

FDA's New Rule for "Healthy" Claim Has Broad Implications for Food Industry

Legal Alert
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The U.S. Food and Drug Administration (FDA) recently finalized its long-awaited rule for the use of "healthy" claims on food labels. The final rule brings welcome clarity for food companies but has broad legal and business implications for their products.

Under the [final rule](#), foods labeled as "healthy" (or "healthful" or other derivatives) must meet certain nutritional guidelines, including specific limits on added sugars, sodium and saturated fats, while also providing certain minimum amounts of food groups, such as fruits, vegetables, protein foods or whole grains.

Key updates in the final rule include:

- **Added sugars:** Foods that qualified as "healthy" under FDA's prior rules may no longer qualify under the final rule because of their added sugar content. These include yogurts, fortified breakfast cereals, fruit snacks and snack bars that are high in added sugars. Now, there are stricter limits on the amount of added sugar permitted in a "healthy" product.
- **Sodium:** While largely maintaining the sodium limits proposed in the draft rule, FDA provides greater flexibility in its final rule for sodium limits in mixed products. A mixed product must contain at least foods from two food groups, as explained more below.
- **Saturated fats:** Limits on saturated fats are also largely maintained. However, the final rule effectively increases these limits for some foods with naturally occurring saturated fats (e.g., products made with seafood, nuts, seeds and soybeans).
- **Food group equivalents (FGEs):** The final rule emphasizes food groups. In general, a "healthy" food must include at least one of the recognized food groups or subgroups

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(known as a "food group equivalent" or FGE). These are (a) vegetables; (b) fruits; (c) grains; (d) dairy; and (e) protein foods (i.e., game meat; seafood; eggs; beans, peas, or lentils; and nuts, seeds or soy products).

This represents a shift from the FDA's prior approach, which relied heavily on individual nutrient thresholds without requiring the inclusion of nutritional food groups. Now, as part of a "whole-of-government" approach, these adjustments aim to ensure that the "healthy" claim better aligns with current nutritional science and the Dietary Guidelines for Americans.

There are several ways that a food label may make a "healthy" claim.

1. Automatic qualification: The following foods automatically qualify for the "healthy" claim:

- **Individual foods or mixed products** composed of one or more of the following food groups **with no added ingredients except water:** vegetables, fruits, whole grains, fat-free and low-fat dairy, lean meat, seafood, eggs, beans, peas, lentils, or nuts and seeds.
- **Beverages:** All water, tea and coffee with less than 5 calories per FDA-established reference amount customarily consumed (known as RACCs) and per labeled serving.

2. Meets FGE criteria: A food product may also qualify for the "healthy" claim if it meets one of the following FGE criteria:

- **Individual food:** An individual food with at least one FGE and meets the respective nutrient limits. This is measured per RACC for foods with a RACC greater than 50 grams or 3 tablespoons or per 50 grams for foods with a RACC up to 50 grams or 3 tablespoons. Notably, certain oil products do not require an FGE to make the "healthy" claim, provided they meet relevant nutrient limits.
- **Mixed product:** A mixed product with at least one FGE and no less than 1/4 of an FGE from at least two food groups that meets respective nutrient limits. A "mixed product" is a class of "combination foods" that contains at least one total FGE and no less than 1/4 FGE from at least two food groups.
- **Main dish:** A main dish with at least two FGEs and no less than 1/2 of an FGE from at least two food groups that meets respective nutrient limits. A "main dish" is a class of "combination foods" commonly understood to be a main dish and contains food from at least two food groups, provided it weighs at least 6 ounces per labeled serving and contains at least 40 grams of food from each of at least two food groups.
- **Meal product:** A meal product with at least three FGEs and no less than 1/2 of an FGE from at least three food groups that meets respective nutrient limits. A "meal product" is a class of "combination commonly understood to be a breakfast, lunch or dinner meal,

provided it weighs at least 10 ounces per labeled serving and contains at least 40-gram portions of food from at least two food groups.

This final rule will likely have significant implications for food manufacturers and food brands. Food companies may need to reformulate products and/or revise labeling practices to comply with the updated criteria. This may drive innovation but could also impose additional costs, such as for companies that produce and rely on plant-based dairy alternatives or novel proteins, such as those made from mycoprotein and algae.

At the same time, the rule's publication resolves a legal gray area that has persisted in consumer litigation. In recent years, many lawsuits challenging "healthy" claims were paused by courts, pending publication of FDA's final rule. With the new rule in place, these cases can proceed, potentially opening the floodgates to renewed scrutiny of food labels under the updated standard.

For businesses in the food industry, FDA's final rule underscores the importance of proactive compliance and close monitoring of litigation trends. Companies should evaluate how their products align with the new "healthy" definition, but also look out for potential legal challenges as plaintiffs test the boundaries of FDA's new rule.

By staying on top of these regulatory and legal developments, food companies can better navigate the complex and evolving landscape of food labeling and consumer litigation.

For questions or guidance on how the FDA's rule impacts your products, contact Foster Garvey's [Food & Beverage](#) team.

Limits Established under FDA's Final Rule on "Healthy" Claims