DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2016–D–2335]

RIN 0910–AI13

Food Labeling: Nutrient Content Claims; Definition of Term ''Healthy''

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing this final rule updating the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and Federal dietary guidance, especially the Dietary Guidelines for Americans (Dietary Guidelines), regarding how consumers can maintain healthy dietary practices. This final rule revises the requirements for when the term ''healthy'' can be used as an implied nutrient content claim in the labeling of human food products to help consumers identify foods that are particularly useful as the foundation of a nutritious diet that is consistent with dietary recommendations.

DATES: This rule is effective February 25, 2025. The compliance date of this final rule is February 25, 2028.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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I. Executive Summary

A. Purpose of the Final Rule

This final rule updates the requirements for when the term ''healthy'' can be used as an implied nutrient content claim in the labeling of human food products to help consumers identify foods that can serve as the foundation of a nutritious diet that is consistent with current dietary recommendations. Consumers rely on food labels when navigating the marketplace to make informed choices about the foods they purchase for themselves and their families. FDA plays an important role in ensuring that the labels or labeling of food for human consumption, including claims on labels or labeling that market a food, are accurate, truthful, and not misleading. One such claim that FDA has regulated is the term ''healthy'' on product labels. Since 1994, we have recognized that when a manufacturer uses labeling that describes a product as ''healthy'' in the nutritional context, it is making an implicit claim about the level of nutrients in the product. In particular, such a claim implies that the nutrient content of the food may help consumers maintain healthy dietary practices. Given that nutrition science has evolved since the 1990s, this final rule updates the definition of ''healthy'' to be consistent with current nutrition science and Federal dietary guidance to help ensure that consumers have access to more complete, accurate, and up-to-date information on food labels. This final rule is also consistent with the longstanding purpose of this implied nutrient content claim to indicate that the nutrient levels of a food may help consumers maintain healthy dietary practices and furthers FDA's goals in accordance with its statutory mandate to prevent misleading labeling and reduce consumer confusion that can result from the use of inconsistent definitions for nutrient content claims.

In addition, updating the ''healthy'' nutrient content claim is one initiative action listed in the White House National Strategy on Hunger, Nutrition, and Health under the pillar of empowering all consumers to make and have access to healthy choices (Ref. 6). FDA, as part of this whole-of-government approach, broadly seeks to help reduce the burden of diet-related chronic diseases. Doing so will advance health equity, because diet-related chronic diseases are experienced disproportionately by certain racial and ethnic minority groups and those with lower socioeconomic status. For further discussion regarding the scope of the problem Americans face from diet-related chronic diseases, please see the proposed rule, 87 FR 59168 at 59170. We are committed to accomplishing these goals, in part, by prioritizing nutrition initiatives that can help improve dietary patterns in the United States. An important aspect of reducing the burden of diet-related chronic diseases, as well as advancing health equity, is helping consumers access nutrition information that allows them to identify healthier choices. As discussed further in section V. (''Comments on the Proposed Rule and FDA Response''), nutrient content claims, such as ''healthy,'' as well as other claims made on labels or in the labeling of foods act as quick signals on food packages. These statements may help consumers, particularly those with lower nutrition or health literacy, quickly and easily identify foods that can be the foundation of a healthy dietary pattern. Additionally, as discussed further in section V. (''Comments on the Proposed Rule and

FDA Response''), our review of the products available in the current marketplace demonstrates that the updated ''healthy'' criteria allow affordable, accessible, and culturally preferred [1] nutrient-dense foods within different food groups and subgroups to bear the ''healthy'' claim, including frozen, canned, dried, and other shelf-stable products. This final rule is one part of FDA's broader commitment to help reduce diet-related chronic diseases and also to advance health equity by helping consumers to identify foods that can be the foundation of a healthy dietary pattern. While there has been consistency in many of the recommendations in Federal dietary guidelines and the underlying nutrition science on which they are based, we intend to remain aligned with the most current nutrition science reflected in Federal dietary guidelines and will continue to update our regulations and policies, as appropriate.

B. Summary of the Major Provisions of the Final Rule

This final rule updating the definition of ''healthy'' includes provisions that:

- Establish parameters for use of the term ''healthy'' or derivative terms ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'' as an implied nutrient content claim on the label or in labeling of a food that suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, where there is also implied or explicit information about the nutrition content of the food on the label or in the labeling (§ 101.65(d)(1) and (3)) (21 CFR 101.65(d)(1) and (3))).
- Establish a framework based on food groups and nutrients to limit (NTL) for the ''healthy'' claim.
- Establish that ''food group,'' for the purposes of the ''healthy'' claim, refers to the groups of foods recommended in the *Dietary Guidelines, 2020–2025* (for adults and children 2 years of age and older), which are vegetables, fruits, dairy, grains, protein foods, as well as oils (§ 101.65(d)(2)).
  - The *Dietary Guidelines, 2020–2025* does not categorize oils as a ''food group,'' but they emphasize that oils are one of the six core elements of a healthy dietary pattern, along with vegetables, fruits, grains, dairy, and protein foods, and recommend daily intake objectives for oils, similar to the food groups. Therefore, we include oils as a food group for purposes of this rule.
  - For purposes of this rule, when we refer to foods as recommended or encouraged by the *Dietary Guidelines, 2020–2025,* we are referring to only those foods that are recommended or encouraged for adults and children 2 years of age or older because that is the population for which the claim is intended.
- Establish food group equivalents (FGEs) that identify qualifying amounts of foods from each food group based on nutritional content (§ 101.65(d)(2)).
- An FGE contains the following: (§ 101.65(d)(2))
  - Vegetable—1/2 cup equivalent (c-eq)
  - Fruit—1/2 cup equivalent
  - Grains—3/4 ounce (oz) equivalent whole grain
  - Dairy—2/3 cup equivalent
  - Protein foods:
    - Game meat—1½ oz equivalent
    - Seafood—1 oz equivalent
    - Egg—1 oz equivalent
    - Beans, peas, or lentils—1 oz equivalent
    - Nuts and seeds, or soy products—1 oz equivalent
- Require that, to bear a claim subject to this rule, individual food products, mixed products, main dishes, and meals must meet FGEs and specific limits for added sugars, saturated fat, and sodium based on a percentage of the Daily Value (DV) for these nutrients. To bear a claim that is subject to this rule:
  - An individual food that has a reference amount customarily consumed (RACC, used to determine serving size), greater than 50 grams (g) or greater than 3 tablespoons (Tbsp) and meets the following conditions per RACC; or an individual food that has a RACC of 50 g or less or 3 Tbsp or less and meets the following conditions per 50 g of food: (§ 101.65(d)(3)(ii)(A) and (B))

[1] The term ''culturally preferred foods'' is used here to describe safe and nutritious foods that meet the diverse tastes and needs of customers based on their cultural identity (Ref. 46).

To bear a claim subject to this rule, if the food is…		It must contain at least...	The added sugars 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 cup equivalent vegetable	2% DV	10% DV	5% DV
A fruit product		1/2 cup equivalent fruit	2% DV	10% DV	5% DV
A grain product		3/4 oz equivalent whole grain	10% DV	10% DV	5% DV
A dairy product		2/3 cup equivalent dairy	5% DV	10% DV	10% DV
Protein Foods	Game meats	1 1/2 oz equivalent	2% DV	10% DV	10% DV
	Seafood	1 oz equivalent	2% DV	10% DV	5% DV, excluding saturated fat inherent in seafood
	Egg	1 oz equivalent	2% DV	10% DV	10% DV
	Beans, peas, and lentils	1 oz equivalent	2% DV	10% DV	5% DV
	Nuts, seeds, and soy products	1 oz equivalent	2% DV	10% DV	5% DV, excluding saturated fat inherent in nuts, seeds, and soybeans
Oils	100% Oil		0% DV	0% DV	20% of total fat
	Oil-based spreads whose fats come solely from oil		0% DV	10% DV	20% of total fat
	Oil-based dressing containing at least 30% oil and oils meet the requirements in § 101.65(d)(3)(ii)(A) or (B)(6)(*i*)		2% DV	10% DV	20% of total fat

○ A mixed product that meets the following conditions per RACC (§ 101.65(d)(3)(iii)):

To bear a claim subject to this rule, if the mixed product contains at least…	The added sugars content must be no greater than…	The sodium content must be no greater than…	Excluding saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than…
One total FGE with no less than 1/4 FGE from at least two food groups	10% DV	15% DV	10% DV

○ A main dish product as defined in § 101.13(m) (21 CFR 101.13(m)) that meets the following conditions per labeled serving: (§ 101.65(d)(3)(iv))

To bear a claim subject to this rule, if the main dish product contains at least…	The added sugars content must be no greater than…	The sodium content must be no greater than…	Excluding saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than…
Two total FGEs with no less than 1/2 FGE from at least two food groups	15% DV	20% DV	15% DV

○ A meal product as defined in § 101.13(l) that meets the following conditions per labeled serving: (§ 101.65(d)(3)(v))

To bear a claim subject to this rule, if the meal product contains at least…	The added sugars content must be no greater than…	The sodium content must be no greater than…	Excluding saturated fat inherent in seafood, nuts, seeds and soybeans in soy products (if applicable), the saturated fat content must be no greater than…
Three total FGEs with no less than 1/2 FGE from at least three food groups	20% DV	30% DV	20% DV

• Provide that individual foods or mixed products that are comprised of one or more of the following foods encouraged by the Dietary Guidelines, with no other added ingredients except for water: vegetable; fruit; whole grains; fat-free and low-fat dairy; lean meat, seafood, eggs, beans, peas, lentils, nuts and seeds, automatically qualify (*i.e.,* without having to meet the FGE and nutrients to limit (NTL) requirements) for the ''healthy'' claim because of their nutrient profile and positive contribution to an overall healthy diet. § 101.65(d)(3)(i))

• Provide that all water, tea, and coffee with less than 5 calories per RACC and per labeled serving automatically qualify for the ''healthy'' claim. (§ 101.65(d)(3)(vi))

• Require the establishment and maintenance of certain records for foods bearing the ''healthy'' claim where the FGE contained in the product is not apparent from the label of the food. The records must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. During an inspection, such records must be provided to FDA upon request for official review and photocopying or other means of reproduction. (§ 101.65(d)(4))

C. Legal Authority

We are issuing this final rule to update the definition of the implied nutrient content claim ''healthy'' consistent with our authority in sections 201(n), 403(a), 403(r), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(n), 343(a), 343(r), and 371(a)). We are also relying on our authority under sections 403(r), 403(a), 201(n) and 701(a) of the FD&C Act for certain records requirements.

D. Costs and Benefits

In the current marketplace, about 5 percent of all packaged foods are labeled as ''healthy.'' Because nutrition science has evolved over time, updating the definition of the implied nutrient content claim ''healthy'' to more closely align with nutrition science underpinning the *Dietary Guidelines, 2020–2025* will better inform consumers who are selecting those products to choose a more healthful diet, which may result in lower incidence of diet-related chronic diseases, including cardiovascular disease (CVD) and type 2 diabetes. Quantifiable benefits of the rule are the estimated reduction over time in all-cause mortality stemming

from consumers that rely upon the ''healthy'' implied nutrient content claim selecting and consuming more healthful foods. Discounted at 3 percent over 20 years, the mean present value of benefits is estimated at $686 million, or $46 million annualized. This is calculated through the inverse association between a Healthy Eating Index score and all-cause mortality (Ref. 44). Quantifiable costs to manufacturers associated with updating the ''healthy'' claim are reformulating, labeling, and recordkeeping. Discounted at 3 percent over 20 years, the mean present value of costs is estimated at $403 million, or $27 million annualized. Potential costs of rebranding certain foods are discussed qualitatively. Net benefits are estimated at $283 million, or $19 million annualized.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/Acronym	What It Means
APA	Administrative Procedure Act
CDRR	Chronic Disease Risk Reduction Intake
CVD	Cardiovascular Disease
Dietary Guidelines	Dietary Guidelines for Americans
DV	Daily Value
DRV	Daily Reference Value
c-eq	Cup Equivalent
DRI	Daily Reference Intake
DGAC	Dietary Guidelines Advisory Committee
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FGE	Food Group Equivalent
FPED	U.S. Department of Agriculture Food Patterns Equivalents Database
GRAS	Generally Recognized As Safe
FSDU	Foods for Special Dietary Use
HHS	U.S. Department of Health and Human Services
G	Gram
IOM	Institute of Medicine
OMB	Office of Management and Budget
National Academies	National Academies of Sciences, Engineering, and Medicine
NFL Final Rule	Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule
NHANES	National Health and Nutrition Examination Survey
NSLP	National School Lunch Program
NLEA	Nutrition Labeling and Education Act
NTE	Nutrients to Encourage
NTL	Nutrients to Limit
oz-eq	Ounce Equivalent
Mg	Milligram
Oz	Ounce
PRA	Paperwork Reduction Act
RDI	Reference Daily Intake
RACC	Reference Amount Customarily Consumed
PHO	Partially Hydrogenated Oil
Tbsp	Tablespoon
TFP	Thrifty Food Plan
USDA	U.S. Department of Agriculture
USPTO	U.S. Patent and Trademark Office
WHO	World Health Organization
WIC	Special Supplemental Nutrition Program for Women, Infants and Children
Dietary Guidelines, 2020-2025	*Dietary Guidelines for Americans, 2020-2025*
2020 DGAC Report	Scientific Report of the 2020 Dietary Guidelines Advisory Committee

III. Background

A. Need for the Regulation/History of This Rulemaking

In the **Federal Register** of May 10, 1994 (59 FR 24232), we published a final rule (the 1994 rule or original rule) entitled ''Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy' '' amending § 101.65(d) to define the term ''healthy'' as an implied nutrient content claim under section 403(r) of the FD&C Act. The definition established in 1994 (original definition) was linked to certain requirements in the Nutrition Facts label at § 101.9 (21 CFR 101.9) and serving size regulations at § 101.12 (21 CFR 101.12) that were in effect in 1994. The 1994 rule established parameters for use of the implied nutrient content claim ''healthy'' or related terms (such as ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'') on the label or in the labeling of a food that is useful in creating a diet that is consistent with dietary recommendations, if the food meets certain nutrient conditions. Under the 1994 rule, these conditions included specific criteria for nutrients that must be met for the food to bear such claims. These criteria included limits on total fat, saturated fat, cholesterol, and sodium, and minimum amounts (10% of DV) of nutrients whose consumption is encouraged, such as vitamin A, vitamin C, calcium, iron, protein, and dietary fiber. Under the 1994 rule, foods must meet all limits and contain the minimum amount of at least one nutrient to encourage (NTE) to bear the ''healthy'' claim. The required nutrient criteria varied for certain food groups (*e.g.,* different criteria for seafood, game meat, and raw fruits and vegetables). The 1994 rule also linked the claim with an explicit or implicit claim or statement about a nutrient (*e.g.,* ''healthy, contains 3 grams of fat'').

Nutrition science and Federal dietary guidance have evolved since 1994. Since that time, FDA has issued final rules updating the Nutrition Facts label and serving size information for packaged foods to reflect new scientific information. This includes the final rules ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (81 FR 33742, ''NFL Final Rule''), and ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments'' (81 FR 34000, ''Serving Size Final Rule'') which were published on May 27, 2016. These rules (codified primarily at part 101 (21 CFR part 101)) included changes to the nutrients that must be declared on the Nutrition Facts label. For example, the Nutrition Facts label must now include a declaration of the amount of added sugars in a serving of a product, based on our conclusion that evidence regarding dietary patterns and health outcomes supports a mandatory declaration of added sugars (§ 101.9(c)(1)(iii)). The updates also included changes to the DV of certain individual nutrients to reflect changes in recommended intake levels based on current nutrition science. The Nutrition Facts label declaration requirements and DVs for individual nutrients significantly inform the regulations for nutrient content claims, such as ''healthy.'' The NFL Final Rule and the Serving Size Final Rule reflect the nutrition science in the Dietary Guidelines, other consensus reports, national survey intake data, and research regarding consumer use and understanding of the food label.

As the *Dietary Guidelines, 2020–2025* explains, current nutrition science focuses ''on consuming a healthy dietary pattern'' (Ref. 1). Current nutrition science emphasizes nutrient-dense foods, such as fruits, vegetables, and whole grains, as core elements of a healthy dietary pattern. ''Nutrient-dense'' foods and beverages are defined as foods and beverages that provide vitamins, minerals, and other health-promoting components and have little or no added sugars, saturated fat, and sodium (Ref. 1). These foods, which contain a variety of important nutrients, work synergistically as part of a dietary pattern to help improve health (Ref. 1). A number of these nutrient-dense foods were not able to bear the ''healthy'' claim under the 1994 rule (*e.g.,* salmon due to fat amounts). Further, the 1994 rule permitted manufacturers to use the claim ''healthy'' on some foods that, based on updated nutrition science and Federal dietary guidance, contain levels of nutrients that would not help consumers maintain healthy dietary practices (*e.g.,* certain foods that are high in added sugars). We have long recognized the need to update the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and Federal dietary guidance. Consequently, in the **Federal Register** of September 29, 2022 (87 FR 59168), we issued a proposed rule to amend the definition of ''healthy'' to ensure that foods bearing the claim are foods that may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance; in other words, nutrient-dense foods that are foundational to a healthy dietary pattern. The preamble to the proposed rule discussed, in some detail, the reasons why we felt it necessary to update the definition of ''healthy'' as an implied nutrient content claim (see 87 FR 59168 at 59169 through 59173).

