INTRODUCTION

Terms and phrases on food labels used to connote the healthfulness of products are ubiquitous. In the US, the term “healthy” was first defined by the Food and Drug Administration (FDA), but the term is also regulated by the United States Department of Agriculture (USDA) for use on the labels of most meat, poultry, and egg products. FDA defined the term in 1993, shortly after Congress enacted the Nutrition Labeling Education Act (NLEA) (an amendment to the Food, Drug, and Cosmetic Act, or FDCA). The NLEA reflects a common regulatory approach to diet-related disease: provide consumers with more information about certain aspects of the nutritional composition of food products so they can make healthier and more nutritious choices. Unfortunately, this approach fails to account for eaters that have varying degrees of, if any, choice. Additionally, it reflects a set of assumptions about consumers’ ability to understand the myriad information included on a food label and its relationship to health.

According to the Centers for Disease Control and Prevention’s (CDC) most recent data, diet-related chronic health conditions are the leading cause of death in the United States. These chronic diseases—obesity, diabetes, cardiovascular disease, and cancer—are largely preventable through healthy diet and good nutrition. Nutritionally inadequate diets exacerbate the risk of chronic diet-related disease. However, all Americans do not have equal access to healthful and nutritious foods. Diet-related chronic disease disproportionately impacts certain racial and ethnic groups and people with lower socioeconomic status. Since the start of the COVID-19 pandemic, these inequities have only increased, particularly because communities of color experienced far worse health outcomes from COVID due to underlying chronic disease.

Health claims can incentivize competition in the marketplace and influence product improvements. According to one market research firm, 60 percent of consumers look to food and beverage products to support their overall health. However, the same survey found “widespread confusion” as consumers try to decipher what is and is not healthy. Because health claims are proving to be profitable for business, manufacturers are creating new products or adapting existing products to be healthier. However, advocates have long pushed for front-of-package label statements or rating systems to replace or supplement the current back-of-package Nutrition Facts label to provide a full nutritional picture and minimize the impact some health claims may have on consumers.

Given the severity of diet-related disease and its continued increase in the US population, it has become clear that strategies to provide limited nutrition information to consumers at the point of sale are not achieving their intended consequence of improving public health. And, for the purpose of inducing a sale, many foods with labels containing claims related to health and nutrition are high in other unhealthy nutrients. For example, a food product label might include a front of package claim stating that the product is “high fiber,” leading a consumer to conclude it represents a healthy and nutritious option, when in fact, it may also contain a high amount of added sugars. Research shows that consumers rely heavily on food packaging claims when making purchasing decisions—particularly those related to what they perceive as the “healthfulness” of a product. Given the importance of this issue from both a public health and a consumer protection perspective, this issue brief explains how use of the term “healthy” on food products is regulated.
TERMS ASSOCIATED WITH HEALTH-RELATED LABELS

Health claims on food products can be confusing. First, they are based on recommended daily values (DVs) of specific nutrients, such as calcium, vitamin A, niacin, or occasionally a specific food group (for example, fruits or vegetables). Consequently, they cannot wholly account for products that may have other healthy ingredients or some that are not as healthy.

In addition, these terms are not required to be on labels, meaning manufacturers can voluntarily choose whether to use them.15 Finally, there are several categories of claims and varying levels of scientific evidence required for each, as described below.

1. **What is an implied nutrient content claim?**

Implied nutrient content claims characterize a food or ingredient by the presence or absence of certain nutrients or ingredients in certain amounts.16 In this context, an implied nutrient content claim could describe a food as having healthy levels of total fat, saturated fat, cholesterol, and sodium, and certain vitamins, as defined by FDA’s regulations authorizing use of the claim.17 For example, a food can be labeled healthy if it contains one gram or less of saturated fat per serving, or ten percent or more of the recommended daily value of vitamin A, vitamin C, calcium, or iron.

2. **What is an authorized health claim?**

Authorized health claims link a food or a specific ingredient or nutrient to the risk of a disease or health-related condition, such as:

- Fruits and vegetables and a reduced risk of cancer
- Calcium and a lower risk of osteoporosis
- Fat and a greater risk of cancer
- Sodium and a greater risk of high blood pressure18

These health claims must be written in a way that helps consumers understand the nutrient’s importance in their daily diet and the relationship between the nutrient and the disease. For example: “While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.”19

These claims require preapproval from FDA before inclusion on a food or dietary supplement product label. For an authorized health claim to be approved by FDA, there must be significant scientific agreement (SSA) among qualified experts that the claim is “supported by the totality of publicly available scientific evidence for a substance/disease relationship.”20 Because of this evidentiary requirement, FDA intends the standard to provide “a high level of confidence” in the claim.21
3. What is a structure/function claim?

