

POSSIBLE CHANGES TO FOOD LABELING UNDER THE BIDEN ADMINISTRATION

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Under the Trump administration, substantial funds were diverted away from the U.S. Food & Drug Administration (FDA) and other federal agencies with oversight responsibilities for the nation's food and beverage industries. This led to reductions in personnel, fewer inspections, and more relaxed enforcement across the industry. Now, with President Biden in office, we may expect to see an increase in the federal government's regulation of food, beverages, and dietary supplements.

Food labeling and advertising may become subject to more stringent regulations and enforcement. Food labeling historically has been an important area of regulation by the FDA, and significant policy and regulatory developments may occur over the next four years. Notably, industry stakeholders expect a long-awaited definition of "healthy" to be issued, to reflect the evolution of nutrition science. For instance, in the past, there was a greater emphasis on total fat content. We have since learned that some fats promote health while others do not. An updated and more precise definition along these lines at the federal level could impact pending litigation across the country, while clarifying the manner in which food companies may package and sell certain products.

The following alert provides an overview of current food labeling requirements, as well as a summary of various changes anticipated during the course of the Biden administration.

1. Food Labeling - Overview

Under President Biden, the Federal Trade Commission (FTC) may become more aggressive in its enforcement of advertising laws against businesses in all areas, including the food, beverage, and dietary supplement industries in coordination with the FDA. This may lead to stricter regulation and enforcement of product labeling and advertising.

The FDA is responsible for ensuring that food sold in the United States (whether produced domestically or imported) is safe, wholesome, and properly labeled. Food products are governed by the federal Food, Drug, and Cosmetics Act, as amended by the Nutrition Labeling and Education Act (NLEA), as well as the Fair Packaging and Labeling Act. Under the NLEA, most food and beverages must bear nutrition labeling, and those labels which include nutrient content claims and certain health

Attorneys

Christine Bonaguide Paul Comeau Reetuparna Dutta George Eydt Emily Florczak Andrew Freedman Neil Friedman Nathaniel Lucek Ryan Lucinski Michael Maxwell Elizabeth McPhail R. Kent Roberts Hugh Russ III Christian Soller Daniel Spitzer James Zawodzinski Jr.

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messages must comply with various requirements. Label appearance, placement, and contents (including origin, nutrition facts, allergens, nutrient content, and health-related claims) are specifically prescribed; the pertinent regulations change frequently. The FDA has announced that January 1, 2024 will be the uniform compliance date for final food labeling regulations that are issued in calendar years 2021 and 2022. However, if a food labeling regulation involves special circumstances justifying a compliance date other than January 1, 2024, the FDA may determine that a different compliance date is appropriate for that particular regulation.

Initial areas of focus for the Biden administration will include product labeling (including country of origin claims), food safety (such as technology-enabled traceability and standardized recordkeeping), and protection of food supply chains. It is also expected that interagency collaboration relating to food safety matters and enforcement will increase.

2. "Healthy Food" Defined

In defining "healthy," regulators must first sift through voluminous comments submitted by food companies, health groups and other advocates. After a public hearing in March, the comment period closed on April 26, 2021. Some favored the continued inclusion of certain beneficial nutrients, like vitamins, minerals, and fat in the new definition. Others promoted a more general focus on beneficial food groups, such as whole grains, fruits, and vegetables, while others preferred more of a hybrid model (i.e., a combination of the two).

For over a decade, numerous consumer-protection groups as well as individual consumers have brought lawsuits against food companies, arguing that their use of the term "healthy" in their packaging, labeling, and advertising is misleading, due to the presence of added sugars, chemicals, fats, and other harmful ingredients.

For example, in Zemola v. Carrington Tea Company, LLC, 2017 WL 4922974 (S.D. Cal. Oct. 27, 2017), a putative class action lawsuit was commenced against a producer of coconut oil for marketing its products as "inherently healthy" and making other purportedly misleading health and wellness claims when the consumption of this product, due to its high saturated fat content, may actually increase the risk of cardiovascular heart disease and other morbidity. It was further alleged that the product labeling conveys a concrete message to a reasonable consumer that coconut oil is a healthier alternative to other cooking oil. Doing so arguably targets the large pool of consumers willing to pay more for foods they perceive as healthy, thereby constituting false and misleading marketing practices.

These claims survived an immediate motion to dismiss for failure to state a cause of action, which argued, in large part, that because the nutrition label accurately reflected that the coconut oil is comprised of 100% fat, it is not misleading. In denying this motion and allowing the claims to stand, the Court reasoned that, because the Complaint sufficiently pled the reliance and causation elements (i.e., that the representations concerning the product's nutrition were relied upon in purchasing and consuming it), it is a jury's role to determine whether the marketing practices were, in fact, deceptive.

The Zemola Court also denied the alternative application to stay (or suspend) the action pending the FDA's reconsideration of the term "healthy," primarily because, as of 2017 (and unlike now), the timing of that reconsideration - and whether it would yield any changes to the existing definition - remained unclear.



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Similarly, in *Hadley v. Kellogg Sales Co.*, 243 F.Supp.3d 1074 (N.D. Cal. 2017), Kellogg was sued for advertising its cereals as "Heart Healthy," a "Good Source of fiber," and "nutritious" despite the excessive amount of sugar comprising these products. Although the Court dismissed these claims based on various procedural deficiencies - such as the failure to plead with adequate particularity the amount of *added* sugar in the Kellogg products, as opposed to *total* sugar, and a causal connection between that added sugar and unhealthfulness - the Court did so without prejudice. Meaning, the Complaint could be re-filed in a manner that cured these deficiencies.

But in *Truxel v. General Mills Sales*, *Inc.*, 2019 WL 3940956 (N.D. Cal. Aug. 13, 2019), based on similar facts (i.e., the characterization of cereals and snacks as "healthy" notwithstanding their high sugar content), the Complaint was dismissed with prejudice (without that same opportunity to re-file), under the rationale that because General Mills accurately and fully disclosed the sugar content of its products on its labels, a reasonable consumer cannot claim "to have been misled in that regard."

The *Truxel* Court seemed to place the burden on consumers to determine for themselves, based on the product label, whether consumption of the products is "healthy," as opposed to blindly relying on the manufacturer's characterization, particularly where there is no consensus on what constitutes "healthy" from the top (FDA) down. In turn, the Court also seemed to suggest that consumers should be able to discern fact (sugar content) from opinion or marketing buzzwords ("healthy") and decide for themselves whether consumption promotes or impedes their overall health.

These cases underscore the divergent outcomes arising from the litigation of food and beverage labeling issues. The long-awaited definition of "healthy" by the FDA is likely to provide greater guidance to the Courts and predictability to litigants concerning the outcomes of these sorts of disputes centered around the ever-evolving question of what constitutes healthy food, and the circumstances under which its manufacturers may advertise it as such.

If you have any questions about food labeling, or about food and beverage law and FDA regulation generally, please contact Christine Bonaguide, Mila Buckner, Emily Florczak, or Christian Soller, or any other member of the Hodgson Russ Food & Beverage practice.

