FDA's Updated "Healthy" Nutrient Content Claim

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Disclosures

AFFILIATION/FINANCIAL INTEREST	ENTITIES
Grants/Research Support	N/A
Scientific Advisory Board/Consultant/Board of Directors	N/A
Owner	N/A
Speakers Bureau	N/A
Stock Shareholder	N/A
Employee	U.S. Food and Drug Administration
Other	N/A

Ultra-Processed Foods

- FDA & USDA request for information (RFI) to help develop a uniform definition of ultra-processed foods
  - Issued: July 24, 2025
  - Comment period deadline: October 23, 2025
- FDA & NIH joint Nutrition Regulatory Science Program

Background: "Healthy" Claim

- **Voluntary nutrient content claim established in 1994**

- **Original criteria:**
  - Limits for total fat, saturated fat, cholesterol, and sodium
  - Requirement for certain amount of a beneficial nutrient (e.g., protein, fiber, calcium, vitamin A)
  - No longer consistent with current nutrition science, Federal dietary guidance (e.g., Dietary Guidelines for Americans), or the updated Nutrition Facts label

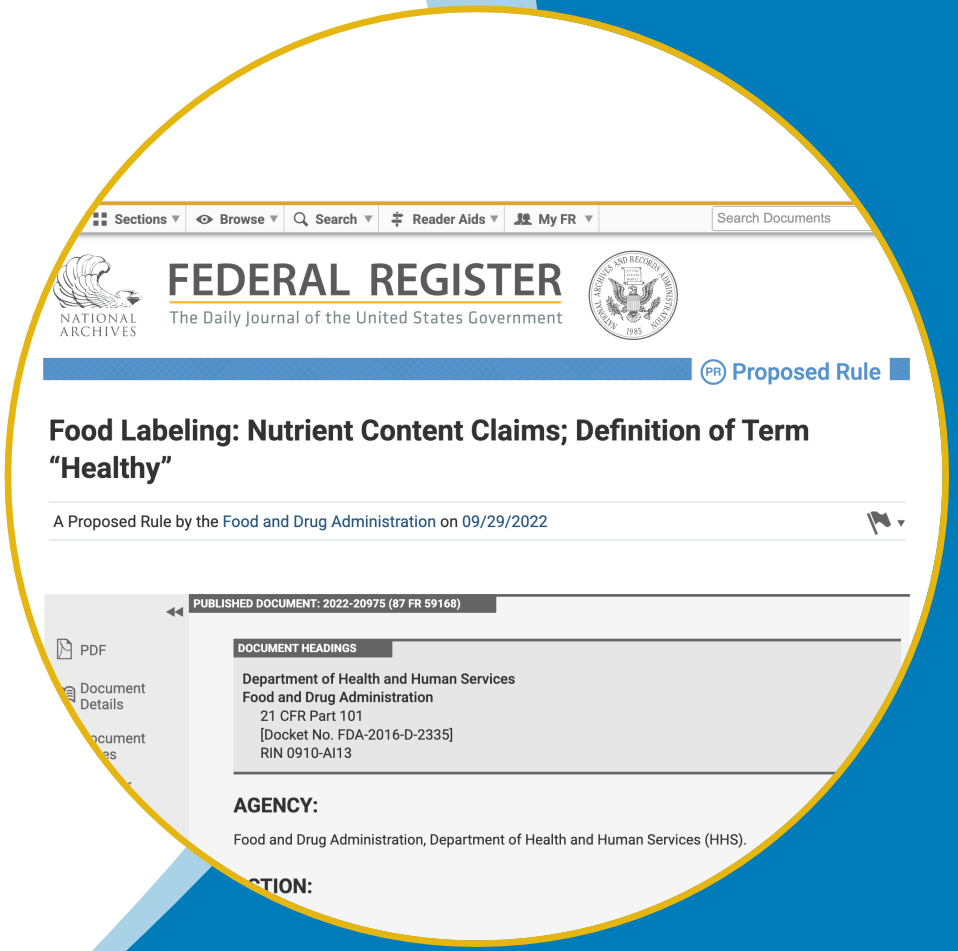
12 g Added Sugars

13 g Added Sugars

Does not contain whole grains

Updating the "Healthy" Claim

- Proposed rule:
  - Issued September 29, 2022
  - 400+ public comments received to the proposed rule, many with detailed feedback
- Final rule:
  - Issued December 27, 2024
  - Effective date: April 28, 2025
  - **Compliance date: February 25, 2028**



