Executive Summary

For the second time, California’s Office of Environmental Health Hazard Assessment (“OEHHA”), the Proposition 65 lead agency, has proposed new regulations which, if adopted, will have a significant impact on business’s burden of complying with California’s Proposition 65 warning requirements. The latest proposals, which are likely to be adopted and will probably be effective in an as yet undetermined date in 2018, include the following:

- They eliminate the current generic “safe harbor” warning, in most instances require specific reference to a listed chemical in the warning, and shift the burden to the company to prove that the specifically named chemical creates an exposure at a level that requires a warning.

- They eliminate companies’ ability to include the warning in product literature, use and care guides, and the like.

- They include font size requirements, specific internet and catalog warning requirements, in some instances, foreign language requirements, and pre-purchase warning requirements that actually conflict with the statutory language.
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- The environmental warning requirements (e.g., signage at office buildings and the like) are much more onerous; and
- They impose limits on companies' ability to convey supplemental information about Proposition 65 (e.g., web site statements, customer letters and hand-outs and the like) that are vague and probably violate First Amendment commercial speech protection.
- They provide some additional protection for retailers.

Our summary follows:

**Background**

You will recall that California’s Proposition 65, the law that makes it unlawful for a business with ten or more employees to expose a person in California to any of 850+ chemicals without giving “clear and reasonable warning.” Early last year, we advised our clients of some proposed major changes to the regulations concerning what was meant by “clear and reasonable warning.”

These regulations were met with major objections from industry, including exhaustive analysis and critique by the California State Chamber of Commerce. We participated in that effort. Some of our clients, or their trade associations, were also participants. As a result, OEHHA revised some proposed regulations, withdrew others, and issued some new ones. While the overall result is an improvement, the new proposed regulations, if adopted, will significantly increase Proposition 65’s burden on industry and require major changes to the way many companies avoid Proposition 65 liability.

**Text for the New Safe Harbor Product Warnings**

The regulations that have been in place for many years provide for “safe harbor warning” language – language which, if used, is “deemed to be clear and reasonable.” The safe harbor warnings state “WARNING: This product contains a chemical known to the State of California to
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Cause” either “cancer” or “birth defects or other developmental harm.” While the regulations permit other language, the “safe harbor” avoids litigation over whether or not a warning is “clear and reasonable.” Many companies doing business in California combine the two safe harbor warnings and include the combined warning with all their products.

Under the new regulations, if they are adopted, this approach will no longer work. The proposed regulations include the following key elements:

- To be a “safe harbor” warning, the language must specifically name at least one chemical which exists in the chemical at a level for which a warning is required. The relevant level is the level of exposure, not the content of the chemical. It has been our experience that few companies have the resources to determine whether an exposure is at the level requiring a warning, which can be far more expensive than defending or settling a Proposition 65 case.
- The warning must appear to the right of a black exclamation point in a yellow equilateral triangle in a bold black outline, except that if the rest of the label is in black and white, the pictogram can be in black and white.
- Thus, the safe harbor warnings now read as follows:
  - For carcinogens:
    
    ![WARNING: This product can expose you to [name of one or more chemicals], a chemical [or chemicals] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/product.](image)

  - For reproductive toxicants:
    
    ![WARNING: This product can expose you to [name of one or more chemicals], a chemical [or chemicals] known to the State of California to cause birth defects or other reproductive harm. For more information go to www. P65Warnings.ca.gov/product.](image)

  - For chemicals listed as both:
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⚠️ WARNING: This product can expose you to [name of one or more chemicals], a chemical [or chemicals] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www. P65Warnings.ca.gov/product.

The new proposed regulations also contain “truncated” warnings. While these were designed for product / packaging so small there is no room for the full warning, the regulations allow their use on any products. The truncated warnings are these:

⚠️ WARNING: Cancer -- www.P65Warnings.ca.gov/product
⚠️ WARNING: Reproductive Harm -- www.P65Warnings.ca.gov/product
⚠️ WARNING: Cancer and Reproductive Harm-- www.P65Warnings.ca.gov/product

These warnings need not identify a particular chemical.

**Warning Location**

The current regulations provide that a product warning can appear on the “label or labeling.” The regulations define “labeling” very broadly as “any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.” Based on this, it has been completely appropriate, and lawful, to place the warning in the manual or use and care guide.

However, the new regulations, while retaining the “labeling” definition for other purposes, eliminate “labeling” as a location for warnings, requiring either a label with one of the long warnings or an “on-product” label with one of the truncated warnings. The regulations also permit product-specific shelf signs or tags at each point of display of the product.

**Internet and Catalog Sales**

Proposition 65 requires a clear and reasonable warning before exposure occurs. Until now, neither the regulations nor any other interpretation of Proposition 65 have required a warning before a product was sold. That would change under the new proposal. OEHHA
proposes that “[f]or catalog purchases, the warning must be provided in the catalog in a manner
that clearly associates it with the item being purchased.”

An even bigger change is the internet purchase warning requirement: “For internet
purchases, the warning must be provided by a clearly marked hyperlink using the word
“WARNING” on the product display page, or otherwise be prominently displayed to the
purchaser before the purchaser completes his or her purchase of the product.” And “a warning
is not prominently displayed if the purchaser must search for it in the general content of the
website.”

