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California’s Proposition 65: The Target is Moving — Will it Land on You?

Compliance and Ethics


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CHEAT SHEET

- ***A "toxic" headache.*** Since 1986, manufacturers and retailers have been targeted under the Proposition 65 law by single-issue plaintiff enforcers.
- ***You can check out anytime you like, but you can never leave.*** Even if you are not based in California, you may be liable under this law — merely selling or shipping products to California is enough.
- ***Beware the big 12.*** You must notify customers if your products contain 12 sanctioned chemicals — these include lead, arsenic and formaldehyde — and more are coming soon.
- ***Be "clear and reasonable."*** Companies selling products containing the offending chemicals in California must issue a clear and reasonable warning; as of January 2016, the standard for warnings will change again.

California's unique "toxic warning" law, Proposition 65, has been on the books in the United States for 30 years, yet it continues to trap the unwary manufacturer and retailer and funnel millions of dollars to a cottage industry that seemingly exists for just one purpose: lining their pockets with your company's hard-earned profits. As the list of chemicals "known to the State of California to cause cancer, birth defects or other reproductive harm" grows, so do the opportunities for private attorney general enforcers to expand their enforcement actions against national and international companies. Although initiated with good intentions, Proposition 65 has come to be viewed by some in the business community as legalized extortion, providing economic boons for plaintiff enforcers and their attorneys, with little real benefit to the people of California.

As if the existing landscape were not difficult enough, the rules are about to change, and not for the better. Understanding and anticipating these impending changes will allow businesses to evaluate compliance strategies and transition into the next generation of doing business in a Proposition 65 world.

What is Proposition 65?

California's Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted by California voters in November 1986. It was promoted as a way to protect the state's drinking water supply and provide information to California consumers concerned with the existence of toxic chemicals in their environment, workplaces and homes, as well as in their consumer goods. Allowing for private enforcement was seen as an efficient mechanism for relieving strain on overstretched public enforcement resources. Proposition 65's drafters even anticipated it would become a model for the United States. However no other US state has followed suit.

Proposition 65 requires California to publish a list of chemicals known to "cause cancer or birth defects or other reproductive harm." Since its inception, the list has grown exponentially to include more than 800 chemicals ranging from the esoteric (1-[(5-Nitrofurfurylidene)-amino]-2-imidazolidinone) to the mundane (wood dust); from the rarely encountered (mustard gas) to the everyday result of baking bread and roasting coffee (acrylamide); from the tangible (lead, cadmium) to the ephemeral (tobacco smoke, marijuana smoke); from the

specific (toluene, formaldehyde) to the generic (gasoline engine exhaust, diesel particulate matter). The list of chemicals continues to expand. Ethylene glycol (e.g., automobile antifreeze) was listed June 19, 2015. Styrene, Aloe Vera, whole leaf extract and Goldenseal root powder are just some of the many “chemicals” currently under consideration.

Consumers encounter Proposition 65 chemicals daily, in plastics, shampoo, cosmetics, dietary supplements, jewelry, keys, foods and a myriad of other everyday products. Workers handle circuit boards, tools with PVC-coated handles, and painted surfaces. Families drive cars, play sports, go to school, park in parking garages, eat in restaurants and walk on airport jetways. Proposition 65 chemicals “known to the State of California to cause cancer, birth defects or other reproductive harm” are ubiquitous and unavoidable. They are everywhere.

How does a chemical get on the list?

A chemical is “known to the state to cause cancer or reproductive toxicity” if, in the opinion of a majority of a panel of experts appointed by the governor of California, the chemical has been shown through “scientifically valid testing according to generally accepted principles” to cause cancer or reproductive toxicity. The panels (one for carcinogens and one for developmental and reproductive toxicants) review published research and other information and consider public comments to determine if a chemical meets the “clearly-shown-to-cause” standard to be placed on the list.

A chemical can also be placed on the list if has been identified as causing cancer or birth defects or other reproductive harm under the California Labor Code or by another California agency, a federal agency or an “authoritative body” such as the US Environmental Protection Agency, US Food and Drug Administration (FDA), National Institute for Occupational Safety and Health, National Toxicology Program, and International Agency for Research on Cancer.

What does Proposition 65 require of businesses?