When FDA first defined healthy in 1994 (59 FR 24232), we concluded that ''the fundamental purpose of a 'healthy' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines'' (59 FR 24232 at 24233). Under this framework, which is continued under this rule, foods that do not qualify for use of the claim are not deemed to be ''unhealthy'' or unable to provide any nutritional benefits to consumers. Nor does the healthy definition, as established in this rule, represent a determination by FDA that consumers should only choose foods that qualify for the ''healthy'' claim or completely avoid choosing foods that do not qualify for the ''healthy'' claim. The current *Dietary Guidelines, 2020–2025* (Ref. 1) focuses on the importance of a healthy dietary pattern as a whole and its role in promoting health, reducing risk of chronic diseases, and meeting nutrient needs. Although nearly all foods can be incorporated into a healthy dietary pattern to some extent, current nutrition science emphasizes nutrient-dense foods, such as fruits, vegetables, and whole grains, as core elements of a healthy dietary pattern (Ref. 1). Moreover, foods that meet the requirements for ''healthy'' as defined in this rule are foods that, because of their overall nutrition profiles, can be the ''foundation'' or ''building blocks'' of a healthy dietary pattern recommended by the Dietary Guidelines.

Foods that do not meet the requirements defined in this rule to bear the ''healthy'' claim could, however, have beneficial nutritional attributes and these nutritional attributes can be communicated to consumers in many different ways. For example, use of other nutrient content claims, such as ''low'' (*e.g.,* ''low saturated fat'' in § 101.62(c) (21 CFR 101.62(c))) or ''high'' (§ 101.54(b) (21 CFR 101.54(b))) can inform consumers interested in intake of specific nutrients. In addition, a food label can include health claims, which are different than nutrient content claims in that they show how a food or food component may reduce the risk of a disease or health-related condition. Other claims (*e.g.,* structure/

function claims) can describe, for example, the role of a nutrient intended to affect the normal structure or function of the body. Additionally, dietary guidance statements are a type of voluntary labeling statement that can be used on labels that represent or suggest that an individual food or food group may contribute to or help maintain a nutritious dietary pattern. Dietary guidance statements provide manufacturers with a broad range of messages beyond characterizing the nutrient content of the food (compared with nutrient content claims such as ''healthy'') and can communicate to consumers that a food or food group may contribute to or help maintain a nutritious dietary pattern. Different nutrition labeling claims communicate different meanings to consumers, and there are different criteria for their use. However, certain statements may be considered more than one type of claim, depending on the context in which they are used and taken together with the labels or labeling as a whole. As such, that a food may qualify for another type of claim does not automatically make the food eligible for the ''healthy'' claim, just as that a food qualifies for the ''healthy'' claim does not mean a food will meet the requirements for other claims. The criteria for each of the different claims must be met to use that specific claim and manufacturers are free to use any applicable claims for which they qualify and make truthful and non-misleading statements on food labels or labeling.

B. Summary of Comments to the Proposed Rule

We received approximately 400 comments on the proposed rule, each containing one or more comments on one or more provisions of the rule. We received comments from industry; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress, State, and local Governments; and other organizations. In section V. (''Comments on the Proposed Rule and FDA Response''), we summarize these comments, respond to them, and explain any revisions we made to the proposed rule. The topics addressed most frequently in the comments include:

- Many comments support the proposed rule on the grounds that it would help consumers make better, healthier choices, and generally improve the nutritional knowledge of the average consumer in the United States.
- Similarly, numerous comments support the proposed rule on the grounds that it could help combat the high rate of obesity and diet-related chronic diseases and illnesses in the Unites States.
- Although many comments support updating the ''healthy'' definition and acknowledge the need for consistency with current nutrition science and Federal dietary recommendations, particularly the Dietary Guidelines, a number of comments request changes to provide more flexibility and, according to the comments, increase the number of foods that could qualify for the ''healthy'' claim. Such comments range in scope, from small increases in the allowable nutrient levels to the addition of entire new sets of criteria.
- Many comments request that we simplify and streamline the criteria for combination foods (mixed products, meals, and main dishes) to allow more flexibility in formulations and recipes for combination foods recommended by the Dietary Guidelines.
- Several comments suggest entirely different, alternative frameworks for the definition of ''healthy'' such as changes to the FGE criteria, permitting NTE as part of the criteria, and changes that would allow products with a small RACC to use the claim.
- Other comments recommend changes, including both higher or lower limits, to the nutrient limits for added sugars, saturated fat, and sodium.
- Some comments also address other topics in the proposed rule, including some for which we specifically requested comments and information. For example, some comments discuss exemptions from the FGE criteria and/or nutrient limits for certain foods, such as fish/seafood, certain plant-based proteins or plant-based beverages, tart fruits, and beverages other than plain water, such as coffee and tea. Other comments discuss bottled water containing other ingredients, such as flavors.

C. General Overview of the Final Rule

We provide a detailed overview of the final rule above in section I.B (''Summary of the Major Provisions of the Final Rule''). In support of our consideration of the comments received on the proposed rule, we conducted reviews of databases of products available in the current marketplace to determine what foods in the marketplace would meet certain FGE and NTL criteria in the proposed rule (Ref. 2). As a result of comments received and, in some cases, also supported by the marketplace review we conducted to evaluate those comments, we have made several changes to the proposed criteria to provide additional flexibility, which will result in more foods qualifying to bear the ''healthy'' claim while still aligning with current nutrition science and Federal dietary guidelines. Such changes include, but are not limited to, the following:

- The rule applies the ''healthy'' criteria to individual foods with a RACC of 50 g or less or 3 Tbsp or less on a per 50 g basis instead of a per RACC basis (§ 101.65(d)(3)(ii)(A) and (B)). This results in foods consumed in small amounts that are recommended for healthy dietary patterns qualifying for the claim.
- The rule expands the proposed exemption for raw, whole fruits and vegetables to provide that an individual food or mixed product that is comprised of one or more of the foods encouraged by the Dietary Guidelines, with no other added ingredients except for water, automatically qualifies for the ''healthy'' claim without meeting the specified criteria because of its nutrient profile and total contribution to an overall healthy diet. Such foods are vegetables; fruits; whole grains; fat-free and low-fat dairy; and lean meat, seafood, eggs, beans, peas, lentils, nuts, and seeds (§ 101.65(d)(3)(i)).
- The rule makes several changes to the FGE criteria from what we proposed, including:
  - The FGE for dairy is ⅔ c-eq instead of ¾ c-eq.
  - For combination foods (mixed products, main dishes, and meals), the rule provides additional flexibility in the proportions required for FGEs. For mixed products, the proposed rule would have required ½ FGEs from each of the two food groups. The final rule requires that each food group component should have no less than ¼ FGE and that the combined amount of two or more different groups be equal to one total FGE (*e.g.,* ¼ FGE from one food group and ¾ FGE from the second food group) (§ 101.65(d)(3)(iii)). For main dish products and meal products, the proposed rule would have required exactly 1 FGE each of two or three different food groups, respectively. The final rule requires that each food group component have no less than ½ FGE to comprise the total of 2 FGEs for main dish products and 3 FGEs for meal products (§ 101.65(d)(3)(iv)–(v)). This increased flexibility for FGE requirements will result in more products, such as plant-based patties, being able to meet the FGE requirements for combination foods while still containing meaningful amounts of the different food groups.

○ Vegetable and fruit powders that are produced by drying whole vegetables and fruits and grinding into powder form have similar nutrient content to whole vegetables and fruits, and they may be considered in calculation of the vegetable and fruit FGEs for the ''healthy'' claim.

• The rule makes a number of changes to the nutrient to limit criteria from what we proposed, including:

○ The rule provides more flexibility for sodium in mixed products by increasing the limit from ≤10% DV to ≤15% DV per RACC (§ 101.65(d)(3)(iii)).

○ The rule provides more flexibility for added sugars in whole grain products by increasing the limit from ≤5% DV to ≤10% DV for the grains group (§ 101.65(d)(3)(ii)).

○ The rule finalizes an added sugars limit for individual fruits, vegetables, and protein foods of ≤2% of the DV in consideration of the addition of small amounts of added sugars through seasonings and recipes, as well as for the functional attributes of sugars (§ 101.65(d)(3)(ii)).

○ The rule excludes the inherent saturated fat in seafood from the saturated fat limit for seafood products and lowers the saturated fat limit for seafood products to ≤5% DV, to provide more flexibility for seafood, which has a fat profile that is predominantly beneficial unsaturated fats but has amounts of naturally occurring saturated fat that can vary across and within different types of seafood (§ 101.65(d)(3)(ii)). This approach is consistent with the proposed approach for nut and seed products.

○ For combination foods (mixed products, main dishes, and meals), the rule streamlines the NTL criteria so that there is one limit each for saturated fat, sodium, and added sugars for mixed products, for main dishes, and for meals (*i.e.,* limits do not vary based on food groups within each category) (§ 101.65(d)(3)(iii)–(v)).

• The rule expands the exemption for plain and plain, carbonated water to include all water, tea, and coffee with less than 5 calories per RACC and per labeled serving (§ 101.65(d)(3)(vi)). The exemption includes carbonated or noncarbonated water, coffee, and tea, containing non-caloric ingredients such as flavors, no- or low-calorie sweeteners, vitamins, and minerals.

IV. Legal Authority

We are issuing this rule to update the definition of the implied nutrient content claim ''healthy'' consistent with our authority in sections 201(n), 403(a), 403(r), and 701(a) of the FD&C Act. These sections authorize FDA to adopt regulations that prohibit labeling that is false or misleading in that it fails to reveal facts that are material in light of the representations that are made with respect to consequences that may result from consuming the food or uses terms to characterize the level of any nutrient in a food that has not been defined by regulation by FDA.

Congress passed the Nutrition Labeling and Education Act (NLEA) of 1990 (Pub. L. 101–535), with three basic objectives: (1) to make available nutrition information that can help consumers in selecting foods that can lead to healthier diets; (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary of HHS; and (3) to encourage product innovation through the development and marketing of nutritionally improved foods (58 FR 2302, January 6, 1993). The NLEA created section 403(r)(1)(A) of the FD&C Act, which provides specifications for a claim made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (2) of the FD&C Act to be in the label or labeling of the food. The statute permits the use of these label and labeling claims that expressly or by implication characterize the level of any nutrient in a food, but only if the claims are made in accordance with FDA's authorizing regulations (section 403(r)(1)(A) and (r)(2)(A) of the FD&C Act). Such claims are referred to as ''nutrient content claims.''

Nutrient content claims can either be claims that expressly characterize the level of a nutrient (express claims, such as ''low fat'') or claims that by implication characterize the level of any nutrient (implied claims, like the ''healthy'' claim or ''high in oat bran''). Nutrient content claims are typically based per RACC. This allows nutrient content claims on foods to be considered consistently across products and product sizes. In rulemaking to implement section 403(r)(1)(A) and 403(r)(2) of the FD&C Act shortly after the enactment of the NLEA, we determined that a claim that states that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices is a claim that characterizes the levels of nutrients in a food (''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms,'' 58 FR 2302 at 2374 to 2375, January 6, 1993). That rulemaking resulted in regulations defining ''implied nutrient content claims'' as including claims that imply that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. As the preamble explained, ''[t]he claims are essentially saying that the levels of nutrients in the food are such that the food will contribute to good health'' (58 FR 2302 at 2375).

FDA issued another regulation in 1994, in which we defined ''healthy'' when the term is used as an implied nutrient content claim (59 FR 24232, May 10, 1994). The preamble to the 1994 final rule explained that the statute requires that FDA define terms by regulation before they are used as nutritional claims in food labeling; more specifically, under the terms of section 403(r)(1)(A) and 403(r)(2) of the FD&C Act, a nutrient content claim would misbrand a food unless it is made in accordance with a definition of the Secretary of HHS (and, by delegation, FDA) or with one of the other provisions in section 403(r)(2) of the FD&C Act (59 FR 24232 at 24234). The preamble explained that FDA had already determined that, when used in the nutritional labeling context, the term ''healthy'' is making an implied claim about the levels of the nutrients in the food; that is, that these levels are such that the food would be useful in achieving a total diet that conforms to current dietary recommendations (56 FR 60421 at 60423, November 27, 1991). Accordingly, FDA established a definition for ''healthy'' when it is used in a nutritional context.

This rulemaking updates the definition of ''healthy'' when used as an implied nutrient content claim, based on current nutrition science and Federal dietary guidance. The updates also reflect the science underlying the changes made to the Nutrition Facts label in the 2016 update to that labeling requirement. As explained in section III. (''Background''), our updated criteria for ''healthy'' incorporate both food group and NTL requirements. These changes are intended to ensure that foods bearing the implied nutrient content claim ''healthy'' are nutrient-dense foods that may help consumers maintain healthy dietary practices, based on current nutrition science and Federal dietary guidance. The fundamental purpose of this rulemaking furthers the Congressional objectives underlying the NLEA of providing nutrition information to consumers to help in selecting foods that can lead to healthier diets and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims.

The revised definition of ''healthy'' is consistent with the framework

established by the statute and regulations as informed by current science. The statutory language describes nutrient content claims as claims in the label or labeling of a food that expressly or by implication characterize the level of any nutrient in a food (section 403(r)(1)(A) of the FD&C Act). FDA regulations define ''implied nutrient content claims,'' in part, as claims that imply that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. The statute's reference to characterizing the level of any nutrient and the regulation's reference to maintaining healthy dietary practices incorporate a scientific component because both the characterization and the assessment of healthy dietary practices involve an evaluation of the impact of diet on health. As science evolves over time, the understanding of how nutrient levels should be characterized and appropriate measures for maintaining healthy dietary practices may also evolve. Thus, it is appropriate and consistent with the regulatory framework for FDA to update definitions related to implied nutrient content claims based on current science.

The term ''healthy'' can be an implied nutrient content claim because it suggests that the food, because of its nutrient content, may help consumers maintain healthy dietary practices. The 1994 definition of the claim discussed levels for nine different individual nutrients: fat, saturated fat, cholesterol, vitamin A, vitamin C, calcium, iron, protein, and fiber (§ 101.65(d)(2)(i)). As discussed elsewhere in this document, in recent years the Dietary Guidelines have shifted to recommending healthy dietary patterns and the consumption of food groups in certain quantities to achieve adequate nutrient intake, based on the understanding that each food group contributes an array of important nutrients to the diet (*Dietary Guidelines, 2020–2025*). The *Dietary Guidelines, 2020–2025* reflects the current scientific understanding that nutrients are not consumed in isolation and focuses its recommendations on consuming a variety of nutrient-dense foods, across all food groups, as part of a healthy dietary pattern. Specifically, the *Dietary Guidelines, 2020–2025* states that because foods provide an array of nutrients and other components that have health benefits, nutritional needs should be met primarily through eating a variety of nutrient-dense foods. Additionally, the *Dietary Guidelines, 2020–2025* recommends increasing intakes of certain food groups and subgroups to shift intakes of underconsumed dietary components closer to recommendations.

As we have long explained, the ''healthy'' claim thus ''characterizes the level of [some] nutrient[s] in a food'' by implicitly stating that the food contains nutrients at levels or in combinations that help consumers maintain healthy dietary practices. Our 1994 definition sought to ensure that the use of that claim would help consumers who choose to maintain such dietary practices, would not be misleading, and would reduce consumer confusion. That definition did so by tying the use of the claim to circumstances in which the claim accorded with then-accepted scientific and medical understandings. As the underlying science has developed—in ways reflected in the *Dietary Guidelines, 2020–2025*—the definition of the claim must be updated to ensure that our regulation continues to serve its original functions.

The final rule's definition of ''healthy'' includes food groups that provide a number of different nutrients. It thus reflects the conclusion that the use of the term ''implicitly'' characterizes the overall nutrient content of the food, rather than focusing on one individual nutrient in isolation, as with an express nutrient content claim. Each food group that is included in the food group requirement for the updated definition of the ''healthy'' claim represents the inclusion of multiple important nutrients. The use of food groups better accounts for how all these nutrients contribute, and may work synergistically, to create a healthy dietary pattern and improve health outcomes. It thus better accounts for how the use of the ''healthy'' claim implicitly characterizes the level of nutrients in a food—as containing nutrients in sufficient levels and combinations that contribute to healthy dietary patterns, which can lead to better health outcomes. By requiring products to contain a certain amount of a food group, the final rule will help ensure foods bearing the ''healthy'' claim contain a variety of important beneficial nutrients and, therefore, help Americans meet recommended nutrient intakes and maintain healthy dietary patterns.

In addition to section 403(r)(2) of the FD&C Act, we are issuing this rule under section 701(a) of the FD&C Act, which states that we may issue regulations for the efficient enforcement of the FD&C Act and has been interpreted to apply to ''effectuate a congressional objective expressed elsewhere in the Act'' (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Sup. 1179, 1183 (D. Del. 1980)).

We are also relying on our authority under sections 403(r), 403(a), 201(n), and 701(a) of the FD&C Act, to finalize records requirements designed to ensure that the use of the ''healthy'' claim is accurate, truthful, and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where FDA has found such records to be necessary (*National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693–94 (D.C. Cir. 1978)). The recordkeeping applies only to foods voluntarily bearing the ''healthy'' claim for which an adequate analytical method to determine FGE is not available or the amount cannot be discerned from the label alone. The records will allow us to verify that the product meets the requirements to bear the claim and that use of the nutrient content claim ''healthy'' is truthful and not misleading. Thus, the records requirements will help in the efficient enforcement of the FD&C Act (see discussion in section V.I (''Records Requirements'') for more information).

