

Proposed Prop. 65 Regulations Make California More Unfriendly Market, Create More Obligations for Businesses

California Issues Proposed Regulations Regarding Prop. 65

California's Safe Drinking Water and Toxic Enforcement Act of 1986 [Cal. Health & Safety Code §25249.5 et seq.], known as Prop. 65, has created numerous hurdles for manufacturers and distributors who want to sell their products to the expansive California market. On January 12, 2015, the Office of Environmental Health Hazard Assessment ("OEHHA") released proposed modifications to Prop. 65 which, if adopted, would make those hurdles even larger, especially for those in the food industry.

Prop. 65 already requires businesses to warn the public when they sell a product, or maintain a premises, in California which contains certain chemicals (a list of over 900) known to cause cancer or birth defects or other reproductive harm. If a product sold or premises maintained in California contains a listed chemical and a reasonable warning is not posted on or near the product at its point of sale or the premises, Prop. 65 provides that businesses can be subject to enforcement lawsuits by the Attorney General or citizens, which commonly seek statutory penalties paid to the State and attorneys' fees. These suits have continued to increase since Prop. 65 was enacted, as self-proclaimed watchdog firms profit greatly from them, while businesses suffer significant expense defending and resolving these citizen suits.

The newly proposed regulations take aim at Article 6 of Prop. 65, which governs the requirements and methods for providing the necessary warnings to insulate parties from citizens suits. On first blush, they require a change to the language that has been deemed reasonable for decades, add the use of a pictogram for signaling the perceived danger of the exposure, and require increased language parity for products sold with other languages on the labels. However, the proposed regulations go further than simply changing the form of warnings; the regulations also address other types of exposures and responsibilities under Prop. 65 that were either not addressed before, or only marginally addressed, for example, food & dietary supplements and petroleum product industrial emissions. The new regulations will have a significant impact on a number of businesses and industries. For those in the food industry, an audit of their food

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products and facilities will be essential to putting protocols in place to limit exposure.

Proposed Regulations Make Changes To *Per Se* Reasonable Warning Across Industries

Currently, Prop. 65 allows for compliance with its warning requirements through the use of a prescribed warning, deemed to be *per se* reasonable, and thus insulate businesses from citizen suits. The current *per se* reasonable warning is simple, short, and consistent across most products and exposure types. Under the proposed regulations, that will change.

- *Per Se* Reasonable Language Revised: OEHHA has proposed slightly modified text for its *per se* reasonable warning. Thus, even companies currently in full compliance by their use of warnings on products and premises will need to revise all warning language if and when the proposed regulations are enacted;
- Warning Language From Exposure To Exposure Will Vary: In addition to the new text for the basic warning language, for certain products, food and dietary supplements, environmental exposures, diesel fuel exposures, parking structures, and smoking areas, just to name a few, OEHHA has identified slightly different language for each one's *per se* reasonable warning;
- Twelve Chemicals Singled Out On Labels: For 12 of the over 900 listed chemicals, the proposed regulations require a specific identification of that chemical on any products or premises in which they are contained. The list of 12 – being called the "Dirty Dozen" by industry experts – includes:
 - 1) Acrylamide; (2) Arsenic; (3) Benzene; (4) Cadmium; (5) Carbon monoxide; (6) Chlorinated Tris; (7) Formaldehyde; (8) Hexavalent Chromium; (9) Lead; (10) Mercury; (11) Methylene Chloride; and (12) Phthalate[s];
- Introduction Of Warning Icon: Most types of exposures will require that the warning start with an image of an exclamation point in a triangle (universal warning sign);
- Website Address: All *per se* reasonable warnings must include direction to a new Prop. 65 web address (not yet live) to be hosted by the State for each type of exposure – e.g., www.P65Warnings.ca.gov/food or www.P65Warnings.ca.gov/product.

Any products or premises currently in compliance with Prop. 65 by virtue of a *per se* reasonable warning will need to have their warnings changed if and when these regulations are enacted. However, the provision does have a two year grace period before it would become applicable. So, companies have time to review their current Prop. 65 exposures and ensure they are prepared for the enactment of the regulations.

