

FDA Publishes Rule Updating ‘Healthy’ Nutrient Content Claim

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On December 27, 2024, [the US Food and Drug Administration \(FDA\)](#) published its final rule to update the definition for “healthy” claims on food labels. The new rule uses current nutrition science to both expand and restrict which foods can now be labeled “healthy” based on the implied nutrient content, updating regulations that have been unchanged since 1994. Rather than focus on the level of particular nutrients in a food, such as vitamin A, vitamin C, calcium, iron, protein and fiber, which under the prior rules could easily be added via fortification to less nutrient-dense foods, the new regulations emphasize foods with stronger overall nutrient content – and, for the first time, reflect limits on added sugars.

Under the new framework, “healthy” foods are those with strong overall nutrition profiles, with both a minimum amount of content from designated food groups (vegetables, fruits, dairy, grains, protein or oils) and limited added sugars, saturated fat and sodium. Such foods can serve as a foundation for a healthy dietary pattern recommended by the [Dietary Guidelines for Americans, 2020 – 2025](#), allowing consumers to quickly discern which foods are nutrient-dense and can help them achieve a well-rounded diet.

Under the new rule, when can ‘healthy’ be used as an implied nutrient content claim in the labeling of food products?

Under the revised rules, an implied nutrient content claim is one that suggests a food may help consumers maintain healthy dietary practices due to its nutrient content, where there also is implicit or explicit information about the food’s nutrition content somewhere on the food’s labeling (see 21 CFR 101.65 (a) & (d)). Such claims may only use the term “healthy” on labeling of individual food products, mixed products, main dishes and meals when the product meets the new food group equivalents (FGEs) and specific limits for nutrients to limit (NTL) based on a percentage of the daily value (DV) for these nutrients, in the following scenarios:¹

1. Individual food

Under the new rules, individual food products like salmon and wheat pasta can qualify for the “healthy” claim, provided they meet specific FGE and NTL requirements. The new criteria will also allow food products consumed in smaller servings² like natural cheeses and 100% olive oil to qualify to use the “healthy” claim, provided they meet specific FGE and NTL requirements.

Foods that qualified for “healthy” claims under the original rule but may struggle to meet the new limits include fortified white bread, fruit snacks, highly sweetened yogurt and highly sweetened cereal.

The chart below visually summarizes the required amounts of each food group – i.e., the food FGEs and the maximum limits for NTL for a food product to qualify for the “healthy” claim.

Updated criteria for certain food groups and sample foods

Per reference amount customarily consumed

oz = ounce

g = grams

mg = milligrams
DV = daily value

Food groups	Food group equivalent minimum	Added sugar limit	Sodium limit	Saturated fat limit
Grains product	3/4 oz whole-grain equivalent	10% DV (5g)	10% DV (230 mg)	5% DV (1 g)
Dairy product	2/3 cup equivalent	5% DV (2.5 g)	10% DV (230 mg)	10% DV (2 g)
Vegetable product	1/2 cup equivalent	2% DV (1 g)	10% DV (230 mg)	5% DV (1 g)
Fruit product	1/2 cup equivalent	2% DV (1 g)	10% DV (230 mg)	5% DV (1 g)
Protein foods				
Game meat	1 ½ oz equivalent	2% DV (1 g)	10% DV (230 mg)	10% DV (2 g)
Seafood	1 oz equivalent	2% DV (1 g)	10% DV (230 mg)	5% DV (1 g)*
Egg	1 egg	2% DV (1 g)	10% DV (230 mg)	10% DV (2 g)
Beans, peas and lentils	1 oz equivalent	2% DV (1 g)	10% DV (230 mg)	5% DV (1 g)
Nuts, seeds and soy products	1 oz equivalent	2% DV (1 g)	10% DV (230 mg)	5% DV (1 g)*

Oils				
100% oil	N/A	0% DV	0% DV	20% of total fat
Oil-based spreads	N/A	0% DV	10% DV (230 mg)	20% of total fat
Oil-based dressing**	N/A	2% DV (1 g)	10% DV (230 mg)	20% of total fat
*Excluding saturated fat inherent in nuts, seeds, soy products and seafood				
** Must contain at least 30% oil				

2. Combination foods

The new rule also contains specific regulations to address “healthy” claims by mixed products, main dish products and meal products, each requiring that the foods meet specific minimum amounts from the FGEs and limit the amount of added sugar, sodium and saturated fat. The limits for these foods are generally higher than for individual foods, e.g., permitting between 10% – 20% of the DV of added sugar if the foods meet the FGEs. Trail mix, for example, composed of dried fruit and nuts is a mixed product that could qualify for the “healthy” claim. A main dish could qualify, if it contains a half-cup of vegetables and 1 1/2 ounces of whole grains, totaling the two full FGEs required by the statute, if it also meets the limits on added sugar, saturated fat and sodium.

3. Beverages

All water, tea and coffee with less than 5 calories per labeled serving can make a “healthy” claim. This includes carbonated or noncarbonated water, coffee, and tea, containing noncaloric ingredients such as flavors, no- or low-calorie sweeteners, vitamins, and minerals. But many other beverages, particularly highly sweetened products, will no longer be able to use “healthy” on their labels.

4. Recognized nutrient-dense foods

Individual food and mixed products that contain one or more of the following nutrient-dense foods and do not contain any added ingredients, besides water, will automatically qualify for the “healthy” claim:

- Vegetables
- Fruits
- Whole grains
- Fat-free or low-fat dairy
- Lean meat, seafood, eggs, beans, peas, lentils, nuts and seeds

This exemption also includes the “raw, whole” versions of foods, including a variety of shelf-stable and/or economical forms of foods. For example, frozen or sliced fruits and vegetables, 100% whole-grain flours, dried beans, peas, lentils, frozen seafood, chopped nuts and certain nut butters (i.e., only containing nuts), with no added ingredients other than water, automatically qualify without needing to meet the new requirements.