The authority granted to FDA under sections 701(a), 403(r), 403(a)(1), and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without access to such records, FDA would not know whether the food meets the proposed requirements to bear the ''healthy'' claim consistent with section 403(r) of the FD&C Act, and whether the use of the claim is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether a food that is voluntarily bearing a ''healthy'' nutrient content claim is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be kept under § 101.65(d)(4). Failure to make and keep records and provide the records to FDA, as described in § 101.65(d)(4), would result in the food bearing the ''healthy'' claim being misbranded under sections 403(r) and 403(a)(1) of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received approximately 400 comments on the proposed rule. We received comments from consumers; consumer groups; academia; trade organizations; industry (*e.g.,* food manufacturers); public health organizations; public advocacy groups; Congress, State, and local government agencies; and other organizations. In the remainder of this section, we summarize these comments, respond to them, and explain any revisions we made to the proposed rule. Where we did not receive comments and do not have additional discussion in this final rule, we finalized the proposed provisions without change.

We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value, importance, or the order in which comments were received.

B. General Comments

Many comments make general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision.

(Comment 1) The majority of the comments express general support for updating the ''healthy'' implied nutrient content claim to make it consistent with current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025,* noting the claim has not been updated since the 1990s. Numerous comments note that the proposed rule would help consumers make better, healthier choices for purchasing and consuming food, generally improve the nutritional knowledge of the average U.S. consumer, and give consumers information that could help combat the high rate of obesity and diet related chronic diseases and illnesses in the United States.

(Response 1) We agree with the comments that support updating the ''healthy'' implied nutrient content claim. Nutrition science has evolved since the 1990s when FDA first established a definition for the implied nutrient content claim ''healthy,'' and the purpose of this rule is to update the definition to be consistent with current nutrition science and Federal dietary guidance, such as the *Dietary Guidelines, 2020–2025,* to help ensure that consumers have access to more complete, accurate, and up-to-date information in the labeling of human food products. As more fully discussed in section III. (''Background''), the fundamental purpose of a ''healthy'' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that is consistent with current dietary guidelines. The current *Dietary Guidelines, 2020–2025* focuses on the importance of a healthy dietary pattern as a whole and its role in promoting health, reducing risk of chronic diseases, and meeting nutrient needs (Ref. 1). Therefore, foods that qualify for ''healthy'' are those foods that are particularly useful in helping consumers with creating healthy dietary patterns. As discussed, with this framework, we emphasize that foods that do not qualify for use of the claim are not necessarily ''unhealthy'' or unable to provide any nutritional benefits to consumers. Foods that meet the requirements for the ''healthy'' claim are foods that, because of their overall nutrition profiles, can be a ''foundation'' for a healthy dietary pattern recommended by the *Dietary Guidelines, 2020–2025.* Foods that do not meet the requirements could, however, have attributes that are beneficial. As more fully discussed above in section III. (''Background''), these beneficial attributes can be communicated to consumers in other ways. We reiterate that an inability to meet the requirements for use of the claim ''healthy'' does not necessarily make a food unhealthy and that manufacturers can communicate the nutritional qualities of their foods through other applicable label claims and any truthful and non-misleading statements they want to include.

(Comment 2) Some comments recommend the term ''healthy'' continue to evolve as science around nutrition changes and ask us to clarify our intentions to update the claim in the future, as needed.

(Response 2) Although the Dietary Guidelines are published every 5 years to reflect current nutrition science, and some of its specific recommendations have evolved as scientific knowledge has grown, many of its foundational recommendations have remained consistent over time (*e.g.,* recommending increased consumption of fruits, vegetables, and whole grains, and diets low in saturated fat and sodium). As discussed in the proposed rule (87 FR 59168 at 59170), advancements in nutrition science have provided a greater understanding of, and focus on, the importance of healthy dietary patterns, and how dietary components act synergistically to affect health. The *Dietary Guidelines, 2020–2025* has a particular focus on the importance of dietary patterns as a whole, with recommendations to help Americans make choices from across and within all food groups within calorie needs to add up to an overall healthy dietary pattern (Ref. 1). The *Dietary Guidelines, 2020–2025* also includes recommendations to limit daily intake of added sugars, saturated fat, and sodium, and emphasizes ''shifts,'' or replacement of less healthy food choices with nutrient-dense foods, as methods for consumers to achieve a healthy dietary pattern. The scientific evidence discussed in the *Dietary Guidelines, 2020–2025* and the Scientific Report of the 2020 Dietary Guidelines Advisory Committee (2020 DGAC report), and the recommendations based on that nutrition science, have informed this rulemaking and are the primary basis for the criteria that we have established for the ''healthy'' nutrient content claim. While there has been consistency in many of the recommendations in Federal dietary guidelines and the underlying nutrition science on which they are based, we intend to remain aligned with the most current nutrition science reflected in Federal dietary guidelines and will update our regulations and policies, as appropriate. However, we note that the updated definition of ''healthy'' is designed to be flexible and to accommodate possible changes in updated recommendations, as discussed further below in this section. For example, instead of tying the nutrient limits to absolute values, the criteria are provided as percentages of the DV.

(Comment 3) Some comments ask FDA to clarify that our work to update the ''healthy'' definition does not signal that other foods do not have a role to play in a healthy dietary pattern or something broader, such as whether a food is ''good'' or ''bad'' or ''some other broader policy recommendation.'' Some comments assert that allowing some foods to be labeled as ''healthy'' could lead consumers to infer all other foods are unhealthy, even if such foods have beneficial components, which could limit options for low-income and vulnerable populations.

Several comments assert that ''healthy'' diets vary across cultures, ages, and disease states and suggest that, for example, a healthy diet for an individual recovering from an eating

disorder is vastly different from a healthy diet for someone who has heart failure. The comments argue that allowing foods to be labeled as ''healthy'' implies that foods without those labels are ''unhealthy'' and could exacerbate eating disorders and possibly trigger relapse or otherwise prevent recovery. Some comments claim that FDA is incorrectly indicating that ''healthy'' is the same for everyone and suggest that our focus should instead be on giving people the tools to evaluate the specific nutrients that are in food and that we should consider removing the ''healthy'' claim altogether and refocus labeling efforts on clear and concise labeling that is sensitive to multiple cultures, disease states, and ages.

(Response 3) In this rule, we are updating the criteria for the ''healthy'' nutrient content claim so that it aligns with current nutrition science and Federal dietary guidance. The fundamental purpose of a ''healthy'' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in creating a diet that is consistent with current dietary guidelines. As discussed, with this framework, we emphasize that foods that do not qualify for use of the claim or do not use the claim are not necessarily ''unhealthy'' or unable to provide any nutritional benefits to consumers. Foods that meet the requirements for the ''healthy'' claim are foods that, because of their overall nutrition profiles, are useful as a foundation for a healthy dietary pattern recommended by the *Dietary Guidelines, 2020–2025.* The scientific evidence that informs the Dietary Guidelines is representative of the U.S. population, including people who are healthy, people at risk for diet-related chronic conditions and diseases (*e.g.,* CVD, type 2 diabetes, and obesity), and some people who are living with one or more of these diet-related chronic illnesses (Ref. 1). The *Dietary Guidelines, 2020–2025* states that a ''fundamental premise of the *2020–2025 Dietary Guidelines* is that nearly everyone, no matter their health status, can benefit from shifting food and beverage choices to better support healthy dietary patterns'' and explains that it is essential that medical organizations and health professionals adapt the Dietary Guidelines to meet the specific needs of their patients (Ref. 1). For consumers who would like to evaluate the specific nutrients that are in a food or beverage, the Nutrition Facts label is an available tool. The comments did not provide, and we are not aware of, evidence that a food labeled ''healthy'' for the narrow purpose of making a voluntary nutrient content claim could adversely impact those with eating disorders. We plan to undertake consumer education efforts related to the ''healthy'' claim, which we expect to include highlighting the importance of choosing a variety of nutrient-dense foods within and across different food groups and subgroups.

(Comment 4) Some comments argue that the proposed rule would not cause a ''significant'' change in consumer behavior or diet, warning that a ''healthy'' claim on processed and packaged products could discourage consumers from buying whole fruits and vegetables. However, such comments also note that an update to the ''healthy'' definition would make food products labeled with the claim align with current nutrition standards and lead to more healthy products being sold. The comments also assert that packaged food products are ''essential'' for communities that cannot afford exclusively fresh foods, and state that the new definition would help customers identify healthier options.

(Response 4) Nutrient content claims such as ''healthy'' are intended to provide consumers with information to help them quickly and easily identify foods that can be the foundation of a healthy dietary pattern. We agree that the updated ''healthy'' claim, which focuses on food groups and NTL, will better align with current nutrition science and support consumers, including those who frequently purchase packaged foods, in identifying healthier options. We disagree that the updated healthy claim could discourage consumers from buying whole fruits and vegetables. Both processed and packaged foods as well as fresh, whole foods, such as fruits and vegetables will be able to qualify for the ''healthy'' claim. Foods that qualify for the healthy claim that are not packaged can have the claim communicated to consumers through signage and other materials in the store. Therefore, through use of the ''healthy'' claim, consumers will have additional information on foods throughout the grocery store that can help make more informed decisions.

(Comment 5) Some comments oppose the proposed definition of ''healthy,'' asserting that the term ''healthy'' is not easily definable, will be used inconsistently, can quickly become outdated, and is a subjective term that can be applied differently for different people. Some comments assert that this change would allow food manufacturers to incorrectly label what the comments consider unhealthy foods as ''healthy,'' thus allowing manufacturers to mislead and deceive consumers. Some comments oppose the rule by asserting that government control over food labeling and promulgation of rules about what can be called ''healthy'' is unnecessary.

(Response 5) The rule establishes updated criteria for the narrow use of the term ''healthy'' as a voluntary nutrient content claim. As discussed in section IV. (''Legal Authority''), Congress passed the NLEA with three basic objectives: (1) to make available nutrition information that can help consumers select foods that can lead to healthier diets; (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary of HHS; and (3) to encourage product innovation through the development and marketing of nutritionally improved foods. The NLEA created section 403(r)(1)(A) of the FD&C Act, which provides specifications for a claim made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (2) of the FD&C Act to be in the label or labeling of the food. The statute permits the use of these label and labeling claims that expressly or by implication characterize the level of any nutrient in a food, but only if the claims are made in accordance with FDA's authorizing regulations (section 403(r)(1)(A) and (r)(2)(A) of the FD&C Act). Hence, establishing a definition of ''healthy,'' when used as a nutrient content claim, is necessary for such claims to be lawfully made and is partially intended to serve the very purpose these general comments opposing the rule use to argue against it, namely, to avoid consumer confusion and misleading claims. The fundamental purpose of this rulemaking furthers the Congressional objectives underlying the NLEA of providing nutrition information to consumers to help in selecting foods that can lead to healthier diets and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims. Further, under section 403(r)(1)(A) and (r)(2) of the FD&C Act, use of the ''healthy'' nutrient content claim would misbrand a food unless it is made in accordance with the regulatory definition we are establishing in this rule.

C. Food Group Equivalents

1. General Comments

(Comment 6) Numerous comments support using food groups as criteria in the definition of the claim ''healthy,'' stating that the change from focusing on individual nutrients better reflects the Dietary Guidelines, ensures that more nutrient-dense foods are included in the ''healthy'' definition, increases flexibility for certain products, avoids shifting nutrient guidelines, and is clearer to consumers. The comments mention that use of the food group criteria will enhance the messaging around the importance of creating healthy eating habits as opposed to a framework that targets individual foods. Some comments also provide that basing the ''healthy'' definition on food groups rather than individual nutrients is more consistent with evolving nutrition science that emphasizes dietary patterns. One comment mentions that requiring products to meet food-based criteria may help minimize or avoid unintended consequences of a focus solely on individual nutrients.

Some comments oppose use of food groups as criteria in the definition of the claim ''healthy,'' as opposed to individual nutrients, claiming the FGEs are too complex and difficult to calculate, that there is too much variance in nutrients within certain food groups, and the healthfulness of foods should be based on different individual nutrients. One comment claims that FDA has not adequately justified the move from only considering nutrients to also including food groups in the definition of the ''healthy'' claim.

(Response 6) We agree that the food group approach is in alignment with the *Dietary Guidelines, 2020–2025,* which places an emphasis on a healthy dietary pattern as a whole, rather than on individual nutrients or foods in isolation. The *Dietary Guidelines, 2020–2025* states that because foods provide an array of nutrients and other components that have health benefits, nutritional needs should be met primarily through a variety of nutrient-dense foods. The *Dietary Guidelines, 2020–2025* provides that a healthy dietary pattern consists of nutrient-dense forms of foods and beverages, in recommended amounts, across all food groups and recommends increasing intakes of certain food groups and subgroups to move intakes of underconsumed dietary components closer to recommendations.

We disagree that the FGE approach is too complex and note that there are several currently available resources that can help with calculation. As discussed further herein, the food groups and the FGE amounts are based on information contained in the *Dietary Guidelines, 2020–2025;* as such, the *Dietary Guidelines, 2020–2025* is a helpful resource in determining the amounts of foods necessary to meet FGEs. The USDA Food Patterns Equivalents Database (FPED) also provides information about cup- and ounce-equivalents of different foods and beverages to assist with calculations (Ref. 3). Additionally, FDA recognizes the importance of time for industry to determine the FGE amounts in their products, and we have set the rule's compliance date as being 3 years from the rule's effective date. We intend to provide additional resources for manufacturers to help determine FGE amounts before the compliance date. The additional resources may include guidance documents for industry, information on the FDA website, FAQs, direct communications in response to questions, or online webinars.

(Comment 7) Many comments support using food groups as criteria in the definition of the claim ''healthy,'' but ask that the rule maintain a level of reliance on individual beneficial nutrients or include requirements for beneficial nutrients as an alternative to ensure that important nutrients are not missed by the rule focusing too heavily on food groups. Some comments support the food group approach, but request that the updated ''healthy'' criteria permit a food to qualify if it meets both the NTL and either the food groups to encourage or the original NTE criteria.

(Response 7) We discussed in section III. (''Background'') that the purpose of a ''healthy'' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in creating a diet that is consistent with current dietary guidelines. The current *Dietary Guidelines, 2020–2025* (Ref. 1) focuses on the importance of a healthy dietary pattern as a whole and its role in promoting health, reducing risk of chronic diseases, and meeting nutrient needs. Therefore, based on current dietary recommendations and nutrition science, foods that qualify for ''healthy'' are those foods that are particularly useful in helping consumers create healthy dietary patterns. As described by the *Dietary Guidelines, 2020–2025,* a healthy dietary pattern ''consists of nutrient-dense forms of foods and beverages across all food groups, in recommended amounts, and within calorie limits.'' The *Dietary Guidelines, 2020–2025* also describes that ''[c]ommon characteristics of dietary patterns associated with positive health outcomes include relatively higher intake of vegetables, fruits, legumes, whole grains, low- or non-fat dairy, lean meats and poultry, seafood, nuts, and unsaturated vegetable oils, and relatively lower consumption of red and processed meats, sugar-sweetened foods and beverages, and refined grains.'' (Ref. 1). The original definition for the ''healthy'' nutrient content claim was based solely on individual nutrients, both minimum amounts and specific limits. This approach is inconsistent with current nutrition science regarding healthy dietary patterns and their effect on health and development of chronic disease. Foods that contain certain NTE, such as certain individual vitamins, minerals, or fiber, can be beneficial to consumers. However, highlighting those foods as ''healthy'' would not necessarily help consumers in the overall construction of healthy dietary patterns, in which nutrient-dense foods from across all of the recommended food groups and subgroups provide an array of nutrients and ensure overall nutrient adequacy from the diet. Including requirements for minimum amounts of foods from the recommended food groups better reflects the overall nutrient content of foods and how nutrients in the food groups and subgroups may work together as part of a healthy dietary pattern. Thus, we decline to include individual NTE criteria in the final rule.

(Comment 8) Some comments assert that FDA's proposed FGE is sometimes larger than the serving size of the product itself, particularly for products with small serving sizes that would be unable to qualify as ''healthy'' because they could not provide an FGE per RACC. Examples of types of foods discussed in the comments include certain whole grain bread products, certain snack foods, natural cheeses, and many yogurts. The comments state that these smaller RACC products would be excluded from making ''healthy'' claims solely based on their serving size. The comments request that FDA modify the criteria for products with small RACCs to require a smaller contribution to the FGEs. The comments suggest various different modifications to the criteria, including lowering the required FGE amounts, adjusting the criteria for the claim to incrementally increase based on food size, and adopting a category with criteria for foods with small RACCs.

(Response 8) In the proposed rule (87 FR 59168 at 59177), we determined the FGEs based on the cup- and ounce-equivalents and recommended daily food group amounts developed for the

Healthy U.S.-Style Dietary Pattern for ages 2 and older in the *Dietary Guidelines, 2020–2025* (Ref. 1). The proposed thresholds for the FGEs were set so that foods that bear the claim ''healthy'' contain enough of the food group that they could help consumers achieve the recommended daily food group amounts. Foods that do not contain the minimum FGE amount for their food group would not meet the requirements and not be eligible to bear the claim. As many comments point out, however, there are many foods that are included in the food groups recommended by the Dietary Guidelines, and fit into healthful dietary patterns, that are in forms whose RACCs are smaller than the minimum FGE requirement. After evaluating nutrient-dense foods with small RACCs across the recommended food groups and subgroups, we have determined that many of these foods with RACCs smaller than the proposed FGEs could qualify for use of the claim ''healthy'' if their RACC sizes were similar to those of typical individual foods and if they met all the other requirements for the use of the claim (Ref. 2).

FDA has previously addressed challenges related to foods with small RACCs in its nutrition labeling regulations. For example, in the context of eligibility for ''low'' nutrient content claims, FDA provided different criteria for eligibility to use the ''low fat'' claim based on the RACC of the individual food (§ 101.62(b)(2)). In the context of the low-fat claim, FDA applies different criteria based on RACC size to ensure that a food does not qualify for a ''low fat'' claim solely because it is consumed in small amounts.

