

FDA Supports Exempting Coffee From California's Cancer Warning Law

Requiring a cancer warning on coffee would be more likely to mislead consumers than to inform them.

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Statement from FDA Commissioner Scott Gottlieb, MD, on FDA's support for exempting coffee from California's cancer warning law

Ensuring that food is safe and truthfully labeled is one of our fundamental responsibilities at the U.S. Food and Drug Administration. Consumers deserve accurate information about the food they eat and how it can affect their health and nutrition. That's why Congress entrusted the FDA to serve as the nation's expert on food safety and labeling and to craft predictable, uniform federal requirements on matters within our jurisdiction. Consistent with that authority, we work to provide the best advice possible to Americans about the foods they eat based on the most recent scientific information, taking into account the food's benefits in addition to any potential health risks.

Part of our mission in this space means ensuring that food product labeling doesn't contain false or misleading statements about safety or nutrition. This includes statements that food manufacturers make on their own initiative. But it also includes statements that may be compelled under state law.

Simply put, if a state law purports to require food labeling to include a false or misleading statement, the FDA may decide to step in.

That's why we were deeply concerned when a court recently ruled that a California law – known as Proposition 65 – may require coffee sold in California to be labeled with a cancer warning because of the presence of a chemical called acrylamide. Under Proposition 65, California requires that certain products contain cancer warnings if they will expose consumers to chemicals that California health authorities have identified as causing cancer. But requiring a cancer warning on coffee, based on the presence of acrylamide, would be more likely to mislead consumers than to inform them.

Acrylamide can form in many foods during high-temperature cooking, such as frying, roasting and baking. Acrylamide in food forms from sugars and an amino acid that are naturally present in food. It doesn't come from food packaging or the environment. In coffee, acrylamide forms during the roasting of coffee beans. Although acrylamide at high doses has been linked to cancer in animals,

and coffee contains acrylamide, current science indicates that consuming coffee poses no significant risk of cancer. This finding was reflected in a comprehensive report by the World Health Organization's International Agency for Research on Cancer.

The good news is that, based on this science, the California agency that administers Proposition 65 has proposed a regulation to exempt coffee from a Proposition 65 cancer warning.

The FDA strongly supports this proposal.

As a science-based agency, the FDA is committed to ensuring that information being presented on a food's label is accurate and not misleading. That's why today the FDA sent a letter to the California Office of Environmental Health Hazard Assessment expressing our support of this proposed regulation that would exempt coffee from a Proposition 65 cancer warning.

We've taken this position because we too have carefully reviewed the most current research on coffee and cancer and it does not support a cancer warning for coffee. In fact, as our letter to California states, such a warning could mislead consumers to believe that drinking coffee could be dangerous to their health when it actually could provide health benefits. Misleading labeling on food violates the Federal Food, Drug, and Cosmetic Act. No state law can require food to bear a warning that violates federal law.

Strong and consistent evidence shows that in healthy adults moderate coffee consumption is not associated with an increased risk of major chronic diseases, such as cancer, or premature death, and some evidence suggests that coffee consumption may decrease the risk of certain cancers. To this end, current dietary guidelines published by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture state that moderate coffee consumption (three to five cups a day or up to 400 mg/day of caffeine) can be incorporated into healthy eating patterns.

This is not the first time the FDA has expressed concerns about Proposition 65 warnings based on the presence of acrylamide in foods. The FDA previously wrote to California stating our concerns about acrylamide warnings for foods because such warnings may mislead consumers about the risks posed by foods containing acrylamide and encourage consumers to alter their diets in ways that may not benefit their health. A prime example is whole grain foods. We recognize that some of these products may contain acrylamide. But we also know that consumption of whole grains is beneficial for health and nutrition. Labeling whole grain foods with a cancer warning may cause American consumers to avoid foods that would have a benefit to their health, including avoiding foods that may reduce cancer risks.

The FDA has undertaken a number of activities on acrylamide since the discovery of acrylamide in foods in 2002, including performing toxicology research, conducting food surveys and exposure assessments and issuing [guidance for industry on mitigating the formation of acrylamide during food production](#). Given the widespread presence of acrylamide in foods, it isn't feasible to completely eliminate acrylamide exposure.

Removing any one or two foods from your diet would not have a significant effect on overall

exposure to acrylamide. This is why the FDA's best advice is that consumers adopt a healthy diet, consistent with the [Dietary Guidelines for Americans \(2015-2020\)](#). It emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products; includes lean meats, poultry, fish, beans, eggs, and nuts; healthy oils, and limits saturated fats, trans fats, sodium, and added sugars.

Assuring that consumers have access to transparent science-based nutrition information is a pivotal element of the FDA's public health mission. These goals are encompassed in the multi-year [Nutrition Innovation Strategy](#) that we announced in March. This Innovation Strategy involves a series of synergistic actions intended to modernize the FDA's approach to nutrition, help reduce the burden of chronic disease that stems from poor nutrition, including obesity, diabetes, heart disease and a variety of cancers, and to remove barriers to industry innovation.

In line with our Nutrition Innovation Strategy, we strongly support exempting coffee from a cancer warning. The scientific community has conducted a substantial amount of research on the issue of whether coffee causes cancer, and the totality of that research has found inadequate evidence to establish that coffee causes cancer and suggests that coffee may even reduce the risk of some cancers.

We're dedicated to providing science-based information to consumers in an effort to benefit health and nutrition. And we remain committed to ensuring product labeling provides the most factual, easy-to-understand information needed to inform diet selections.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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