Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Martin J. Hahn
Xin Tao

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Re: **California Judge Rules Against the Coffee Industry in Notable Acrylamide Proposition 65 Case**

Food companies and retailers doing business in California should take note of the recent proposed statement of decision in the case challenging the coffee industry's failure to warn of the presence of acrylamide in coffee under Proposition 65. On March 28, 2018, the Superior Court of California at Los Angeles County issued a proposed statement of decision ruling the coffee industry failed to meet their burden of proof on their alternative significant risk level (ASRL) affirmative defense. [1] To the extent the ruling is not overturned on appeal, it would set the precedent for applying the ASRL for other listed substances that form during the cooking of food.

Acrylamide is not intentionally added to coffee. Instead, when coffee beans are roasted, a chemical reaction (the Maillard reaction) occurs causing the asparagine and sugars in coffee beans to form the chemical. FDA reports "acrylamide is found mainly in foods made from plants, such as potato products, grain products, or coffee" and that generally it is "more likely to accumulate when cooking is done for longer periods or at higher temperatures." [2] In the past few years, bounty hunters have filed multiple actions against companies marketing foods in California that contain acrylamide and do not bear the Proposition 65 warning. In light of the recent ruling, it would be prudent for companies that manufacture or market food products that contain acrylamide to reexamine their obligations under Proposition 65.

Proposition 65 Listing of Acrylamide

By way of brief background, California's Proposition 65 requires the Governor of California to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. Businesses are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone in California to a listed chemical. [3] Acrylamide has been listed as a carcinogen under Prop 65 since 1990. Researchers did not discover the presence of acrylamide in foods until April 2002.

The mere presence of acrylamide in a food product does not automatically trigger a legal obligation to warn. Under the "safe harbor" exemption, a Proposition 65 warning is not required if the company can establish that the level of the acrylamide would result in an exposure level that is within a "safe

[1] Council for Education and Research on Toxics (CERT) v. Starbucks Corporation (Starbucks), No. BC435759 (L.A. Super. Ct., filed April 13, 2010).
[2] *Acrylamide Questions and Answers* (March 10, 2016) accessible at https://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm053569.htm#1
[3] Cal. Health & Safety Code § 25249.6.

harbor." OEHHA has established the following safe harbor levels for acrylamide: No Significant Risk Levels (NSRLs) at 0.2 µg/day for cancer and Maximum Allowable Dose Levels (MADLs) at 140 µg/day for reproductive toxicity.

Proposition 65 permits private litigants or "bounty hunters" to bring private lawsuits to enforce the warning requirements. [4] A "bounty hunter" seeking to sue for failure to warn as required by Proposition 65 must notify the potential defendant and state prosecutors of the alleged violation and its intent to sue 60 days before a suit may be filed. [5] These 60-day notices are publicly posted on the State's Office of the Attorney General's website. [6] As of today, there are a total of 273 60-day notices filed alleging companies failed to provide warnings for acrylamide in consumer products. There also have been multiple consent judgments for various foods that have set the level that does not require a Proposition 65 warning.

Acrylamide Coffee Litigation

The Council for Education and Research on Toxics (CERT) originally filed the lawsuit in 2010 with 91 defendants involved at one point in the litigation. In essence, CERT claimed that the defendants failed to provide warnings to millions of Californian consumers that coffee contains acrylamide in violation of Proposition 65 since June 2002. In the complaint, CERT alleged that testing of ready-to-drink coffees shows that a single 12-ounce serving of the product contains approximately 10 times more acrylamide than the NSRL established by OEHHA. The Court bifurcated the trial into two phases:

- Phase I of the trial covered Defendants' affirmative defenses of (1) "no significant risk level"; (2) First Amendment; and (3) federal preemption; and
- Phase II addressed the issue of Defendants' affirmative defense of an "alternative significant risk level."

At the conclusion of Phase I of the trial, the Court ruled the Defendants failed to meet their burden of proof by a preponderance of evidence in their affirmative defenses of "no significant risk level," First Amendment, and federal preemption to avoid the requirement of the cancer warning. Phase II of the trial contains the court's ruling on the ASRL.