For the proposed ''healthy'' definition, the reverse situation is present in that certain foods recommended for healthful dietary patterns would be unable to meet the FGE criteria for the claim due to being typically consumed in small amounts. Because we do not intend to exclude foods consumed in small amounts that are recommended for healthful dietary patterns, the final rule applies the ''healthy'' criteria to individual foods with a RACC of 50 g or less or 3 Tbsp or less on a per 50 g basis instead of a per RACC basis (§ 101.65(d)(3)(ii)(B)).

In the context of the ''low fat'' claim, FDA defined small RACC foods as ''individual foods that have a RACC of 30 g or less or 2 Tbsp or less.'' For the purposes of the ''healthy'' claim, to most appropriately include the variety of foods recommended by the Dietary Guidelines for healthful dietary patterns, which was supported by our review of food products in the current marketplace (Ref. 2), we are defining small RACC foods as foods with a RACC of 50 g or less or 3 Tbsp or less.

This change to the criteria for small RACC foods acknowledges that there have been a number of changes to individual RACC sizes since nutrient content claim criteria for foods with small RACC sizes, such as for the ''low fat'' claim (§ 101.62(b)(2)), were implemented. As an example, medium weight cereals initially had a RACC size of 30 g, which would fall under the small RACC description included in other nutrient content claims such as the ''low fat'' claim. In 2016, FDA updated the RACC size for medium weight cereals to 40 g (§ 101.12(b)). Thus, medium weight whole grain cereals are no longer considered a food with small RACC under the nutrient content claim of ''low fat.'' If we were to define small RACCs as ''individual foods that have a RACC of 30 g or less or 2 Tbsp or less'' for purposes of the ''healthy'' claim, medium weight whole grain cereals would not be considered to have a small RACC size, would have the ''healthy'' criteria applied on a per RACC basis (40 g), and would not meet the whole grain FGEs. However, medium weight nutrient-dense whole grain cereals, which are recommended as part of a healthy dietary pattern, will meet the whole grain FGE criterion for the ''healthy'' claim on a 50 g basis. As demonstrated when we reviewed the current marketplace (Ref. 2) in our data analysis, whole grain cereals are just one of many nutrient-dense foods recommended as part of a healthy dietary pattern that would not meet the FGE criteria on a 30 g basis but would meet them on a 50 g basis. Therefore, to ensure that nutrient-dense foods that are recommended for healthful dietary patterns are able to qualify for the ''healthy'' claim, the final rule applies the ''healthy'' criteria to individual foods with a RACC of 50 g or less or 3 Tbsp or less on a per 50 g basis instead of a per RACC basis (§ 101.65(d)(3)(ii)(B).

We have also made other changes that will result in more nutrient-dense foods with serving sizes that are smaller than the proposed FGE requirements being able to qualify for the ''healthy'' claim. For example, we have expanded the proposed exemption for raw, whole fruits and vegetables (see Response 9) and lowered the FGE requirement for dairy (see Response 29). We did not receive comments that the proposed FGE requirements were too restrictive for other food groups and subgroups, aside from concerns regarding products with small RACC sizes and the dairy FGE requirement. Therefore, we are finalizing the FGE requirements as proposed for the other food groups and subgroups.

(Comment 9) Many comments support the exemption in the proposed rule that would allow any raw, whole fruits and vegetables, including any whose RACC size might be smaller than the fruit and vegetable FGE requirements, to qualify for the ''healthy'' claim. Some comments note, however, that other fruit and vegetable options, such as frozen fruits and vegetables or chopped fruits and vegetables (without added ingredients), would not meet the proposed automatic qualification for raw, whole fruits and vegetables. Some comments mention that, while fresh or raw avocados would qualify under the exemption as proposed, frozen avocados would not. The comments request that the exemption for raw, whole fruits and vegetables be expanded to include other forms, such as frozen and chopped fruits and vegetables.

Some comments note that other food groups recommended by the Dietary Guidelines also include many similar, single-ingredient foods that align with recommendations in the guidelines but would not qualify for the ''healthy'' claim under the proposed rule. The comments assert that the FGE and NTL criteria are not necessary for these types of products because they are nutrient-dense foods encouraged by the Dietary Guidelines. The comments request that we expand the exemption for raw, whole fruits and vegetables to other single-ingredient nutrient-dense foods recommended by the Dietary Guidelines or include an additional category for nutrient-dense whole foods recommended by the Dietary Guidelines to ensure that these types of foods can also qualify for the ''healthy'' claim without needing to meet the FGE and NTL criteria.

(Response 9) We do not intend to exclude nutrient-dense single-ingredient foods that are foods encouraged by the Dietary Guidelines from qualifying for the updated ''healthy'' definition. We agree that it is not necessary for such foods to meet additional criteria because they are nutrient-dense foods encouraged by the Dietary Guidelines that can help consumers maintain healthy dietary practices by serving as a foundation for a healthy dietary pattern. Therefore, we have revised the rule to expand the exemption for raw, whole fruits and vegetables to include individual foods or mixed products that are comprised of one or more of the following nutrient-dense foods encouraged by the Dietary Guidelines (for adults and children 2 years of age and older), with no other added

ingredients except for water: vegetables; fruits; whole grains; fat-free and low-fat dairy; and lean game meat, seafood, eggs, beans, peas, lentils, nuts, and seeds (§ 101.65(d)(3)(i)). Individual foods and mixed products that contain these nutrient-dense foods encouraged by the Dietary Guidelines and do not contain any added ingredients, besides water, will automatically qualify for the ''healthy'' claim because of their nutrient profile and positive contribution to an overall healthy diet. Such products do not need to meet the FGE and NTL requirements for individual foods or mixed foods. For example, foods such as fish and lean game meats, skim milk, brown rice, and the many other single-ingredient nutrient-dense foods encouraged by the Dietary Guidelines can use the ''healthy'' nutrient content claim without having to meet the FGE and NTL requirements.

For similar reasons to those discussed above, we are also expanding the exemption so that it will not be limited to ''raw, whole'' versions of foods encouraged by the Dietary Guidelines, but rather will include other forms of these 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, and 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 FGE and nutrient to limit requirements. Additionally, as a result of the expansion of this exemption, single-ingredient foods encouraged by the Dietary Guidelines that have small RACC sizes (*e.g.,* frozen avocado pieces) will now qualify even if their RACCs are smaller than the FGE amounts for their respective food groups or subgroups.

Certain mixed products are also eligible for the exemption. A mixed product that contains multiple single-ingredient foods encouraged by the Dietary Guidelines (without additional ingredients besides water) but does not meet the FGE requirements for a mixed product to qualify for ''healthy'' (*i.e.,* contain 1 total FGE) will fall under the expanded exemption and will automatically qualify for the claim (§ 101.65(d)(3)(i)). We have determined that these types of products (*i.e.,* mixed products that contain only nutrient-dense foods that are encouraged by the Dietary Guidelines without added ingredients besides water) can also serve as part of a foundation for a healthy dietary pattern because of their nutrient profile and positive contribution to an overall healthy diet. Many of these types of products, regardless of whether they are individual foods or mixed products, would also meet the FGE and NTL criteria for individual foods or mixed products; however, this exemption allows manufacturers to more easily determine and verify compliance with the updated ''healthy'' criteria, particularly for mixed products. For example, a product that contains two ingredients that are each a food encouraged by the Dietary Guidelines—such as a frozen mix of a vegetable and a whole grain, or a blend of 100% juices that contains 80% fruit juice and 20% vegetable juice—and does not contain additional ingredients besides water, will automatically qualify under the expanded exemption in § 101.65(d)(3)(i). We are finalizing the expanded exemption under § 101.65(d)(3)(i) as: 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: (1) vegetable; (2) fruit; (3) whole grains; (4) fat-free and low-fat dairy; and (5) lean meat, seafood, eggs, beans, peas, lentils, nuts, and seeds. Additionally, because the standard information required on the food label, such as the list of ingredients for such a product, provides sufficient information to verify that the food meets the ''healthy'' criteria, records will not be required to demonstrate compliance with the FGE requirements for products that qualify for the automatic exemption in § 101.65(d)(3)(i) and (d)(4).

We are not expanding the exemption to main dishes or meals because those products serve different roles in the diet. Main dish products, defined by our regulations at § 101.13(m), are larger in size (weighing at least 6 oz per labeled serving) than individual foods and mixed products, and are intended to make a major contribution to a meal (*i.e.,* contain most of the components of a meal). A main dish product might include, for example, a frozen entrée that is intended to be eaten with additional items to form a full meal. Because of their size and the larger contribution that they make to the overall diet, we are requiring in § 101.65(d)(iv) that main dish products contain at least two total FGEs per labeled serving with a minimum of a ½ FGE for each of the two food groups, and that they meet NTL criteria (see Section V.E ''Combination Foods'' for further discussion of requirements for mixed products, main dishes, and meals). Meal products, defined at § 101.13(l), are larger in size (weighing at least 10 oz per labeled serving) than main dish products and are intended to provide all food for a single eating occasion (*i.e.,* a complete meal). An example of a meal is a frozen dinner that includes an entrée, vegetable side, and dessert. Because of their size and the larger contribution that they make to the overall diet, we are requiring in § 101.65(d)(v) that meal products contain at least three total FGEs per labeled serving with a minimum of a ½ FGE for each of the three food groups. It is important that main dishes and meals contain a minimum amount of different food groups (*i.e.,* meet the FGE criteria) because their size and larger contribution in the diet means that it is particularly important for them to contain an array of nutrients and to help consumers achieve the recommended daily food group amounts and meet nutritional needs, and therefore we are not including main dishes and meals in the expanded exemption.

For simplicity, throughout the rule we will refer to this exemption as the ''single-ingredient exemption'' and will generally refer to these nutrient-dense foods that are encouraged by the Dietary Guidelines with no added ingredients, except for water, as ''single-ingredient foods encouraged by the Dietary Guidelines.'' We again note, however, that these single-ingredient foods encouraged by the Dietary Guidelines and the single-ingredient exemption, also include individual foods and mixed products that contain multiple single-ingredient foods with no added ingredients, except for water (*e.g.,* a frozen mix of a vegetable and a whole grain, or a blend of 100% juices that contains 80% fruit juice and 20% vegetable juice).

(Comment 10) Some comments also recommend that herbs and spices be able to qualify for the ''healthy'' claim. These comments assert that herbs and spices can reduce consumption of added sugars, sodium, and saturated fat by making nutrient-dense foods more palatable without adding calories. Additionally, the comments state that herbs and spices increase the consumption of nutrient-dense foods such as vegetables, fruits, and healthy grains. Some comments assert that spices meet the definition of vegetable products, but provide that given their small RACC, spices would not be able to meet the proposed FGE criteria.

(Response 10) We agree that herbs and spices can play an important role in the diet by replacing seasonings and ingredients that contribute sodium, saturated fat, and added sugars to the diet. They can also help increase the palatability of nutrient-dense foods. However, because of their primary use

as a flavoring for foods, they are typically consumed in such small quantities that they generally do not contribute a meaningful amount of nutrients to the diet. The *Dietary Guidelines, 2020–2025* mentions that spices and herbs can help flavor foods when reducing added sugars, saturated fat, and sodium, and that they can also contribute to the enjoyment of nutrient-dense foods (Ref. 1). Some herbs are included as examples in the vegetable food group in the *Dietary Guidelines, 2020–2025* (*e.g.,* cilantro, basil, and chives). Foods or ingredients that are considered to be part of the vegetable food group can also contribute toward the FGE requirement for vegetables in different forms, such as dried forms (see Response 44).

(Comment 11) Some comments suggest that FDA allow foods with small RACCs to satisfy their FGE requirement by having a component from a recommended food group as the first ingredient on the ingredient declaration. The comments suggest this ''first ingredient'' approach both for foods with small RACCs and as an alternative to the FGE requirement, not limited to foods with small RACCs. In the ''first ingredient'' approach, there would be no absolute amount of a food group required; the approach would require only that the component from a qualifying food group would be the ingredient of the greatest weight in a food.

(Response 11) We decline to adopt the ''first ingredient'' approach suggested by the comments. The regulations regarding ingredient declaration require only that ingredients be listed in descending order of predominance by weight (21 CFR 101.4(a)). A descending order by weight does not, however, provide any indication of a significant or meaningful amount of an ingredient. Being listed first in the ingredient declaration only indicates that a food has proportionally more of that ingredient compared to each of the other ingredients individually. For example, a food could contain 10 different ingredients, and, although the first ingredient may weigh more than each of the other nine ingredients individually, the total sum of the other nine ingredients could proportionally outweigh the first ingredient. The overall food in that case would not be likely to have a significant amount of the first ingredient from a recommended food group and therefore would not meaningfully contribute to the recommended daily food group amounts. Therefore, using the first ingredient in an ingredient list to determine FGEs would not be a reliable way to help consumers identify foods that can help them meet recommended food group amounts, nor would it effectively address challenges related to the qualification of foods with small RACCs. As discussed in Response 8, the rule includes criteria specific to small RACC foods.

(Comment 12) Many comments request that FDA provide more guidance on what counts as an FGE and how to calculate the FGE contribution of a food. The comments note that the proposed FGE amounts are in volume, and that the volume of a food will vary considerably based on the form of the food. Some comments ask that FDA provide a standard methodology, calculator, and/or database that manufacturers could use to determine FGEs for their products.

(Response 12) We determined FGE amounts based on the cup- and ounce-equivalents developed for the Healthy U.S.-Style Dietary Pattern for ages 2 and older in the *Dietary Guidelines, 2020–2025* (Ref. 1). The *Dietary Guidelines, 2020–2025* provides information on the many types of foods that are contained in each food group in the food patterns (see Ref. 1, Appendix A3–2, footnote b) and descriptions of how much of those foods are needed to meet a cup- or ounce-equivalent (see Ref. 1, Appendix A3–2, footnote c). Additionally, there are other resources available, such as the FPED, which provides further information about cup- and ounce-equivalents of different foods and beverages (Ref. 3). FDA understands that, depending on the type and form of an individual food, manufacturers may benefit from additional information on how to determine the amount necessary to meet the FGE amounts required for their foods to be eligible for the ''healthy'' claim. The final rule sets a compliance date that is 3 years from the effective date, and we intend to provide additional resources to help manufacturers comply with the final rule before the end of the compliance period. The additional resources may take the form of guidance documents for industry, information on the FDA website, FAQs, direct communications in response to questions, or online webinars, as discussed in Response 6.

(Comment 13) Many comments request that FDA make clear that the list we provided for FGEs in the preamble to the proposed rule is not exhaustive.

(Response 13) The marketplace for food products is wide in scope and continually evolving and therefore cannot be comprehensively covered by the examples of FGEs described in this rule. Thus, the list of examples of FGEs we provided in the proposed rule and in the final rule is not an exhaustive list.

2. FGEs Based on Four Eating Occasions Per Day

(Comment 14) Some comments express concern with the assumption in the proposed rule that the typical American dietary pattern consists of three meals and one snack per day (*i.e.,* four eating occasions). The comments assert that the dietary habits of Americans have shifted over the past several years from a primarily meal-based diet to one that includes more snacking or ''ready to eat'' meals. The comments suggest that FGEs should not be based on a consumption pattern of four eating occasions per day. Another comment notes that the recommendations in the *Dietary Guidelines, 2020–2025* were based on the assumption that Americans consume three meals per day and two snacks.

Some comments question the equal division among the four eating occasions. For example, some comments suggest that snacks should be weighed differently than meals due to size. One comment recommends that meals carry three times the ounce equivalent (oz-eq) as a snack for the nutrient recommended daily allowance.

(Response 14) Our review of consumption patterns indicates that the typical American dietary pattern consists of three meals and one snack per day, *i.e.,* four eating occasions (not including beverage-only eating occasions) (Ref. 2). These data signify that individuals have four opportunities in a day to meet the recommended daily food group amounts in the Healthy U.S.-Style Dietary Pattern, and thereby satisfy their nutritional needs. The food group amounts recommended by the *Dietary Guidelines, 2020–2025* (*e.g.,* 2 c-eq/day of fruit) are total recommended amounts for the day, not for individual foods, meals, or snacks. The recommended daily amounts of food groups provided by the *Dietary Guidelines, 2020–2025* are not dependent on number of eating occasions. In determining the food group requirements for ''healthy,'' the total daily amount of food groups are divided across the number of eating occasions as determined by the data from national consumption surveys. National consumption data over the last several decades, (*i.e.,* the USDA Continuing Survey of Food Intakes by Individuals 1989–91 and Diet and Health Knowledge Survey 1989–91 (CSFII/DHKS 1989–1991) through the 2015–2016 National Health and Nutrition Examination Survey

(NHANES)) (Refs. 2, 36, and 37) demonstrate that the highest percentage of the U.S. population ages 4 and older reported four eating occasions per day. Note that we excluded beverage-only eating occasions from our analysis of the 2015–2016 NHANES data to focus only on eating occasions that provided consumers with a meaningful opportunity to consume foods from all the recommended food groups.

While some comments question the equal division among the four eating occasions, we decline to change this method for the final rule. For this rule, we analyzed the most current national consumption data, the 2017-March 2020 NHANES (Refs. 2 and 38), and determined that the median number of eating occasions (meals plus snacks) per day continues to be four eating occasions (not including beverage-only eating occasions) (Refs. 2 and 38). The data from NHANES 2017–2020 describe both the number of meals eaten per day and the number of snacks eaten per day. The data demonstrate that the highest percentage of people reported eating three meals per day. The highest percentage of people also reported eating one snack per day. Analysis of the combined eating occasion data show that the highest percentage of people reported having four eating occasions per day (meals plus snacks). We note that a study cited in the comments examined the same NHANES data that we used in our analysis. However, the study considered reports of beverage-only occasions whereas we excluded beverage-only occasions. Therefore, total number of eating occasions are different.

