



August 29, 2018

Ms. Monet Vela
California Environmental Protection Agency
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Re: Proposed Adoption of 27 Cal. Code. Reg. § 25704 – Exposures to Proposition 65
Listed Chemicals in Coffee Posing No Significant Risk of Cancer

Dear Ms. Vela:

I am the Director of the Center for Food Safety and Applied Nutrition (“CFSAN”) at the United States Food and Drug Administration (“FDA”). I write on behalf of FDA in support of the Office of Environmental Health Hazard Assessment (“OEHHA”) proposed regulation, 27 Cal. Code. Reg. § 25704. The proposed regulation would, in effect, provide that the presence of acrylamide in coffee that is formed during the roasting of coffee beans does not require coffee manufacturers and sellers to provide consumers with a Proposition 65 cancer warning. As is discussed in more detail below, FDA strongly encourages OEHHA to adopt the proposed regulation because the most current research on coffee and cancer does not support a Proposition 65 cancer warning for coffee and such a warning could therefore be misleading to consumers. I also note that FDA has previously expressed concerns about Proposition 65 cancer warnings for foods when those warnings are based on the presence of acrylamide.

A. Background on Proposition 65.

As you know, the California Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly referred to as “Proposition 65”), requires the Governor to publish and update annually “a list of those chemicals known to the state to cause cancer.” Cal. Health & Safety Code § 25249.8(a). This “list must include not only those chemicals that are known to cause cancer in humans, but also those that are known to cause cancer in experimental animals.” *Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333, 345 (2004) (citing *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d. 425 (1989)).¹

Proposition 65 prohibits businesses from exposing any individual to a chemical known to the state

¹ Proposition 65 also applies to chemicals known to the state to cause reproductive toxicity. Neither the proposed regulation nor this letter address reproductive toxicity.

to cause cancer “without first giving clear and reasonable warning to such individual.” Cal. Health & Safety Code § 25249.6. For food products, such a warning may state as follows:

WARNING: Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/food.²

Businesses are exempt from the warning requirement if “they can show that the exposure poses no significant risk [of cancer] assuming lifetime exposure at the level in question.” Cal. Health & Safety Code § 25249.10(c).

OEHHA – the agency responsible for administering Proposition 65 – may also adopt regulations that exempt certain products from the warning requirement. *Id.* at § 25249.12(a). For example, by regulation, foods containing a Proposition 65 listed chemical are exempt from the warning requirement if “the chemical is naturally occurring in the food.” 27 Cal. Code. Reg. § 25501(a); *see, e.g. People ex rel. Brown v. Tri-Union Seafoods, LLC*, 171 Cal. App. 4th 1549 (2009) (tuna containing Proposition 65 listed chemical was exempt from warning requirement because the chemical was naturally occurring in tuna). OEHHA adopted that exemption because many Proposition 65 listed chemicals are naturally occurring in foods and “the absence of such an exemption could unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could distract the public from other important warnings on consumer products.” *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1991) (rejecting challenge to the regulation and quoting OEHHA’s Final Statement of Reasons for the regulation).

B. A Proposition 65 cancer warning for coffee based on the presence of acrylamide could be misleading to consumers.

Coffee contains acrylamide – a chemical that was added in 1990 to the Proposition 65 list of chemicals known to cause cancer. Acrylamide is not present in raw coffee beans; it forms from a chemical reaction that occurs when the coffee beans are roasted. In an ongoing Proposition 65 lawsuit filed by a public interest group, a California trial court has tentatively ruled that the presence of acrylamide in coffee necessitates a Proposition 65 cancer warning.³

The currently proposed regulation states: “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.” Adoption of this regulation would mean that the presence of acrylamide in coffee does not necessitate a Proposition 65 cancer warning in California.

FDA strongly encourages OEHHA to adopt the proposed regulation because a Proposition 65 cancer warning for coffee could be misleading in light of the most current scientific evidence regarding coffee and cancer.

