

What is California Proposition 65?

- SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT
- Supported on a 1986 California referendum by 63% of voters.
- Proposition 65 requires businesses to provide warnings to Californians about significant exposures to chemicals which cause cancer, birth defects or other reproductive harm.
- The law applies to items that Californians purchase, or may be exposed to in their homes, workplaces, public places, or substances that are released into the environment. ¹
- Proposition 65 requires California OEHHA to publish a [list of chemicals](#) known to cause cancer, birth defects or other reproductive harm and update it at least once a year. The list now includes over 900 substances. ¹

¹ “About Proposition 65 - What is Prop 65?”. OEHHA. <https://oehha.ca.gov/proposition-65/about-proposition-65>. 30 April 2018.

What is Changing?

- Originally, Proposition 65 warnings were required to state that a chemical is present that causes cancer or reproductive harm.
- Revised OEHHA regulations require new warnings on products manufactured after **August 30, 2018**:
 - Specific Language on warning labels to identify the specific chemical/risk
 - Specific warning requirements for retail/public signs
 - Visible warning requirements for Internet and Catalog Sales
 - Unless the business can show that the anticipated exposure level is below significant risk levels for cancer (NSRLs) or below Maximum Allowable Dosage Levels (MADLs) believed to cause birth defects or other reproductive harm.

Source: <https://oehha.ca.gov/proposition-65/>.

Who is Required to Provide Warnings?

- Manufacturers
- Producers
- Importers
- Distributors
- Retailers
- Website Sales

Everyone in the supply chain!



Responsibility to Provide Warnings


- Manufacturer/Packager/Importer/Supplier/Distributor:
 - *Must Affix warning label to the product;*
- Or
- **Provide written notice** to authorized agent for resellers which:
 1. States that a warning is required
 2. Includes the name, description or identifying information for the product
 3. Includes all necessary warning materials
 4. *The Business providing written notice must **obtain confirmation of receipt**, electronically or in writing.*



New Warning Labels


Examples of Acceptable Warning Labels Under the New Regulations

Cancer




WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information, visit www.P65Warnings.ca.gov.

Combined Cancer/Birth Defect



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Birth Defect



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Truncated on Product Warning



WARNING: Cancer and Reproductive Harm—
www.P65Warnings.ca.gov

Type Size: The warning text must be the same size as other consumer information presented on the package and may not be smaller than 6-point type.

Potential for Abuse

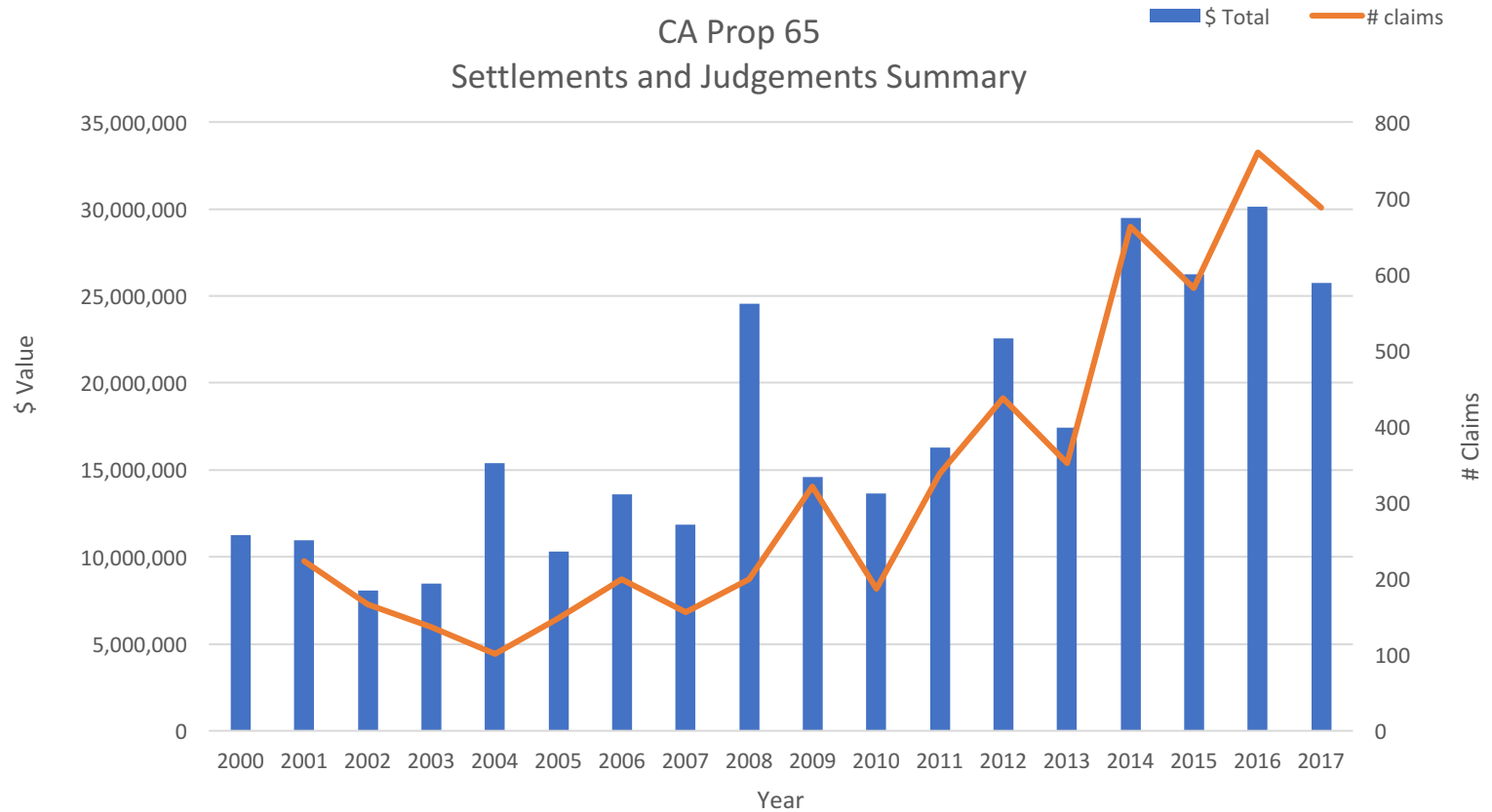
Under most federal or state environmental regulations, the government is in charge of ensuring that businesses comply with the law.

