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DANGERS FOR VENDORS OF PRODUCTS IN CALIFORNIA

Proposition 65 is a ballot initiative approved by California voters in 1986 which potentially impacts every manufacturer, importer, distributor, and retailer with an expectation the products will be sold in California. These companies need not be located in California. Its official title is the "Safe Drinking Water and Toxic Enforcement Act of 1986," commonly called "Prop 65." It is codified in Health & Safety Code §§25249.5, et seq. and requires that the State publish a list of chemicals known to cause cancer, birth defects, or other reproductive harm and imposes two sets of regulatory criteria on businesses using these listed chemicals. The chemical list, which is updated at least once per year, currently includes over 800 chemicals. The Prop 65 program is administered by the Office of Environmental Health Hazard Assessment (OEHHA), which is a part of the California Environmental Protection Agency (Cal/EPA).

Prop 65 has two components. First, it prohibits California businesses from knowingly discharging significant amounts of the listed chemicals into sources of drinking water. Second, it requires that businesses notify all potentially exposed users in California about significant amounts of the listed chemicals in their products. Each component of Prop 65 has its own time frame for compliance following the listing of a chemical. The second component is the primary focus hereafter.

WHAT ARE THE CHEMICALS? Chemicals are added to the Prop 65 list via "qualified experts", "authoritative bodies", etc. The listed chemicals are both naturally occurring and synthetic, and not just individual chemicals, but also compounds as well as ingredients in products such as drugs, pesticides, solvents, common household products, dyes, and foods. Listed chemicals may also be used in manufacturing and construction. Examples include alcoholic beverages, coal emissions, arsenic, nickel, diesel fumes, estrogens, leather dust, lead, benzene, phthalates, chromium, Aspirin, wood dust, tobacco, Aloe Vera, and tetracycline. Chemicals occasionally are delisted by OEHHA as scientific opinions change. For example, in 1989 saccharin was added as a chemical causing cancer, but was delisted in 2001.

WHAT ARE THE WARNING REQUIREMENTS? Prop 65 does not require that businesses reformulate to remove listed chemicals, which can have continued use if the businesses warn about these potential chemical exposures. Instead, the statute provides that 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 clear and reasonable warning. The method of warning depends upon the nature of the item containing the chemical. For example, warnings can include labeling a consumer product, posting signs at the workplace, distributing notices at a rental housing complex, or publishing notices in a newspaper. Businesses are not required to report what warnings they have issued and why. The warnings must be conspicuous when compared to other information

contained on the same label and must be presented in a way that is likely to be read and understood by an ordinary individual. There is concern that the citizens of California are habituated and de-sensitized to Prop 65 warnings, essentially not paying attention at all to the warnings, some of which they see printed in newspapers, in their utility bills, and at grocery stores. Whether a business decides to reformulate or to keep the chemical and warn can, in part, depend upon the nature of the product. A business might decide to reformulate if the chemical in an ingredient in a product intended for children, but might decide to warn if the chemical is an ingredient in a product such as a pesticide that consumers have an expectation presents dangers and must be handled with caution.

PROP 65 ENFORCEMENT: Lawsuits to enforce Prop 65 can be filed by three types of entities—(1) the California Attorney General's Office; (2) district attorneys and city attorneys for cities with populations exceeding 750,000 people (Los Angeles, San Diego, San Francisco, and San Jose are the only four California cities currently satisfying this criteria), and; (3) "individuals acting in the public interest", which are also called "private enforces." By far the vast majority of lawsuits are filed by private enforcers.

PRIVATE ENFORCERS: Private Enforcers must provide a business with "60-Day Notice" before filing suit. The 60-Day Notice is designed to allow the business time to investigate the alleged violation and take corrective actions. Government prosecutors are not required to provide 60-Day Notices. Private enforcers must provide copies of 60-Day Notices to all of the previously mentioned government enforcers and can only file suit if the government enforcers decide not to do so. The suit can be filed in any superior court. The 60-Day Notice must include a certificate of merit, which is a declaration stating that the case is meritorious. If a court determines after trial that there was no actual or threatened exposure to a listed chemical, the court can review the foundation for executing the certificate and issue sanctions. Furthermore, 2017 amendments to the statute provide that (1) the Attorney General is required to send a letter to the private enforcer and the recipients of the Notice when the Attorney General has reviewed the certificate and determined there is no merit to the action and (2) the foundation for the certificate of merit is discoverable.

PROP 65 PENALTIES: Penalties for violating Prop 65's consumer notification provisions can run as high as $2,500 per violation per day. In assessing the amount of a civil penalty courts must consider seven factors focusing on the violations and the level of culpability of the offender: (a) the nature and extent of the violation; (b) the number of and severity of the violations; (c) the economic effect of the penalty on the violator; (d) whether the violator took good faith measures to comply with this chapter and the time these measures were taken; (e) the willfulness of the violator's misconduct; (f) the deterrent effect that the imposition of the penalty would have on both the violator and the regulated community as a whole; and (g) any other factor that justice may require. The California Attorney General must be notified of each proposed settlement such that it can determine if the settlement is in the public interest and, if not, to object. All settlements are posted on the Attorney General's website, so settlements cannot be private/confidential. Seventy-five percent of all civil penalty settlements are paid to the State, while the other 25% are kept by the private enforcers. Prop 65 is silent as to attorney's fees, but other California statues that allow for attorney's fees have been found to apply to Prop 65, allowing private enforcers to collect their billed fees.