Structure/function claims describe how a food or ingredient can impact or maintain the structure or function of the body. For example, common structure/function claims include “fiber promotes regularity” or “calcium helps create strong bones.” Unlike authorized health claims, structure/ function claims do not need FDA preapproval, but manufacturers are required to have substantiation that the claim is truthful and not misleading.\(^{22}\)

4. What is a qualified health claim?

Qualified health claims are supported by some scientific evidence, but do not meet the significant scientific evidence standard required for authorized health claims.\(^{23}\) To ensure that qualified health claims are not false or misleading to consumers, qualified health claims must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. An example of a qualified health claim is, “Scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, may reduce the risk of diabetes mellitus type 2.”\(^{24}\)

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### Quick Glance: Health Claims

<table>
<thead>
<tr>
<th>HEALTH CLAIM TYPE</th>
<th>TYPE OF STATEMENT/ MEANING</th>
<th>LEVEL OF SCIENTIFIC EVIDENCE REQUIRED</th>
<th>FRONT OF PACKAGE DISCLAIMER REQUIRED?</th>
<th>FDA PREAPPROVAL REQUIRED?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implied nutrient claim</td>
<td>Specific to nutrient amount per serving, related to recommended daily value (“less than 1 gram”)</td>
<td>High</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Authorized health claim</td>
<td>Relationship between a type of food (e.g., vegetables) or nutrient (e.g., calcium) and health condition (e.g., cancer, osteoporosis)</td>
<td>High</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Structure/function claims</td>
<td>Relationship between a nutrient and structure/ function of the body (e.g., calcium creates strong bones)</td>
<td>Needs substantiation that the claim is truthful and not misleading</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Qualified health claim</td>
<td>Varied</td>
<td>Some</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

These terms are also described on the Labels Unwrapped website, under the section "Regulated Voluntary Labels Claims," [here](https://labelsunwrapped.org).
RELATIONSHIP BETWEEN “HEALTHY” CLAIMS AND THE DIETARY GUIDELINES FOR AMERICANS

First released in 1980, the Dietary Guidelines for Americans (DGAs) provide recommendations on food and beverage choices to promote a healthy diet and meet nutritional needs and prevent the occurrence of diet-related disease.25 Importantly, the DGAs serve as the foundation for federal policy and programs addressing nutrition.26 In December 2020, the United States Department of Agriculture (USDA) and the Department of Health and Human Services (HHS), the two agencies charged with developing the guidelines and updating them every five years,27 jointly released the 2020–2025 Dietary Guidelines for Americans, which includes three important changes in approach. First, the DGAs reflect the acknowledgment that diet-related chronic disease represents a “major public health problem” in the United States.28 Second, the 2020–2025 Dietary Guidelines focus on healthy dietary patterns29 rather than on consumption of individual foods or nutrients, recognizing that people consume foods and beverages in combinations over a period of time.30 Finally, for the first time, the 2020–2025 DGAs use a lifespan approach to healthy dietary pattern recommendations beginning at infancy, which includes consideration of specific dietary needs at different life stages.31 Specifically, the DGAs include four main recommendations: (1) adhere to a healthy dietary pattern appropriate to each stage of life; (2) tailor consumption of “nutrient dense”32 products to reflect individualized preferences, culture, and budget; (3) attempt to meet the needs of different food groups with “nutrient dense” choices; and (4) limit consumption of alcoholic beverages and products with high amounts of sugar, salt, and saturated fat.33

The DGAs provide science-based recommendations regarding what the average American34 should eat and drink to promote health, reduce risk of chronic disease, and meet nutrient needs. In the 1980s, two landmark reports were released: the Surgeon General’s Report on Nutrition and Health and the National Research Council’s report Diet and Health: Implications for Reducing Chronic Disease Risk.35 These reports described the relationship between diet and the leading causes of death among Americans (for example, heart disease, cancers, stroke, and diabetes) and suggested that changes in dietary patterns could lead to a reduced incidence of many chronic diseases.36

The core elements that make up a healthy dietary pattern include:37

- Vegetables of all types—dark green; red and orange; beans, peas, and lentils; starchy; and other vegetables
- Fruits, especially whole fruit
- Grains, at least half of which are whole grain
- Dairy, including fat-free or low-fat milk, yogurt, and cheese, and/or lactose-free versions and fortified soy beverages and yogurt as alternatives
- Protein foods, including lean meats, poultry, and eggs; seafood; beans, peas, and lentils; and nuts, seeds, and soy products
- Oils, including vegetable oils and oils in food, such as seafood and nuts

MYPLATE.GOV IS BASED ON THE DIETARY GUIDELINES FOR AMERICANS, 2020-2025
As a result, the DGAs shifted in focus from recommending specific nutrients to recommending a more holistic diet based on a variety of foods, yet the approach used by FDA to authorize “healthy” labels remained nutrient-based.