The typical sizes of meals and snacks may differ but are not weighted differently when dividing the recommended daily food group amounts to determine the FGE amounts. This is because the meals and the snack are all eating occasions that provide consumers with an equal opportunity to consume foods from the recommended food groups. For example, the recommended daily amount for fruit is 2 cups per day, and consumers have the opportunity to consume fruit at all three meals and at a snack. Therefore, it is reasonable to divide the recommended daily amount for fruit among the four eating occasions equally, which results in an FGE amount of ½ c-eq of fruit (2 c-eq divided by four eating occasions). We further note that this method is consistent with FDA's method in previous labeling rulemakings and relies on the same rationale (see final rules on general requirements for health claims and nutrient content claims in food labeling, 58 FR 2478 at 2495 and 58 FR 2302 at 2379–2380).

3. FGEs for Vegetables

(Comment 15) Some comments request that FDA provide more guidance on how to convert various forms of fruit and vegetable groups into a ½ c-eq vegetables per RACC that we proposed as the FGE amount for vegetables, taking into consideration the changes in density that occur from processing steps such as chopping, pureeing, grating, and cooking. The comments also ask that FDA provide guidance on how to convert dried fruits and vegetables, including those in powdered forms, into the whole equivalent ''single strength'' form for purposes of determining the food group contribution.

(Response 15) We are aware that the examples of FGEs described in the proposed rule did not represent all possible forms of foods, including different forms of vegetable products, such as chopped, dried, or grated vegetables. However, as noted in the proposed rule, the FGEs are based on the cup- and ounce-equivalents developed for the *Dietary Guidelines, 2020–2025* (Ref. 1). The *Dietary Guidelines, 2020–2025* and the FPED (Ref. 3), which is used to develop the Healthy Dietary Patterns for the guidelines, provide detailed information about cup- and ounce-equivalents of different foods and beverages and are resources that can help manufacturers determine the appropriate FGE amounts. For example, the FPED describes that sliced, diced, or chopped raw vegetables are given the same cup weight and the cup weights are typically the average weights of different cuts. The FPED provides the example of raw carrots which are assigned a 125-gram cup weight, which is an average of one cup of sliced (122 g) and chopped (128 g) carrots (Ref. 3). We note that, as explained in Response 44, vegetable powders may be considered in the calculation of vegetable FGEs, which represents a change from the proposed rule.

(Comment 16) Some comments support FDA's approach to include FGEs in the proposed ''healthy'' criteria on the basis that it would encourage increased consumption of fruits and vegetables but assert that the proposed approach to FGEs may limit products that can meet the requirements because they do not provide the required amount of FGEs. The comments assert that FDA should allow products to count ''partial FGEs,'' which could allow additional products to meet the FGE requirement for vegetables.

(Response 16) As explained in Response 8, we do not intend to exclude foods consumed in small amounts that are recommended for healthful dietary patterns, including various vegetable products. Thus, we revised the rule at § 101.65(d)(3)(ii)(B) to provide methods for addressing the qualification of foods with small RACCs. We also revised the rule, at § 101.65(d)(i), to include a single-ingredient exemption, which expands the exemption for raw, whole fruits and vegetables to other nutrient-dense forms of fruits and vegetables (as well as to foods in other food groups). The expanded exemption will result in more fruit and vegetable products (*i.e.,* single-ingredient fruits and vegetables without added ingredients besides water) qualifying for ''healthy,'' regardless of their RACC size (*e.g.,* chopped or frozen fruits and vegetables). This single-ingredient exemption is discussed in Response 9.

(Comment 17) Some comments urge FDA to consolidate the food groups for fruits and vegetables. The comments assert that combining the fruit and vegetable food groups would avoid ''arbitrary distinctions'' for products that contain a mixture of fruits and vegetables, and that a product that contains meaningful amounts of fruits, vegetables, or fruits and vegetables together should be treated the same, regardless of the precise contribution to the fruit group versus the vegetable group. One comment requests that FDA combine the fruit and vegetable groups for children ages 1–3 to provide flexibility for foods that contain meaningful amounts of fruits and vegetables collectively.

(Response 17) We decline to combine the fruit and vegetable food groups in this final rule. Fruits and vegetables are considered different food groups in the Dietary Guidelines and have separate daily recommended intake amounts. As noted on the MyPlate website (*https://www.myplate.gov/*), while botanically, most vegetables are considered fruits, the two groups are separated for nutritional and culinary purposes, meaning distinctions are made based on nutrient content, use in meals, and taste (*e.g.,* fruits are generally considered sweet or tart, while vegetables are not). Each food group provides a particular array of nutrients, and the recommended intake amounts of the different food groups reflect dietary patterns that are associated with positive health outcomes (Ref. 1). Healthy dietary patterns include intakes of foods from across the different food groups recommended by the Dietary Guidelines, including the fruit and vegetable food groups. Thus, vegetables

and fruits are distinct food groups that contribute their own nutrients and have separate recommended amounts for healthy dietary patterns. This distinction is applicable to foods directed at all ages, including foods intended for consumption by children over 2 years of age. As discussed in the Dietary Guidelines, individuals in all life stages are encouraged to consume foods from across all food groups to meet nutrient intake needs. Finally, the comments suggesting combining the vegetable and fruit group FGEs did not provide information on the benefits of combining the two food groups nor the effects such an action would have on the ability to construct healthy dietary patterns, and thus we have no basis on which to make such a change.

Considering the conventional distinction between fruits and vegetables in diets and food preparation purposes, the differences in nutrient contributions from the two food groups, and consistency with the Dietary Guidelines, we do not agree that the vegetable and fruit food groups should be combined. The rule, therefore, retains the framework of the vegetable food group and fruit food group as two distinct food groups. However, we have modified the criteria in other ways to provide additional flexibility for mixed products, for example, with the expanded single-ingredient exemption for nutrient-dense foods encouraged by the Dietary Guidelines (see Response 9, § 101.65(d)(3)(i)), and for mixed products, main dishes, and meals, for example, through added flexibility in the proportions required for FGE requirements (see Response 106, § 101.65(d)(3)(iii)–(v)). These modifications should help address the comments' concerns relating to the requirements for mixed products containing a mix of fruits and vegetables. For example, mixed products, such as a frozen mix of fruit and vegetables or a blend of 100% juices that contains 80% fruit juice and 20% vegetable juice, that do not contain additional ingredients besides water, will automatically qualify to bear the claim under the expanded single-ingredient exemption.

4. FGEs for Fruits

(Comment 18) Some comments request that FDA provide more guidance on how to convert various forms of fruit and vegetable groups into a ½ cup, taking into consideration the changes in density that occur from processing steps such as chopping, pureeing, grating, and cooking. One comment notes that moisture and solid levels vary among fruits and vegetables, and the conversion of 1 cup fresh or cooked fruits or vegetables to ½ cup dried fruits and vegetables may not accurately reflect all types of fruits and vegetables. The comment requests that FDA allow food companies flexibility to use reasonable options for determining FGEs of their products when converting between dried and rehydrated forms of fruits and vegetables.

(Response 18) We recognize that additional information on FGEs may be helpful and we respond to the comments requesting options for determining FGEs for different forms of fruit products, such as dried and rehydrated fruits (with regard to both vegetables and fruits) above in section V.C.3 (''FGEs for Vegetables''). We also provide information about available resources to support the determination of FGE amounts in Response 6 and 12.

(Comment 19) A number of comments do not support a ''healthy'' claim being on 100% fruit juice. One comment provides that, although 100% fruit juice in small amounts may offer a way for people to obtain important nutrients and contribute to dietary recommendations for fruit intake, 100% fruit juice is likely to be overconsumed because of its high palatability and accessibility. The comment says that the presence of a ''healthy'' claim may promote excess consumption of 100% fruit juice, which could contribute large amounts of unnecessary calories and sugar to the diet. Some comments note that the *Dietary Guidelines, 2020–2025* provides that whole fruit is the preferred way to meet the recommended fruit intake amounts.

(Response 19) We disagree that 100% juice should not be able to qualify to bear the ''healthy'' claim. The *Dietary Guidelines, 2020–2025* states that foods in the fruit food group include both whole fruits and 100% juice, and the Healthy U.S.-Style Dietary Pattern for ages 2 and older includes 100% juice as a food that contributes to the healthy dietary pattern. As discussed in the 2020 DGAC report, 100% juice is a nutrient-dense food that does not contribute energy through added sugars and contributes to meeting nutrient and food group needs (Ref. 8). The comments suggesting that 100% fruit juices being labeled as ''healthy'' may promote excess consumption do not provide evidence that would contradict or cause us to question the *Dietary Guidelines, 2020–2025.* As discussed elsewhere, the purpose of this rule is to help consumers identify foods that are particularly useful in creating a diet that is consistent with dietary recommendations. Based on the contributions of 100% juice, including both fruit and vegetable juice, to healthy dietary patterns as presented in the *Dietary Guidelines, 2020–2025* and Healthy U.S.-Style Dietary Pattern for ages 2 and older, we are including 100% fruit and vegetable juice among foods that are eligible to bear the ''healthy'' claim (Ref. 1). Additionally, we include in this rule a single-ingredient exemption for nutrient-dense foods that are encouraged by the Dietary Guidelines with no added ingredients, except for water (see Response 9).

(Comment 20) Some comments do not support fruit puree and fruit paste being able to qualify for the ''healthy'' claim because, according to the comments, they often do not contain fiber-containing parts of the whole fruit and are seldom consumed independently. For example, if the whole fruit or vegetable is not used in making the purees or pastes, such as if the skin is removed from apples before making applesauce, then the purees could have lower fiber content than the whole fruit or vegetable.

(Response 20) As stated in the proposed rule (87 FR 59168 at 59184), FDA considers concentrated fruit and vegetable purees and pastes to be fruits and vegetables for the purpose of calculating FGEs because these products are essentially fruits and vegetables that have been processed to change the physical form of the fruit or vegetable and to remove moisture. While removal of the skin of fruits and vegetables for concentrated fruit and vegetable purees and pastes may affect total fiber content compared with whole, intact fruits and vegetables, the *Dietary Guidelines, 2020–2025* includes purees, such as applesauce, in the food groups for fruits without qualification related specifically to fiber content. Fruits and vegetables provide a wide array of nutrients and are consumed in a wide variety of forms. Some forms of fruits and vegetables are consumed without skins, even when the skins are edible, such as in canned and frozen varieties. Even with the removal of fruits and vegetable skins, the overall nutrient profiles of purees and pastes remain within the range of the varied available forms of fruits and vegetables. For the development of the Healthy U.S.-Style Dietary Pattern, the FPED also included applesauce puree with a c-eq of 245 g. Similarly, pastes, such as tomato paste, are included in the food group for vegetables and the FPED provides a c-eq of 120 g. Fruit and vegetable purees and pastes are foods that are included in the fruit and vegetable food groups in the Dietary Guidelines. Thus, under the final rule, fruit and vegetable purees and paste are eligible to bear a ''healthy''

claim as individual vegetable foods, if they meet the applicable FGE and NTL criteria (see § 101.65(d)(3)(ii)). Furthermore, fruit and vegetable pastes and purees that contain no other ingredients, except for the addition of water, would be included under the single-ingredient exemption (see Response 9, § 101.65(d)(3)(i)). In addition, although fruit pastes and purees can be used as ingredients in foods such as yogurts and bakery products, the mere presence of pastes and purees in those products does not enable such products to qualify for use of the claim. Food products, such as bakery products containing fruit pastes and purees, would continue to be evaluated based on the overall criteria set forth for their food category. Likewise, packaged products of fruit pastes and purees would be evaluated on the criteria set forth for fruit products, regardless of any potential use as ingredients in other food products.

5. FGE for Grains and Whole Grains

(Comment 21) Many comments support the general approach to grain products (*i.e.,* that grain products must contain a ¾ oz-eq of whole grains to bear the ''healthy'' claim) and mention that the approach supports consumers in achieving the Dietary Guidelines recommendation that at least half of total grains consumed be whole grains. However, some comments assert that grain products should have to meet additional criteria to qualify for the ''healthy'' claim, such as being required to be nearly 100% whole grain and minimally processed.

(Response 21) We developed the FGEs to help consumers identify foods that can help them meet the recommended daily food group amounts as described in the *Dietary Guidelines, 2020–2025* and the Healthy U.S.-Style Dietary Pattern. Whole grains are grains that have the entire grain kernel, which includes the bran, germ, and endosperm, while refined grains have been processed to remove the bran and germ. Some refined grains are enriched. Enriched grain products are refined grains that have specific nutrients added back to replace losses of the nutrients that occur during processing (Ref. 4). Setting the FGE for grain products at ¾ oz-eq of whole grains helps consumers identify foods that can help them meet the recommended 3 oz-eq of whole grains per day. Although some comments suggest that grain products labeled ''healthy'' should be entirely whole grains and/or minimally processed, we find that those conditions are unnecessary if the food contains an FGE of whole grains. A food that contains a full FGE of whole grains, but is not 100% whole grain or is processed, still contributes to meeting the recommended daily amount of 3 oz-eq of whole grains per day, which supports the primary objective of the FGEs. Therefore, we decline to require proportions of overall whole grains or processing limitations to whole grain foods beyond the criteria set in the definition. We note that the *Dietary Guidelines 2020–2025* recommends that any refined grains that consumers choose be enriched grains.

(Comment 22) Some comments request that we adjust the proposed FGE requirement for whole grains to align with the recommendations in the *Dietary Guidelines, 2020–2025,* which is 8 g of whole grains per 1 oz-eq (*i.e.,* if half of the grains are whole grains). One comment provides that the *Dietary Guidelines* recommends 6 ounce-equivalents of grain foods per day, with at least half of those being whole grains. According to the comment, under the proposed rule, foods with 8 g whole grain per oz-eq that meet the nutrient limits for saturated fat, added sugars, and sodium would not qualify for the ''healthy'' claim. The comment suggests that FDA align the whole grain threshold with the recommendations in the *Dietary Guidelines, 2020–2025* of 8 g per oz-eq. The comment also recommends that the requirements for the whole grain criteria be provided in grams present per reference amount.

(Response 22) Although the *Dietary Guidelines, 2020–2025* provides individuals with multiple strategies to facilitate shifts in eating habits, the primary objective of the food group recommendations is to help consumers meet the recommended 3 oz-eq of whole grains per day. Both the *Dietary Guidelines, 2020–2025* and the FPED explain that a 1 oz-eq of whole grains is 16 g of whole grains. The comments suggest that the criteria should align with one of the strategies to facilitate shifts in eating habits discussed in the *Dietary Guidelines, 2020–2025* to choose foods whose grain components are comprised of at least 50% whole grains, which would be 8 g per oz-eq. However, the FGE requirement for whole grains included in the updated ''healthy'' criteria is based on the Dietary Guidelines' recommended amount of 3 oz-eq of whole grains per day. To determine the amount of FGE required for a food to bear the ''healthy'' claim, the recommended daily food group amounts are divided among the four eating occasions typically consumed. Consequently, the rule sets the FGE for grains at ¾ oz-eq of whole grains (see § 101.65(d)(2)), which would be calculated as 12 g of whole grains per RACC (16 g of whole grains multiplied by ¾). Therefore, we are not lowering the amount of whole grains needed to qualify, as the goal of this FGE is to help consumers identify foods that can help them reach the 3 oz-eq per day recommended for whole grains. The strategies discussed in the *Dietary Guidelines, 2020–2025* to help people consume more whole grains can be helpful, however, and can be communicated to consumers in many ways, both on food labels and through communications and education outside of labeling.

Additionally, we decline to shift to using gram amounts as the basis for compliance with the FGE requirements, as suggested by the comment. As discussed in Response 33, the concepts of cup and ounce equivalents incorporate the calculation of the specific gram weights of individual foods. The use of oz-eq for the whole grain FGE allows for the calculation of gram amounts for individual foods. FGEs in cup- and ounce-equivalents allow for the calculation of specific amounts of FGEs in foods, including in grams, that exist in a wide variety of forms and that could be measured in different measurement units.

(Comment 23) Some comments on the whole grain FGEs request that we provide additional guidance and examples on how to calculate the FGEs. The comments also indicate that the FGE calculations could potentially exclude a wide variety of foods which are inherently whole grain, such as whole wheat flour, and foods made from whole grains, such as whole wheat bagels.

(Response 23) We discuss some examples of resources for the determination of FGE amounts in Response 12. As noted in Response 12, the final rule sets a compliance date that is 3 years from the effective date, and we intend to provide additional resources to help manufacturers comply with the final rule before the end of the compliance period. Additionally, because of the single-ingredient exemption that we are providing (§ 101.65(d)(3)(i)), single-ingredient whole grains that meet the criteria for the single-ingredient exemption would automatically qualify for the claim without having to meet FGE or NTL criteria.

(Comment 24) Several comments assert that refined grain foods with an inherent or fortified nutrient to encourage should be able to bear a ''healthy'' claim as they can be part of a healthy dietary pattern and are encouraged by the *Dietary Guidelines,*

2020–2025. The comments mention that the *Dietary Guidelines, 2020–2025* does not require that all grains are whole, but instead encourages people to ''make half their grains whole'' and to choose enriched grain products when consuming refined grains. The comments provide that enrichment and fortification of grains improves intake of several nutrients, including nutrients such as iron and folate, which are critical for women of childbearing age.

Some comments note that although FDA's food group approach to ''healthy'' labeling is conceptually reasonable and may work well for some food groups, the approach raises concerns when applied to the grain group. The comments urge FDA to ensure that the ''healthy'' criteria do not unintentionally discourage consumption of other grain foods recommended by the Dietary Guidelines, including enriched grains, asserting that less than 8% of Americans consume the minimum recommendation for whole grain foods and that fiber is an underconsumed food component. The comments ask that the ''healthy'' labeling distinguish staple grain foods from ''indulgent grain products'' that should be consumed less often.