ARE THERE EXEMPTIONS? Businesses with less than ten employees need not comply with either the discharge requirements or the notification requirements of Prop. 65. Also, there are defenses concerning "safe harbors" and issues of bioavailability. Other defenses include federal preemption,

prescription drugs, and chemicals naturally occurring in food. Finally, no warnings are required for the first twelve months after a chemical is added to the Prop 65 list. Some of these defenses are discussed in the following paragraphs.

NATURALLY OCCURRING EXEMPTION: Human consumption of a food shall not constitute an "exposure" for purposes of Prop 65 if the person responsible for the exposure can show that the chemical is naturally occurring in the food. Furthermore, when a consumer product contains a listed chemical and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, exposure can only occur as to that portion of the chemical from other sources. Unfortunately, the current regulations make it difficult to prove the defense. The defendant must provide the natural background of the chemical in the area where the food is grown or raised, prove the chemical did not result from any known human activity, and prove that by good manufacturing practices the chemical exists in its lowest feasible level. One appellate court decision found that mercury in tuna is naturally occurring. It is unlikely that most defendants can afford to spend the millions of dollars the tuna industry probably spent to establish the applicability of this defense to its product.

SAFE HARBOR LEVELS: OEHHA develops numerical guidance levels, known as safe harbor numbers for determining whether a warning is necessary and whether discharges of a chemical into drinking water sources are prohibited. However, a business may choose to provide a warning simply based on its knowledge, or assumption, about the presence of a listed chemical without attempting to evaluate the levels of exposure. OEHHA has adopted safe harbor exposure levels for some chemicals, but not for the vast majority. A business has "safe harbor" from Prop 65 warning requirements and discharge prohibitions if exposure to a chemical occurs at or below these levels. These safe harbor levels consist of No Significant Risk Levels ("NSRL") for chemicals listed as causing cancer and Maximum Allowable Dose Levels ("MADL") for chemicals listed as causing birth defects or other reproductive harm. If a business proves that its product exposes average users to a chemical at a level below that established by OEHHA, then the exposure from the product is within the safe harbor level and the business is exempt from the requirements of Prop 65. Safe harbor numbers are not the concentration or the percent of a chemical in a product, but are the dose or exposure measured in ug/day (millionth of a gram) from typical use of a product. However, most Prop 65 settlements have morphed into content requirements for ease of implementation.

NSRL means that exposure to the amount of chemical in a product would result in no more than one case of cancer out of every 100,000 individuals who were exposed to the chemical over a 70-year time period. MADL is the level at which a chemical would have no observable effect, even if an individual were exposed to 1,000 times that level. If there is a safe harbor number for the chemical in question, it is the burden of the business to establish that the use of the product results in an exposure at or below the safe harbor level. This involves hiring experts to run exposure assessments to determine how much exposure occurs through typical use of the product, which typically is more expensive than settling. If there is no safe harbor level for a chemical, businesses that expose individuals to that chemical would be required to provide a Prop 65 warning unless the businesses can show that the anticipated exposure level will not pose a significant risk of cancer or reproductive harm by establishing the NSRL or MADL. Again, the process of determining anticipated levels of exposure to listed chemicals can be very complex and costly. Of course, the business should expect to face the argument that there are no safe harbor levels for the chemicals. The presentation of this type of scientific evidence can be very expensive.

RECENT STATUTORY AMENDMENTS: On August 30, 2016, California adopted amendments to the Prop 65 warning requirements which include new criteria for what constitutes a clear and reasonable warning. Businesses warning about exposure to a Prop 65 listed chemical may use either the current or new version of warning until the new requirements take effect on August 30, 2018. The changes include the following:

- Text of warnings must be the same size as other consumer information presented on packaging and may not be smaller than 6-point type.
- The warnings must specifically identify at least one toxic chemical.
- Non-English language warnings are required in certain situations.
- The warnings must include a warning symbol that is an equilateral triangle with an exclamation point. The triangle must have a bold outline. If the printing of the label that includes the warning is in color, the triangle must be yellow. This symbol is followed by the word WARNING in capital letters and bold print the same size as the triangle symbol.
- For consumer products, a simplified label on the product may be used that includes the warning symbol and text, and then describes the endpoint of the exposure, either "cancer" or "reproductive harm" followed by the web address www.p65warnings.ca.gov.
- The full warning text is required for catalogues and websites when no warning label is provided on the product and may be used on consumer products if desired. The warning must be provided in a manner which clearly associates the warning with the item being purchased.
- The new statutory language goes into detail about acceptable warnings and methods of transmission for area and environmental warnings, and particular language for some specific products and businesses such as food and drinks, furniture, amusement parks, etc.

A sample warning is shown below:

CONCLUSION: The fact that a product bears a Prop 65 warning does not on its face render the product unsafe. Prop 65 is more about a "right to know" than a pure product safety law. However, many businesses are concerned that consumers may interpret the warnings to mean that products are unsafe. This concern often results in businesses deciding to reformulate products instead of warning. Prop 65 has been a very expensive statute for businesses throughout the United States and the world. Expenses incurred include providing and installing warning information, testing products, research and development of alternative chemicals to use in the place of listed chemical, and defending litigation. Many business are proactive in dealing with Prop 65, including by evaluating potential exposure risks from the use of products and identifying compliance strategies for products. Dillingham & Murphy has more than 20 years of experience in minimizing these expenses by avoiding litigation and if litigation is not avoided by resolving cases quickly.