But California's Proposition 65 contains a unique "citizen lawsuit" provision. That means **private citizens can file lawsuits against businesses they claim aren't fully complying with the law.**

There are strong incentives for citizens/organizations to file lawsuits :

- citizens or organizations that bring lawsuits are awarded one-quarter of the civil penalty paid by a business found in violation
- Many businesses opt to settle lawsuits out of court.
- There is no requirement that organizations or individuals prove that they have been injured in any way.
- The plaintiffs' attorneys' fees are substantial

Settlements and Judgements



Data accessed 4/26/2018 from <https://oag.ca.gov/prop65/annual-settlement-reports>

CA Prop 65 and Electronic Components

- A recent RINA study found that 102 of the over 900 substances listed in the latest CA Prop 65 List may be found in mechanical or electrical products.
- Based on review of the CA Prop 65 substance list, BomCheck found that 28 of the Prop 65 substances are already identified in RoHS, REACH, or POPS regulations or on the REACH Candidate list.
- Component Manufacturers and Finished Product Manufacturers should assess the potential for exceeding “safe harbor” levels and provide labeling and warnings where appropriate.

Source: <https://demo.bomcheck.net/proposition65>

Risks

- Insufficient P65 Labeling and Warning Information from Manufacturers.
 - Some Manufacturers believe that components are not “consumer products” so they are not at risk.
 - Some Manufacturers believe that there is no general exposure risk of chemicals on or in components.
 - Some Manufacturers do not consider potential exposure to employees in California Manufacturing operations.
 - Some Manufacturers’ rely on assumptions and generalizations not supported by toxicology work.
 - Product changes and Substance List changes
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- Lack of due diligence by Distributors to question their supply base.
 - Lack of relabeling policy for repackaging by Distributors
 - Lack of notification on Internet orders, catalogue orders, phone orders
 - Lack of records supporting due diligence and customer notification.
 - Lack of Litigation response plans

Risk of “Over-warning” ?

“When faced with this rather vexing reality, businesses often choose to provide a warning instead of risking a lawsuit because Proposition 65 statutorily places the legal burden on the business to prove that no warning is required, a burden which makes defending Proposition 65 cases expensive.

Rather than risk being embroiled in litigation involving a battle of the experts at trial, businesses often will instead elect to voluntarily provide a warning out of an abundance of caution in order to shield themselves from the inevitable threat of litigation that would otherwise exist if they did not warn.

These types of prophylactic warnings have contributed to the oft-criticized “over warning” problem under Proposition 65, wherein many Proposition 65 warnings are provided to shield off a legal challenge rather than to warn consumers of actual chemical exposures.

Despite being a criticized practice, over warning often is the right business decision because it has historically been an extremely safe course of action from a liability standpoint.”

<https://calchamberalert.com/2017/03/31/proposition-65-compliance-challenges-include-warning-rules-litigation-threat/>

Manufacturer Prop 65 Compliance Considerations

- Identify chemical content at the MPN Level
- Compare to the current Prop 65 Substance List
- Consider potential exposure paths for downstream manufacturers and end customers for listed substances.
- Conduct toxicology reviews to determine if potential exposure levels are exceeded.
- Determine warning requirements at the MPN Level
- Develop a customer notification plan (Policy, Labels, Warning Instructions)
- Communicate to customers (Distributors, Direct Customers).
- Monitor changes in the P65 Substance List and Product Changes.
- Focus on Litigation Prevention.
- Develop a Litigation Response Plan.

Distributor Prop 65 Compliance Considerations

- Survey Suppliers to determine how they are going to address Prop 65 compliance.
- Update Distributor Supplier Specifications/Contracts with Supplier Prop 65 requirements.
- Develop Distributor Prop 65 Position Statements for Customers
- Add P65 Warning fields to product files
- Add Warning label text to inventory labels as appropriate.
- Add Prop 65 warning to Web sites at the line item level.
- Add Prop 65 warning to Printed catalogs
- Employee training on labeling and component handling safety.
- Focus on Litigation Prevention.
- Develop a Litigation Response Plan.

Important Note:

The material in this presentation is provided as general information and is not intended to be used as legal advice. Please refer to Proposition 65 requirements posted on the OEHHA website and seek the advice of qualified counsel.

Additional Resources

- [OEHHA Prop 65 Page](#)
- [Listed Chemicals](#)
- [California Attorney General Prop 65 website](#)
- [List of AG Settlements Regarding Prop 65](#)
- [Current Prop 65 Statutes](#)
- [Prop 65 Regulations](#)