The Current Ruling

The current opinion concerns Phase II, during which the Court ruled the Defendants failed to meet their burden of proof on their ASRL affirmative defense. The ASRL defense is based upon defendants' interpretation of the regulation that provides an exception of using a cancer risk of 1 in 100,000 where sound considerations of public health support an alternative level, as, for example where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination. [7]

The Court noted the regulation does not state that a quantitative risk assessment is not required for carcinogens in cooked foods. As such, the above language cannot be construed as an exception to the quantitative risk assessment requirement. Instead, to raise a successful defense of an "alternative significant risk level," the Court concluded that Defendants must pass the following three-prong test:

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[4] *Id.* § 25249.7(d).
[5] *Id.* § 25249.7(d)(1).
[6] Office of the Attorney Gen., Cal. Dep't of Justice, *60-Day Notice Search*, https://oag.ca.gov/prop65/60-day-notice-search.
[7] 27 CCR § 25703(b).

(a) establish that acrylamide is created by cooking or processing necessary to render the coffee safe or palatable; b) demonstrate that "sound considerations of public health" justify applying an alternative (less strict) risk level; and c) present persuasive evidence of what would be an appropriate alternative risk level, taking into account the identified public health considerations.

If any of these three factors are absent, the alternative risk level defense would not apply. As such, for the defendants in the current case to prevail, the Court noted they must prove that:

(1) sound considerations of public health support an alternative level for exposure to acrylamide in their coffee products,
(2) such alternative level is derived from a quantitative risk assessment, and
(3) that assuming lifetime exposure to the products, the exposure to acrylamide from Defendants' coffee products is below such alternative level.

The Court found that, although the Defendants' expert performed a quantitative risk assessment of acrylamide, he did not undertake a quantitative risk assessment for acrylamide in coffee. Hence, the defendant failed to undertake the type of quantitative risk assessment that is necessary to quantify the risk of cancer from exposure to acrylamide in coffee. The Court also found the Defendants' expert "did not calculate an ASRL based on sound considerations of public health for exposure to acrylamide from consumption of coffee." The opinion recognizes the FDA expert, Dr. David Kessler, argued for the use of a 1 in 10,000 level of risk because (1) that is the level FDA used when assessing cancer risk for PCBs in fish and inorganic arsenic in rice and (2) OEHHA had once proposed (but ultimately rejected) regulating acrylamide in bread and cereal at the 10^{-4} level. The court concludes, "these rationales lack scientific support, are not based on sound considerations of public health, and provide inadequate grounds for an alternative risk level." The court reached this conclusion without providing any support for is position. In addition, the Court faulted the Defendants for failing to provide a quantitative risk assessment for individual products.

It is unclear why the Court rejected the Defendant's evidence. It is also unclear what scientific support the Court would have considered appropriate for demonstrating "sound considerations of public health" because the court concludes the Defendants failed to meet the standard without providing insight on the type of data that it would have considered appropriate. For example, the Court noted evidence showed that roasting coffee beans is necessary to make coffee palatable and roasting coffee reduces microbiological contamination. The court stated the "Defendants did not offer substantial evidence to quantify any minimum amount of acrylamide in coffee that might be necessary to reduce microbiological contamination or render coffee palatable." The Court also held the evidence offered by Defendants that coffee itself confers some benefit to human health was not persuasive and was refuted by Plaintiffs' evidence. Apparently, the fact that acrylamide is unavoidably created during cooking by itself will not pass this Court's muster for establishing an ASRL defense. Disappointingly, the court reached these summary conclusions without providing a reasoned explanation as to why it rejected the Defendant's evidence. Given the absence of court's reasons, the decision leaves unaddressed many important issues with regard to how the ASRL should be applied.

Another notable statement from the ruling is that the Court rejected the acrylamide data generated by the third-party laboratory holding the data are "scientifically unreliable and inadmissible." The Court characterized the analytical chemistry method used to generate the acrylamide data as "a novel and untested scientific technique that has not been generally accepted in the scientific community." The court reached this conclusion without providing any discussion or reason for challenging the reliability of the results. The statement reinforces the importance of making certain analytical laboratories are using valid methods when analyzing products for listed substances.

In conclusion, the Court ruled that Defendants failed to satisfy their burden of proving that sound considerations of public health support an alternative risk level for acrylamide in coffee. The Defendants have until April 10, 2018, to file objections.

Phase III of the trial will focus on the civil penalties that should be awarded for failing to provide the Proposition 65 warning on coffee sold in California.

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We will continue to closely monitor all developments related to California's Proposition 65. If you have any questions, or if we can be of any assistance, please do not hesitate to contact us.