Proposition 65 contains two requirements, more aptly described as prohibitions, applicable to any business that employs 10 or more persons. First, it prohibits a business from discharging to “a source of drinking water” any of the chemicals on the Proposition 65 list. Because California has designated virtually all fresh water as a potential drinking water source, this prohibition was initially seen as the primary impact of Proposition 65. Predictions, however, were wrong, and it is Proposition 65’s second prohibition that has garnered the most attention and spawned the most litigation.

Proposition 65’s most notorious provision prohibits a business from “knowingly and intentionally” exposing any person to a chemical on the list without first providing a “clear and reasonable” warning:

> “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 a clear and reasonable warning to such individual . . . .”
>
> Cal. Health & Safety Code § 25249.6.

You are “doing business” in California

Many businesses based outside California have never heard of Proposition 65, but ignorance is not

bliss. Proposition 65 applies to anyone “doing business” in California. If you sell your products in California, you are “doing business” in California. If you ship your products to California, you are probably “doing business” in California. If your products are advertised in California, you may be “doing business” in California.

Even if you do not have a place of business in California, directly sell, market, manufacture or otherwise distribute products in California, you may still be “doing business” in California. Do you warrant your products comply with all laws? Do you have supply agreements that obligate you to step in for your customer if you breach a warranty? Do you have business relationships you cannot afford to put in jeopardy? If you are doing business and your products find their way to California, Proposition 65 will, in some manner, eventually affect you.

What if I don’t know the chemical is present?

Proposition 65 applies to those who “knowingly and intentionally” cause an exposure to a listed chemical. When Proposition 65 was approved in 1986, the voters were told:

> “These new laws will not take anyone by surprise. They apply only to businesses that **know** they are putting one of the chemicals out into the environment, and that **know** the chemical is actually on the Governor’s list.”

Ballot argument in favor of Proposition 65 (emphasis in original).

A court in San Francisco interpreted this to mean the manufacturer or retailer was required to have actual knowledge that a listed chemical was in its product and that a person would be exposed by using the product. This interpretation, however, is not universal.

For example, the Office of Environmental Health Hazard Assessment (OEHHA) has adopted a regulation inserting a negligence standard into the definition of “knowingly” under Proposition 65. “Negligence” only requires constructive knowledge, not actual knowledge. Under a “constructive knowledge” standard, knowledge is imputed if a person knew or should have known, through the exercise of reasonable care, that an exposure to a listed chemical would occur as a result of the normal use of the product.

Despite the adverse ruling in the only case that has decided this issue, the bounty hunter community continues to assert that “knowingly” under Proposition 65 includes constructive knowledge. Until a California appellate court addresses this issue, private enforcement litigation continues to allege the defendant “knew or should have known” an exposure was occurring.

Clear and reasonable warning

Proposition 65 prohibits exposing an individual to a listed chemical unless that person first receives a “clear and reasonable warning.” What exactly is a clear and reasonable warning?

Under the code, a clear and reasonable warning is one that uses a “method … reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure.” A warning may be on the product’s label, or it may be displayed on a shelf tag near the product in the store. The key is that it must be “prominently

placed … with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use."

As for the content of the warning itself, regulations currently provide some guidance by establishing "safe harbor" warning language, although the specific language is likely to change soon, as is discussed later. Use of the safe harbor language is optional, but if it is used, the warning is deemed to be "clear and reasonable" as a matter of law. As a result, the safe harbor language is the default language that forms the foundation for virtually every warning now being given.

The current safe harbor language for consumer products states:

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

There are common variants of this, such as warnings that reference only cancer or those that reference only birth defects or other reproductive harm, depending on the basis for adding the particular chemical to the Proposition 65 list. Others may replace the initial phrase with "Use of this product will expose you to …" but they all start with the word "WARNING" in all capital letters and virtually all close with the phrase "known to the state of California to cause [cancer, birth defects or other reproductive harm.]" It is often asserted by the plaintiffs that qualifying the potential for exposure with the word "may" (as in "this product *may* contain a chemical …" or "use of this product may expose you a chemical …") does not constitute a "clear and reasonable" warning; however, this position has never been tested in court.

At present, the safe harbor language does not require inclusion of the specific chemical that triggers the warning requirement. Thus, a warning placed on a product for one chemical — lead found in PVC-coated tool handles, for example — will protect the manufacturer if another chemical — one of the phthalates, perhaps — is later added to the list and is also in the same PVC coating. This broad protection may change, however, if proposed regulations are adopted.

