

Seismic Changes in Store for California Proposition 65

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California's notorious "Proposition 65" regulatory program is poised to undergo substantial changes that will make compliance more burdensome and less certain. In January, the Office of Environmental Health Hazard Assessment ("OEHHA") proposed major revisions to the regulatory program that is responsible for the ubiquitous signs across the state warning the public of exposure to toxic substances, as well as dozens of lawsuits brought each month by private citizen enforcement groups. OEHHA proposes a fundamental rewrite of the provisions governing warning labels and text, as well as to establish a website that will collect and provide related information to the public. In addition, an important legal challenge has been launched against the "safe harbor" threshold for lead, which, if successful, could require warnings to be posted on all products containing *any* amount of lead.

PROPOSITION 65 TODAY

Proposition 65 was adopted by voter referendum in 1986 as the Safe Drinking Water and Toxic Enforcement Act. The law requires businesses who expose individuals in California to substances deemed by the state to cause cancer or reproductive harm to provide a clear and reasonable warning before exposure. OEHHA implements Proposition 65 and maintains a list of chemicals, over 900 currently, identified as carcinogens and reproductive toxins for which warnings may be required.

Under the program, businesses have some discretion regarding the manner in which a warning is provided, so long as it is "reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individuals prior to exposure." The warning "message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." The regulations provide that if certain specific text is used, the warning is deemed to be *per se* compliant ("WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.").

The failure to provide a warning can subject violators to penalties of up to \$2,500 per day and per exposure. The state Attorney General may bring a lawsuit to enforce the law's requirements, and many of the most high profile cases are handled in this manner. However, most cases are brought under the law's "bounty hunter" provision, which allows private plaintiffs to bring an action seeking penalties for alleged violations. Each month, scores of new cases are filed mostly by approximately a dozen highly active private plaintiff groups alleging failure to warn due to the presence of listed substances. Products containing lead and phthalates have been cited most frequently in 60-day notices and complaints filed over the last several years, as have exposures to tobacco smoke and diesel exhaust. Thus, the law leaves businesses vulnerable not only to scrutiny from state regulators, but from private citizens as well.¹

Several important, though somewhat limited, exemptions are provided. For example, a warning is not required for “naturally occurring” substances in a food product, and businesses with less than 10 employees are not subject to the requirements. Most significantly, a warning is not required if an exposure is so low as to create no significant risk of cancer or reproductive harm (per stringent standards specified under the regulations). While the exemption provides entities with some relief from liability, the burden rests on the business to demonstrate that a particular exposure level poses no significant risk. This task often is prohibitively expensive, as it can require extensive testing and technical analysis. To facilitate compliance, OEHHA has adopted “safe harbor” warning threshold levels for approximately 300 substances that helps eliminate some of the uncertainty in determining what exposure level requires a warning. However, these “safe harbor” levels generally are very low, in accordance with highly conservative and non-scientific risk assumptions. It is important to note that “safe harbor” thresholds identify the level of *exposure* to, and not the product content of, a substance that is deemed not to pose a risk or require a warning.

Ultimately, Proposition 65 is the source of lawsuits against many businesses for failure to provide a warning. These cases often are brought against companies that are unaware that low levels of listed chemicals (such as lead and phthalates) are present in their products. When confronted with a lawsuit from a plaintiffs group, these businesses often rationally decide to settle the case by agreeing to provide a warning and paying a penalty, typically in the range of \$20,000-\$150,000 or more, instead of facing the costs during litigation of establishing that an exposure is exempt from warning requirements. Hence, historically, the statute has encouraged over-warning, as businesses may provide warnings even where an exemption may apply simply to avoid costs.

PROPOSED REVISION OF WARNING STANDARDS

The proposed rulemaking would revise substantially the constituent elements of a “clear and reasonable” warning. The simple generic warning statement that currently is deemed *per se* compliant would be replaced with new requirements that would make compliance, and the warning labels, more burdensome. The proposal would mandate that warning labels:

1. Include a yellow-and-black exclamation point triangular symbol;
2. Use the more direct statement that "This product can expose you to a chemical [or chemicals] known to the State of California to cause" cancer, birth defects, or other reproductive harm, as appropriate;
3. Include other languages if the product displays information in those additional languages; and
4. Include on the label a web address for a newly proposed OEHHA website (further discussed below).

In addition, the revised regulations also would require the specific identification in the warning text of 12 chemicals, the so-called “dirty dozen” (if present in the product above levels requiring a warning): acrylamide, arsenic, benzene, cadmium, carbon monoxide, chlorinated tris, formaldehyde, hexavalent chromium, lead, mercury, methylene chloride, and phthalates.

SPECIFIC WARNING REQUIREMENTS FOR CERTAIN EXPOSURES

Under the proposal, certain types of exposures would be subject to additional or alternative requirements. These provisions would apply to: diesel engines, passenger vehicles, enclosed parking facilities, designated smoking areas, petroleum products, service stations and vehicle repair

facilities, food, alcoholic beverages, restaurants, prescription drugs, dental care, raw wood products, furniture products, and amusement parks.

Food/Nutritional Supplements

With respect to food exposures, including from dietary supplements, the proposed new warning text would require the following statement:

WARNING: Consuming this product can expose you to a chemical [or chemicals] known to the State of California to cause [cancer and/or birth defects or other reproductive harm].

Further, the warning must direct consumers to an OEHHA website: “For more information go to www.P65Warnings.ca.gov/food.”

