



California court's narrow Prop 65 coffee ruling should not be misinterpreted

Product Liability Alert

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Press coverage of a recent, high-profile preliminary decision under California's Proposition 65 law may prompt readers to a simple, erroneous conclusion: "coffee causes cancer." In reality, the decision made no such finding, and while, if the decision stands, its practical impact could be big for coffee makers, a careful understanding of the narrow basis of the ruling is important for coffee consumers and for all manner of product-based companies doing business in California.

On March 28, 2018, Judge Elihu Berle issued a preliminary decision in favor of the plaintiffs in *Council for Education and Research on Toxics v. Starbucks Corp. et al.*, BC435759 (California Superior Court, County of Los Angeles). In that case, the plaintiffs alleged that the defendants, sellers of ready-to-drink coffee, failed to warn consumers that the coffee exposed them to a known carcinogen – acrylamide – in violation of California's Proposition 65.

Acrylamide forms during the coffee roasting process. It is also a byproduct when starchy foods, such as potatoes and cereal grains, are cooked at high temperatures. (For instance, it is found in french fries.) The litigation, filed in April 2010, named over 90 defendants, many of whom reached settlements earlier in the case.

In cursory summaries of Judge Berle's tentative opinion, media outlets have been reporting that coffee must carry

Prop 65 cancer warnings (eg, WARNING: This product can expose you to chemicals including acrylamide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov). But this simplified statement does not capture important elements of the opinion and its underlying litigation from a legal and scientific perspective.

A brief history of the case: the arguments, the experts, the testimony

In Phase I of this case (filed eight years ago), the defendants argued that the acrylamide present in coffee did not exceed the Prop 65 No Significant Risk Level (NSRL) of .2 micrograms per day established by California's Office of Environmental Health Hazard Assessment (OEHHA). Below that level of exposure, no warning would be required. Defense experts focused their testimony on the overall mixture of coffee (a complex liquid with hundreds of chemicals at varying levels). They explained that many studies have shown coffee, as a whole beverage, does not increase cancer risks (some studies even suggest coffee may decrease cancer risks).

The plaintiff argued that Prop 65's regulations required a "quantitative risk assessment" focused on acrylamide only, ignoring the overall mixture of coffee. Judge Berle essentially agreed, concluding that defendants failed their legal burden by not using a "quantitative risk assessment" – the only type of risk assessment "utilized by the relevant scientific community to assess the risk of a carcinogen in a mixture" – to quantify the acrylamide exposure from drinking coffee and calculate the risk level of the acrylamide itself, not the mixture.

Judge Berle's March 28 proposed statement of decision covers Phase II of the trial, which addressed the defendants' affirmative defense based on an Alternative Significant Risk Level (ASRL). Specifically, Prop 65 allows an exemption to warning requirements even where the NSRL is exceeded *if* "sound considerations of public health support an alternative level" – for example, where "chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination." But, Judge Berle determined, the same problem exists for the defendants as did in Phase I. An ASRL must also be derived from a "quantitative risk assessment" – *ie, acrylamide in coffee*, not acrylamide generally, and not coffee as a product, must be the focus.

The defendants argued for an acrylamide ASRL because acrylamide is formed by the cooking (or roasting) necessary to render coffee palatable and/or safe. But the defendants again did not utilize a quantitative risk assessment focused specifically on acrylamide in coffee in determining their proposed ASRL. While the defendants' expert performed a quantitative risk assessment of acrylamide generally, he did not undertake a quantitative risk assessment for acrylamide in coffee. Judge Berle found this to be a fatal flaw. He decided the defendants' expert had not calculated the ASRL based on "exposure to acrylamide from consumption of coffee," as required.

The defendants also presented a second expert's testimony to rationalize an ASRL ten times greater than the NSRL of .2 micrograms per day. The expert asserted: (1) FDA had regulated other carcinogens in two unrelated foods based on a similar, more lenient cancer risk standard; and (2) OEHHA had once proposed, but ultimately rejected, regulating acrylamide in bread and cereal products at the more lenient level. The court rejected these rationales, finding they "lack scientific support, are not based on sound considerations of public health, and provide inadequate grounds for an alternative risk level."

Finally, noting that the method the defendants used to test products for acrylamide had not been generally accepted in the scientific community, the court asserted that the lab's data regarding the acrylamide levels in defendants' products was unreliable and inadmissible. To the extent experts relied on this flawed data (for example, in conducting exposure assessments), their testimony was also deemed inadmissible.

Acrylamide in coffee, Prop 65 and cancer

No part of Judge Berle's ruling means that coffee causes cancer. Nothing in the plaintiff's case even asserts that coffee causes cancer. The complaint, and the rulings, simply mean that California has found that acrylamide exposure can increase the risk of cancer, that Proposition 65 therefore requires cancer warnings unless the NSRL safe harbor is met or an ASRL is established, and that the NSRL and ASRL must be analyzed by only focusing on acrylamide in coffee – not coffee as a whole, and not acrylamide alone.

Many would argue that type of analysis has little real-world value. After all, regardless of the strictures of Prop 65 statutes and regulations, people in the real world don't drink acrylamide or "acrylamide in coffee," they drink coffee

– with all of the substances that beverage contains.

A comprehensive 2011 acrylamide study noted that "studies on dietary intake of acrylamide and cancer risk suffer from several potential sources of bias" and recognized the "misclassification of acrylamide exposure because of limitations of both the instruments used to assess food intake... and in the use of nutrient databases to estimate acrylamide intake." That study, while noting that cancer risks cannot yet be ruled out, concluded that "epidemiologic studies do not suggest an increased risk of cancer from dietary or occupational exposure to acrylamide." Regardless of these scientific uncertainties and obstacles, Prop 65 law requires what it requires.

While Judge Berle's proposed ruling is in some ways unprecedented, it is narrow. If it stands, ready-to-drink coffee may now be served with Prop 65 cancer warnings attached. That will not change coffee's makeup, nor will it signify that coffee causes cancer.

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