When are warnings required?

Proposition 65 does not require that any person suffer any actual harm as a result of an exposure to a Proposition 65 chemical for a violation to occur. A Proposition 65 warning is required for any *exposure* to one of the listed chemical *unless* the exposure is low enough to pose "no significant risk of cancer" or is "significantly below levels observed to cause birth defects or other reproductive harm."

For chemicals identified as carcinogens, the "no significant risk level" or "NSRL" is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. For chemicals determined to cause birth defects or changes to male or female reproductive systems or to embryonic growth, the level above which a warning is required is 1,000 times lower than the "no observable effect level," or "NOEL." The NOEL is the level of exposure at which there is no effect observed in either human or animal studies. Thus, a Proposition 65 warning is required if the potential exposure to a reproductive toxicant exceeds 1/1000th of the NOEL.

What happens if I don’t warn?

Exposing individuals to a Proposition 65 chemical without first giving a warning carries penalties of up to $2,500 per violation. Multiply that by the number of units sold to consumers and the potential penalties are mind-numbing. Proposition 65 may be enforced by the California attorney general, by district attorneys or by city attorneys in larger cities. However, as has likely become evident from the discussion thus far, most enforcement activity is in the form of lawsuits brought by private individuals.

Proposition 65 allows any person to file a lawsuit to enforce Proposition 65 so long as they give the public prosecutors and the target company 60 days advance notice. If none of the public officials initiates an enforcement action, the path is clear for the private person to do so. As an incentive to bring these suits, private enforcers are allowed to keep 25 percent of the penalties they recover, hence the common term, “bounty hunters.”

Before you receive a 60-day notice …

- Examine your supply agreements.
    - Does your supplier warrant there are no Proposition 65 chemicals in their products?
    - Does your agreement require they defend and indemnify you if they breach their warranty?
- Examine your distributor/retailer agreements.
    - Do you warrant your products comply with “all laws”?
    - Do you warrant there are no Proposition 65 chemicals in your products?
    - Do you agree to defend and indemnify your customers if you breach your warranty?
- Do you have information that would alert you to the likely presence of a Proposition 65 chemical?
    - SDSs/MSDSs?
    - Other information from your suppliers?
    - Have 60-day notices been sent to other companies for similar products?
    - Is it “common knowledge” – i.e., “brass may contain lead” or “plastics may contain phthalates”?
- Consider whether a person acting with reasonable care (i.e., causing an exposure “without … negligence”) would:
    - Ask their suppliers if their products contain any Proposition 65 chemicals?
    - Develop a testing program for common Proposition 65 chemicals?

The greatest driver of these private enforcement lawsuits, however, is the attorney’s fees. Although Proposition 65 itself contains no entitlement to attorney’s fees, Proposition 65 plaintiffs routinely allege they are acting in the public interest as a “private attorney general.” In California, a “private attorney general” may recover his or her attorney’s fees from the defendant, although (absent a finding that the suit was frivolous) the defendant has no reciprocal right to recover its fees from the plaintiff.

In reality, the usual plaintiff faces little risk because Proposition 65 contains one more twist: If the plaintiff shows an exposure to a listed chemical without a warning has occurred, the burden of proof shifts to the *defendant* to prove that the exposure was too low to require a warning. This requires the

defendant to establish: the normal use of the product; the individual's exposure to the chemical during normal use; and that the resulting exposure does not exceed either the NSRL or 1/1000th of the NOEL. Establishing these elements of the defense is no easy task. First, establishing "normal use" of a consumer product is not as simple as it may sound. Is a consumer product used daily? Weekly? Seasonally? Perhaps only two or three times a year? How often it is applied or consumed and in what quantities? Is it used exclusively by adults, or can children come into contact with it? Is there a potential that children will put the product in their mouth? What will be admissible evidence of "normal use" is not always obvious. The case specific inquiries are too numerous to list.

