

MEMORANDUM

From: Martin J. Hahn
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Date: September 5, 2017

Re: California's Proposition 65 Warning Requirements for Furfuryl Alcohol Will Become Effective Soon

Effective September 30, 2017, California's Office of Environmental Health Hazard Analysis (OEHHA) will require warnings for consumer products containing furfuryl alcohol under the Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65). Furfuryl alcohol is a food contaminant that can occur in a potentially significant number of thermally processed foods because it forms as a result of the Maillard reaction that gives many foods a characteristic brown color. ^{1/} As has been the case with other food contaminants listed under the Proposition 65, we expect private litigants to file lawsuits after the warning requirement becomes effective. Companies marketing or manufacturing food products that undergo a Maillard reaction should consider whether furfuryl alcohol is forming and should evaluate their potential obligations and exposure in anticipation of the September 30 effective date.

Proposition 65 Listing of Furfuryl Alcohol

For background, 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. ^{2/} OEHHA listed furfuryl alcohol under Proposition 65 on September 30, 2016, as a chemical known to the state to cause cancer for purposes of Proposition 65. Proposition 65 provides a one-year grace period before warnings are required after a chemical is listed. As such, the compliance date for Proposition 65 warning statements for furfuryl alcohol-containing products is September 30, 2017.

Furfuryl alcohol is widely present in food products that have been thermally processed. An article in the scientific literature identifies the levels of furfuryl alcohol found in a wide variety of food products.^{3/} Below we identify some of the foods in the publication with the higher levels, listed in descending order of furfuryl alcohol concentration.

- Roasted/instant coffee

^{1/} See, Okaru, Alex O., and Dirk W. Lachenmeier. "The Food and Beverage Occurrence of Furfuryl Alcohol and Myrcene—Two Emerging Potential Human Carcinogens?." *Toxics* 5.1 (2017): 9.

^{2/} Cal. Health & Safety Code § 25249.6.

^{3/} See *supra* note 1.

- Bread and baked goods
- Ice cream
- Candy
- Juice/beverages
- Toasted nuts

Please note, we do not know whether the levels of furfuryl alcohol reported in these products is representative of the levels typically found in foods. We also are not providing an assessment of whether the levels in any of these products would require a Proposition 65 warning. We are merely identifying these foods to bring to the industry's attention the fact that a literature reference exists identifying these foods as being sources of furfuryl alcohol.

“Safe Harbor” Exemption

It is important to note the mere presence of a listed chemical under the Proposition 65 does not automatically trigger the warning requirements. Many companies rely on the Proposition 65 “safe harbor” exemption for not putting warning labels on the products. Under the “safe harbor” exemption, no Proposition 65 warnings are required if the businesses can establish the level of a listed chemical in the products would result in a dietary intake level that is within a “safe harbor.” ^{4/} If the substance exceeds the safe harbor or is otherwise present at a level that triggers Proposition 65, it is advisable to provide the warning if it is not possible to reduce the exposure to levels that do not trigger the Proposition 65 warning.

OEHHA has established safe harbor levels, in the form of No Significant Risk Levels (NSRLs) for cancer-causing chemicals and Maximum Allowable Dose Levels (MADLs) for chemicals causing reproductive toxicity, for many of the chemicals listed under Proposition 65. However, as of today, there is no established OEHHA “safe harbor” NSRL for furfuryl alcohol. In the absence of an OEHHA “safe harbor,” a company may determine its own “safe harbor” level based on sound toxicology principles and self-assess whether its products, although containing a listed substance, present a potential exposure that falls within the safe harbor level and thus does not require a warning statement. ^{5/}

The Proposition 65 exemptions for “naturally occurring” listed substances may also provide relief for some manufacturers. The Proposition 65 regulations also establish special requirements for the labeling of listed substances that form naturally during the processing of food. ^{6/}

“(4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the “lowest level currently feasible,” as this term is used in Title 21, Code of Federal Regulations, Section 110.110, subdivision (c) (2001).”

Furfuryl alcohol that forms during the Maillard reaction would be exempt from the warning requirements to the extent a company can demonstrate it is present at the “lowest level currently feasible.” It has been our experience that it can take significant data to demonstrate the level of the listed substance is the “lowest level currently feasible.” The manufacturer should have data demonstrating it has manufactured the product under conditions that result in the lowest levels of furfuryl alcohol formulation, such as data demonstrating modifications in the manufacturing process

4/ See *supra* note 2.

5/ 27 CCR § 25801.

6/ See 27 CCR § 25501.

would not result in lower levels of furfuryl alcohol. Moreover, the assessment typically requires a case-by-case assessment of the manufacturing process and there is no formal mechanism by which OEHHA will set the lowest level currently feasible. It has been our experience these levels are typically set through negotiation after an action has been initiated. Regardless, to the extent a food company could develop data demonstrating the level of the furfuryl alcohol in the product is the lowest level currently feasible, the company would have a legal basis to argue a Proposition 65 Warning is not required. Of course, there can be no assurance OEHHA, the bounty hunters, or the courts would agree with the assessment that the level is the lowest level currently feasible.

Brace for Furfuryl Alcohol Proposition 65 Litigation

Proposition 65 permits private citizens or “bounty hunters” to bring private lawsuits to enforce the warning requirements. Violations of Proposition 65 are subject to civil penalties of up to \$2,500 per day per violation. Further, under Proposition 65, 25% of any assessed penalty goes to a successful plaintiff. Unsurprisingly, there are a number of plaintiff law firms specializing in Proposition 65 litigation in California. A “bounty hunter” 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. After the listing becomes effective on Sep. 30, 2017, food products in California that are found to contain furfuryl alcohol could be subject to 60-day notices. It is likely that bounty hunters will use information in the public domain to target those food products that are known to contain furfuryl alcohol. Because the literature identifies roasted/instant coffee, bread and baked goods, ice cream, candies, juice beverages, and toasted nuts as foods that contain furfuryl alcohol, we suspect the bounty hunters may first focus their attention on foods in these product categories. Any food that contains detectable levels of furfuryl alcohol, however, could be subject to a 60-day notice.

If you manufacturer or market any product that undergoes a Maillard reaction, there is the potential for furfuryl alcohol to form. For such companies, it would be prudent to engage legal counsel to assess the impact of the listing decision on compliance with Proposition 65.

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