THE BLACK BOX: PROPOSITION 65 CONSIDERATIONS FOR THE FOOD & BEVERAGE INDUSTRY

by ALEXANDRA N. KRASOVEC

California is well known as a state of many regulations. Among them, perhaps one of the most prominent in the minds of consumers and businesses alike is Proposition 65, formally known as the Safe Drinking Water and Toxic Enforcement Act of 1986, California Health & Safety Code section 25249.5-25249.14. Companies doing business in California are required to assess whether any of their products meet certain triggering criteria—namely, whether the product causes an exposure to Proposition 65 List chemicals in a level sufficient to require provision of a "clear and reasonable" warning under the Act. Cal. Health & Safety Code § 25249.6 (1987).

Undoubtedly, anyone who lives in California—as well as observant visitors to our great state—have seen Proposition 65 warnings in many locations, including in business establishments and on product packaging. Indeed, these warnings are known to traverse state lines, and have been slapped on products sold nationwide in an effort to ease compliance efforts and avoid complicating manufacturing and distribution processes. While Proposition 65 has been the impetus for change in the formulation of many products, Proposition 65 warnings have been criticized as lacking meaningful, substantive information and leading to warning fatigue.

New Proposition 65 Warning Regulations

In an effort to address the concerns surrounding Proposition 65 warnings, the Office of Environmental Health Hazard Assessment (OEHHA)—the agency that administers Proposition 65—issued new warning regulations that became fully effective on August 30, 2018. The new regulations can be found in Title 27 of the California Code of Regulations, Article 6. Under these amendments, many warnings will now take on a new look. The regulations identify those components that are deemed to comply with Proposition 65's warning requirement, specifically with respect to content based upon method of transmission. Since these "safe harbor" provisions are merely meant to identify warnings deemed to be sufficiently "clear and reasonable," a business can still opt to provide an alternative warning that diverges from the regulations. However, if a warning is not in compliance with the new "safe harbor" warning regulations, the business will carry the burden of showing that the warning is "clear and reasonable."

As a general rule, the new regulations require greater detail than previously accepted warnings. In order to be considered within the "safe harbor," the new warnings include, among other things, identification of at least one each of the Proposition 65 List chemicals and reproductive toxicants contained in the product, and an explicit reference to the OEHHA web address for Proposition 65 matters: www.P65Warnings.ca.gov. *See* 27 C.C.R. §§ 25601-25603 (2018). This new content provides consumers with more detail than previously accepted warnings.

The new regulations also address certain categories of exposures and products—one such focus concerns food and beverage items. 27 C.C.R. § 25607.1-25607.6, 25607.31 (2018). The warning regulations cover exposure to Proposition 65 List chemicals in food products and alcoholic beverages, including where such exposure occurs at restaurants or other food facilities by virtue of the sale of these products for immediate consumption. These warnings are to be provided on product packaging and in stores via food product labels, shelf tags, and notices posted by way of signs and menus in eating establishments. 27 C.C.R. §§ 25607.1, 25607.3(3) (2018). While not specific to food, the regulations also require e-retailers and other businesses with online points of sale to provide warnings online, even if the products contain an on-product warning. 27 C.C.R. § 25602(b) (2018); *see also* 27 C.C.R. § 25602(c) (2018) (explaining catalogue purchase requirements).

In practice, all of these components work together to cause businesses to assess their products and supply chain, encourage reformulation to avoid the need for a warning, and otherwise ensure warning obligations are met through noticeable and informative means.

> The most notable foods targeted for acrylamide under Proposition 65 include potato chips, french fries, cereal, and—one of the legal profession's favorite beverages—coffee.