Comments & Marketplace Review

Feedback

Marketplace Review

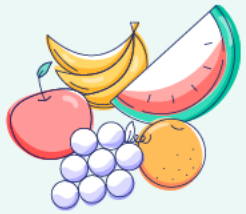
Aligning with the *Dietary Guidelines for Americans*

Updated "Healthy" Claim: Framework

HAVE

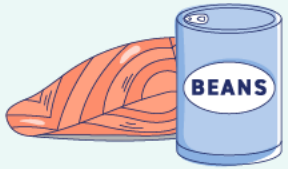
a certain amount of one or more of the following food groups:

Vegetables

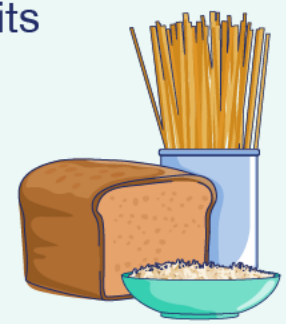


Fruits

Dairy



Protein Foods



Whole Grains

AND

NOT HAVE TOO MUCH:

Saturated Fat

Sodium

Added Sugars

Nutrition Facts

4 servings per container

Serving size 1 1/2 cup (208g)

Amount per serving

Calories **240**

	% Daily Value*
Total Fat 4g	**5%**
Saturated Fat 1.5g	**8%**
Trans Fat 0g	
Cholesterol 5mg	**2%**
Sodium 430mg	**19%**
Total Carbohydrate 46g	**17%**
Dietary Fiber 7g	**25%**
Total Sugars 4g	
Includes 2g Added Sugars	**4%**
Protein 11g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 6mg	35%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Overview of Updated Criteria

- Criteria for food group equivalents (FGE) & nutrients to limit
- Products with small Reference Amounts Customarily Consumed (RACCs)
- Single-ingredient foods exemption
- Water, tea, and coffee

Food Group Equivalents and Nutrients to Limit Criteria for Individual Foods*

Food Groups	Minimum Food Group Equivalents Requirement	Saturated Fat (SFA) Limit	Sodium Limit	Added Sugars Limit
Grains	¾ oz-eq (whole grain)	5% DV	10% DV	10% DV
Dairy	2/3 cup-eq	10% DV	10% DV	5% DV
Vegetable	½ cup-eq	5% DV	10% DV	2% DV
Fruit	½ cup-eq	5% DV	10% DV	2% DV
Game Meat	1 ½ oz-eq	10% DV	10% DV	2% DV
Seafood	1 oz-eq	5% DV (excluding inherent SFA)	10% DV	2% DV
Egg	1 oz-eq	10% DV	10% DV	2% DV
Beans, Peas, Lentils	1 oz-eq	5% DV	10% DV	2% DV
Nuts, Seeds & Soy Products	1 oz-eq	5% DV (excluding inherent SFA)	10% DV	2% DV
Oil-based Dressing	___	20% of total fat	10% DV	2% DV
Oil-based Spread	___	20% of total fat	10% DV	0% DV
100% Oil	___	20% of total fat	0% DV	0% DV

*Per Reference Amount Customarily Consumed (RACC).

DV = Daily Value. SFA: 5% DV = 1g; 10% DV = 2g. Sodium: 5% DV = 115mg; 10% DV = 230mg. Added Sugars: 2% DV = 1g; 5% DV = 2.5g; 10% DV = 5g.

Food Group Equivalents and Nutrients to Limit Criteria for Mixed Products, Main Dishes, and Meals

Food Product	Minimum Total Food Group Equivalents (FGE) Requirement	Saturated Fat Limit	Sodium Limit	Added Sugars Limit
Mixed Products	1 FGE*	10% DV (2 g)	15% DV (345 mg)	10% DV (5 g)
Main Dishes	2 FGE**	15% DV (3 g)	20% DV (460 mg)	15% DV (7.5 g)
Meals	3 FGE**	20% DV (4 g)	30% DV (690 mg)	20% DV (10 g)

*Mixed Products may not have less than ¼ food group equivalent (FGE) from at least 2 food groups.

**Main Dishes and Meals may not have less than ½ FGE from at least 2 or 3 food groups, respectively.

DV = Daily Value. SFA: 5% DV = 1 g**;** 10% DV = 2 g; 15% DV = 3 g; 20% DV = 4 g, 25% DV = 5 g. Sodium: 10% DV = 230 mg; 15% DV = 345 mg; 20% DV = 460 mg; 30% DV = 690 mg. Added Sugars: 5% DV = 2.5 g**;** 10% DV = 5 g; 15% DV = 7.5 g; 20% DV = 10 g.