Regulations Reach Several New Areas, Including Food and Dietary Supplements

Beyond just changing the language for the single generic warning, the proposed regulations contain revised and/or augmented warning requirements related to certain types of product and environmental exposures previously not the focus of Prop. 65 regulations and citizen suits, but which may become larger targets should the regulations be approved and implemented.

Under the proposed regulations, additional or alternative warnings would be required for certain product exposures: food and dietary supplements, alcoholic beverages, passenger vehicles, prescription drugs,

dental care, and furniture products. The proposed regulations also address additional or alternative requirements for certain premises and environmental exposures: restaurants, amusement parks, diesel emissions, enclosed parking facilities, designated smoking areas, petroleum emissions, service stations and vehicle repair facilities.

Of these, the requirements for food warnings and warnings for environmental exposure are likely to impact the food industry most directly.

- Food And Dietary Supplement Warnings: The regulations contain warning requirements related to the sale of food products that contain any of the listed chemicals, at or above safe harbor levels, if such exist for the listed chemical. In these cases, manufacturers need to:
 - Select the best method of communicating the warning based on pre-set choices: on-food, shelf tag / sign, electronic device or process prior to or during the purchase;
 - Choose the appropriate warning language from pre-set choices based on the type of harm caused by the listed chemical and the chosen method for warning;
 - Address chemical specific warnings, if the food contains any of the chemicals singled out for disclosure in the "Dirty Dozen;"
 - Ensure that if any labeling about the food is provided in languages other than English, the warning must also be in that additional language; and
 - Provide on any internet sales pages a clearly marked hyperlink warning on the food display page, before purchase.
- Environmental Warnings – General & Petroleum Emissions From Industrial Operations: The regulations contain two revised warning requirements related to environmental exposures caused by work done or equipment used on a premises which releases any of the listed chemicals. For a premises or facility whose operation can cause the emission of any of the listed chemicals, owners need to:
 - Select the best method of communicating the warning based on pre-set choices: sign posted at all public entrances to the affected area, notice mailed or sent electronically every 3 months to occupants in affected area, or a warning (¼ page) published in a newspaper (and its electronic version) every 3 months, with a map of affected area;
 - Choose the appropriate warning language from pre-set choices based on the type of harm caused by the listed chemical and the chosen method for warning; and
 - Ensure that if any affected areas or impacted demographics are regularly addressed by the company in another language, that the warning is also in that additional language.

Proposed Regulations Reduce Burden of Prop. 65 On Retailers

The proposed regulations make explicit that the goal of Prop. 65 is not to penalize retailers, but more to reach the product manufacturers, food producers, and premises owners, as they are the ones with the real control over the use of the listed chemicals and who stand to profit most from the sale of the product or use

of the premises. Under the proposed regulations:

- Warning Burden Shifted Expressly To Manufacturers: Manufacturers and producers must: (1) provide a compliant warning on the product/food/good; or (2) provide written notice to retailer, including: that a warning is required; exact name or description of product; all necessary warning materials; a receipt and acknowledgement from retailer at time of initial distribution and every 180 days thereafter during which the item is offered for sale.
- Retailer Rarely Responsible For Failure To Warn: A retailer is responsible only when one of the following occurs: it sells the product under its brand or trademark; has knowingly and intentionally introduced a listed chemical; has covered, obscured or altered a warning; has received warning information and sold the product without posting; or has actual knowledge of the exposure and there is no upstream entity that the courts or a citizen suit can reach.

Conclusion

These regulations will, at a minimum, require all companies that have products/food sold or premises located in the state of California which contain one or more of the listed chemicals, to update their current warnings to the modified language. More likely, the additional categories of products and further warnings will require companies to audit the make-up of and warning protocols for their products and premises, and prepare a plan for compliance with the impending regulation changes. While the proposed regulations are still in the review process, the effort OEHHA put into the draft suggests that it has given a great deal of consideration to its proposal, and we are not likely to see sweeping changes to the new provisions. After the public comment period closes on April 8, 2015, we expect OEHHA to move quickly to address comments and push the regulations forward.

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