

BACKGROUNDER

FDA'S NEW HEALTHY DEFINITION



BACKGROUND INFORMATION

The U.S. Food and Drug Administration (FDA) has updated the "healthy" claim definition for food labeling to be consistent with current nutrition science and federal dietary guidance. The new definition of "healthy" may be used starting April 28, 2025 (Effective Date).

The FDA is an agency within the U.S. Department of Health and Human Services (HHS) tasked with protecting public health through various means, including the safety and security of our nation's food supply.

This document explains the criteria for use of the "healthy" claim under the FDA's new definition. You can review the entire final definition here in the Federal Register. An infographic from FDA is also available here.

IN AN EGG SHELL



The new definition of "healthy" is aligned with current nutrition science and federal dietary guidance, namely the 2020-2025 Dietary Guidelines for Americans (DGAs) and the updated Nutrition Facts Label. The new regulation of "healthy" emphasizes the importance of healthy dietary patterns and nutrient-dense foods and beverages, much like the DGAs. The FDA's new definition uses a food group-based approach, prioritizing nutrient-dense foods, in addition to nutrients to limit, which are sodium, saturated fat, and added sugars. This is based on the understanding that each food group contributes various important nutrients to the diet.

NUTRIENTS TO LIMIT:







Shell eggs (regardless of production method) automatically qualify for the "healthy" claim.

In addition, all other nutrient-dense foods that are encouraged by the DGA (vegetables; fruits; whole grains; fat-free and low-fat dairy; and lean meat, seafood, beans, peas, lentils, nuts and seeds) with no added ingredients except water, automatically qualify for the "healthy" claim.

Other foods that are labeled as "healthy" must contain a certain amount of food from at least one food group or subgroup and meet the thresholds for nutrients to limit. The criteria is adjusted for each food product group.

For example, an individual food that utilizes eggs as an ingredient, must contain at least one food group equivalent of egg (50 grams or 1 large egg) and meet criteria for nutrients to limit in order to be labeled "healthy."



NUTRITION CENTER





WHAT HAS CHANGED

Nutrition science has evolved significantly in the 30 years since "healthy" was originally defined by the FDA in 1994. Thus, you will find some key differences in the new definition.

Notably, total fat is no longer included in the nutrients to limit. Instead of recommending lower fat intake overall, dietary guidance has now shifted to focus on the types of fat. The DGAs recommend limiting saturated fat to 10% of daily calories for those 2 years and older, and replacing excess saturated fats with health-promoting unsaturated fats like monounsaturated fat and polyunsaturated fat. Thus, saturated fat remains as a nutrient to limit and total fat has been removed.

Since 2015, the DGAs do not make a specific recommendation regarding a daily limit on dietary cholesterol. Similarly, cholesterol is also no longer included as a nutrient to limit in the new healthy definition. Additionally, the disclosure statement that is required when making nutrient-content claims for eggs, "See nutrition information for cholesterol content," is not required for the use of the claim "healthy."

Nutrients to encourage are also no longer included in the new definition as the new food group approach ensures that essential nutrients are covered. The DGAs recommend consuming various food groups and subgroups for a diet that is nutritionally adequate. The FDA stated a concern that including criteria for nutrients to encourage could incentivize the fortification of foods that do not contribute a meaningful amount of a food group (for example, white bread fortified with calcium).

FDA has indicated they are continuing to explore the development of a "healthy" symbol that manufacturers could use on food labels. This symbol is not yet available, however, the word "healthy" may be claimed on labels and in labeling. For more information, see FDA's webpage on "Use of the Term Healthy on Food Labeling."

1994 DEFINITION 2024 DEFINITION

LIMIT:

LIMIT:

- Saturated fat
- Sodium
- Added sugars

ENCOURAGE:

Nutrients to encourage are no longer included in favor of a food group approach.

Some foods that did not qualify as "healthy" under the 1994 definition, but can now use the "healthy" nutrient content claim include:

Eggs

Higher-fat fish, (e.g. Salmon)

Avocados

Certain oils

Nuts and seeds / Water

Products that qualified for "healthy" in the original definition, but do not under the new definition include:

White bread

Highly sweetened yogurt

X Highly sweetened cereal







DETAILS OF THE RULE

Below, is more detailed information about the requirements for a food to be labeled as "healthy." Foods that may qualify to use the term "healthy" are broken into six categories:

- Foods that are the foundation of a healthy dietary pattern
- Individual foods
- Water, tea, and coffee
- Mixed products
- Main dish products
- Meal products

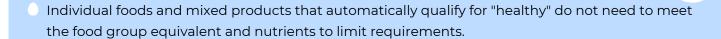


For extended details about each category, please reference the final rule on the Federal Register.

FOODS THAT ARE THE FOUNDATION OF A HEALTHY DIETARY PATTERN:

An individual food or mixed product that is comprised of one or more of the following foods that are the foundation of a healthy dietary pattern, with no other added ingredients except for water:

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



Shell eggs are healthy.