Even if "normal use" can be established, the defendant must then examine the nature and extent of the alleged exposure resulting from that use. If a person would normally touch a product, how much of the chemical is left on the person's hands? Under what conditions? How much is absorbed through the skin? How often does a person touch their hands to their mouth? How much of the chemical is transferred to the mouth and ingested? How much is absorbed through the gastrointestinal tract? Can the chemical be inhaled? What is the concentration in the surrounding air resulting from use of the product? How much of the chemical is inhaled? How much of that is absorbed into the body? Without this foundational information, it is impossible to reach the ultimate question of whether a pre-exposure warning was not required. Since the defendant bears the burden of proof, it will be found to have violated Proposition 65 if it is unable to answer all these questions with admissible evidence.

In most cases there is little or no scientific research on many of these issues, requiring a lengthy and costly adventure through expert testimony, testing, consumer surveys and evidence development. It is little wonder, then, that most companies faced with the prospect of high-risk litigation and a trial with large costs and large potential exposure will choose the simpler path of placing a warning on their product, reformulating the product, or just pulling out of the California market altogether, and paying a negotiated (and extortionate) amount in penalties and attorneys' fees.

No warning required for "naturally occurring" chemicals in food, but …

Proposition 65 was intended to reduce toxic chemicals added to products or the environment. Accordingly, consuming a Proposition 65 chemical in a food is not an "exposure" to a listed chemical to the extent that the person responsible can show that the chemical is naturally occurring in the food. But what does "naturally occurring" mean?

A chemical is "naturally occurring" if (a) its presence in a food is not due to any human activity; and (b) if its level has been reduced to "the lowest level currently feasible" during production and processing.

In this era of global industrialization and global food production, do you know exactly which fields or orchards the ingredients in your food product came from? Can you establish that a Proposition 65 chemical found in your food product is not the result of any human activity, current or historic? Can you prove the level of the chemical was reduced to "the lowest level currently feasible" during the growing and processing of your food product? Remember, it's the defendant's burden to prove no warning is required.

Although the "naturally occurring in food" exemption furthers the stated goals of Proposition 65, the unfortunate reality is that most food producers conclude proving a Proposition 65 chemical is "naturally occurring" is simply impossible.

What’s at stake?

The abuses under Proposition 65 are legendary. What was sold to the voters as a consumer protection statute has turned out to be primarily a mechanism for lawyers to extract large amounts of money from companies trying to do business in California. Of course, others would characterize it differently — claiming they are forcing manufacturers to reformulate their products to remove unsafe ingredients and reduce consumers’ exposure to unsafe chemicals — but the numbers tell the story.

In 2014, for example, over 1,400 60-day Notices were served, often naming multiple companies. Companies paid over $30 million to settle private Proposition 65 enforcement actions. On average, more than 70 percent of this these dollars went to the plaintiffs’ firms as attorneys’ fees. Penalties comprised only 15 percent of the $30 million number, with the balance, labeled as “payments in lieu of penalties,” going to organizations that share the enforcers’ perspective.

While the averages are disturbing, the details can be shocking. In one case, a settlement was reached for $1.1 million, of which only $36,000 was for penalties and the bulk of the rest — over $1,000,000 — was for attorney’s fees. In another case, the California attorney general actually stepped in to oppose a plaintiff ’s firm’s request for over $4 million in fees.

Of course, these figures do not include the costs to companies that are targeted by these bounty hunters. The costs of disruption to ordinary business, the cost of adding warnings to products already in the pipeline, and the cost of outside counsel are all significant expenses for any business. When confronting Proposition 65, an ounce of prevention is easily worth a pound of cure.

When you receive a 60-day notice …

- Involve counsel, whether in-house or outside.
    - Working through counsel can protect information with attorney-client and attorney work product confidentiality.
- Do you employ fewer than 10 employees?
    - Include full-time and part-time employees.
    - Even if you have fewer than 10 employees, do you nonetheless have obligations (contractual or simply to preserve good will) to your retailers or other customers that may oblige you to respond on their behalf?
- Are you subject to California’s jurisdiction?
    - Have you “purposefully availed yourself of the California forum for doing business”?
    - Do you have contacts with California that would make it fair to hale you before a California court?
    - Do you have obligations (contractual or simply to preserve good will) to your retailers or other customers that may nonetheless oblige you to respond on their behalf?
- Are you an out-of-state manufacturer and is the alleged exposure a workplace exposure?
    - Proposition 65 may not be enforced against out-of-state manufacturers for workplace exposures in California.
- Can you confirm the presence of a Proposition 65 chemical in the product?
    - Is it possible the notice was sent without a sample result to back it up? (Yes, this has happened.)

