

FDA Issues Final “Healthy” Rule

January 8, 2025

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On December 19, 2024, the U.S. Food and Drug Administration (FDA) issued its long-awaited final rule updating the requirements for when the term “healthy” can be used as an implied nutrient content claim in food labeling.¹ Overall, the final rule looks much like the proposed rule², with several new elements of flexibility. The final rule retains the proposed criteria of permitting healthy claims for foods containing both 1) a certain quantity of food group equivalents (FGE) (such as fruits, vegetables, whole grain, dairy, and protein foods) and 2) no more than specified amounts of added sugars, sodium, and saturated fat, referred to as nutrients to limit (NTL). Below are some key provisions from the final rule, followed by our more detailed summary.

- Although FDA notes that foods containing nutrients to encourage (NTE) can be beneficial to consumers, FDA declined to allow eligibility for a healthy claim based on NTEs such as fiber, protein, iron, etc.³
 - Relatedly, FDA also declined to allow eligibility for a healthy claim based on a food having a FGE listed as the first ingredient on the label.
- With respect to dairy, FDA revised the FGE from 3/4 cup equivalent in the proposed rule to 2/3 cup equivalent in the final rule based on its marketplace review of dairy foods.
- Citing its primary objective of helping consumers meet the recommended 3 ounce equivalent of whole grains per day, FDA maintained the proposed whole grains FGE of 12 grams whole grains per reference amount customarily consumed (RACC), which is higher than the 8 grams whole grains per ounce equivalent recommended by the Dietary Guidelines for Americans (DGA).
- FDA made slight increases to the allowable amounts of NTLs, allowing more nutrient-dense foods recommended by DGA to be labeled as “healthy.” For example, the rule allows added sugars at $\leq 2\%$ of the Daily Value (DV) per RACC for individual fruits, vegetables, and protein

¹ *Food Labeling: Nutrient Content Claims; Definition of Term “Healthy”*, 89 Fed. Reg. 106064 (Dec. 27, 2024).

² HL Update, *FDA proposes updated criteria for “healthy” claims in labeling*, (Sept. 28, 2022), available at <https://www.hoganlovells.com/en/publications/fda-proposes-updated-criteria-for-healthy-claims-in-labeling>.

³ FDA explained that while foods with certain NTEs can be beneficial to consumers, highlighting such foods as “healthy” does not necessarily help consumers identify the nutrient-dense foods across all recommended food groups that make up a healthy dietary pattern.

foods. The rule also provides more flexibility for sodium in mixed products by increasing the limit from $\leq 10\%$ DV to $\leq 15\%$ DV per RACC.

- Additionally, FDA incorporated some flexibility for foods with small RACCs, such as hummus. This flexibility is a change from the proposed rule that did not allow foods to qualify for a healthy claim if its RACC is smaller than the FGE.
 - As a result, if the RACC is 50 grams or less or 3 tablespoons or less, it must meet the healthy criteria on a per 50 gram basis; if the food has a RACC greater than 50 grams or 3 tablespoons, it must meet the healthy criteria on a per RACC basis.
- FDA maintained the distinction between individual foods and mixed products, with separate criteria for main dishes and meals.
- Vegetable & fruit powders may count toward the vegetable and fruit FGEs provided that they are produced by drying whole vegetables and fruit and grinding them into powdered form.⁴
- Finally, the rule allows certain foods to automatically qualify for the healthy claim.
 - The “single ingredient exemption” allows individual foods or mixed foods comprised of one or more of foods encouraged by the DGA (i.e. vegetables, fruit, whole grains, fat-free and low-fat dairy, lean meat, seafood, eggs, beans, peas, lentils, nuts and seeds) to automatically qualify, as long as they contain no other added ingredients.⁵
 - All non-carbonated and carbonated water, tea, and coffee with less than 5 calories per RACC and per labeled serving automatically qualify, including those that contain non-caloric ingredients such as flavors, no- or low-calorie sweeteners, vitamins and minerals.

The compliance date is February 25, 2028. Additional details about the final rule follow.