Unique Issues for the Food & Beverage Industry

Unlike the great majority of manufactured consumer products, the food and beverage industry has a number of additional obstacles to overcome in attempting to comply with Proposition 65. For one, exposure happens through ingestion, which means exposure to any Proposition 65 List chemical is direct and potentially more significant than other methods. Additionally, some food products contain Proposition 65 List chemicals simply by virtue of how and where that food is grown (e.g., in soil). Then, factor in the obstacle of bi-products that result from cooking these natural ingredients, such as by roasting or frying, which can lead to Proposition 65 List chemicals making appearances in ways that are effectively unavoidable. Altogether, this is a recipe for "exposure," necessitating a warning under Proposition 65, even where the very food product itself is a widely consumed and recommended component of a healthy diet.

There are numerous examples of the impact that Proposition 65 can have on the food and beverage industry and a history of settlements to show for it. Over the course of 2018, there have been a number of developments surrounding Proposition 65 labeling within this particular industry, two of which are examined below.

Adoption of Exemption Levels for Naturally Occurring Arsenic in Rice

According to the FDA, "Rice, a staple of the global diet, is a leading dietary source of inorganic arsenic, both because of how it is commonly consumed and because as rice plants grow, the plant and grain tend to absorb arsenic more readily than other food crops." U.S. Food & Drug Admin., *Arsenic in Rice and Rice Products* (Sept. 21, 2018), www.fda.gov/food/foodborneillnesscontaminants/metals. "Arsenic is present in the environment as a naturally occurring substance or as a result of contamination from human activity. It is found in water, air, food, and soil in organic and inorganic forms." *Id*. Arsenic is a Proposition 65 List chemical. Consequently, a Proposition 65 warning would be required where the level of arsenic exceeds the safe harbor levels identified by the OEHHA.

While not a natural component of rice, environmental factors have led to arsenic's presence in rice grown in certain regions across the United States. OEHHA, *New Section 25501.1 Naturally Occouring[sic] Concentrations of Listed Chemicals in Unprocessed Foods; Inorganic Arsenic in White and Brown Rice* (issued Aug. 9, 2018), https://oehha.ca.gov/proposition-65/crnr/new-section-255011-naturally-occuring-concentrations-listed-chemicals. Consequently, in considering the application of Proposition 65, the OEHHA determined to identify exemption levels for inorganic arsenic in rice. *See id*.; 27 C.C.R. § 25501.1(a) (adopted Aug. 9, 2018). The OEHHA's action puts into practice the "naturally occurring" exemption under Proposition 65. This exemption provides that,

"[h]uman consumption of a food shall not constitute an 'exposure' for purposes of [Proposition 65] to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food." 27 C.C.R. § 25501(a) (2018). "[A] chemical is 'naturally occurring' if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained." 27 C.C.R. § 25501(b) (2018).

The OEHHA's treatment of arsenic in rice is one example of using regulatory mechanisms to address the conundrum of Proposition 65 List chemicals in food. While this particular regulation does not apply to processed foods, it is an example of the OEHHA working to bring clarity to the application of Proposition 65 warning requirements within the food and beverage industry.

Finally, Positive Developments in the Saga of Acrylamide

Another example of the threat of Proposition 65 to the food and beverage industry can be seen in the ongoing battle over the treatment of the carcinogen *acrylamide.* The OEHHA counsels that acrylamide "is formed in certain plant-based foods during cooking or processing at high temperatures, such as frying, roasting, grilling, and baking." OEHHA, *Acrylamide Fact Sheet*, https://www.p65warnings.ca.gov/fact-sheets/acrylamide (*last visited*, October 21, 2018). The most notable foods targeted for acrylamide under Proposition 65 include potato chips, french fries, cereal, and—one of the legal profession's favorite beverages—coffee.

The application of Proposition 65 to these food products is a seasoned debate, that has caused numerous companies to settle for millions. Recent developments have taken on a more positive tone for the food and beverage industry. For example, in July, the Second District Court of Appeals held that Proposition 65 labeling requirements for cereals containing acrylamide were preempted by federal law, finding that the warnings would "pose an obstacle" to the "important national policy of increasing consumers' intake of whole grains." *Post Foods, LLC v. Superior Court*, 25 Cal. App. 5th 278, 295-98 (2018) (emphasizing FDA in advisory letters to California's regulators and Attorney General recommending against requiring Proposition 65 warnings for acrylamide on food, including breakfast cereal).