    - Do you have available information that may have been overlooked, e.g., SDSs/MSDSs or other product information?
- Consider if and when to notify your retailers/customers.
    - Should they pull your products off their shelves?
    - Are you prepared to provide warning labels or shelf signs?
    - Prompt action can be used to argue for reduced penalties.
- Consider whether to tender the defense to your supplier(s).
    - Do your agreements provide you with a basis to demand they defend you?
    - Can you benefit from Commercial Code warranties of merchantability or fitness for a particular purpose?
- Begin to establish a counter-claim for costs and attorney's fees – is there merit to their "certificate of merit"?
    - Request the other side's test results and other information.
    - Confirm your request and their response in writing or by e-mail.
    - Unless otherwise agreed, "settlement communications" may admissible for purposes other than to establish fault, e.g., to demonstrate the other side was being unreasonable, running up attorney's fees, etc.

Changes are on the way — but not necessarily for the better

Recognizing that Proposition 65 is not serving it intended purpose, California's Governor Edmund G. Brown has proposed to reform Proposition 65. He promised to find ways of "ending frivolous 'shake-down' lawsuits, improving how the public is warned about dangerous chemicals and strengthening the scientific basis for warning levels."

Two years later, the only piece of the governor's proposals to see daylight is a set of proposed changes to the regulations governing "safe harbor" warnings. These revised regulations, originally circulated for comment in March 2014, propose to significantly alter the requirements for a warning to be deemed "clear and reasonable" as a matter of law. The proposed regulations have been through one public comment period and were revised and rereleased in January 2015. Another public comment period closed in April 2015 and comments are being considered. OEHHA has announced it intends to adopt new warning regulations by January 2016, and since there was little material change reflected in the current draft from the version published in 2014, it seems likely the new regulations will be virtually identical to the most recent draft.

Although "voluntary," these new regulations will establish a new "floor" for the minimum requirements for a "clear and reasonable" warning and will confirm that the manufacturer or importer is principally liable for insuring the ultimate consumer receives an adequate warning. Unlike current regulations, the proposed law would exonerate a retailer unless the retailer alters the product, obscures any warning, or has actual knowledge of the presence of a listed chemical. The new regulations will also establish a mechanism by which the manufacturer can be pass responsibility down the supply chain to the retailer. Finally, as previously noted, the new regulations will require that certain chemicals be specifically identified by name in the text of the warning itself. These changes will require even companies that are fully compliant now to reexamine their product lines and revisit their current warning programs. The opportunities for the private enforcement industry to capitalize on the new minimum requirements are certain to expand as well.

The new “clear and reasonable” warning

Under the proposed regulations, a “safe harbor” warning, at a minimum, requires:

- The warning must contain a pictogram, a black-outlined yellow triangle with an exclamation point in it;
- The word “WARNING” must be in bold type;
- The standard language will change from “This product contains…” to “This product can expose you to…”;
- If the anticipated exposure involves one of 12 chemicals, that chemical must be specifically identified in the warning;
- The warning must reference a new web site OEHHA propose to build with information supplied by manufacturers and from other sources; and
- The warning must be given in multiple languages if multiple languages are used elsewhere on the label.

A warning label that complies with the new requirements will look something like this:

Alternatively, the company may use a simplified version that contains the pictogram, the word “WARNING,” either “cancer” or “reproductive harm” or both, and a reference to the OEHHA Proposition 65 website:

The regulations also provide specialized language for particular types of exposures such as those from food, alcoholic beverages, raw wood products, automobiles and diesel engines, parking garages, amusement parks and others.

Businesses will have two years to sell-through products with existing warning labels, although one wonders how the existing language can constitute a de-facto “clear and reasonable” warning once the agency that promulgated it has determined it is not “clear and reasonable.” Litigation will likely provide an answer.

The “big 12” list of chemicals

The chemicals proposed for specific reference in future safe harbor warnings were chosen for a variety of reasons, including that they have been the subject of significant private enforcement activity or because they have received attention in the popular press and therefore are likely to be recognized by the public. Notably, the risk from an exposure to the chemical was not one of the factors considered.