Background

The previous “healthy” criteria had been in place since 1994 and took a nutrient-based approach, imposing limits on total fat, saturated fat, cholesterol, and sodium; and requiring minimum amounts of nutrients whose consumption are encouraged, such as vitamin A, vitamin C, calcium, iron, protein, and dietary fiber. These criteria, according to FDA, were outdated in several respects, including (a) the sole focus on nutrients without considering food group contributions, (b) the lack of an added sugars limit, and (c) the focus on total fat rather than the type of fat. FDA had previously issued enforcement discretion with respect to some of the existing criteria in the healthy regulation until the rule could be updated.

The new “healthy” criteria is part of the Biden-Harris White House National Strategy on Hunger, Nutrition, and Health and seeks to reduce the burden of diet-related chronic diseases. To that end, FDA cites the reduction of diet-related chronic diseases as a potential benefit of the rule.

⁴ In contrast, powders made from 100% juice or juice concentrate with the addition of maltodextrin do not count towards the fruit and vegetables FGE.

⁵ The “single ingredient exemption” also applies to a variety of shelf-stable and/or economical forms of foods, including, frozen or sliced fruits and vegetables; 100% whole grain flours; dried beans, peas, and lentils; frozen seafood; chopped nuts; and certain nut butters (i.e., only containing nuts), with no added ingredients other than water. The exemption also applies to single-ingredient foods encouraged by the DGA that have small RACC sizes (e.g. frozen avocado pieces).

Overall Approach

After conducting a marketplace review to determine which foods would meet certain FGE and NTL criteria in the proposed rule, FDA made certain changes to provide additional flexibility, resulting in more foods qualifying for a “healthy” claim while still aligning with current science and the DGA.

FDA notes that the healthy definition does not represent a determination by FDA that consumers should only choose foods that qualify or completely avoid choosing foods that do not qualify for the “healthy” claim. Moreover, FDA states that nearly all foods can be incorporated into a healthy dietary pattern to some extent, but healthy foods are ones intended to form the foundation or building blocks of a healthy dietary pattern recommended by the DGA.

Food Group Equivalents

Under the final rule, there are separate standards for individual foods, mixed products, main dishes, meal products, and raw whole fruits and vegetables. Generally, to qualify as “healthy,” food products must contain a FGE from at least one of the food groups or subgroups (e.g., fruit, vegetable, dairy, whole grains, protein) recommended by the DGA, where the following FGEs are used:

- 1/2 cup equivalent (eq) vegetable
- 1/2 cup-eq fruit
- 3/4 oz-eq whole grain
- 2/3 cup-eq dairy
- Protein foods: 1 oz-eq for seafood; eggs, beans, peas, and soy products; and nuts and seeds; and 1 1/2 oz-eq for game meats

Although FDA does not categorize oils as an FGE, it does include oils as a food group for purposes of the rule, noting that the DGA emphasizes oils as one of the six core elements of a healthy dietary pattern, along with vegetables, fruits, grain, dairy, and protein food. Accordingly, oils made from 100% oil, oil-based spreads whose fats come solely from oil, and oil-based dressing containing at least 30% oils may also qualify as healthy.

FDA established the FGEs based on four eating occasions a day, retaining its approach from the proposed rule and citing data that the typical dietary pattern consists of three meals and one snack per day. In doing so, FDA declined to adopt an approach based on three meals and two snacks, which would have been consistent with the DGA.

Fruits and Vegetables

- While FDA declined to combine the fruit and vegetable groups for purposes of determining FGE eligibility as requested by stakeholders, it did allow some flexibility in the “single-ingredient exemption” for mixed foods. For example, a blend of 100% juices that contains 80% fruit juice and 20% vegetable juice qualifies under this exemption.
 - Relatedly, FDA maintained eligibility for 100% juices, commenting that 100% juices are nutrient dense foods.
- FDA also classified concentrated fruit and vegetable purees and pastes as fruits and vegetables for the purposes of FGE eligibility.

Dairy

- With respect to dairy alternatives, FDA only allows plant-based milk alternatives and plant-based yogurt alternatives whose overall nutritional content is similar to dairy foods (e.g. provide similar amounts of protein, calcium, potassium, vitamin D, and other nutrients) to qualify with other dairy products as part of the dairy FGE.
 - To that end, FDA considers fortified soy beverages and yogurts as nutritionally comparable to dairy. FDA also noted that non-soy based milk alternatives such as almond milk or oat milk may be nutritionally comparable to dairy if they are produced with nutritional profiles similar to dairy.