Another comment asserts that the ''healthy'' nutrient content claim should allow refined or enriched grains to use the healthy claim if they provide a good or excellent source of fiber and meet the added sugar, saturated fat, and sodium limits. According to the comment, the main concern cited in the *Dietary Guidelines, 2020–2025* regarding refined grains is that they commonly contain added sugar, sodium, and saturated fat. The comment states that if a product meets the criteria for added sugars, sodium, and saturated fat and contains one or more components of public health concern (*i.e.,* those that are underconsumed in the U.S. population) at meaningful levels, that product should be included in a healthy eating pattern.

(Response 24) As previously stated, the purpose of the ''healthy'' claim is to highlight those foods that are particularly useful in creating a diet that is consistent with current dietary guidelines. For grains consumption, the *Dietary Guidelines, 2020–2025* states that healthy dietary patterns include whole grains and limit the intake of refined grains. While refined grains can be included in a healthy diet, the objective identified in the *Dietary Guidelines, 2020–2025* is to meet the recommended daily amount of grain foods intake mostly through whole grains. Most Americans already meet the recommendations for overall grain intake in their diets. However, 98% do not meet the whole grain intake recommendations, and 74% consume more refined grains than recommended (Ref. 1). The ''healthy'' claim can help consumers identify the whole grain foods that are characteristic of a healthy dietary pattern so that they may shift grain consumption from predominantly refined grains to more whole grains. Although we recognize that some refined grain foods are staple foods for some groups and may contain important nutrients such as iron or fiber, they are not among the core elements included in healthy dietary patterns. For this reason, the FGEs for grain foods in the rule are set to a specific amount of whole grains, not refined grains (§ 101.65(d)(2)). Additionally, a food that contains a full FGE of whole grains, but is not 100% whole grain (*i.e.,* also contains refined grains), could still meet the FGE criteria to qualify for the ''healthy'' claim. Even though the food is not 100% whole grain, it would still contribute to meeting the recommended daily amount of 3 oz-eq of whole grains, which supports the primary objective of the FGEs. While certain foods containing refined or enriched grains may not contain any whole grains, they could contain full FGEs from other food groups, such as vegetables. Based on the entire composition of the food product and the presence of other food group components, these products may also be able to qualify for the ''healthy'' claim.

(Comment 25) A number of comments mention that the proposed rule would disqualify many grain foods, including the majority of ready-to-eat cereals on the market, from using the term ''healthy.'' The comments note that research shows ready-to-eat cereal is one of the most affordable, accessible, and nutrient-dense breakfast choices a person can make.

(Response 25) As discussed in the previous response, whole grains are core elements of a healthy dietary pattern; accordingly, the rule sets the grain FGE with whole grain requirements and does not include requirements for refined grains. Ready-to-eat cereals that are comprised primarily of refined grains instead of whole grains may not be able to meet the FGE for whole grains in the rule and qualify for use of the ''healthy'' claim. However, there are many cereals on the market that are made with whole grains, and our review of the current food marketplace showed that many of these cereals contain the rule's required FGE amount of whole grains (Ref. 2). Furthermore, while there are cereals made with whole grains that do not currently meet the FGE for whole grains in the rule, some have levels of whole grain that are close to the ¾ oz-eq FGE amount, and manufacturers could choose to reformulate the product to meet the rule's FGE requirement, should they want the product to qualify for the ''healthy'' claim.

Ready-to-eat cereals currently made with refined grains, and those with whole grains in amounts that do not meet the required FGE amount, can still play a role in the diets of consumers. Foods that do not qualify for use of the claim are not necessarily ''unhealthy'' or unable to provide any nutritional benefits to consumers. As previously discussed, the purpose of the ''healthy'' claim is to highlight those foods that are particularly useful in creating a diet that is consistent with current dietary guidelines. Ready-to-eat cereals, especially those without or with low levels of added sugars, sodium, and saturated fat, can provide numerous nutrients, such as iron or folate, and manufacturers can continue to communicate those nutritional attributes in many different ways.

(Comment 26) One comment requests lowering the proposed ¾ oz-eq of whole grain per RACC requirement for products with a RACC of 15 g or less to 0.375 oz-eq per RACC. The comment expresses that many of its products that mainly contain whole grains would be unable to qualify as ''healthy'' under the proposed rule because, given their small RACC, they would not be able to meet the ¾ ounce-equivalent of whole grain.

(Response 26) As discussed earlier, we acknowledge that certain foods recommended by current nutrition science and Federal dietary guidance would be unable to meet the proposed criteria for the healthy claim due to being typically consumed in small amounts. Therefore, the rule now applies the ''healthy'' criteria to individual foods with a RACC of 50 g or less or 3 Tbsp or less on a per 50 g basis instead of a per RACC basis (see § 101.65(d)(3)(ii)). Applying the ''healthy'' criteria to grain products that have RACCs of 15 g on a 50 g basis, results in foods of this RACC size to meet the FGE of ¾ oz-eq of whole grains. For example, a grain food with a RACC of 15 g that contained 0.375 oz-eq of whole grains, which would be equal to 6 g of whole grains, can qualify on a per 50 g basis. The calculated amount of whole grains in that food would be 20 g of whole grains per 50 g (50 g divided by 15 g and then multiplied by 6 g and then rounded up to 20 g). This food qualifies for the FGE of ¾ oz-eq (12 g). Therefore, lowering the FGE amount, as suggested in the comment, is unnecessary, and the

concern raised by the comment is addressed by the fact that foods of that RACC size can now meet the whole grain FGE on a per 50 g basis. As such, we decline to lower the FGE amount. The final rule retains the FGE requirement for grains of ¾ oz eq whole grains (§ 101.65(d)(3)(ii)(B)).

(Comment 27) Some comments express that FDA's sole focus on whole grains as the criteria for grain products to qualify for the ''healthy'' claim is overly simplistic and would not address the Dietary Guidelines recommendations of a balanced diet. The comments request that FDA provide updated educational resources for consumers on choosing all types of grains, including enriched refined grains without solid fats or sugars, to meet Dietary Guidelines recommendations.

(Response 27) The objective of the *Dietary Guidelines, 2020–2025* is to encourage consumption of those foods and food groups that are common in healthy dietary patterns, and the ''healthy'' claim can help consumers identify foods that are particularly useful in helping them achieve a diet consistent with current dietary recommendations. We explained earlier why the criteria for the ''healthy'' claim will focus on whole grains and not refined grains, as whole grains are core elements of healthy dietary patterns. For the same reasons, we intend to focus our educational efforts on consumption of whole grains. We have, however, expressed throughout this rule that foods that are unable to qualify for the ''healthy'' claim are not ''unhealthy'' and can still be incorporated as part of a healthy dietary pattern. We plan to also incorporate this messaging in consumer education efforts related to the ''healthy'' claim.

(Comment 28) One comment asserts that the labeling of grain foods is confusing in part due to misleading advertising and encourages FDA to improve the labeling of whole grains to improve transparency for consumers. The comment asks that whole grain products that meet the criteria for the ''healthy'' labeling claim be required to disclose the percentage of both whole and refined grains.

(Response 28) We have determined that setting the FGE for grain products at ¾ oz-eq of whole grains helps consumers identify foods that can help them meet the *Dietary Guidelines, 2020–2025* recommended 3 oz-eq of whole grains per day. A food that contains a full FGE of whole grains, but is not 100% whole grain, still contributes to meeting the recommended daily amount of 3 oz-eq, which supports the primary objective of the FGEs. For these reasons, we decline to require additional information about grain content or any other qualifying criteria as part of the ''healthy'' claim. However, if manufacturers choose to do so, they may use other claims and truthful and non-misleading statements about the nutritional qualities of their foods in addition to the use of the ''healthy'' claim. For example, a food that bears a ''healthy'' claim could also make claims about whole grain or fiber content, provided that the food meets all applicable requirements for such claims.

6. FGE for Dairy

(Comment 29) Some comments disagree with the proposed ¾ c-eq per RACC for the dairy group to qualify for the ''healthy'' claim, stating that it is confusing to consumers and places an unnecessary burden on industry. The comments assert that the ¾ c-eq for dairy is less actionable for consumers because it does not equate to a recommended serving as provided in the *Dietary Guidelines.*

Some comments urge FDA to adopt an FGE of ½ c-eq dairy for natural cheese. The comments note that few cheeses would qualify for the ''healthy'' nutrient content claim under the proposed ''healthy'' definition. A number of comments assert that using the proposed ¾ c-eq for dairy would cause many cheeses, including fat-free or low-fat forms, to be unable to bear the ''healthy'' claim, based solely on the amount of serving equivalents set by the *Dietary Guidelines, 2020–2025* and the defined RACCs. The comments also state that it may be difficult to determine whether a cheese is eligible for a healthy claim, because cheeses have varying weights and densities.

(Response 29) In response to these comments, we reviewed the current marketplace related to the RACC sizes of different dairy products and the amounts of FGEs contained in those foods (Ref. 2). This review showed that the comments were correct that a number of dairy foods, including some cheeses and many yogurts, would not meet the proposed FGE of ¾ c-eq of dairy. However, the amount of dairy in many of those products was close to meeting the FGE amounts (ranging from about 0.69 to 0.71 c-eq per RACC). Dairy products, including milk, yogurt, and cheese, especially in fat-free and low-fat forms, are included in the *Dietary Guidelines, 2020–2025* as core elements of healthy dietary patterns. Although the proposed FGE threshold was set to help consumers identify foods that could help them meet the recommended daily amount of dairy, we do not intend to exclude nutrient-dense foods that are recommended for healthful dietary patterns. We have already addressed the issue of foods with small RACCs in Response 8 and the methods provided for addressing small RACC foods will result in many dairy foods with small RACCs, such as natural cheeses, being able to meet the FGE amounts. However, there are some other dairy foods that do not have small RACCs and that still would not meet the FGE amounts. Therefore, we have revised the FGE threshold for dairy in the rule to ⅔ c-eq per RACC (see § 101.65(d)(2)). Examples of ⅔ c-eq of dairy are ⅔ cup fat-free or low-fat milk, yogurt, or lactose-free versions of these products, or fortified soy beverage or yogurt alternatives; and 1 oz natural cheese or ⅔ oz processed cheese.

As discussed, the FGE threshold was set to help consumers identify foods that could help them meet the recommended daily amount of dairy, which is 3 c-eq per day. With an FGE set at ⅔ c-eq and an opportunity for consumption at four eating occasions per day, the daily amount achieved would be 2 ⅔ c-eq of dairy per day (⅔ c-eq multiplied by four), and the total amount consumed would be close to the recommended 3 c-eq daily intake. Setting the FGE at a lower level will result in more dairy foods being able to meet requirements for the ''healthy'' claim, which could provide more dairy options labeled as ''healthy'' for consumers to choose from. Dairy products are underconsumed in the United States, with 90% of consumers not meeting the daily recommendation currently (Ref. 1). The adjustment to the dairy FGE is similar to how adjustments were made to some FGEs in the proposed rule, such as the vegetable food group, which is also underconsumed. Because vegetables are underconsumed with 90% of consumers not meeting the vegetable intake recommendation, the FGE amount was slightly rounded down to ½ c-eq. Setting the FGE requirements for underconsumed food groups at a slightly lower amount makes it easier for foods in those groups to qualify for the claim and allows for more foods on the market to be labeled ''healthy.'' More nutrient-dense dairy options being able to be labeled as ''healthy'' may help consumers in identifying and choosing nutrient-dense dairy options that can help them meet the daily recommendation.

Although some comments suggest setting the FGE threshold at even lower amounts than ⅔ c-eq, such as ½ c-eq, amounts lower than ⅔ c-eq would make meeting the daily recommended amount

for dairy difficult. Requiring a minimum of ⅔ c-eq for the dairy FGE to meet the FGE requirement for the ''healthy'' claim would enable consumers to identify dairy products that would help them approach meeting the daily recommended amounts for dairy and result in many nutrient-dense dairy options qualifying for the ''healthy'' claim. We note that the FGE amounts are criteria for manufacturers to use when determining if a product qualifies for the ''healthy'' claim. The presence of a ''healthy'' claim on a product that meets the criteria will simply help consumers to identify foundational foods for building healthy dietary patterns. To support this goal, we intend to engage in consumer education efforts related to the ''healthy'' claim.

(Comment 30) One comment notes that there are disparities in dairy consumption related to race and ethnicity, with non-Hispanic Black and Asian children and adults consuming the least amount of dairy. The comment also mentions that lactose intolerance is significantly more prevalent among Black and Hispanic Americans than in non-Hispanic white populations, and that natural cheeses such as cheddar, mozzarella, and Monterey Jack are ''virtually lactose-free'' dairy options upon which individuals with lactose intolerance rely. According to the comment, limiting the labeling of cheese as a ''healthy'' food could further widen the disparity gap in dairy consumption. The comment asserts that dairy consumption needs to be encouraged across age, race, and ethnic groups to achieve the daily dairy recommendation as a part of healthy eating patterns to help advance health equity. Some comments note that plant-based dairy foods are alternative dairy sources for those with lactose intolerance.

(Response 30) The criteria for foods to bear the ''healthy'' claim are intended to help consumers identify foods that are foundational to a healthy dietary pattern. As noted in Response 29, we have lowered the FGE amount for dairy to ⅔ c-eq, which will result in more dairy foods being able to meet the FGE requirements for the ''healthy'' claim and may result in more dairy options labeled as ''healthy'' for consumers to choose from (*e.g.,* more yogurts). There are other options in the dairy group for individuals who are lactose intolerant that could qualify for ''healthy,'' such as certain lactose-free versions of dairy products or certain dairy products that are naturally lactose-free. Also, fortified soy milk, and plant-based dairy alternatives with similar nutrient composition as dairy are included in the dairy food group for the purposes of the ''healthy'' claim, which can provide alternatives to individuals who are lactose-intolerant. The *Dietary Guidelines, 2015–2020* discusses that key nutrient contributions from dairy foods include calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, vitamin B12, zinc, choline, and selenium (Ref. 4). As we noted earlier in this rule, while not all dairy foods may qualify for use of the claim, the use of the ''healthy'' claim on some foods is not intended to signal that all other foods are ''unhealthy,'' including foods consumed by certain subgroups of the population (see section III.A (''Need for the Regulation/History of This Rulemaking''). Other foods are still available for consumption and manufacturers can communicate truthful and non-misleading information about lactose-free foods or information that encourages culturally appropriate consumption of dairy foods on the food label outside of use of the ''healthy'' claim.

(Comment 31) Some comments assert that ambiguity in the determination of the FGEs of certain dairy foods, including yogurt, could lead to inconsistency in manufacturer calculations of FGEs and confusion among consumers. A number of comments request that FDA provide a list, examples, or maintain a database for manufacturers to use in calculating the amount of FGEs delivered by each food.

(Response 31) The comments on the dairy FGEs echoed the requests in the comments across the food groups for guidance in determining the FGE amounts for foods in this group. We provide a general discussion on available resources to support determination of FGE amounts in Response 12. For example, fluid milks and yogurts are calculated at 245 g for a one c-eq in the FPED database (Ref. 3). As noted in Response 12, the final rule sets a compliance date that is 3 years from the effective date, and we intend to provide additional resources to help manufacturers comply with the final rule before the end of the compliance period.

(Comment 32) Some comments request guidance regarding what dairy alternatives might be considered ''healthy.'' Some comments note that, according to the Dietary Guidelines, alternative beverages such as almond, rice, coconut, or hemp milks are not nutritionally equivalent to milk and are therefore not included in the dairy foods group. The comments note that dairy foods contribute nutrients such as calcium, vitamin D, and potassium to the American diet. One comment provides that, according to the Dietary Guidelines, only fortified soy products are nutritionally similar to dairy products and can serve as a replacement to dairy products. However, other comments support the inclusion of plant-based dairy alternatives in the dairy group. The comments mention that many people do not consume dairy products for a variety of reasons, such as allergy, intolerance, cultural practices, or preference. Many comments that support inclusion of plant-based dairy alternatives in the dairy group request that FDA set forth specific nutritional criteria that plant-based dairy alternatives must meet to qualify for the ''healthy'' claim. One comment asserts that if FDA permits nutritional comparisons between plant-based and traditional dairy products through the use of the term ''healthy,'' then FDA should require the plant-based products to bear the imitation labeling outlined in § 101.3(e) (21 CFR 101.3(e)).