INDIVIDUAL FOODS:

Any foods that are comprised entirely or almost entirely of one food group. For example, oatmeal with a small amount of raisins would count as a grain, yogurt with a small amount of granola would count as dairy.

To be labeled "healthy," foods in this category must have at least 1 food group equivalent per Reference Amount Customarily Consumed (RACC) and meet the thresholds for nutrients to limit for that food group or subgroup.

Both food group equivalents and nutrients-to-limit criteria are adjusted for each food group. Refer to the chart on page 4 for specific criteria.

WATER, TEA, AND COFFEE:

All water, tea, and coffee with less than 5 calories per 12 fl oz (360 mL) and per labeled serving may bear the claim









NUTRIENTS TO LIMIT CRITERIA BASED ON FOOD GROUP AND RACC

Food Groups	Food Group Equivalent Minimum	Added Sugar Limit	Sodium Limit	Saturated Fat Limit
Grains	3/4 oz whole-grain equivalent	10% DV (5g)	10% DV (230 mg)	5% DV (1g)
Dairy	2/3 cup equivalent	5% DV (2.5g)	10% DV (230 mg)	10% DV (2g)
Vegetable	1/2 cup equivalent	2% DV (1g)	10% DV (230 mg)	5% DV (1g)
Fruit Product	1/2 cup equivalent	2% DV (1g)	10% DV (230 mg)	5% DV (1g)
Proteins	Food Group Equivalent Minimum	Added Sugar Limit	Sodium Limit	Saturated Fat Limit
Game Meat	1 1/2 oz equivalent	2% DV (1g)	10% DV (230 mg)	10% DV (2g)
Seafood	l oz equivalent	2% DV (1g)	10% DV (230 mg)	5% DV* (1g)
Egg	1 oz equivalent	2% DV (1g)	10% DV (230 mg)	10% DV (2g)
Beans, Peas, and Lentils	1 oz equivalent	2% DV (1g)	10% DV (230 mg)	5% DV (1g)
Nuts, Seeds, and Soy Products	1 oz equivalent	2% DV (1g)	10% DV (230 mg)	5% DV* (1g)

*Excluding inherent saturated fatty acids (SFA) for seafood and nuts, seeds and soy products

Oils	Food Group Equivalent Minimum	Added Sugar Limit	Sodium Limit	Saturated Fat Limit
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 (1g)	10% DV (230 mg)	20% of total fat

*Must contain at least 30% oil and saturated fat level of the oil must be equal or less than 20% of the total fat

 $Abbreviations: RACC = Reference\ Amount\ Customarily\ Consumed,\ oz = ounce,\ g = grams,\ mg = milligrams,\ DV = Daily\ Value$

Reference: U.S. Food and Drug Administration. Food Labeling: Nutrient Content Claims; Definition of Term "Healthy" Final rule. 2024; Available from: U.S. Food and Drug Administration. "Use of the Term 'Healthy' in Food Labeling."









COMBINATION FOODS:

Foods with meaningful amounts of more than one food group with criteria based on the categories below.

- Mixed products: Similar in size to an individual food but contain more than one food group. For example, a granola product with half whole grains and half nuts. To be labeled "healthy" these products must have one total food group equivalent with no less than 1/4 food group equivalent from at least two food groups and meet thresholds for nutrients to limit.
- Main dish products: These are meant to make a major contribution to a meal and are larger in size than mixed products and individual foods. To be labeled as "healthy" these products must contain at least 2 food group equivalents (not less than 1/2 food group equivalent from a least 2 different food groups) and meet thresholds for nutrients to limit.
- **Meal products:** These are intended to be a full meal for a single eating occasion and are larger than main dish products. To be labeled "healthy" these products must contain at least 3 food group equivalents (not less than 1/2 food group equivalent from at least 3 different food groups) and meet thresholds for nutrients to limit.

For more specifics related to combination foods, see definitions here.



KEY TERMS

HEALTHY DIETARY PATTERN: "A healthy dietary pattern consists of nutrient-dense forms of foods and beverages across all food groups, in recommended amounts, and within calorie limits." Essential components of a healthy dietary pattern include vegetables, fruits, dairy, grains, protein foods, and oils.

NUTRIENT-DENSE FOODS AND BEVERAGES: "Nutrient-dense foods and beverages provide vitamins, minerals, and other health-promoting components and have little added sugars, saturated fat, and sodium. Vegetables, fruits, whole grains, seafood, eggs, beans, peas, and lentils, unsalted nuts and seeds, fat-free and low-fat dairy products, and lean meats and poultry—when prepared with no or little added sugars, saturated fat, and sodium— are nutrient-dense foods."

% DAILY VALUE (DV): DVs are reference amounts of nutrients to consume or not to exceed each day. The specific limits for added sugars, saturated fat and sodium are based on % DV.

FOOD GROUP EQUIVALENT (FGE): The amount of food from a particular food group that is required.

REFERENCE AMOUNT CUSTOMARILY CONSUMED (RACC): The basis for determining serving size. The specific limits for the three nutrients to limit (saturated fat, sodium, and added sugar) are based on the RACC.