The framework underlying the existing "healthy" claim is, in some respects, inconsistent with current nutrition science and Federal dietary guidance. For example, the Dietary Guidelines, 2020-2025, which reflect current nutrition science, are centered on the importance of dietary patterns. In contrast, the existing criteria for "healthy" only include requirements for individual nutrients. Under this solely individual nutrient-based framework, foods that are encouraged by the Dietary Guidelines, 2020-2025 . . . are sometimes not able to meet the [] criteria...for use of the claim "healthy." 39

The DGAs are accompanied by many educational resources that could be considered more user friendly than the Nutrition Facts label. In fact, studies show that only one-third of consumers frequently use the complex Nutrition Facts label and that consumers with lower educational attainment and lower incomes are even less likely to use the label, increasing inequitable access to nutrition information under current labeling policies. 40

A high-profile example of an unallowable use of the term “healthy” as a health claim involves the food company KIND. In 2015, FDA sent KIND a warning letter saying their use of “healthy” on some of their bars was not permitted because the bars exceeded the amount of saturated fat allowed per serving under the definition of “healthy.” The bars' saturated fat levels exceeded the one gram allowed but contained ingredients, such as peanuts, that are recommended in the DGAs as part of a healthy diet. The KIND case illustrates the disconnect between the DGAs and the regulation of the use of “healthy” on labels. In a citizen petition, KIND argued that the DGAs have shifted to emphasize ingredients versus nutrients (for example, “eat whole grains and lean meats” versus “eat 25 g complex carbs and 30 g protein”), but the standard for “healthy” uses an outdated approach that focuses on nutrient levels only.
REVISITING THE DEFINITION OF “HEALTHY” ON LABELS

To help consumers make informed purchasing decisions and use what for many are limited food dollars wisely, advocates have repeatedly called on FDA to update its definition or guidance for use of the term “healthy.” In 2016, FDA issued a proposed rule soliciting comments through a set of questions in accordance with the agency’s 2016–2025 strategic plan for its food and veterinary medicine programs and a citizen petition requesting the agency take action. In 2020, USDA also issued a notice to expand use of the term “healthy” on meat, poultry, and egg product labels.41

FDA received over 1,000 comments in response to its 2016 notice; however, the agency took no significant action until September 2022 when it released a proposed rule to update the definition of the term “healthy.” In the 2022 notice, FDA acknowledged that the current definition of the term allows food products to bear the claim “healthy” even when they “contain levels of nutrients that would not help consumers maintain healthy dietary practices.”42

Consequently, FDA is proposing to define “healthy” using a “food group-based approach” in combination with limits on certain nutrients (saturated fat, sodium, and added sugars) to align use of the term with current nutrition science, the updated Nutrition Facts label, and the recommendations included in the Dietary Guidelines for Americans, 2020–2025.44 Under the new requirements, food products will have to include a “certain amount of food (a food group equivalent’) from at least one of [the] recommended food groups or subgroups (e.g., ½ cup of fruit or ¼ cup dairy)” from the DGAs in addition to limits on sodium, saturated fats, and added sugars to include a “healthy” claim on the label.45

The claim “healthy,” when used in the nutritional context of food labeling, is an implied claim that the levels of nutrients in the food are such that the food may help consumers maintain healthy dietary practices.43

Additionally, FDA proposes removing “minimum amounts of nutrients [of concern] to encourage” from the “healthy” criteria because of the focus on food groups which incorporates those concerns to “ensure overall nutritional adequacy.”46

Generally, this proposal addresses many of the concerns raised by advocates in response to FDA’s 2016 request for information. The new criteria would consider “overall nutrient content” rather than individual nutrients, in addition to nutrient density, limit certain nutrients, and contemplate the use of symbols and ratings systems to help consumers easily understand the information.47 As of the date of this writing, FDA is still receiving comments on its proposal, but since the proposal is one component of a set of strategies the agency is pursuing to improve health and nutrition, it seems likely the main components of the proposed rule will be finalized into regulation.

<table>
<thead>
<tr>
<th>FOOD GROUP AND/OR SUBGROUP</th>
<th>FOOD GROUP EQUIVALENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetables</td>
<td>½ cup equivalent vegetable</td>
</tr>
<tr>
<td>Fruits</td>
<td>½ cup equivalent fruit</td>
</tr>
<tr>
<td>Grains</td>
<td>¾ ounce (oz) equivalent whole grain</td>
</tr>
<tr>
<td>Dairy</td>
<td>¾ cup equivalent dairy</td>
</tr>
<tr>
<td>Protein Foods</td>
<td>Game meats 1½ oz equivalent</td>
</tr>
<tr>
<td></td>
<td>Seafood 1 oz equivalent</td>
</tr>
<tr>
<td></td>
<td>Egg 1 oz equivalent</td>
</tr>
<tr>
<td></td>
<td>Beans, peas, and soy products 1 oz equivalent</td>
</tr>
<tr>
<td></td>
<td>Nuts and seeds 1 oz equivalent</td>
</tr>
</tbody>
</table>

SOME OF THE LABELS FDA HAS CONSIDERED AS A GRAPHIC REPRESENTATION OF THE IMPLIED NUTRIENT CONTENT CLAIM.