Updated Criteria for Sample Foods

	Yogurt (individual food)	Trail Mix (mixed product)	Frozen Salmon Dinner (meal)
Amount of food groups required	**1 FGE* 2/3 cup yogurt**	**1 total FGE with at least ¼ FGE from 2 or more food groups Ex. 1/8 cup dried fruit and ¼ oz nuts**	**3 total FGE with at least ½ FGE from 3 or more food groups Ex. 1 oz salmon, ½ cup green beans, ¾ oz brown rice**
Nutrients to Limit (no more than)**	**2 g saturated fat 230 mg sodium 2.5 g added sugars**	**2 g saturated fat*** 345 mg sodium 5 g added sugars§**	**4 g saturated fat*** 690 mg sodium 10 g added sugars**

* A food group equivalent (FGE) is the minimum amount of a food group required. ** Amounts based on percentage of the Daily Value for that nutrient.

*** Saturated fat inherent in nuts, seeds, soy products, and seafood does not contribute to limit.

§ Enforcement discretion from added sugars limit for cranberry and tart cherry products if amount of added sugars does not exceed amount of total sugars in a comparable product.

Products with Small RACCs

- Reference Amounts Customarily Consumed (RACCs) are the basis for establishing serving size for foods
- Comments noted that some foods with small RACCs could not meet the minimum food group equivalent (FGE) amounts because of their small size
- Final rule: FGE & nutrients to limit criteria are calculated on a **50 g basis** for foods with **RACCs < 50 g or 3 tablespoons**

Single-Ingredient Foods Exemption

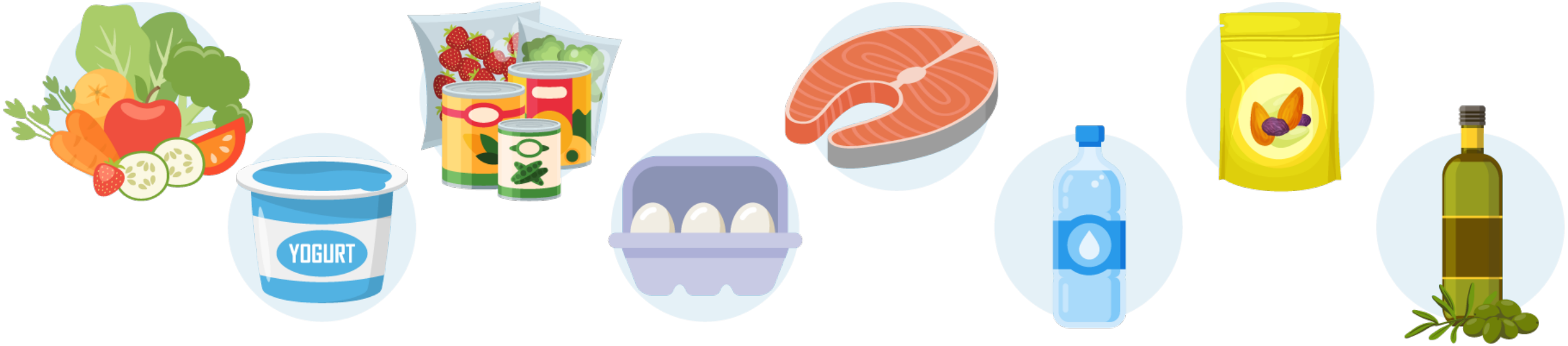
- **Proposed rule**: exemption for raw, whole fruits and vegetables
  - Automatically qualify without having to meet food group equivalent (FGE) and nutrients to limit (NTL) criteria
- **Final rule**: expands exemption to foods encouraged by the *Dietary Guidelines* with no additional ingredients other than water ("single-ingredient foods")
  - Automatically qualify without having to meet FGE and NTL criteria
  - Examples: whole or sliced fruits, vegetables; unsalted nuts; brown rice; frozen mixed vegetables




Other Products that Qualify for the Updated Claim

- **Water** with < 5 calories per serving
- **Tea and coffee** with < 5 calories per serving

