

# RECENT FEDERAL AND STATE ACTIONS IN SUPPORT OF PROPOSITION 65 EXEMPTION FOR COFFEE REINFORCES NEED FOR SCIENCE-BASED NUTRITION INFORMATION

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The words "coffee" and "cancer" have been used in sentences together more over the past several years than the coffee industry ever could have contemplated — or wanted. And, in light of the current scientific evidence regarding consumption of coffee as it relates to cancer, its distaste for those headlines and that discussion is not unjustified. Recent action taken by the U.S. Food and Drug Administration ("FDA"), the California Office of Environmental Health Hazard Assessment ("OEHHA"), and the U.S. Congress illustrate active resistance to state labeling laws that conflict with science-based nutrition information, including California's Safe Drinking Water and Toxic Enforcement Act, better known as Proposition 65 ("Prop. 65"). Prop. 65 requires warning labels on products sold in California for about 900 chemicals known to cause cancer, birth defects, or other reproductive harm. OEHHA is the agency that administers and enforces the statute in California. The statute itself allows private citizens, advocacy groups, and attorneys to sue on behalf of the state and collect civil penalties and attorneys' fees for failure to provide required warnings. While the statute may have been viewed as well-intended and effective in certain instances, it is now regarded by many as lacking the necessary scientific support, and thus unnecessarily burdening businesses and simultaneously confusing consumers.

Coffee has been targeted by Prop. 65 enforcers because of acrylamide, a chemical produced as a byproduct of various baking and roasting processes, particularly with starchy foods, but also in the roasting of coffee beans. Very large doses of acrylamide have been linked to cancer in mice. However, both the National Cancer Institute and the World Health Organization's International Agency for Research on Cancer ("IARC") have concluded there is no consistent evidence that dietary acrylamide exposure is associated with the risk of any type of cancer in human beings. In fact, IARC found that coffee is associated with a reduced risk for certain types of cancer, including liver and uterine cancer, and there are additional health benefits due to the strong antioxidant effects.

Despite the current scientific evidence, earlier this year, after eight years of litigation between numerous coffee companies against Council for Education and Research on Toxics, a California superior court ruled against the coffee companies. The Los Angeles court found that the defendants' experts had failed to convince the court that coffee should be exempted from the controversial statute and that warnings would be required on ready-to-drink coffee. While the ruling itself did not mean coffee causes cancer, media reporting and a general lack of understanding of the statute contributed to further confusion over the safety of coffee. Much protest, debate, and dispute followed, mainly centered around the strong and consistent scientific evidence disproving any link between coffee and cancer in humans.

On June 15, 2018, OEHHA announced that despite the court's ruling, it was siding with science. It issued a notice of proposed rulemaking, stating, "Exposures to Proposition 65-listed chemicals in coffee that are produced as part of and inherent in the processes of roasting coffee beans and brewing coffee pose no significant risk of cancer." This proposed rulemaking could exempt coffee from Prop. 65's warning requirements.

Last week, the FDA made its position known as well. Commissioner Scott Gottlieb issued a detailed statement strongly supporting an exemption for coffee from the Prop. 65 warning requirement. See the full statement [here](#). Part of the FDA's mission, he said, is "ensuring that food product labeling doesn't contain false or misleading statements about safety or nutrition. This includes ... statements that may be compelled under state law. Simply put, if a state law purports to require food labeling to include a false or misleading statement, the FDA may decide to step in." Commissioner Gottlieb went on to say the California court's ruling "deeply concerned" the Agency and that it strongly supports OEHHA's proposed regulation because it has carefully reviewed the most current research on coffee and cancer, and the science does not support a cancer warning for coffee. In fact, requiring a cancer warning on coffee "could mislead consumers to believe that drinking coffee could be dangerous to their health when it actually could provide health benefits. Misleading labeling on food violates the Federal Food, Drug and Cosmetic Act."

This is not the first time the FDA has made its feelings regarding Prop. 65 known. In 2003 and 2006, the FDA wrote to OEHHA, expressing concerns that labeling cereals and some other foods with Prop. 65 warnings could confuse consumers and lead to even worse health outcomes. The FDA's guidance and letters urged that Prop. 65 warnings should not be placed on foods unless science supports such a warning. This past July, a California appellate court sided with 59 breakfast cereal brands in finding that federal law preempts a Prop. 65 lawsuit challenging the cereal's lack of warnings due to acrylamide content. The appellate court found that any California-mandated labeling would run counter to federal policy goals aiming to increase Americans' consumption of whole grains. The court relied heavily on the FDA guidance and advisory letters in reaching its decision.

The FDA's recent statements on coffee further emphasize the goals of the Agency's Nutrition Innovation Strategy, which was announced in March of 2018. See the full announcement [here](#). The strategy includes a variety of planned actions to help reduce chronic conditions and diseases caused by poor nutrition, and increase industry innovation in this area. Providing consumers with transparent science-based nutrition information is a hallmark of this strategy.

The FDA is not the only authority that wants to see Prop. 65 enforcement changed. A bipartisan group of U.S. Congress members have introduced bills in the U.S. Senate ("S 3109") and House of Representatives ("HR 6022"), collectively dubbed the "Accurate Labels Act", that seek to ensure that Prop. 65 and other warnings are based on sound, scientifically-based evidence and risk analyses. If the bills were to become law, Prop. 65 enforcement would change dramatically. HR 6022 has been referred to the House Committee on Energy and Commerce, and S 3109 is before the Committee on Commerce, Science and Transportation. Regardless of broad industry support, the bills, like those who oppose Prop. 65, face a steep uphill battle.

Noteworthy federal and state actions regarding the need for science-based nutrition information is a significant step for consumers and industry alike. K&L Gates will continue to monitor and provide updates on further developments in this area. Stakeholders in the food, beverage, and nutrition sectors should consider engaging

with key policymakers to help impact policy outcomes. K&L Gates can facilitate engagement with Congress and help you assess the opportunities and risks involved.

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