Protein Foods

- Beans, peas, and lentils can count toward either the vegetable or protein foods group. Moreover, powders of protein products, such as chickpea powders or legume powders can be included in FGE calculations if the powders are “essentially the dried/dehydrated and ground forms of the original, whole food.”
- In contrast, FDA declined to include protein isolates and concentrates under the “protein group,” emphasizing that the “healthy” criteria’s goal is shifting from focusing on individual nutrients to focusing on nutrient-dense foods, and that protein isolates and concentrates are nutrients extracted from foods, rather than whole, nutrient-dense foods in and of themselves.

Combination foods

- While individual foods must contain at least one full FGE from one group to qualify for a “healthy” claim, the rule allows flexibility in the proportions of FGEs required for combination foods to qualify. Instead of needing to have multiple full FGEs each from separate groups (e.g., one full FGE from the grains group and one full FGE from the vegetables group), the final rule requires that
 - mixed products must contain at least one total FGE with at least 1/4 FGE from each of at least two different food groups;
 - main dishes must contain at least two total FGEs with at least 1/2 FGE from each of the two food groups; and
 - meals must contain at least three total FGEs with at least 1/2 FGE from each of the three food groups.

Nutrients to Limit

- FDA maintained its approach of including NTL thresholds for added sugars, sodium, and saturated fat, and not including such thresholds for total fat, trans fat, cholesterol, calories, or other nutrients.
- The agency also maintained its approach of establishing a baseline threshold for each NTL, and then adjusting that baseline up or down for specific food categories, noting that certain foods inherently contain saturated fat while others do not, and therefore different levels are warranted.

- In establishing NTL thresholds, FDA notes that it does not rely on the same assumption of four eating occasions per day as it does for establishing FGEs in part because doing so might result in consumers exceeding the DGA's recommended daily limits for NTLs.

Added sugars

- FDA notes that while “there is not an independent association between added sugars and disease,” excess consumption of added sugars has implications for whether individuals can consume a healthy dietary pattern, which in turn is associated with reduced risk of diet-related disease.
- Accordingly, FDA maintained the proposed baseline of no more than 5% DV per RACC (with adjustments for certain categories), which is based on the standard for “low” nutrient content claims for other nutrients.
- In maintaining the baselines of no more than 5% DV per RACC, FDA rejected calls to establish a baseline of 10% to 20% DV in certain categories, stating that its goal is to help consumers intake *less than* 10% of calories from added sugars per day.
 - FDA maintained the added sugars limit of 5% DV per RACC for dairy based on its marketplace review.
 - However, FDA did increase the added sugars limits from 0% to no more than 2% DV per RACC for fruits, vegetables, and protein foods. The rule also provides more flexibility for added sugars in whole grain products by increasing the limit from $\leq 5\%$ DV to $\leq 10\%$ DV per RACC. FDA adjusted the limits accordingly for mixed products, main dishes, and meals.
- FDA intends to exercise enforcement discretion for cranberry and tart cherry products with added sugars that meet the fruit FGE criteria and NTL thresholds for sodium and saturated fat, but contain added sugars for palatability in an amount that is no greater than the amount of total sugars in comparable products with inherent sugars but no added sugars (e.g., unsweetened raisins, 100% grape juice).
- Finally, FDA retained its position that products with low- or no-calorie sweeteners are not precluded from bearing a “healthy” claim.

Sodium

- FDA maintained the proposed baseline sodium limit of no more than 10% DV per RACC for individual products, which is about half of the sodium limit for the outgoing healthy criteria.
 - In doing so, FDA rejected calls to set a baseline limit of 20% DV, noting that there is little room to consume foods high in sodium while still maintaining a healthy dietary pattern and that a lower “healthy” sodium limit aligns with FDA's initiatives related to voluntary sodium reduction in foods.
- The agency also rejected calls to adopt a limit of no more than 5% DV per RACC, explaining that this would not be practical because it would limit the ability of nutrient dense foods to qualify for a healthy claim.
- FDA also granted more flexibility for sodium limits in certain categories.

- For example, FDA raised the sodium limit for mixed products from no more than 10% DV per RACC to no more than 15% DV per RACC in the final rule, which will provide more flexibility for products such as soup.