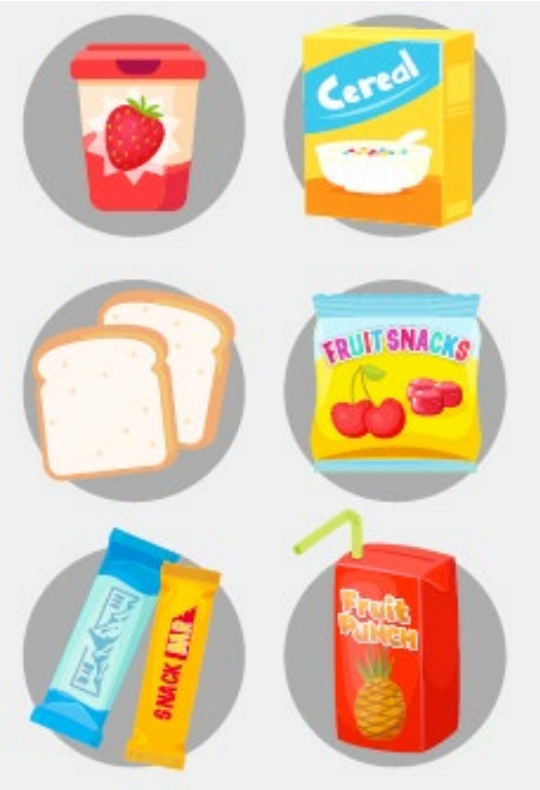
Examples of Products that Could Qualify for the Updated "Healthy" Claim



- **Fresh whole fruits and vegetables**
- **Frozen, chopped, dried, or canned fruits and vegetables***
- **Salmon**
- **Trail mix with nuts and dried fruit***
- **Plain low-fat or fat-free yogurt**
- **Eggs**
- **Water**
- **100% olive oil**

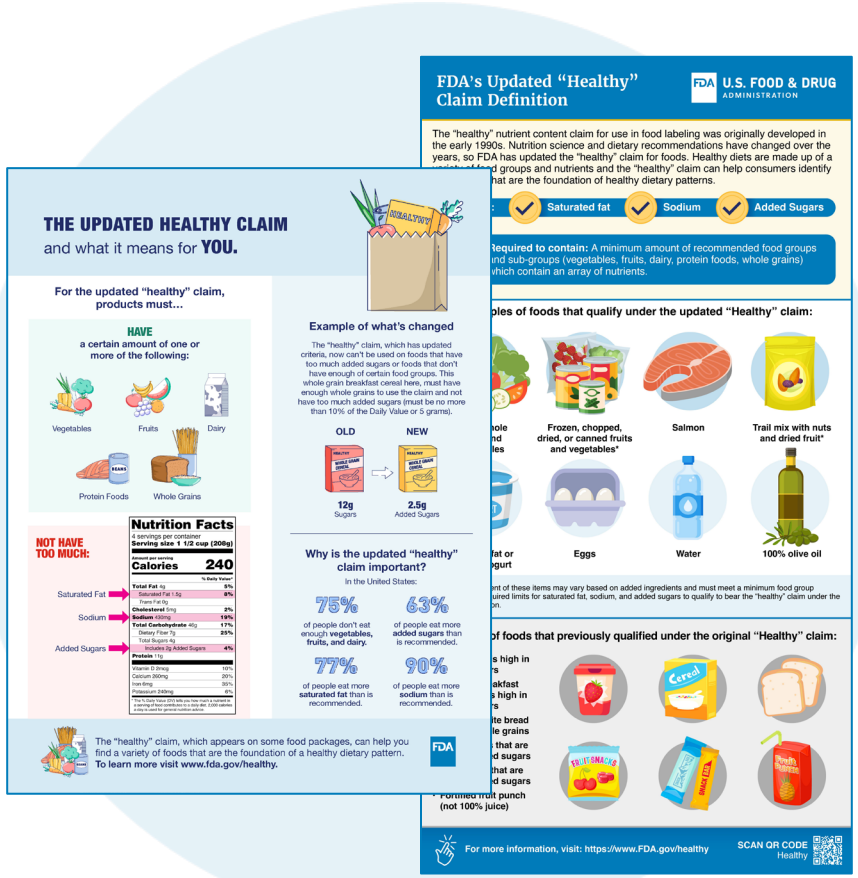
*Nutritional content of these items may vary based on added ingredients. If they contain added ingredients other than water, they must meet a minimum food group amount and required limits for saturated fat, sodium, and added sugars to qualify to bear the updated "healthy" claim.

Original Claim



Updated Claim

Resources



For more information, visit: https://www.FDA.gov/healthy

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