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