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PERSPECTIVE

Ruling in Proposition 65 coffee case not entirely unpredictable

By Anthony J. Cortez and Will Wagner

A Los Angeles judge has ground the coffee industry to a halt by ruling that both ready-to-drink and bagged coffee sold in California must be accompanied by a cancer warning. *Council for Education and Research on Toxics*, BC435759 (L.A. Super Ct., filed April 13, 2010). The lawsuits alleged that Starbucks plus 90 other entities were violating the Safe Drinking Water and Toxic Enforcement Act of 1986 — aka Proposition 65. The ruling was based on the presence of acrylamide in coffee products, a chemical present in many foods and beverages consumed on a daily basis and could have wide-ranging implications for not only the coffee industry but for many other industries currently involved in acrylamide-related litigation.

Proposition 65 requires businesses to warn consumers prior to purchasing products that may cause cancer or reproductive harm. The state maintains a list of substances that it believes are known to cause cancer and/or reproductive harm; more than 950 substances are currently listed. When a product sold in California contains certain concentrations of even one of these substances, Prop 65 requires that a clear and reasonable warning be provided to consumers prior to purchase. In most instances, this means a warning on a product label stating that the substance is "Known to the State of California" to cause cancer, reproductive harm, or both." In 2018 updated requirements will come into effect, and will be even stricter than they have been in the past in terms of reporting and labeling.

Acrylamide

Acrylamide is a common chemical compound formed during high temperature cooking in certain foods and beverages. Because it is formed through the cooking process and is not an intentionally added ingredient, it is difficult to control the amount of acrylamide in a product. Evidence known to date casts serious doubt on whether acrylamide really causes cancer.

The International Agency for Research on Cancer classified acrylamide as a Group 2A *probable* carcinogen, which caused California to add acrylamide to its list of chemicals known to cause cancer in 1990, triggering Prop, 65 requirements. The agency did not list acrylamide as a Group 1 *known* carcinogen, and the findings of other authoritative bodies such as the National Cancer Institute and the World Health Organization have concluded that acrylamide and coffee are not carcinogens.

Currently, no agency has classified acrylamide as a "known" carcinogen. Yet, according to this new ruling, coffee sold in California must state exactly that.

The Lawsuit

Various lawsuits were initiated in 2010 and 2011 against coffee-industry businesses, alleging the existence of acrylamide in coffee. The plaintiff contended that the concentration of acrylamide in coffee posed a danger to California consumers and required a warning label.

During phase one of the trial in 2013, Starbucks and the co-defendants asserted that no violation of Prop. 65 had occurred because the amount of acrylamide ingested by the average consumer is below the "safe harbor" threshold. Many substances on the Prop. 65 list have a "safe harbor" expressed in micrograms per day, under which Prop. 65 warnings are not required. However, the acrylamide safe harbor is only 0.2 micrograms per day — a tiny amount for a product such as coffee that is ingested consistently at high volumes — so the court ruled that coffee exceeds the safe harbor threshold.

Defendants then spent the next several years preparing a second defense — that compelling public health justifications support an alternative (higher) level of consumption of acrylamide in coffee. If a product exceeds the safe harbor threshold for a given Prop. 65 substance, a warning is typically required; however, a business can attempt to convince a court that sound considerations of public health support a higher exposure rate of that substance. In arguing that compelling reasons justify higher exposure rates of acrylamide in coffee than provided in the safe harbor rate of 0.2 micrograms per day, defendants relied heavily on experts to prove their case.

Phase two of the trial, in late 2017, did not achieve the desired outcome for the defendants. In an order released late last month, the judge made clear that he did not find the defendants' experts to be credible or to have opinions based on reliable scientific processes. The March 28 order was short on reasoning as to how such conclusions were reached. The court ruled that the defendants failed to prove that sound considerations of public health supported a higher level of acrylamide exposure than 0.2 micrograms per day. The result — warning labels will now be required on the subject products, along with the defendants potentially paying significant civil penalties.

This Result was not Entirely Unpredictable

When acrylamide was placed on the Prop. 65 list in 1990, there was limited scientific support that it caused cancer. Since then, as noted by the National Cancer Institute, "a large number of epidemiological studies ... in humans have found no consistent evidence that dietary acrylamide exposure is associated with the risk of any type of cancer." Also, as stated by the American Institute for Cancer Research, scientific studies do not indicate that the consumption of coffee is correlated with higher risks of cancer. Despite this clear scientific evidence, California regulators have thus far opted not to reconsider the decision to list acrylamide as a substance known to cause cancer or to raise the regulatory safe harbor for acrylamide above the extremely low 0.2 micrograms per day — a level lower than the safe harbor for lead (pb).

Moreover, acrylamide is not artificially placed into coffee products — it occurs naturally during the brewing process. California regulations include an exception for substances that are "naturally occurring" in products. This was done, in part, because the voter pamphlet for Prop. 65 suggested that its intent was to require warnings for substances that were intentionally added to products. However, the regulation is interpreted so narrowly that almost no companies can rely on the "naturally occurring" exception for protection from Prop. 65 requirements without substantial expense and protracted court proceedings. Thus, with the acrylamide safe harbor hopelessly low and unsupported by current data, coupled with an interpretation of "naturally occurring" that renders the exception nugatory, it is no surprise defendants ended up with a ruling such as this.

Proposition 65 was created to protect California consumers by giving them access to accurate information; however, in this case, given the lack of scientific research supporting that acrylamide causes cancer, the question has to be asked, "are consumers being protected?"

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