Navigating Proposition 65: Ensuring Safe Drinking Water and Compliance in California

Abstract:

California proposition 65 states that no toxic chemicals should present in safe drinking water or in any product. The Ca prop 65 act came into enforcement in 1986. California state published a list of chemicals known to cause cancer (or) birth defects (or) reproductive harm. Proposition 65 enables California's to make informed decisions about their exposures to these chemicals. Proposition 65 also prohibits California business from knowingly discharging significant amounts of listed chemicals into source of drinking water. California Proposition 65 became law in November 1986, when California voters approved it by a 63-37 percent margin. This list was first published in 1987 and must be updated at least once a year. It now includes over 1013 chemicals. Prop 65 applies only in California state. The official name of Proposition 65 is the Safe Drinking Water and Toxic Enforcement Act of 1986.



Introduction:

The Safe Drinking Water and Toxic Enforcement Act, also known as proposition 65, was introduced in the state of California in 1986 by popular vote. Proposition 65 requires the state to publish and maintain an updated list of chemicals known to cause cancer, birth defects and reproductive harm. The current proposition 65 contains 1013 chemicals and last updated on November 17, 2023. The list is administered by the Office of Environment Health Hazard Assessment (OEHHA) and is updated at least once a year.

Scope:

The scope of the law is therefore extensive, given it has the potential to involve an unlimited variety of substances as more medical and environmental data is gathered. The ever-expanding list of restricted substances make it essential for companies to understand Proposition 65, how it affects them and how they can meet its requirements.

Proposition 65 requires two key commitments from the corporate sector. First, it obliges companies who make or sell products in California to give "clear and reasonable warning" to consumers if their product contains a listed chemical. This could include labelling, signage or public notices. Once a substance is added to the list, the company has 12 months to achieve compliance with the warning requirements. Failure to provide an adequate warning can subject companies in violation to fines of up to \$2,500 per day, per exposure incident.

Second, Proposition 65 prohibits companies from knowingly discharging these substances into the states drinking water sources. This creates a need for accurate testing mechanism and efficient data collection platforms to help companies demonstrate their compliance. Adherence to the discharge prohibition must be achieved within 20 months of the chemical in question being listed by the state.

Substance added to the list:

Carcinogen Identification Centro (CIC) and Development and Reproductive Toxicant (DART) Identification committee. This two are known as the State's Qualified Experts, finds the chemical has been clearly shown to cause cancer, birth defects or other reproductive harm. If the CIC or DART designates one of the following authoritative bodies to identify whether a chemical causes cancer or reproductive harm.

- U.S Environmental Protection Agency (EPA)
- U.S Federal Drug Administration (FDA)
- National Institute or Occupational Safety and Health (NIOSH)
- National Toxicology Program (NTP) and International Agency for Research on Cancer

If an agency requires a chemical to be labelled or identified as causing cancer, birth defects or other reproductive harm (Usually the case for the labelling of prescription drugs). If a chemical meets a Predetermined Scientific Criteria and is identified in the California labour code as causing cancer, birth defects or other reproductive harm.

Safe harbor level:

The law is not a restriction of substances in products. Rather, it requires business to provide a warning to notify California's if they are exposed to chemicals above safe harbor level. The safe harbor level consists of No Significant Risk Levels (NSRLs) for chemicals listed as causing cancer and Maximum Allowable Dose Levels (MADLs) for chemicals listed as causing birth, defects or other reproductive harm. OEHHA has established safe harbor levels, which are measured in micrograms per day, for over 300 chemicals listed. Exposure levels that are below the safe harbor levels are exempt from the requirements of proposition 65.

Consumer product exposure warnings:

Companies that expose persons to a listed substance above the safe harbor level must provide a clear and reasonable warning of the risk, as per the article 6 of the California code of Regulations. If a Product Exposes Individuals to a proposition 65-listed substances, the primary responsibility lies with the manufacturer to apply the

correct warnings.

In August 2016, Article 6 was amended to make the warnings more meaningful to the public. Specifically, the amendment is intended to reduce "over-warning", clarify the responsibilities of manufacturers and retailers to provide warnings, include technological advances in the notification methods used, and increase clarity on how to maintain compliance (such as how and where to provide the warnings.)

Some other key changes associated with the new Article 6 amendment include:

- Tailored warnings for specific products or industries (e.g. Dental care, furniture, diesel engines, automobiles, recreational vessels, amusement parks.)
- Stronger language identifying manufacturers as the primary party responsible for applying the warning.
- Changes to the method for transmitting warnings.
- Changes to the content required within the warning.
- A new obligation for the warnings to specify the name of at least one of the substances that triggered the warning.
- A pictogram to increase the visibility of the warning.



Chemicals - Proposition 65 Warnings Website

Potential Exposure to Acrylamide

Acrylamide is on the Proposition 65 list because it can cause cancer. Exposure to acrylamide may increase the risk of cancer. It can affect the development of the fetus and can harm the male reproductive system. Acrylamide is a chemical that is formed in certain plant-based foods during cooking or processing at high temperatures, such as frying, roasting, grilling and baking. Boiling or steaming foods does not create acrylamide.



Sources of acrylamide in the diet include French fries, potato chips, other fried and baked snack foods, canned sweet potatoes and pumpkin, some cookies, bread crusts and toast.



Tobacco smoke contains acrylamide. It is used for industrial purposes. It is also used to produce polyacrylamide. During pregnancy, acrylamide can pass from the mother to the baby.

How is Proposition 65 enforced:

Enforcement is carried out through civil lawsuits. The California Attorney General's Office (OAG), district attorney and city attorney have the authority to take such actions. In addition, private parties acting in the public interest are also allowed to bring proposition 65 lawsuits, but only if they have provided at least 60 days' notice of the alleged violation of the business as well as to the attorney. If a business is found to be in violation of proposition 65, a count may order the business to stop committing the violation. The penalties can be as high as US\$2,500 per violation per day.

Complying with proposition 65:

The proper use of a warning label provides for full compliance. However, many companies see the warning label as not desirable at point of sale and therefore choose to test their products. Proposition 65 does not have any testing process to achieve compliance.

However, if a company has been party to a settlement, then they are required to test their products and they will be in compliance if the test meets the requirements of the settlement. A company which chooses not to use a proper warning label, and which is not part of a settlement is exposed and can employ testing only to mitigate risk.

Once that process has been established and data is captured, companies will need to evaluate if any substance found within their products exceed safe harbor levels and require the use of warnings. Failure to meet these requirements can result in significant financial penalties, as seen in the Mattel case, but can also entail additional costs associated with re-printing labels, changes to packaging materials and inventory management.

Conclusion:

The proposition 65 protects the state's drinking water sources being contaminated with chemicals known to cause cancer, birth defects and other reproductive harm, and requires business to inform Californians about exposures to such chemicals.

References:

https://www.p65warnings.ca.gov/chemicals

Author:

Kandukuri Niharika, Jr. Compliance Engineer iLenSys Technologies Pvt. Ltd.