² Cal. Code Reg. § 25607.2 (operative Aug. 30, 2018).

³ *See Council for Education and Research on Toxins v. Starbucks Corp.*, 2018 WL 1678204 (Cal. Super. Los Angeles County Mar. 28, 2018).

As OEHHA discusses in its Initial Statement of Reasons, the World Health Organization's International Agency for Research on Cancer ("IARC") recently published *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Drinking Coffee, Mate, and Very Hot Beverages* (Vol. 116) (2018).⁴ Based on its evaluation of more than 1000 studies of coffee and cancer (including prospective cohort studies, population-based case-control studies, and animal studies), IARC found there "is *inadequate evidence* in humans for the carcinogenicity of drinking coffee;" there "is *evidence suggesting lack of carcinogenicity* of drinking coffee in humans for cancers of the pancreas, liver, female breast, uterine endometrium, and prostate;" that "[i]nverse associations with drinking coffee have been observed with cancers of the liver and uterine endometrium;" and there "is *inadequate evidence* in experimental animals for the carcinogenicity of coffee." *Id.* at 425 (emphases in original).

The World Cancer Research Fund ("WCRF") and the American Institute for Cancer Research ("AICR") recently published a report finding "strong evidence" that coffee "probably decreases" the risk of cancer of the liver and endometrium and "limited suggestive" evidence that coffee may decrease the risk of cancer at other sites. *See Continuous Update Project Expert Report 2018: non-alcoholic drinks and the risk of cancer* at 6-10, 34-39.⁵

Moreover, current dietary guidelines published by the United States Department of Health and Human Services ("HHS") and the United States Department of Agriculture ("USDA") state:

Moderate coffee consumption (three to five 8-oz. cups/day or providing up to 400 mg/day of caffeine) can be incorporated into healthy eating patterns. This guidance on coffee is informed by strong and consistent evidence showing that, in healthy adults, moderate coffee consumption is not associated with an increased risk of major chronic diseases (e.g., cancer) or premature death, especially from [cardiovascular disease].⁶

In short, the scientific community has conducted a substantial amount of research on the issue of whether coffee causes cancer, the totality of that research has found inadequate evidence to establish that coffee causes cancer, and that research has found some evidence suggesting that coffee may even reduce the risk of some cancers.

Given the state of the science, a Proposition 65 cancer warning for coffee could mislead consumers

⁴ Available at <http://publications.iarc.fr/566>.

⁵ The WCRF/AICR report is available at www.wcrf.org/sites/default/files/non-alcoholic-drinks.pdf.

⁶ *See* U.S. Department of Health and Human Services and U.S. Department of Agriculture, *2015-2020 Dietary Guidelines for Americans* at 33 (8th Ed. 2015) (available at <https://health.gov/dietaryguidelines/2015/guidelines>); *see also Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture* at 298-99 (2015) (available at <https://health.gov/dietaryguidelines/2015-scientific-report/>) (stating "[c]onsistent observational evidence indicates that moderate coffee consumption is associated with reduced risk of type 2 diabetes and cardiovascular disease in healthy adults" and "consistent observational evidence indicates that regular consumption of coffee is associated with reduced risk of cancer of the liver and endometrium, and slightly inverse or null associations are observed for other cancer sites").

into believing that drinking coffee increases their risk for developing cancer. Such a misleading warning would render the coffee misbranded under the Federal Food, Drug, and Cosmetic Act (“FDCA”). *See* 21 U.S.C. § 343(a)(1) (stating a “food shall be deemed to be misbranded” if its labeling is “misleading in any particular”); *see also National Ass’n of Wheat Growers v. Zeise*, 309 F. Supp. 3d 842, 851 (E.D. Cal. 2018) (stating that where numerous government agencies and health organizations have found no evidence that a chemical causes cancer, a Proposition 65 cancer warning would be “misleading at best” because “the most obvious reading of the Proposition 65 cancer warning is that exposure to [the chemical] in fact causes cancer”). And federal law preempts any state law that would require a warning rendering a product misbranded under the FDCA. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-18 (2011); *see also Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (noting “state law is naturally preempted to the extent of any conflict with a federal statute,” including “where it is impossible for a private party to comply with both state and federal law”). Thus, to the extent that Proposition 65 is interpreted to require a product subject to FDA’s authority under the FDCA to bear a misleading warning that would render the product misbranded under the FDCA, it is invalid under federal law.

