Client Alert

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For Better or Worse: California Solicits Input on Further Revisions to Its Proposition 65 Regulations

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Earlier this year, California's Office of Environmental Health Hazard Assessment (OEHHA), which is charged with implementation of the State's controversial Proposition 65 law, released a "pre-regulatory" proposal to revise its longstanding regulations governing "clear and reasonable warnings." The proposal met with substantial opposition from a broad coalition of businesses and, as a result, a new slimmed-down version is expected to be unveiled by OEHHA later this fall. In the interim, to address other aspects of the business community's criticisms of its prior proposal, OEHHA has just requested that the public submit ideas, by November 17, 2014, concerning several other aspects of the Proposition 65 regulations.

OEHHA's request focuses on key aspects of the few defenses available in Proposition 65 cases:

- **Ability to "Average" Test Results and Product Use When Calculating Levels of Exposure** (27 CCR Sections 25701, 25721, 25801, and 25821). Does any single exposure to a product with a listed chemical trigger the warning requirement, or does the law look to the average exposure that is relevant to the health effect relevant to that chemical? Must the decision whether to warn be based on the highest concentration of a chemical ever found in a product, or does the law look to the average amount of the chemical in the product? To date, courts have been allowed to determine the proper approach based on the evidence presented at trial. OEHHA's request seeks comment on whether the agency should issue regulations on these issues.
- **Exemption for Naturally Occurring Chemicals in Foods** (27 CCR Section 25501). The regulations have long recognized that a business should not have to warn about an exposure to a listed chemical in food if the chemical is "naturally occurring" and reduced to the "lowest level currently feasible." However, the showings necessary to prove this exemption have been heavily contested in litigation. In addition, the California Attorney General's office has objected to a number of settlements in which the parties had otherwise agreed to a specified naturally occurring "allowance." If the views of the Attorney General's Office and most plaintiffs are adopted, relying on this defense would be a risky proposition, rendering it of little benefit, if any.
- **Alternative Risk Levels for Chemicals in Foods Due to Cooking** (27 CCR Section 25703(b)). The current regulations are silent on the criteria for calculating these levels, making their use for purposes of determining compliance, whether by a business in determining if it has to warn or in the course of defending an enforcement action, an uncertain exercise. Even if such alternative levels can theoretically be employed in place of the statute's default assumption of a 1 in 100,000 cancer risk level, they have no impact on the level of exposure at which warnings for chemicals listed for reproductive harm are required.

- **Safe Use Determinations** (27 CCR Section 25204). Safe Use Determinations—essentially declarations by OEHHA that a product does not need a Proposition 65 warning based on its review of a technical submission—are extremely rare, due to uncertainty regarding the level/standard of proof required, the time and cost involved, and general concern regarding the risks, reliability, and utility of the SUD process.

In addition to requesting comment on the need for revisions to these aspects of the existing Proposition 65 regulations, OEHHA has requested public input on:

- **Where Additional "Interpretive Guidance" Is Needed Relative to Proposition 65**;
- **Chemicals to be Prioritized for the Development or Update of Proposition 65 "Safe Harbor" Levels**;
- **How Data on Post-Natal Exposures Should be Used for Purposes of Proposition 65**.

CONCLUSION: BUSINESSES NEED TO GET INVOLVED AND MAKE A RECORD. It is a certainty that OEHHA will hear about these issues from the public enforcement community, environmental groups, and from the lawyers whose practices are devoted to *bringing* private Proposition 65 enforcement actions. It is therefore essential that OEHHA receive thoughtful, specific, well-supported feedback from the regulated community concerning the strengths and weaknesses of the current regulations and obtain businesses' suggestions on the ways they can be improved. If OEHHA revises the regulations, there is likely to be litigation over the outcome so, to preserve their option to challenge any changes that make it harder for them to defend themselves, businesses will need to demonstrate that they made their case in the administrative record. Because statutory amendments of Proposition 65 are exceedingly difficult if not impossible to obtain, this process may well determine the shape and impact of this much-feared law for many years to come.

Morrison & Foerster has the largest and most experienced Proposition 65 practices in the nation, both in terms of the regulatory process and in the defense of Proposition 65 enforcement litigation. We are prepared to provide additional assistance on these issues upon request.

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