As noted above, acrylamide is present in another favorite breakfast item: coffee. Whether Proposition 65 warnings are required for coffee is the central issue in the Los Angeles Superior Court case brought against over ninety sellers and retailers of ready-to-drink coffee. *Council for Educ. and Research on Toxics v. Starbucks Corp.*, BC435759 (filed April 13, 2010) (hereinafter referred to as "Proposition 65 Coffee Litigation"). The Proposition 65 Coffee Litigation, which began nearly nine years ago, has entered its final phase, after the court ruled that defendants failed to meet their burden of proof for the No Significant Risk Level and Alternative Significant Risk Level affirmative defenses, and rejected the defendants' First Amendment and preemption challenges.

On June 15, 2018, the OEHHA proposed a new regulation clarifying that Proposition 65 warnings are not required for coffee. This new regulation would create a No Significant Risk Level for exposures to listed chemicals in coffee. OEHHA Public Notice, Proposed Adoption of New Section Under Article 7 No Significant Risk Levels Section 25704 Exposures to Listed Chemicals in Coffee Posing No Significant Risk (June 22, 2018), https://oehha.ca.gov/proposition-65/crnr/proposed-adoption-new-section-under-article-7-no-significant-risk-levels-section. The OEHHA's proposal acknowledges that "drinking coffee does not pose a significant cancer risk, despite the presence of chemicals created during the roasting and brewing process that are listed under Proposition 65 as known carcinogens." OEHHA Press Release, Proposed OEHHA regulation clarifies that cancer warnings are not required for coffee under Proposition 65 (June 15, 2018), https://oehha.ca.gov/proposition-65/press-release/press-release-proposition-65/proposed-oehha-regulation-clarifies-cancer. Indeed, as the FDA pointed out in its statement supporting the proposed regulation, "requiring a cancer warning on coffee, based on the presence of acrylamide, would be more likely to mislead consumers than to inform them," because it could cause "consumers to believe that drinking coffee would be dangerous to their health when it actually could provide health benefits." FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's support for exempting coffee from California's cancer warning law (Aug. 29, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm618883.htm. While the comment period closed on August 30, 2018, OEHHA action on the proposed regulation is presently pending.

ON POINT
Over the course of 2018, there have been a number of developments surrounding Proposition 65 labeling . . . .

The defendants in the Proposition 65 Coffee Litigation sought a stay pending the OEHHA's regulatory action. The trial court denied this request, but a petition for writ of mandate decided by the California Court of Appeals was successful, leading to a stay of the case. This development leaves open the potential for regulatory mechanisms to (again) alter the application of Proposition 65 to the food and beverage industry.

Conclusion

Taking these food-related developments as case studies, further regulatory action does appear to be a necessary component to clarifying the need for Proposition 65 warnings within the food and beverage industry. The OEHHA's recent action reflects a willingness to provide more clarity surrounding the application of Proposition 65 to food products. Direct application to OEHHA certainly could be a short-stop to limiting litigation and enforcement actions in this space. Food industry advocates may also find hope in *Post Foods*, which shows success is possible under federal preemption strategies, at least where such arguments are pursued before appellate courts.

Alexandra N. Krasovec *is an Associate Attorney at Dorsey & Whitney LLP. She defends companies against litigation arising under consumer protection statutes, and counsels on compliance issues related to those statutes, including Proposition 65.*

This article first appeared in Orange County Lawyer*, December 2018 (Vol. 60 No. 12), p. 30. The views expressed herein are those of the author. They do not necessarily represent the views of* Orange County Lawyer *magazine, the Orange County Bar Association, the Orange County Bar Association Charitable Fund, or their staffs, contributors, or advertisers. All legal and other issues must be independently researched.*