C. FDA has previously expressed concerns about Proposition 65 acrylamide warnings for foods.

Finally, I note that FDA has previously expressed concerns about acrylamide warnings for foods under Proposition 65.

Acrylamide forms in a number of foods during high-temperature cooking, such as frying, baking, and roasting. This acrylamide formation occurs primarily in plant-based foods, notably potato products such as french fries and potato chips; cereal-grain-based foods such as cookies, crackers, breakfast cereals, and toasted bread; and coffee. Scientists first discovered the presence of acrylamide in foods in 2002. Since that time, FDA has conducted several activities relating to acrylamide in foods, including research on acrylamide levels in foods and publication of steps that consumers, growers, manufacturers, and food service operators can take to reduce acrylamide levels in certain foods. *See, e.g., FDA Consumer Update: You Can Help Cut Acrylamide in Your Diet* (2016);⁷ *FDA Guidance for Industry: Acrylamide in Foods* (2016).⁸

However, based on available scientific evidence regarding acrylamide in foods, FDA has not suggested maximum recommended levels for acrylamide in various products. *See FDA Guidance for Industry: Acrylamide in Foods* at 5. And FDA has previously stated that it has concerns about acrylamide warnings for foods because such warnings may mislead consumers about the risks posed by foods containing acrylamide and may encourage consumers to alter their diets in ways that may not benefit their health. *See, e.g., Letter from Dr. Terry Troxell (FDA) to Edward Weil (Cal. Dep’t of Justice) at 2* (Mar. 21, 2006) (stating that “FDA has concerns about the use of warning labels or signs for acrylamide” in food because such warnings may “[c]reate unnecessary

⁷ Available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm374855.htm.

⁸ Available at www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm374524.htm. As noted at page 27 of the Guidance, “A number of mitigation methods have been suggested for coffee, such as steam roasting, vacuum roasting and asparaginase treatment [references], but FDA is not aware of any proven mitigation measures.” More information on FDA’s activities regarding acrylamide can be found at our acrylamide webpage, www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm2006782.htm.

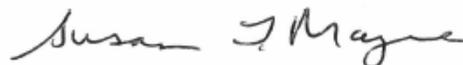
and unjustified public alarm about the safety of the food supply,” “[d]ilute overall messages about healthy eating,” and “[m]islead consumers into thinking that acrylamide is only a hazard in store-bought food”).⁹

Indeed, a California appellate court recently held that federal law preempts Proposition 65 acrylamide warnings on breakfast cereals because such warnings would pose an obstacle to federal nutrition policies aimed at increasing consumers’ consumption of whole grains (which are present in many breakfast cereals). *See Post Foods, LLC v. Superior Court*, 235 Cal. Rptr. 3d 641 (2018). In so holding, the court noted, “FDA’s policy, described in its advisory letters to California’s regulators and Attorney General, is that no Proposition 65 warning for acrylamide should be placed on foods, including breakfast cereals, unless and until the science supports such a warning.” *Id.* at 655.

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For the reasons discussed above, FDA strongly encourages OEHHA to adopt the proposed regulation.

Sincerely,



Susan T. Mayne, Ph.D.
Director
Center for Food Safety
and Applied Nutrition

⁹ *See also* Letter from Dr. Lester Crawford (FDA) to Dr. Joan Denton (OEHHA) at 3 (Jul. 14, 2003) (stating “warning labels based on the presence of acrylamide in food might be misleading”).