The list, as presently proposed, includes the following chemicals:

- Acrylamide
- Arsenic
- Benzene
- Cadmium
- Carbon monoxide
- Chlorinated Tris
- Formaldehyde
- Hexavalent chromium
- Lead
- Mercury
- Methylene chloride
- Phthalate(s)

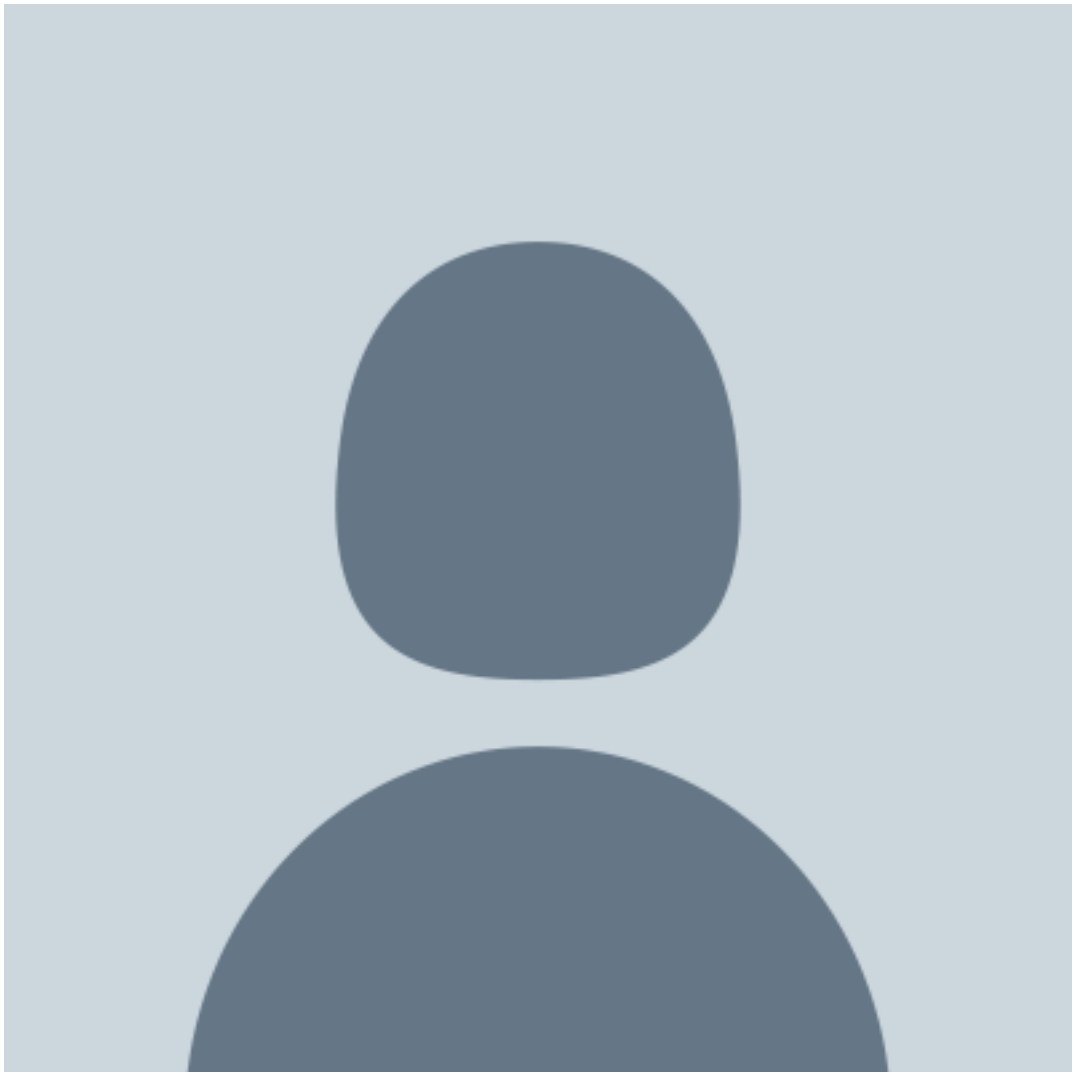
The regulations would allow the list to change over time. In fact, while the regulations have been pending, 1,4-dioxane, tobacco smoke and toluene have been dropped from the list and carbon monoxide, hexavalent chromium, and methylene chloride have been added to the list. No one can predict when or how frequently the target will move again, but each change to the “big twelve” list likely will require every company to reevaluate its product lines and possibly modify every warning label across product categories. OEHHA claims there will be no added cost to business because the using the new “safe harbor” warning is “voluntary.” The business community understandably has a different perspective.