Saturated Fat

- FDA maintained a baseline of no more than 5% DV per RACC for individual products, consistent with the criteria for “low saturated fat” claims. It then adjusted the baseline threshold for saturated fat depending on the food group.
- While FDA maintained the exemption for counting the inherent saturated fat in nuts, seeds, and soy products towards the NTL threshold and extended this exemption to the saturated fat inherent in seafood, the agency declined to increase the saturated fat limit beyond 10% DV per RACC for dairy or to exempt saturated fat inherent in dairy foods.
- FDA also exempted foods eligible for a healthy claim from saturated fat disclosure statements (i.e., “see nutrition information for saturated fat content”) as otherwise required by 21 CFR 101.13(h).

Combination Foods

- FDA provided incremental increases for certain sodium, added sugars, and saturated fats in mixed products, main dishes, and meals. See the appendix for more details.

Exemptions & Automatic Eligibility

- FDA declined to grant automatic eligibility for herbs and spices, because they are typically consumed in small quantities that don’t contribute a meaningful amount of nutrients to a diet.
- Dietary supplements and foods for special dietary use are not exempted from satisfying the regulatory criteria in order to bear a “healthy” claim.
 - However, FDA notes that under some circumstances, a dietary supplement may use the term healthy as part of a “structure/function claim” without being subject to criteria for a “healthy” nutrient content claim.

Scope of the Rule

FDA maintained its position that the revised rule will cover uses of “healthy,” not only when made in direct connection with a statement about a nutrient (express or implied), but also when there is other material on the label (e.g., claims, symbols, images, vignettes) that puts the use of “healthy” into a nutritional context. The agency states it will take a flexible, case-by-case approach in determining whether a use of “healthy” is a healthy nutrient content claim. FDA also retained its position that symbols such as Facts Up Front or MyPlate can put the use of “healthy” into a nutritional context.

FDA rejected comments that the agency should also regulate terms such as “nutritious,” “wholesome,” and “good for you,” noting that it lacks sufficient information to determine whether definitions for those terms are needed and what those definitions should be.

FDA declined to extend the rule to cover claims for foods for children under age two due to the agency’s limited resources, the need for additional time to consider current nutrition recommendations for children under age two, and unique considerations for products for this age group as they relate to the

healthy claim. Further, FDA rejected comments that the final “healthy” rule should also include the voluntary front-of-package “healthy symbol,” noting that its work on the symbol is on a “separate track” and should not delay implementation of the “healthy” rule.

Recordkeeping and Compliance

Recordkeeping

Manufacturers making a “healthy” claim must make and keep written records when the FGE content is not apparent from the label of the food. The records must verify that the FGE requirements are met. Examples of appropriate records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. Such records must be provided to FDA upon request during an inspection. Electronic records need to comply with 21 CFR part 11.

Compliance

In response to requests for guidance on calculating the FGEs, FDA points to the 2020-2025 Dietary Guidelines⁶ and the United States Department of Agriculture Food Patterns Equivalents Database as resources⁷. The agency notes that because there is no nutritional difference between rounded and unrounded values of a nutrient in a food, it does not see a need to specify which value should be used in determining whether a food qualifies to bear the “healthy” nutrient content claim, which is consistent with the agency’s historic position for nutrient content claims.

Manufacturers are not required to comply with the rule until the compliance date of February 25, 2028. However, manufacturers can choose to comply earlier. FDA clarifies that the compliance date applies to the date a product is labeled rather than the date it is introduced into interstate commerce. The agency also confirms that any food manufactured and labeled as “healthy” before the compliance date of the final rule is not subject to state requirements for the claim if the state requirements are not identical to either: (1) FDA’s original requirements in effect as of the date FDA published this final rule; or (2) FDA’s updated “healthy” requirements if state-law requirements go into effect before the compliance date of the final rule.

Legal Authority

FDA argues that it has the legal authority to regulate food groups, as opposed to nutrients, as part of the nutrient content claim for “healthy” because dietary guidance has shifted away from advising people to consume certain nutrients and towards advising people to consume certain food groups. Accordingly, FDA’s position is that its statutory mandate for regulating nutrients extends to food groups, because food groups act as a proxy for multiple important nutrients. FDA further argues that Congress, acting within its power as outlined in *Loper Bright Enters v. Raimondo*, 144 S. Ct. 2244, 2263 (2024), expressly delegated discretionary authority to FDA to give meaning to the statutory term “nutrient.” FDA rejected legal arguments in comments that argued numerous aspects of the rule violated the agency’s statutory authority, the Administrative Procedure Act’s prohibition on arbitrary and capricious rules, and the First Amendment.