Additionally, single-ingredient foods encouraged by the Dietary Guidelines that have small recommended serving sizes (e.g., frozen avocado pieces) qualify even if their serving size is smaller than the FGEs for their respective food groups or subgroups.

Records maintenance

With limited exception, each manufacturer of a food that bears the implied nutrient content claim “healthy” must make and keep written records (e.g., analyses of databases, recipes, formulations, information from recipes or formulations, and/or batch records) to verify that the food meets the FGE requirements of the regulation. These records must be kept for a period of at least two years after introduction or delivery for introduction of the food into interstate commerce.

Compliance date

The rule is effective on February 25, 2025, and is the date on which the Office of the Federal Register will amend the Code of Federal Regulations in 21 CFR 101.65(d) to reflect the new requirements for the “healthy” implied nutrient content claim. But the Trump administration has issued a [regulatory freeze executive order](#), which could delay the effective date of this rule until March 21, 2025, reopen the comment period or allow for additional, unspecified actions by FDA.

The compliance date, meaning the date on which FDA will begin enforcing the rules, is February 25, 2028. This three-year delay is intended to allow the industry sufficient time to update labeling in order to comply with the new requirements.

Enforcement and litigation

A violation of the new regulations will result in a food being misbranded and would entitle FDA to take any number of actions to compel compliance – including issuance of a warning letter, a facility inspection, administrative detention, seizure or criminal prosecution.³

Separate from agency actions, increasingly, private litigants are challenging food labels with class action lawsuits, arguing that the labels violate current Federal Food, Drug, and Cosmetic Act (FDCA) regulations for “healthy” claims and also run afoul of various state consumer protections laws. Such lawsuits may increase after February 2028, as manufacturers try to adapt to these new regulations.

Sweeping change or status quo for the industry?

Disputes about the proper scope of “healthy” claims under FDA rules are nothing new.

The industry may be familiar with the [citizen petition submitted to FDA by KIND](#) requesting an update to its regulations on the use of the term “healthy” as a nutrient content claim in food labeling. This petition followed an FDA Warning Letter issued in March 2015 stating that several KIND products were misbranded for including nutrient content claims that did not meet regulatory requirements. In particular, four KIND products featured claims – such as “Healthy and tasty” and “There’s healthy. There’s tasty. Then there’s healthy and tasty.” – in connection with statements like “good source of fiber” and “no trans fat.” FDA determined that these products were in violation of the “healthy” claim regulation, as they exceeded both the permissible threshold for saturated fat content and the maximum percentage of calories derived from saturated fat for a product to be considered “low saturated fat,” in accordance with 21 CFR 101.62(c)(2).

Notably, KIND’s citizen petition was one of the reasons for FDA’s promulgation of the recent rule change, with the agency specifically referencing the petition in the proposed rule. FDA’s new approach to the “healthy” claim involves a more adaptable, case-specific evaluation of labeling, whereas the circumstances surrounding KIND’s citizen petition underscore the rigidity of the original rule. Under the new rule, companies like KIND that wish to use “healthy” in their logo or slogan may do so, even though the nutrient-dense nuts contain higher levels of fats than permitted by the older rules. In this way, the new rule emphasizes that nutritional context is what matters, and that FDA will assess the context of the use of “healthy” by reviewing the label and labeling in its

entirety, applying a flexible, case-by case approach to determine if the “healthy” claim is used in a nutritional context.⁴

Although the new rule provides greater detail on FDA’s views on “healthy” claims and imposes new limits on added sugars, much of the industry had already been leaning toward more nutrient-dense foods. That said, for those companies that currently use a “healthy” claim on their labeling in a nutrition context, adjusting to the new regulation – which introduces a completely new approach – will require significant learning and adaptation.

In addition, compliance is likely to require significant changes and investment in food packaging, as FDA is exploring the creation of a symbol that food manufacturers could use on labeling to indicate that a product meets the definition of “healthy.” Additionally, FDA recently issued a [proposed rule](#) that would require a front-of-package nutrition label on most packaged foods, with the goal of fighting “an ever-growing epidemic of preventable diet-related chronic diseases.”⁵ With the new administration’s stated focus on “making America healthy again,” we anticipate these rules will remain in effect.

If you have any questions about compliance with this new rule, please contact a member of the Cooley team listed below.

Notes

1. Food group equivalent (FGE) refers to the amount of a food group that must be contained in a food product for it to bear the “healthy” claim. The food groups are vegetables, fruits, grains, dairy and protein foods (game meat, seafood, eggs, beans, peas, lentils, nuts, seeds and soy products). “Nutrients to limit” (NTL) are saturated fat, sodium and added sugars.
2. The rule applies the “healthy” criteria to individual foods that are recommended in smaller servings (50 grams or less, or 3 tablespoons or less, on a per 50 gram basis). This allows foods consumed in small amounts, which are recommended for healthy diets, to qualify for the “healthy” claim.
3. See 21 USC 343(a) and 21 USC 343(r).
4. 89 FR 106133,106134 and 106136.
5. US Food and Drug Administration, “[FDA’s Nutrition Initiatives](#).”

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Key Contacts

Sonia Nath Washington, DC	snath@cooley.com +1 202 776 2120
Son Nguyen Washington, DC	snguyen@cooley.com +1 202 728 7100

Auguste Humphries Washington, DC	ahumphries@cooley.com +1 202 776 2004
Megan Donohue San Diego	mdonohue@cooley.com +1 858 550 6085

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