Although the proposed changes have been presented as the much needed rehabilitation of Proposition 65 and have been touted as the most effective way of providing clarity to wary consumers and businesses alike, the more probable effect will be an increased economic burden on business and an expansion of the already prevalent litigation spurred by Proposition 65. Not only will businesses need to re-vamp existing compliance programs, they will be required to continue to modify distribution models to accommodate California’s new warning requirements and be faced with new and inventive litigation from the next generation of bounty hunters.

Conclusion

As January 2016 approaches and the anticipated “final” regulations are set to arrive, companies “doing business” in California should not only take note of the anticipated changes but actively modify existing compliance programs or implement new compliance programs to address the new requirements and avoid the inevitable economic downside of enforcement.

Bernadette Chala



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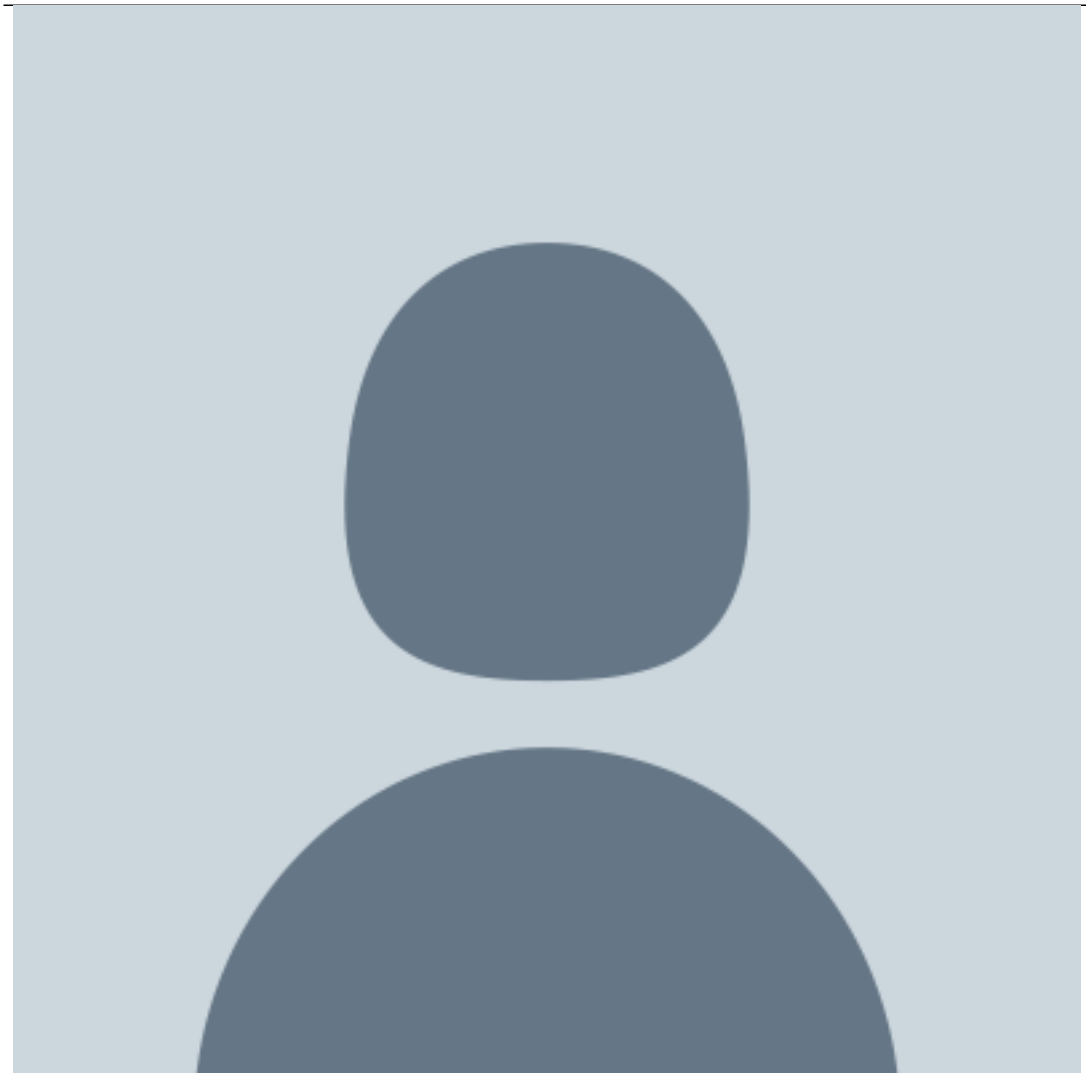