⁶ FDA specifically cites Appendix A3-2, footnotes b and c from the 2020-2025 Dietary Guidelines for Americans. See DGA, *Dietary Guidelines for Americans 2020-2025*, 144-146, available at https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.

⁷ Noting that USDA’s Food Patterns Equivalents Database is particularly helpful for further information about cup- and ounce-equivalents of different foods and beverages. USDA, Agricultural Research Service, Food Surveys Research Group. *Food Patterns Equivalents Database: Methodology and User Guide*, available at <http://www.ars.usda.gov/nea/bhnrc/fsrg>.

The final rule redefining healthy represents a 30-year update to the nutrient content claim regulation. The rule falls within the potential “clawback” period under the Congressional Review Act and we will be monitoring any action the Trump Administration may take with respect to the definition of “healthy.”

Please do not hesitate to contact us if you have any questions.

Appendix A
FDA Updated Criteria for “Healthy” Claims

Eligible Products for “Healthy” Claims

Product	Criteria for bearing “healthy” claim
Raw, whole fruits and vegetables	No additional criteria; all raw, whole fruits and vegetables may bear the claim
Individual food products	A RACC greater than 50 grams or 3 tablespoons; or a RACC 50 grams or less or 3 tablespoons or less and meets requirements per 50 grams of food, and Nutrients to limit (See table below)
Mixed products	At least 1/4 food group equivalent each from at least 2 different food groups, and Nutrients to limit (See table below)
Main dish as defined at 21 CFR 101.13(m)	At least 1/2 food group equivalent each from at least 2 different food groups, and Nutrients to limit (See table below)
Meal as defined at 21 CFR 101.13(l)	At least 1/2 food group equivalent each from at least 3 different food groups, and Nutrients to limit (See table below)
Water	Plain water and plain, carbonated water may bear the claim; tea, and coffee with less than 5 calories per RACC also qualify

An individual food must meet the following criteria per RACC:

If the food is...		It must contain at least...	The added sugar content must be no greater than...	The sodium content must be no greater than....	The saturated fat content must be no greater than...
A vegetable product		1/2 c-eq vegetable	2% DV	10% DV	5% DV
A fruit product		1/2 c-eq fruit	2% DV	10% DV	5% DV
A grain product		3/4 oz-eq whole grain	10% DV	10% DV	5% DV
A dairy product		2/3 c-eq dairy	5% DV	10% DV	10% DV
Protein Foods	(1) Game meats	1 1/2 oz eq	2% DV	10% DV	10% DV
	(2) Seafood	1 oz eq			5% DV, excluding saturated fat

					inherent in seafood
	(3) Eggs	1 oz eq			10% DV
	(4) Beans, peas, and soy	1 oz eq			5% DV
	(5) Nuts and seeds	1 oz eq			5% DV, excluding saturated fat inherent in nuts, seeds, and soybeans
Oils	100% Oil	n/a	0% DV	0% DV	20% of total fat
	Oil-based spreads whose fats come solely from oil		0% DV	10% DV	
	Oil-based dressing containing at least 30% oil and oils meet the requirements in 21 CFR § 101.65(d)(3)(ii)(A) or B(6)(i)		2% DV	10% DV	

A mixed product must (a) contain at least one-fourth a food group equivalent each of two different food groups, and (b) meet the following criteria per RACC:

The added sugars content must be no greater than...	The sodium content must be no greater than...	Excluding saturated inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than ...
10% DV	15% DV	10% DV

A main dish product must (a) contain at least one-half a food group equivalent each of two different food groups and (b) meet the following criteria per labeled serving:

The added sugars content must be no greater than...	The sodium content must be no greater than...	Excluding saturated inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than ...
15% DV	20% DV	15% DV

A meal product must (a) contain at least one-half a food group equivalent each of three different food groups and (b) meet the following criteria per labeled serving:

The added sugars content must be no greater than...	The sodium content must be no greater than...	Excluding saturated inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than ...
20% DV	30% DV	20% DV

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