Safe Harbor Environmental Warnings

Californians are used to seeing Proposition 65 warning signs at the doorway of every
building, warning them in these terms:

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

Under the new regulations, if adopted, this won’t work. Instead, signage warnings must
contain the symbol, identify a specific chemical, and “Clearly identify the area for which the
warning is being provided, including the location and source of exposure”. The “affected area in
which the exposure can occur must be clearly described,” and the warning must use one of the
following sets of text:

⚠️ **WARNING:** Entering this area can expose you to [name of one or more chemicals], a
chemical [or chemicals] known to the State of California to cause [one of the following
disease endpoint descriptions: (a) cancer; (b) birth defects or other reproductive harm;
(c) cancer and birth defects or other reproductive harm]. For more information go to
www.P65Warnings.ca.gov/environmental.

Font Size

For the first time, there are minimum font size requirements. Any product warning must
be no smaller than the largest font size used for any other consumer information on the product,
and in no case smaller than 8 point for the full warning and 6 point for the truncated warning.
This “largest font size” requirement is important, because, for example, if a product label uses a large font for headings or titles, it could be argued that the Proposition 65 warning should be no smaller than the heading or title.

For shelf signs or tags, “[t]he entire warning must be in a type size no smaller than one half the largest type size used for other consumer information on the shelf tag or shelf sign for the same or similar consumer products. In no case shall the warning appear in a type size smaller than 8-point type.”

For environmental warnings, the signage at area entrances must be at least 72 point type.

**Non-English Language Warnings**

Neither Proposition 65 nor the implementing regulations have ever had non-English language warning requirements before. That is about to change. For product warnings, if any “label, labeling [still broadly defined] or sign that provides consumer information about a product contains any languages other than English, the Proposition 65 warning must be provided in that language or languages. Thus, for the appliance or electronics manufacturers who provide instruction manuals or use and care guides in multiple languages, the Proposition 65 warning must appear in all such languages.

There are similar requirements for environmental warnings, internet and catalog sales.

**Limitations on “Supplementary Material”**

Proposition 65 creates a presumption of the duty to warn of exposures to listed chemicals unless the company can show through a complex and expensive legal analysis that the level of exposure to a carcinogen is lower than that which would be expected to result in one additional cancer case in 100,000, or the average daily exposure to a reproductive toxicant is 1/1000 the level that would have any observable biological effect (known as the “No Observable Effect Level.”) Chemicals are often listed based on animal data, with no evidence that they have
ever caused harm to a human. In California, companies are often required to provide warnings about products that unquestionably save lives (e.g., medical devices, sunscreen) and/or have been subjected to a host of regulatory approvals and clearances all over the world.

Not surprisingly, many companies want to make sure their customers know that, notwithstanding the required warnings, their products are safe and have never been known to cause disease in any human. For that reason, many companies post information on their web sites explaining how Proposition 65 works and why they are providing warnings. But OEHHA doesn’t like this. So one of the new regulations states: “A person may provide information to the exposed individual that is supplemental to the warning. . . .In order to comply with this article, supplemental information may not contradict the warning.”

The regulation does not define “contradict.” Instead, OEHHA gives an example of a communication that it considers to be a “contradiction” in violation of the proposed regulation. In the example, an unnamed company provides a handout to customers stating that takes issue with Proposition 65, quotes a newspaper article to the effect that Proposition 65 warnings are ubiquitous in California, and states that toxic doses of wood dust do not occur from consumer uses of the company’s products. OEEHA argues that this handout would be impermissible under the new regulation.

In our view, this proposed prohibition, as OEHHA interprets it, is a clear violation of the First Amendment.

**Retailer Protection**

A common Proposition 65 scenario is this: a retailer buys product from an overseas supplier. It sells the product in California without a warning, and then receives a 60 day notice. Although the retailer knew nothing about what was in the product, it has no practical recourse against the supplier. It therefore ends up defending and/or settling the Proposition 65 claim as if it were the manufacturer.
One of the proposed regulations purports to provide relief to this retailer. The new retailer regulation provides that retailers are not responsible for warnings unless it sells the product under its own brand or trademark, it has knowingly and intentionally caused the chemical to be in the product, it has covered, obscured or altered the warning, its supplier has provided warning materials or offered to provide them, and the retailer has not used the warnings, or

The retail seller has actual knowledge of the potential consumer product exposure requiring the warning, and there is no manufacturer, producer, packager, importer or distributor of the product who [has ten or more employees or has a business location or agent for service in California].

This at first seems helpful. But the regulations then provide that if the retailer receives a sixty day notice, it is deemed to have actual knowledge two days later if it continues to sell the product without warning. Obviously, expecting warning implementation in two days is highly impractical.

**What Happens Next?**

The public hearing and public comment period for these regulations have concluded. Critical comments have been submitted by the California Chamber of Commerce and a number of industry groups, as well as some environmental organizations and attorneys for bounty hunters.

Under California’s Administrative Procedures Act, The Regulations and a Final Statement of Reasons must be filed with the California Secretary of State by November of this year. They will become effective two years after submission, so probably in the second half of 2018.

We suspect that the currently proposed regulations are similar to what will ultimately be filed. Companies with Proposition 65 compliance programs will have to reevaluate their programs soon, in order to be ready for compliance under the new regulations in 2018.