Furniture Products

Furniture product exposures would require a notice or sign no smaller than 8½ by 11 inches displayed at all public entrances or points of display, in no smaller than 28-point type, or a notice on each receipt in no smaller than 12-point type. The notice would be required to state:

NOTICE: Some furniture products can expose you to chemicals known to the State of California to cause cancer, birth defects, or reproductive harm. Please check on-product labeling for warning information.

In addition, a warning would have to be affixed to the furniture product in the same manner and with the same font size as any other warning. The on-product labeling would be required to contain the triangular exclamation point symbol, and state:

WARNING: This product can expose you to chemicals such as [name of “dirty dozen” chemical], which are known to the State of California to cause cancer, birth defects or other reproductive harm, or both.

The warning also would direct consumers to an OEHHA website: “For more information go to www.P65warnings.ca.gov/furniture.”

Environmental Exposures to Petroleum Products from Industrial Operations

The proposed amendments would include specific warning requirements for environmental exposures to petroleum products from industrial operations and facilities. The warning would be accompanied by the yellow exclamation point symbol and read as follows:

WARNING: Crude oil, gasoline, diesel fuel and other petroleum products can expose you to chemicals such as toluene and benzene that are known to the State of California to cause cancer or birth defects or other reproductive harm. These exposures can occur in and around oil fields, refineries, chemical plants, transport and storage operations such as pipelines, marine terminals, tank trucks and other facilities and equipment.

As for other exposure categories, the warning also would provide directions to a web address: “For more information go to: www.P65Warnings.ca.gov/petroleum.”

Vehicle Service and Fueling Stations

Specific warning text also is proposed for exposures at the gas pump and in vehicle repair areas. In conjunction with the yellow exclamation point symbol, the required warning would read:

WARNING: Breathing the air in this area or skin contact with petroleum products can expose you to chemicals that are known to the State of California to cause cancer or birth defects or other reproductive harm, such as benzene, motor vehicle exhaust and carbon monoxide. For more information go to: www.P65Warnings.ca.gov/gasoline.

Similar warning text is specified for the other categories noted above as well.

CLARIFICATION OF RETAILER AND SUPPLY CHAIN RESPONSIBILITY

Responsibility for providing product exposure warnings is clarified in the proposed text. In response to a statutory mandate to minimize burdens on retailers, OEHHA's proposal requires that the manufacturer, producer, packager, importer, or distributor is responsible for adding the warning to a product label or providing a written notice to the retailer regarding the required warning for the product. OEHHA's proposal would impose the warning requirement on the retailer only if one of the following applies:

1. The retailer is selling the product under a brand or trademark that is owned or licensed by the retailer;
2. The retailer has knowingly and intentionally introduced a listed chemical into the product;
3. The retailer has covered, obscured or altered a warning label that has been affixed to the product;
4. The retailer has received warning information and materials (or an offer to provide warning materials) from a supplier and the retailer has sold the product without conspicuously posting those warning materials; or
5. The retailer has actual knowledge of the potential product exposure requiring the warning, and either (A) there is no supplier subject to Proposition 65; or (B) the supplier is a foreign company not subject to U.S. jurisdiction.

PROPOSAL TO ESTABLISH AN INFORMATION REPOSITORY WEBSITE

In a separate but related rulemaking, OEHHA proposes to develop a website that will collect and provide information to the public about exposures of listed chemicals. The URL addresses to appropriate parts of this potential website are proposed to be included in the text of any warning issued under Proposition 65.

The website would include information on exposures, allow for a person to request a correction of material or provide information, and provide links to information compiled by other entities such as the Food and Drug Administration.

OEHHA would be authorized to require businesses to submit, upon request, a variety of information, including with respect to the chemicals for which a warning is being issued, the location and concentration of the chemicals, and other information.

CHALLENGE TO LEAD SAFE HARBOR LEVEL

In addition to the proposed overhaul of the regulations, a recent court case threatens to upset long-standing practice for products that may contain low levels of the substance most frequently cited in

Proposition 65 lawsuits – lead. On January 13, 2015, the Mateel Environmental Justice Foundation, a prominent Proposition 65 plaintiff's group, filed a lawsuit seeking a court determination that the 0.5 micrograms per day (“µg/day”) safe harbor level for lead was not set consistent with the law's 1,000-fold safety factor requirement for reproductive toxicants.² The standard has been in place for more than 25 years, and if declared illegal and inoperative as the plaintiff requests, prior decisions, agreements, and settlements based on the invalidated threshold will be called into question.

Perhaps most significantly, many products have been reformulated based on the existing safe harbor threshold level for lead. The 0.5 µg/day level is among the most stringent lead standards in the world, and an even lower standard would mean that nearly any product that exposes a person to any detectable amount of lead will require a health hazard warning. It has yet to become clear whether the Attorney General will seek to litigate the case, or will prefer to negotiate a settlement.

Comments on the proposed OEHHA rulemakings are due April 8, 2015. For more information about this client advisory or Proposition 65 in general, please contact:

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[1] Before bringing a lawsuit, private groups must take certain preliminary steps, including providing the alleged violator and the Attorney General's office with a notice of the alleged violation 60 days before commencing a lawsuit.

[2] *Mateel Environmental Justice Foundation v. California Office of Environmental Health Hazard Assessment*, No. RG15754547 (Cal. Super. Ct. Alameda Cnty., Jan. 13, 2015).