

**Alert | Health Care & FDA Practice /
Food, Beverage & Agribusiness**



January 2025

FDA Finalizes a New Definition of ‘Healthy’ for Food Labeling

On Dec. 19, 2024, the U.S. Food and Drug Administration (FDA) announced a long-awaited **final rule** **revising the definition of “healthy”** when used in the labeling of food products.

The rule revises the FDA’s criteria for use of terms like “healthy,” “healthful,” and “healthier,” terms that are implied nutrient content claims (NCCs) under FDA regulations in 21 CFR 101.65. To make a compliant “healthy” claim under the new criteria, a food product needs to (1) contain a specified amount of food from at least one of the food groups or subgroups identified, which include fruit, vegetables, grains, fat-free and low-fat dairy, and proteins recommended by the Dietary Guidelines for Americans and (2) contain levels of added sugars, saturated fat, and sodium below certain specified limits. The new definition of “healthy” also includes water, tea, and coffee with five calories or fewer per serving, without having to meet any other criteria.

The FDA, which has regulated the term “healthy” since 1994, noted that the definition needed an update “to be consistent with current nutrition science and Federal dietary guidance, especially the Dietary Guidelines for Americans (Dietary Guidelines), regarding how consumers can maintain healthy dietary practices.” While the effective date of this rule is 60 days from the Dec. 27, 2024, date of publication in the Federal Register, the industry will have over three years to evaluate this new definition of “healthy” and to change packaging and labeling as necessary, as the compliance date is Feb. 25, 2028.

The FDA issued a proposed rule in September 2022, soliciting comments from stakeholders on its revised definition of “healthy.” The FDA then issued its final rule after reviewing over 400 submitted comments. The final rule revises the criteria for determining when the term “healthy,” or derivative terms such as “healthful” and “healthier,” can be legally used as a NCC when labeling human food, beverage, and dietary supplement products to help consumers identify foods that are particularly useful as the foundation of a nutritious diet consistent with dietary recommendations. The FDA amended 21 CFR 101.65(d) by removing various upper limits pertaining to total fat and cholesterol, as well as certain minimums for at least one of fiber, protein, vitamin A, vitamin C, calcium, or iron. Instead, the new definition focuses on just three nutrients: saturated fat, added sugars, and sodium.

In addition to allowing water, tea, and coffee with five calories or fewer to be identified as “healthy,” the FDA, for the first time, has recognized that certain food categories should be recognized as inherently “healthy” when comprising no added ingredients other than water. Those foods include vegetables, fruit, whole grains, fat-free or low-fat dairy, lean meat, seafood, eggs, beans, peas, lentils, nuts, and seeds. This means that companies selling products like avocados and cashews, which were previously excluded because of high levels of naturally occurring saturated fat, may now label these foods “healthy” under the new definition.

The FDA has also introduced the concept of food groups and food group equivalents (FGEs) as an aspect of the “healthy” definition, identifying different ceilings for allowable added sugars, sodium, and saturated fat, based on the food group. For mixed ingredient products, certain threshold levels of one or more of the food groups must be included, in addition to meeting the requisite levels of saturated fat, sodium, and added sugars, in order to use the term “healthy.” The FDA provides a [table](#) listing the various criteria for each type of food or group in the revised 21 CFR 101.65(d).

Included in the revised rule are obligations for manufacturers to make and keep written records to verify that any food promoted with a “healthy” claim meets the FGE requirements. The FDA is also exploring the development of a “healthy” symbol that manufacturers could use to market a product’s “healthy” characteristics, although no symbol has yet been finalized.

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