(Response 32) In the proposed rule (87 FR 59168 at 59187), we determined that including fortified plant-based dairy alternatives among the food options in the dairy group can help consumers identify foods that can help them increase their dairy group intake and meet the dairy group daily intake recommendations. We specifically limited plant-based milk alternatives and plant-based yogurt alternatives that could qualify for the claim to those products whose overall nutritional content is similar to dairy foods (*e.g.,* provide similar amounts of protein, calcium, potassium, vitamin D, and other nutrients) and are used as alternatives to milk and yogurt. We discussed in the proposed rule that, when the *Dietary Guidelines, 2020–2025* published, fortified soy beverages and yogurts were the only alternatives that were nutritionally comparable to dairy, and the composition data evaluated by the *Dietary Guidelines, 2020–2025* demonstrated that the nutrient content in fortified soy beverages and yogurts is similar to that of dairy. Plant-based dairy alternatives are formulated foods, with evolving compositions and formulations. It is possible that plant-based dairy alternatives from sources other than soy, such as almond milk or oat milk, may be produced with nutritional profiles similar to dairy. If plant-based dairy alternatives are formulated with nutritional profiles similar to that of dairy, then it would be appropriate for those products to be considered among the food options in the dairy group. Although not mentioned in the proposed rule, in

addition to plant-based milk and yogurt alternatives, plant-based cheese alternatives are also available on the market. Currently, these plant-based cheese alternatives do not have similar nutrient composition to cheese. However, as with plant-based milk and yogurt alternatives, it is possible that in the future plant-based cheese alternatives may be produced with nutritional profiles similar to that of dairy. If those food products were to become available, they would be considered under the criteria for the dairy group to qualify for use of the ''healthy'' claim. We reiterate that, for purposes of this rule, it is only those plant-based dairy alternatives that have similar nutrition composition to dairy that will be included in the dairy group for purposes of qualifying for the ''healthy'' claim. For example, soy-based yogurt alternatives would need to have similar nutrient composition to traditional milk-based yogurt. Plant-based milk alternatives would, likewise, need to have similar nutrient composition to milk to be considered under the criteria for dairy foods in this rule. While nutrient profiles can vary among different dairy foods, the *Dietary Guidelines, 2015–2020* discusses that key nutrient contributions from dairy foods include calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, vitamin B12, zinc, choline, and selenium (Ref. 4). We note that FDA has also published a draft guidance on the labeling of plant-based milk alternatives, and we requested comment on nutrient profiles of plant-based milk alternatives (Ref. 5). Requiring plant-based products to bear imitation labeling as outlined in § 101.3(e) is outside the scope of this rule.

(Comment 33) Some comments question the use of FGEs, cup- and ounce-equivalents for the criteria for dairy foods. One comment notes that FDA has departed from the use of a defined gram-basis, the RACC, or labeled serving size as the basis for the ''healthy'' claim, without explanation. The comment urges FDA to consider a basis that is specific to certain types of dairy foods or the RACC.

(Response 33) The claim ''healthy' is a nutrient content claim and the criteria are applied on a per RACC basis, as is typically the case with nutrient content claims. The NTL criteria in the ''healthy'' definition are based on grams or milligrams per RACC, similar to other claims, but are reflected as percentages of the DV to allow flexibility in the future if there are changes in the DV for these nutrients. The FGE criteria introduced in the ''healthy'' definition are applied on a cup- and ounce-equivalent per RACC basis to be consistent with how food group recommendations are provided for in relation to dietary patterns. The *Dietary Guidelines, 2020–2025* provides food group recommendations in cup- and ounce-equivalents, such as 3 c-eq of dairy per day for a reference 2,000-calorie diet. The daily recommended amounts of the food groups are spread out throughout the day across an individual's eating occasions. Therefore, the amounts per eating occasion are also in cup- and ounce-equivalents. The concept of equivalents, however, incorporates the calculation of the specific gram weights of individual foods. In the example used earlier in this section for fluid milk and yogurt, 245 g is a one c-eq, as calculated in the FPED database. Calculating the FGE of ⅔ c-eq results in an FGE amount of approximately 163 g for milk and yogurt. The use of cup- and ounce-equivalents allows for the calculation of specific amounts of foods that exist in a wide variety of forms.

(Comment 34) One comment asserts that FDA is providing plant-based dairy alternative products a competitive advantage because manufacturers of these products may choose between two different FGEs (protein foods or dairy).

(Response 34) As discussed in Response 35, there are some foods, namely beans, peas, and lentils, that may be considered under either the protein or the vegetable food group for calculation of FGEs. However, plant-based dairy products that are labeled and marketed as dairy alternatives will be evaluated against the criteria for the dairy food group for the purposes of the ''healthy'' claim, as discussed in Response 32. Therefore, manufacturers of plant-based dairy alternative products are not able to choose between two different food groups for the calculation of FGEs.

7. FGEs for Protein Foods

(Comment 35) One comment says that dry beans, dry peas, lentils, and chickpeas, known as pulses, are rich sources of protein, potassium, and dietary fiber, and provide other important minerals, such as magnesium, choline, and iron, and minimal amounts of added sugar, saturated fat, and sodium to the diet. The comment supports FDA's proposal to permit beans, peas, and lentils to be categorized as either a vegetable or a protein under the rule because the nutrient content is similar to other foods in both the protein and vegetable groups. The comment asserts that pulses are emerging in a variety of new forms, including flours, powders, spreads, purees, pastas, and proteins, and can be used in a wide variety of applications, such as pastas, plant-based entrees, baked goods, and beverages. The comment asserts that these varying forms contain the same nutritional benefits of pulses in their whole form and maintains that FDA should provide flexibility to allow for innovative pulse products to qualify as ''healthy.''

Other comments request that other sources of protein, including protein powders, isolates, and concentrates from whey, soy, and pea, be included in the protein foods group. The comments note that the *Dietary Guidelines, 2020–2025,* includes soy flour, soy protein isolate, and soy concentrate in the protein group and provides that soy includes tofu, tempeh, and products made from soy flour, soy protein isolate, and soy concentrate. The comments assert that all plant-based proteins should be considered part of the protein foods group.

(Response 35) In the proposed rule (87 FR 59168 at 59185), we stated that for individual foods, the nutrient content of beans, peas, and lentils is similar to foods in both the protein foods group and in the vegetable group and may be counted under either food group. Similarly, for combination foods, we proposed that beans, peas, and lentils could be counted as either a protein food or as a vegetable in a combination food (87 FR 59168 at 59191). Our position has not changed on beans, peas, and lentils and these foods can be considered under either of those food groups to qualify for the claim in this final rule. For consideration as vegetables, the FGEs for beans, peas, and lentils is ½ c-eq per RACC and for consideration as protein foods, the FGE is 1 oz-eq per RACC, consistent with the *Dietary Guidelines, 2020–2025* (§ 101.65(d)(3)(ii)).

The daily recommendation for protein foods in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 5½ oz-eq. For all the food groups, we calculated the FGE by dividing the daily amount by four eating occasions (5½ oz equivalents of protein foods divided by four is 1⅜ oz-eq). For the beans, peas, and lentils sub-category of protein foods, we set the FGE at 1 oz-eq, which is lower than 1⅜ oz-eq. We proposed rounding down to 1 oz-eq to increase the number of products containing these subgroups that would be eligible to bear the claim, consistent with the *Dietary Guidelines, 2020–2025,* which encourages consumption of such products (87 FR 59168 at 59188). The rule maintains the 1 oz-eq FGE for beans, peas, and lentils as it provides

sufficient flexibility for a variety of options of nutrient-dense protein foods, including pulses, to be eligible for the claim, which may help consumers identify foods that help them meet the daily recommended amount of protein foods. We decline to include protein isolates and concentrates when calculating what meets the FGE requirement for the protein group. The *Dietary Guidelines, 2020–2025* recommends following a healthy dietary pattern with a focus on meeting food group needs by consuming a variety of nutrient-dense foods and beverages and staying within calorie needs. Although the *Dietary Guidelines, 2020–2025* includes soy protein isolates and concentrates among examples of foods in the protein foods group, these components will not count toward meeting the FGEs for the protein foods group in the rule. The food group approach to the ''healthy'' claim represents a shift from focusing on individual nutrients to nutrient-dense foods. Nutrients that are extracted from foods, such as isolates and concentrates, are not whole, nutrient-dense foods but rather, individual nutrients such as those included in the original definition for the ''healthy'' claim. Because of the shift in the framework toward foods rather than individual nutrients, counting isolated or concentrated protein toward the protein FGEs would not be consistent with the ''healthy'' claim's focus on nutrient-dense foods that serve as the foundation of healthy dietary patterns. The presence of extracted components, such as isolates or concentrates, and information about any potential benefits, however, may be useful to consumers and manufacturers may communicate this information in other ways, (*e.g.,* nutrient content claims, health claims, and other truthful and non-misleading statements on the label).

(Comment 36) One comment asks that FDA provide additional guidance about converting all forms of pulses into c-eq as a vegetable or into ounce equivalents as protein. The comment mentions that the proposed rule does not include information regarding how to account for changes in volume from processing such as milling, grinding, chopping, pureeing, dehydrating, and cooking, and asks FDA to provide calculation guidance to help in determining compliance with the FGE criteria.

(Response 36) We provide information about available resources to support determination of FGE amounts in Response 12. For example, the FPED provides c-eq for beans and provides amounts for different forms such as cooked, uncooked (dry), and canned (Ref. 3). For varieties of a food that are cut pieces of the whole form, as with beans that are chopped, sliced, or ground, the total amount of food in a c-eq of whole food and the cut food would be the same. As noted in Response 12, the final rule sets a compliance date that is 3 years from the effective date, and we intend to provide additional resources to help manufacturers comply with the final rule before the end of the compliance period.

(Comment 37) One comment requests additional clarity regarding plant-based foods, including how ingredients like chickpea powder or legume powder would be treated and whether pea milk, almond milk, and other plant-based milks, whether fortified or not, would be considered protein foods.

(Response 37) Powders of protein products, such as chickpea powders or legume powders, can be included in FGE calculations provided that the powders are essentially the dried/dehydrated and ground forms of the original, whole food. Powders that have ingredients added to them or components of the food removed from them (other than water) would not be considered a form of the original food for the purposes of the ''healthy'' claim. The FPED provides an example for legumes, specifically soy flour, which has a 1 oz-eq of ½ oz (~14 g) (Ref. 3). Plant-based milk alternatives, such as pea milk or almond milk, would be evaluated against the criteria for the dairy food group and not the protein foods group and are discussed in the dairy section V.C.6 (''FGEs for Dairy'').

(Comment 38) A number of comments seek clarification as to whether coconut is considered a nut. One comment mentions that coconut is currently classified as a tree nut under the Food Allergen Labeling and Consumer Protection Act and provides that the saturated fat of a coconut is inherent to the coconut, as is the case with nuts. Other comments note that they are excluding coconut from their discussion of nuts and seeds (and would not support exclusion of saturated fat content of coconut from the overall saturated fat limit, as was proposed for nuts and seeds) because coconut is unusually rich in saturated fat.

(Response 38) While a coconut is botanically a fruit (specifically, a fibrous one-seeded drupe), the *Dietary Guidelines, 2020–2025* does not include coconuts in the nut or the fruit category. In addition, the FPED database used in the modeling of the U.S. Food Patterns describes the ''Nuts and Seeds'' category as ''Peanuts, tree nuts, and seeds; excludes coconut'' (Ref. 3). Instead, the FPED considers coconuts to be solid fats, listing coconuts with other examples of solid fats as ''Coconut meat, raw—Raw coconut meat containing 33.5 grams of fat per 100 grams.'' Because coconut meat contains total fat amounts of over 33 g per 100 g and most of the fat is saturated (29.7 g per 100 g) (Ref. 7), we have determined that coconuts will not be counted as contributing toward the protein foods group (*i.e.,* will not be considered a nut) or the fruit food group, consistent with the *Dietary Guidelines, 2020–2025.*

(Comment 39) Many comments request that FDA enable protein foods with small serving sizes to meet the definition of ''healthy.'' One comment notes that there are a number of nutrient-dense pulse products, such as hummus and roasted chickpeas, that would fall into the ''individual foods'' category but have small RACC serving sizes. The comment asserts that even though these foods provide important nutrients like dietary fiber and protein while providing minimal amounts of added sugar, saturated fat, and sodium, it is mathematically impossible for these small serving sizes to provide the minimum amounts of food groups required by the proposed rule criteria. The comment requests that FDA create a pathway for nutrient-dense foods with small RACCs and serving sizes to meet the definition of ''healthy.'' The comment mentions this could be achieved by allowing products with small RACCs and serving sizes that meet the maximum limits for added sugar, saturated fat, and sodium, to meet the ''healthy'' definition if their first listed ingredient is an NTE. The comment mentions another approach would be to require a smaller amount of FGE for these smaller sized products, such as ¼ FGE.

(Response 39) As discussed in Response 8, we do not intend to exclude nutrient-dense foods consumed in small amounts that are recommended for healthful dietary patterns, including certain protein foods. The final rule includes criteria specific to foods with small RACC sizes in § 101.65(d)(3)(iii)(B). Under the small RACC criteria, foods with a small RACC size (≤50 g) need to meet the criteria per 50 g, which will result in many foods with small RACC sizes being able to meet the FGE amounts. Additionally, with the expanded exemption for single-ingredient foods in § 101.65(d)(3)(i), as further discussed in Response 9, many foods with both larger RACC sizes and small RACC sizes, such as roasted chickpeas, will automatically qualify for the claim, as long as no other ingredients except for water are added.

The comments also mention hummus as a food with a small RACC that may not be able to qualify for the claim. Hummus, which has a RACC of 2 Tbsp, is a mixed product with a number of ingredients. Mixed products, such as hummus, would need to meet the applicable FGE amounts in addition to the NTL criteria to qualify for the claim, as discussed in section V.E.2 (''Mixed Products'').

(Comment 40) One comment supports FDA's inclusion of soy foods and soy milk in the rule but requests that we align the rule with FDA's authorized health claims and qualified health claims under 21 CFR 101.14. The comment notes that many soy foods are not eligible for the proposed ''healthy'' claim even though they are eligible for FDA authorized health claims and qualified health claims.

(Response 40) Foods and food components that are the subjects of health claims that FDA has authorized or for which it considers the exercise of enforcement discretion have an evidence-based relationship of risk reduction with a disease or health-related condition and the language in the health claim communicates this specific relationship. Although many foods that are the subjects of health claims do meet the requirements of the ''healthy'' nutrient content claim, not all foods that are the subject of a health claim are core elements of a healthy dietary pattern, and therefore would not necessarily qualify to bear the ''healthy'' claim (see section III. (''Background'') for further discussion of differences between different nutrition labeling claims).

Whether and how a soy food qualifies for ''healthy'' depends on the food's specific nutrient profile and role in the diet. Some soy foods, such as soybeans, qualify under the single-ingredient exemption (see Response 9). Other foods made from soybeans would be subject to the FGE amounts and NTL criteria for dairy (*e.g.,* soy milk) or for nuts, seeds, and soy products (*e.g.,* tofu) to qualify for the ''healthy'' claim.

8. FGEs for Oils

(Comment 41) A number of comments express support for FDA's proposal to include oils, which includes 100% oils, certain oil-based spreads *(i.e.,* those whose fat content comes solely from oil), and certain oil-based dressings (*i.e.,* those containing at least 30% oil and made from oils that meet the ''healthy'' definition) as a food group, viewing this as consistent with current nutrition science. The comments note that the *Dietary Guidelines, 2020–2025* does not categorize oils as a ''food group'' but emphasizes that oils are one of the six core elements of a healthy dietary pattern and recommends daily intake objectives for oils like the food groups.

Some comments do not support including ''oils'' as a food group. The comments express that allowing oils to be labeled as healthy may unintentionally communicate to consumers that oils are healthy in any amount and could lead to consumer confusion and overconsumption.

(Response 41) Healthy dietary patterns include foods such as vegetable oils with unsaturated fats and are lower in foods high in saturated fats, such as butter, shortening, lard, or coconut oil (Ref. 1). Strategies to shift intakes toward achieving a healthy dietary pattern include cooking with vegetable oils instead of fats like butter. Therefore, to reflect these shifts, as discussed in the Dietary Guidelines, we conclude it is appropriate for certain oils and oil-based products to qualify for the ''healthy'' claim. We are not, however, establishing an FGE for oils in foods made with these oils and oil-based products. We disagree with and are not aware of any information in the comments or elsewhere supporting the argument that including oils as a food group for the purposes of this rule may lead to consumer confusion and overconsumption. We note that we do intend to address oil consumption in our consumer education efforts related to the ''healthy'' claim.

(Comment 42) Some comments do not support allowing oil-based spreads and oil-based dressings to qualify to use the ''healthy'' claim due to concerns that many of these products contain ultra-processed or highly processed oil or other ingredients.

(Response 42) Oils are characteristic components of healthy dietary patterns, and this determination reflects that current dietary recommendations encourage a shift from use and consumption of saturated fats, such as in butter and many salad dressings, to spreads and dressings made predominantly of unsaturated oils. The oils in these foods may be processed to a greater degree than fats such as butter or lard; however, healthy dietary patterns which include unsaturated oils rather than fats high in saturated fats are associated with positive health outcomes (Ref. 1).

(Comment 43) One comment recommends that the requirement for oil-based dressing to have at least 30% oil be lowered to a level of 10% oil.

(Response 43) The replacement of oils for solid fats in the diet is a key reason for the inclusion of oils as core elements of healthy dietary patterns. Shifts from solid fats to unsaturated oils are important strategies for constructing healthy dietary patterns. Therefore, 100% oils and oil-based dressings and spreads that meet specific requirements can qualify for the ''healthy'' claim. Foods that are described as ''oil-based'' for the purposes of the ''healthy'' claim are not intended to identify foods that simply have oils as an ingredient. Rather, the foods identified as oil-based are intended to be foods where oil is a primary component. At ≥30%, oils would typically make up the largest component in the food, with the exception of water. Lowering the oil requirement to ≥10%, however, would not ensure that the food is an oil-based dressing with oils as the largest component, except for any water present. As discussed in the proposed rule, we did not set qualifying FGEs for the oils group, but instead, limit use of the claim to the oils themselves, oil-based dressings, and oil-based spreads, provided they meet the specified criteria. We decline to lower the minimum amount of required oil in oil-based dressings in the rule to 10% oil, consistent with the purpose of the claim and the *Dietary Guidelines, 2020–2025.*

9. FGEs for Fruit and Vegetable Powders

(Comment 44) In the proposed rule, we did not consider vegetable or fruit powders to be vegetables or fruits, respectively, for the purpose of calculating FGEs. Some comments support this approach. One comment asserts that vegetable powders should not qualify as vegetables for purposes of the rule because vegetable powders may be produced or used in a way that modifies the whole vegetable to an extent that removes some essential characteristics that are beneficial when consuming the whole vegetable, which could impact the nutrient content. The comment notes that diets high in vegetables and fruits are beneficial, in part, because the vegetables and fruits displace other less healthy foods, and states that it is unlikely that foods made with vegetable powders would have the same effect. The comment expresses concern that allowing a product with no recognizable vegetable in it to bear the ''healthy'' claim would send the wrong message to consumers. Another comment agrees with the exclusion of vegetable and fruit powders on the basis that they are often used to create ultra-processed snack foods such as vegetable sticks, puffs, and other snack foods that the comment describes as high in fat and salt and low in dietary fiber.