Source: FDA
CONCLUSION

The term “healthy” on food labels can be a quick signal and useful tool for consumers to identify nutritious foods, stretch limited food budgets, reduce nutrition-related chronic conditions, and improve nutrition security. Use of the term, as proposed by FDA in its notice of proposed rulemaking, can also encourage the food industry to reformulate products to improve their overall nutrition.46 Currently, the federal government’s regulatory process is not easily understood by the public. The recommended changes by FDA signal a willingness to begin to address these challenges as part of an overall strategy to improve public health and nutrition.

About the Center for Agriculture and Food Systems at Vermont Law and Graduate School

Labels Unwrapped is a project of Vermont Law and Graduate School’s Center for Agriculture and Food Systems (CAFS) which uses law and policy to build a more sustainable and just food system. With local, regional, national, and international partners, CAFS addresses food system challenges related to food justice, food security, farmland access, animal welfare, worker protections, the environment, and public health, among others. CAFS works closely with its partners to provide legal services that respond to their needs and develop resources that empower the communities they serve. Through CAFS’ Food and Agriculture Clinic and Research Assistant program, students work directly on projects alongside partners nationwide, engaging in innovative work that spans the food system.

For more information visit the Labels Unwrapped website at labelsunwrapped.org.
ENDNOTES


2 Ashkhan Afshin et al., Health Effects of Dietary Risks in 195 Countries, 1990–2017: A Systematic Analysis for the Global Burden of Disease Study 2017, 393 The Lancet 1956, 1968 (2019), https://www.thelancet.com/action/showPdf?pii=S0140-6736%2819%2930041-8 (“many... policies only target consumers but not the wide range of interconnected factors, such as food production, processing, and distribution, that exist throughout the food system.”).


4 See generally Marion L. Neuhofer, The Importance of Healthy Dietary Patterns in Chronic Disease Prevention, 70 Nutr. Rsch. 3 (2019).


6 “Food is accessible when it is affordable and community members can readily grow or raise it, find it, obtain it, transport it, prepare it, and eat it.” Healthy Food Policy Project, HEALTHY FOOD POL’Y Proj., https://healthyfoodpolicyproject.org/ (last visited Nov. 18, 2022).


12 Id.


16 21 C.F.R. § 101.65 (c) (2005).


19 Id.


21 Id.


23 Qualified Health Claims, FDA, https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims (last updated Mar. 7, 2022). Originally, FDA attempted to prohibit these claims from being included on food and dietary supplement product labels given the agency’s concern they might confuse consumers. However, in Pearson v. Shalala, an appeals court determined that FDA did not meet its burden to justify such a restriction on commercial speech under the First Amendment. (For a more detailed discussion of the First Amendment and the food label, see our issue brief entitled “How Does the First Amendment Apply to Food and Supplement Labels?”). Following the Pearson case, FDA created the category of claims known as qualified health claims. Pearson v. Shalala, 130 F.Supp.2d 105 (D.C. 2001).


29 A dietary pattern is “the combination of foods and beverages that constitutes an individual’s complete dietary intake over time. This may be a description of a customary way of eating or a description of a combination of foods recommended for consumption.” USDA & HHS, 2020-2025: MAKE EVERY BITE COUNT WITH THE DIETARY GUIDELINES X (9th ed. 2020).


32 Nutrient dense foods and beverages are those that: “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...,“
The DGAs have been criticized for their failure to account for “nuances of culture and ethnicity at the heart of how Americans feed themselves.” Chaseed-aw Giles, Food Guidelines Change but Fail to Take Cultures into Account, L.A. TIMES (Jan. 29, 2021), https://www.latimes.com/food/story/2021-01-29/american-food-diet-guidelines-cultural.

Committee on Diet & Health et al., Diet and Health: Implications for Reducing Chronic Disease Risk, Nat’l Academies Press, https://nap.nationalacademies.org/read/1222/chapter/1#i (last visited Nov. 18, 2022).

Id.


Expansion of Use of the Term Healthy, 85 Fed. Reg. 15759 (March 19, 2020) (showing how the USDA proposed to expand the use of the term to allow producers to include “healthy” on [food product] labels which: “(1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.”).


Id.