

MEMORANDUM

From: Martin Hahn
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Re: Proposed OEHHA Regulation Declares No Significant Risk of Listed Proposition 65 Chemicals in Coffee

On Friday, June 15th, the California Office of Environmental Health Hazard Assessment (OEHHA) announced a proposed regulation clarifying that exposures to Proposition 65 chemicals in coffee do not pose a significant cancer risk. ^{1/} The proposal follows a recent California Superior Court ruling that the coffee industry failed to meet its burden of proof on its alternative significant risk level (ASRL) affirmative defense to its failure to warn of the presence of acrylamide in coffee under Proposition 65. ^{2/} The proposed regulation is significant as, if adopted, it would effectively exempt coffee products from Proposition 65 carcinogen warning requirements.

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 a listed Proposition 65 carcinogen since 1990, and the Council for Education and Research on Toxics (CERT) filed a lawsuit in 2010 against many coffee industry members alleging that testing of ready-to-drink coffee revealed that a single 12-ounce serving of the product contains approximately ten times more acrylamide than safe-harbor levels established by OEHHA. The Superior Court of California at Los Angeles County rejected the defendants' evidence to the contrary, setting a concerning precedent for the coffee industry.

The newly proposed OEHHA regulation states the following:

§ 25704. Exposures to Listed Chemicals in Coffee Posing No Significant Risk

Exposures to listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.

^{1/} A press release on the proposed regulation is available at <https://oehha.ca.gov/proposition-65/press-release/press-release-proposition-65/proposed-oehha-regulation-clarifies-cancer>.

^{2/} A Hogan Lovells memorandum regarding the recent court decision is available at <https://www.hlfoodlaw.com/wp-content/uploads/sites/357/2018/04/HL-Memo-California-Judge-Rules-Against-Coffee-Industry-in-Proposition-...pdf>.

^{3/} Cal. Health & Safety Code § 25249.6.

Additionally, OEHHA states in the Initial Statement of Reasons ^{4/} that the regulation covers listed chemicals beyond acrylamide. Specifically, the Statement of Reasons states the following listed Proposition 65 carcinogens are also present in coffee:

acetaldehyde, acrylamide, benz(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenz(a,h)anthracene, formaldehyde, furan, furfuryl alcohol, indeno(1,2,3-cd)pyrene, 4-methylimidazole, naphthalene, and pyridine

Therefore, this regulation, once adopted, would exempt coffee products from Proposition 65 carcinogen warning requirements, to the extent that these carcinogens are created by and inherent in the process of roasting coffee beans or brewing coffee. However, the Initial Statement of Reasons makes it clear that the regulation does not address exposures to listed chemicals in coffee that may occur if the chemicals are intentionally added to the coffee mixture or enter the mixture as contaminants through a means other than the inherent process of roasting coffee beans or brewing coffee. OEHHA uses the example of lead, stating that lead added to coffee through a brewing machine or coffee roasting equipment would not be covered by the regulation's protection.

The agency goes on to emphasize repeatedly that coffee is a complex mixture containing many chemicals in addition to the listed substances on the Proposition 65 list, and discusses at length the World Health Organization's International Agency for Research on Cancer's (IARC) findings that coffee consumption is inversely related with cancer. The Initial Statement of Reasons notes the extent of the evidence, stating specifically that IARC reviewed more than 1,000 studies to come to its conclusion. The studies were conducted in humans, animals, in vitro, and with other experimental systems, and they included numerous well-conducted cohort and population-based case-control studies, and several long-term studies in rats and mice. Considering the reductions of specific cancers resulting from coffee drinking, the rich mix of cancer-preventative agents in brewed coffee, and the lack of evidence showing increases in cancers, OEHHA concludes that exposure to listed carcinogens in coffee that are produced as part of and inherent in the processes of roasting and brewing coffee does not pose a significant cancer risk under Proposition 65.

If this proposed regulation is adopted as written, it would reflect the first time OEHHA has exempted a specific food from its warning requirements. Once finalized, the coffee industry would have a basis to conclude Proposition 65 cancer warnings are no longer required for coffee. We note the regulation does not define what constitutes as "created by and inherent in the processes of roasting coffee beans or brewing coffee" and the term may be subject to different interpretations. The regulation also does not address whether the same exemption would apply when coffee is used as an ingredient in food or if it is limited to ready to drink coffee beverages.

For other sectors of the food industry, the fact that OEHHA is willing to issue such a proposed regulation after the court ruling in the coffee litigation is encouraging. It is important to keep in mind, however, that coffee is unique because of the IARC findings that coffee consumption actually helps reduce cancer. It is unclear whether OEHHA would be willing to work with other sectors of the food industry where the industry can also provide strong scientific evidence showing the overall effects of the food consumption does not increase cancer risk. For example, we are aware of studies demonstrating fruit and vegetable consumption reduce the risk of cancer and during the early years of the George W. Bush administration the Food and Drug Administration (FDA) recognized such link as an example of dietary guidance. It is unclear if OEHHA would be willing to extend the precedent to other foods. Once the precedent is established for coffee, however, it would allow industries

^{4/} OEHHA's Initial Statement of reasons is available at <https://oehha.ca.gov/media/downloads/crn/caffeisor061418.pdf>.

marketing products with demonstrated reduced risk of causing cancer to approach OEHHA and ask for a similar exemption.

Written comments to the rule are due on August 30, 2018 and there will also be a public hearing on August 16, 2018. ^{5/} This will undoubtedly be closely watched and we expect many public comments from both the industry and the plaintiff's bar/consumer groups.

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We will continue to monitor any developments related to this proposed OEHHA regulation. Please let us know if you have any questions.

^{5/} Information on the proposed hearing is available at <https://oehha.ca.gov/proposition-65/cnr/proposed-adoption-new-section-under-article-7-no-significant-risk-levels-section>.