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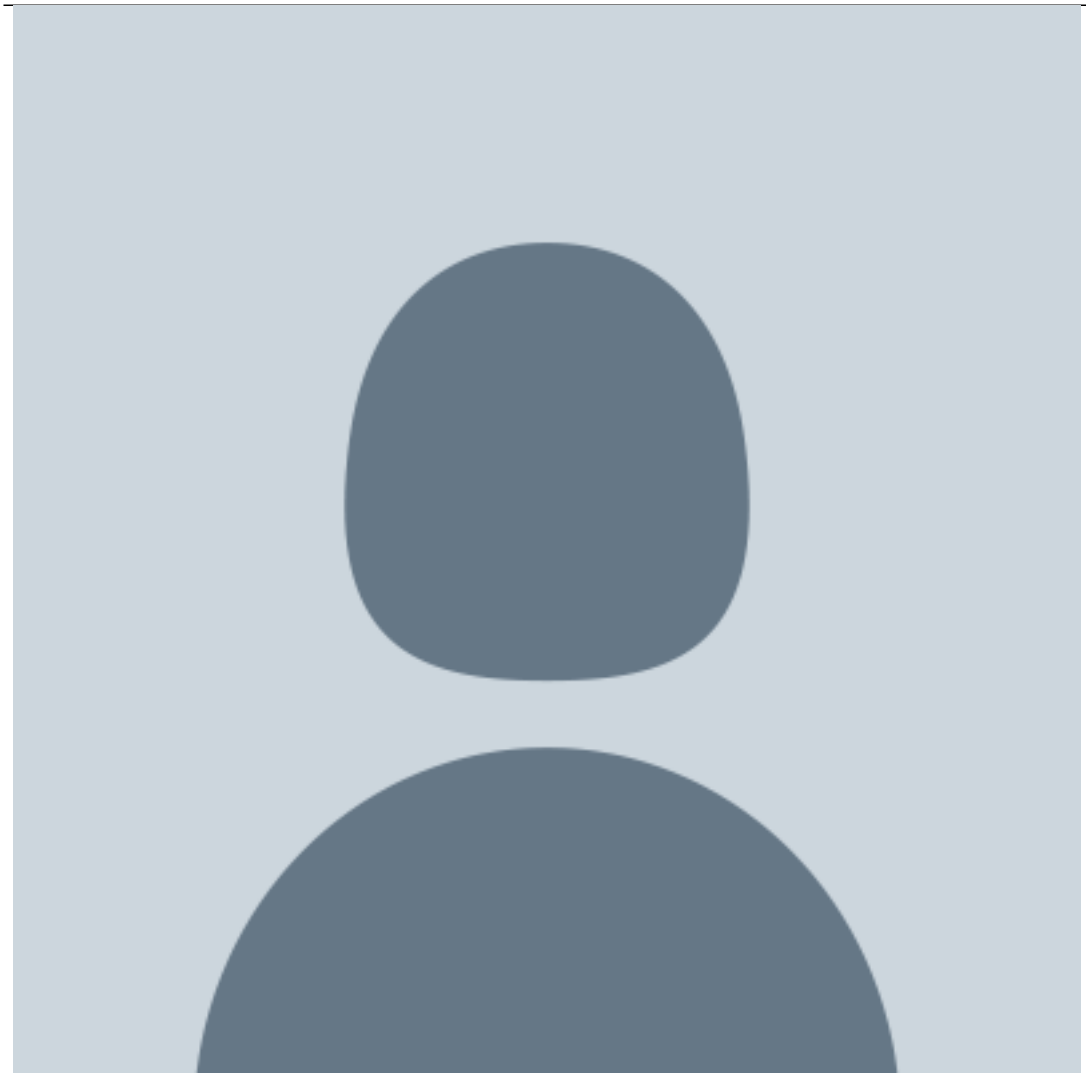

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