Other comments recommend that fruit and vegetable powders, or certain fruit and vegetable powders (*e.g.,* those with

similar nutrient composition as whole fruits and vegetables), be able to contribute to FGEs. For example, some comments ask that FDA allow fruit and vegetable powders that are not derived from juice to contribute to the fruit and vegetable food groups and ask that FDA provide guidance for calculating FGE contributions from fruit and vegetable powders. Several comments provide information or data demonstrating that different fruit and vegetable powders have similar nutrient composition as whole fruits and vegetables. For example, one comment provides an assessment of fresh, dried, and powdered legumes to support the inclusion of powdered fruits, vegetables, and legumes under the ''healthy'' definition. The comment relies on data from the USDA Standard Food Database to demonstrate that the nutritional composition of whole chickpeas, black beans, and navy beans are substantially similar to the powdered forms. The comment provides that chickpea flour, meal, and grits contain more protein and higher dietary fiber levels than a whole, raw chickpea, and mentions that USDA reports similar results for black beans and navy beans. The comments also note that FDA has recognized in its guidance, *Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals,* that fruit and vegetable powders that are not made from juices ''are essentially whole fruits and vegetables that have been processed to change the physical form of the fruit or vegetable to remove moisture.''

One comment supports the inclusion of dried juice powder if 100% juice counts toward the FGEs but provides no data or information to support their recommendation.

(Response 44) In the proposed rule (87 FR 59168 at 59185), we stated that we would consider concentrated vegetable and fruit purees and pastes to be vegetables and fruits for the purpose of calculating FGEs because these products are essentially whole vegetables and fruits that have been processed to change the physical form of the vegetable to remove moisture. We did not include vegetable and fruit powders for the purpose of calculating FGEs because of the potential for these products to be produced or used in a way that modifies the vegetable or fruit to an extent that removes some essential characteristics that are beneficial when consuming the whole vegetable or fruit, which could impact nutrient content. However, we asked for comment regarding whether vegetable and fruit powders should be included for the purposes of FGE calculations, and in particular, any data regarding whether vegetable powders have similar or different nutrient content, or similar or different roles in a healthy dietary pattern, compared to whole vegetables. Comments to the proposed rule describe methods of vegetable and fruit powder production which are essentially only changes to the form and removal of moisture, and thus are similar to the production of purees and pastes. Information provided in the comments shows that the nutrient content of dried and ground powders is similar to the nutrient content of whole, fresh (or dried) varieties of vegetables and fruits. Comments did not provide any information about the processing of powders made from juices or the nutritional composition of powders made from juices.

We disagree that labeling foods with vegetable or fruit powders as ''healthy'' will send the ''wrong message'' to consumers. Foods that qualify for the ''healthy'' claim through the use of vegetable and fruit powders, including processed foods, will meet the minimum FGE requirements of either vegetables or fruits and will not exceed the NTL amounts. Therefore, foods that contain vegetable and fruit powders and bear the ''healthy'' claim will be nutrient-dense foods. Nutrient-dense whole vegetable and fruits in powdered form, or products that contain them, can also displace other ingredients or foods in the diet that are not nutrient-dense.

For this reason, we conclude that vegetable and fruit powders that are produced by drying whole vegetables and fruits and grinding into powder form may be considered in calculation of the vegetable and fruit FGEs. We are aware that some powders made from 100% juice could be less nutrient dense, such as juice powders made with carrier agents or drying aids like maltodextrins (see Food Labeling; Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages Final Rule (58 FR 2897 at 2917, January 6, 1993)). Therefore, powders made through methods with ingredients that are added or taken away, such as powders made from 100% juice or juice concentrate with the addition of maltodextrin, may not be considered in the calculation of vegetable and fruit FGEs. We also address powders of protein products, such as chickpea powders or legume powders, in Response 37. We state that those powders can be included in FGE calculations provided that the powders are essentially the dried/dehydrated and ground forms of the original, whole food. These specific foods (beans, peas, lentils, soy, etc.) can also be considered under the vegetable group as vegetable powders.

10. Other Comments on Food Groups

(Comment 45) Some comments discuss the health benefits associated with plant-based foods marketed as alternatives for other types of foods and recommend that FDA create a separate food group for such plant-based foods and beverages.

(Response 45) There are a number of plant-based foods marketed as alternatives for other types of foods, *e.g.,* soy-based milk alternatives or bean-based patties marketed as hamburger alternatives. As discussed in the section V.C.6 (''FGE for Dairy''), plant-based milk alternatives are subject to the criteria for the dairy food group. Other plant-based alternatives to animal-derived foods, though, vary widely in scope, and are not all similar in content, use, or nutrition. These plant-based alternatives to animal-derived food products are being modeled after many different types of animal-derived foods, including hamburgers, chicken nuggets, hot dogs, ground beef, or fish. The components of plant-based alternatives to animal-derived foods are broad and range from vegetables and fruits, to grains, and to other protein sources, such as beans and nuts. Because of the wide variation among products, it would not be appropriate to consider all plant-based foods marketed as alternatives for other types of food under the same criteria. These products should be considered based on the criteria for their individual ingredients. For example, plant-based alternatives to animal-derived foods that are primarily bean-based would be considered under the protein foods or vegetable food groups. Plant-based alternatives to animal-derived food products also could be considered under the criteria for the categories of combination foods if the products meet the requirements (*e.g.,* a plant-based patty made of beans and grain ingredients that meets the ''healthy'' criteria for a mixed product). Therefore, we do not agree that a separate food group with a different set of criteria should be created for all plant-based foods and beverages marketed as alternatives to other types of food. This approach would be inconsistent with the *Dietary Guidelines, 2020–2025,* which does not have a separate food group for such plant-based foods and beverages. We are also aware of ongoing efforts in the innovation of meat-alternative products with novel protein ingredients from a variety of sources beyond plant-based

proteins. Novel ingredients derived from alternative sources, like mycoprotein and algae, may not fit into the categories of food groups established by the Dietary Guidelines. As efforts toward innovation move forward, we intend to monitor the marketplace and will address issues related to use of ''healthy'' on such products in the future, if necessary.

(Comment 46) One comment recommends adding food groups to encourage, instead of NTE, which, according to the comment, would include groups that have nutritional value, for which current intakes are minimal, or that are linked to decreased chronic disease risk. The comment mentions fruits, vegetables, whole grains, and the subgroup beans, peas, and lentils as candidates for the food groups to encourage. The comment asserts that food groups and subgroups to which ''automatic healthy status'' has been granted should be given a special designation, beyond ''healthy,'' ''to distinguish them from foods that were not granted automatic status and to emphasize their prioritization in healthy dietary patterns.''

(Response 46) We agree with the inclusion of food group requirements instead of requirements for NTE in the definition of ''healthy,'' as further discussed in section V.D.6 (''Nutrients to Encourage''). As described by the *Dietary Guidelines, 2020–2025,* a healthy dietary pattern ''consists of nutrient-dense forms of foods and beverages across all food groups, in recommended amounts, and within calorie limits.'' The criteria established for the definition may vary for individual foods from different food groups and there are foods which fall under the rule's single-ingredient exemption (see Response 9). However, all foods that are able to bear the ''healthy'' claim are foods that are particularly useful in helping consumers to create healthy dietary patterns, which is the purpose of the claim. Therefore, we disagree that certain foods that qualify for the claim should be given any special designations above other qualifying foods.

(Comment 47) One comment notes that the proposed rule does not include provisions for communicating how many servings or FGEs of fruits, vegetables, dairy, protein foods, or grains to incorporate into a daily pattern, and does not include a mention of staying within caloric requirements, both of which are recommendations of the Dietary Guidelines. The comment provides that, even if an individual were to only purchase and consume foods labeled ''healthy,'' they may not achieve a healthy pattern if these foods are not consumed in the appropriate portions for each food group and within calorie limits. The comment suggests that additional on-pack communications, in addition to the term ''healthy,'' could help consumers identify how these foods fit into a healthy pattern.

(Response 47) The purpose of a ''healthy'' claim is to serve as a quick signal to highlight foods that, based on their nutrient levels, are particularly useful in building healthy dietary patterns. While we agree that consumer education is an important part of implementing the ''healthy'' final rule, we have determined that it would not be appropriate to require educational information about the ''healthy'' claim or how to achieve healthy dietary patterns on food labels due to the limited space available and other label requirements. Information and education on healthy dietary patterns are readily available to consumers through various resources, including the Dietary Guidelines and related resources, such as the MyPlate education initiative at *MyPlate.gov*. Further, we plan to undertake consumer education efforts related to the ''healthy'' claim, which could include highlighting the importance of staying within daily calorie limit recommendations and choosing a variety of nutrient-dense foods within and across different food groups and subgroups—two concepts that are an integral part of the *Dietary Guidelines, 2020–2025*. Additionally, the Nutrition Facts label includes information about how certain nutrients fit into the total daily diet. For these reasons, we decline to require additional information on labels about ''healthy'' and healthy dietary patterns, although manufacturers are free to include additional truthful and non-misleading information voluntarily.

(Comment 48) Some comments note that the *Dietary Guidelines, 2020–2025* recognizes that dietary supplements are useful for individuals who cannot otherwise adequately obtain their nutrient needs or have different nutritional needs. The comments ask that FDA exempt dietary supplements from the ''healthy'' nutrient content claim requirements.

One comment asserts that dietary supplements are outside the scope of the ''healthy'' implied nutrient content claim rule because, according to the comment, dietary supplements are, by definition, intended to supplement the diet and are not represented as conventional foods. The comment requests that if dietary supplements are not exempted from the ''healthy'' implied nutrient content claim criteria, then FDA either exercise enforcement discretion related to dietary supplements or establish parameters that would permit dietary supplements to bear the ''healthy'' claim. Another comment seeks clarification as to whether a dietary supplement that does not meet the ''healthy'' claim criteria may still bear the word ''healthy'' as part of a claim related to a products' ability to maintain a healthy structure or function or an otherwise lawful dietary supplement claim.

(Response 48) The proposed rule did not exclude dietary supplements from our definition (87 FR 59168 at 59176). However, as explained in the proposed rule, current nutrition science reflects the view that ''good nutrition does not come from intake of individual nutrients (as dietary supplements often provide) but rather from foods with their mix of various nutrients working together in combination'' (id.). Consistent with this scientific understanding, the ''healthy'' claim is intended to highlight those foods that are particularly useful in constructing healthy dietary patterns, which includes food choices from across the different food groups, and we have included FGE requirements to update the claim definition to focus on such foods. Because this is the intent of the claim, we decline to exempt dietary supplements from the ''healthy'' criteria. However, dietary supplements may bear nutrient content claims, including ''healthy,'' if they meet applicable criteria. Under some circumstances, a dietary supplement product may use the term ''healthy'' as part of a structure/function claim, without being subject to the requirements of the ''healthy'' nutrient content claim (see Response 123).

(Comment 49) Some comments request that medical foods and foods for special dietary use (FSDU) be exempted from the requirements of the ''healthy'' claim. One comment states that, historically, both medical foods and FSDU have not been subject to the ''healthy'' claim criteria. According to the comment, medical foods are exempt from nutrient content claim requirements in § 101.13(q)(4)(ii). The comment also mentions that § 101.65(b)(6) specifically exempts claims for foods for special dietary use from implied nutrient content claim requirements when the claim identifies the special diet of which the food is intended to be a part; the comment asks FDA to maintain this exemption. The comment provides that medical foods

and FSDUs are not intended as conventional foods for use as part of a healthy dietary pattern, but instead, are intended to supplement the diet or meet specific nutrition requirements in specific populations. The comment asserts that medical foods and FSDUs should thus not be subject to the ''healthy'' claim criteria but instead should be allowed to use the term ''healthy'' in a nutritional context, provided that the claim is not otherwise false and misleading.

(Response 49) Medical foods, as defined by section 5 of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), are exempt from nutrient content claim regulations and therefore not subject to this rule (§ 101.13(q)(4)(ii)). Our regulations also exempt certain label statements from FDA nutrient content claim requirements under § 101.13, and this rule does not alter these exemptions. For example, a label statement on a food that complies with a specific provision of 21 CFR part 105 solely to note that a product has special dietary usefulness relative to a physical, physiological, pathological, or other condition, where the claim identifies the special diet of which the food is intended to be a part, is exempt from the requirements in § 101.13 (§ 101.65(b)(6)). However, FDA regulations do not include a general exemption from applicable nutrient content claim labeling requirements for all foods for special dietary uses. Therefore, foods for special dietary uses are subject to the rule if manufacturers choose to include a ''healthy'' nutrient content claim on a label, unless they meet a specific exemption from the requirements of § 101.13. It would be inconsistent with current nutrition science and dietary recommendations on building healthy dietary patterns for a food for a special dietary use that does not meet the requirements of the ''healthy'' claim to bear such claim in a label statement not subject to an exemption.

D. Nutrients to Limit

1. General Comments

(Comment 50) Many comments express general support for having NTL as part of the ''healthy'' framework. These comments assert that nutrient limits combined with FGE requirements better reflect the overall nutrient content of a food, including how nutrients may work together to help build a healthy dietary pattern across different food groups and subgroups, and that the rule's framework is therefore more consistent with the Dietary Guidelines than the original definition. However, some comments suggest that the rule's limits for single ''avoidance nutrients'' contradicts the approach of relying on food groups as a replacement for single favorable nutrients. Other comments acknowledge that chemically altered and highly processed foods high in sugar, sodium, and saturated fats should not be considered ''healthy'' due to their association with increased risks related to obesity and diet-related chronic diseases.

(Response 50) We agree that having limits for saturated fat, added sugars, and sodium as part of the ''healthy'' claim criteria is supported by current nutrition science and Dietary Guideline recommendations. Current intake of saturated fat, sodium, and added sugars exceed recommended amounts for a majority of people in the United States. The *Dietary Guidelines, 2020–2025* includes four over-arching guidelines, including: (1) a guideline to focus on meeting food group needs with nutrient-dense foods and beverages, while staying within calorie limits (where nutrient-dense foods and beverages are described as containing vitamins, minerals, and other health-promoting compounds and containing little added sugars, saturated fat, and sodium) and (2) a guideline to limit foods and beverages higher in saturated fat, sodium, and added sugars. Therefore, the updated ''healthy'' framework, consisting of minimum requirements for food groups as well as limits for saturated fat, sodium, and added sugars, is consistent with current nutrition science and key recommendations in the *Dietary Guidelines, 2020–2025*.

We disagree that having limits for saturated fat, added sugars, and sodium as part of the ''healthy'' criteria contradicts having minimum requirements for food groups (*i.e.,* FGE criteria) as a replacement for minimum requirements for individual beneficial nutrients. Food group requirements better reflect the array of nutrients that are contained in a food rather than one individual beneficial nutrient in isolation. Including limits for saturated fat, sodium, and added sugars, as well as food group criteria, in the framework for the updated ''healthy'' definition better characterizes the overall nutrient content of foods, and as mentioned is consistent with current nutrition science and the *Dietary Guidelines, 2020–2025*. For further discussion of these topics, see section V.C (''Food Group Equivalents'') and section V.D.6 (''Nutrients to Encourage'').

(Comment 51) Some comments support the different limits for saturated fat, sodium, and added sugars, or recommend limits that are more restrictive, noting that intakes of these nutrients are associated with adverse health outcomes and that for a majority of Americans, intakes of these nutrients exceed recommended amounts. However, many comments raise concerns that the proposed limits are too restrictive. For example, some comments assert that the proposed limits on saturated fat, sodium, and added sugars would ''arbitrarily'' disqualify many foods from using the ''healthy'' claim. Some comments contend that the proposed limits are so low that, besides whole foods or single ingredient foods or commodity foods, few products would meet the proposed criteria. For example, some comments note that healthier packaged foods and prepared foods often used by consumers would be excluded from bearing a ''healthy'' claim due to their ''judicious'' amounts of saturated fat, sodium, and added sugars. Another comment argues that the proposed criteria would force manufacturers of meals and main dishes that currently qualify for ''healthy'' to drastically reformulate their products.

(Response 51) Based on data and information received in comments, current nutrition science, and the *Dietary Guidelines, 2020–2025,* and supported by our review of the products available in the marketplace (Ref. 2), we have made adjustments to some requirements, including to some of the NTL criteria, which result in more nutrient-dense foods that are recommended by the *Dietary Guidelines, 2020–2025* being able to qualify for the ''healthy'' claim. Those adjustments are described in the following sections on saturated fat, sodium, and added sugars.

(Comment 52) Some comments support adjusting NTL based on food groups and subgroups, asserting that ''some degree of variation by food group or subgroup is necessary to account for the intrinsic differences in nutrient content of different food groups and each food group's contribution to a healthy diet.'' One comment supports the proposed approach to consider characteristics of the different food groups instead of a ''one-size-fits-all algorithm'' for updating the ''healthy'' definition, stating that the proposed approach is consistent with the principles underpinning the Dietary Guidelines that promote choosing healthy foods from different food groups, which work together synergistically within healthy eating patterns. In contrast, other comments argue that criteria should vary based on RACC size, rather than by food groups, to account for the range of RACC sizes in the individual/mixed foods category and their contribution to a dietary

pattern, arguing that there is little variation in the proposed limits based on food groups (*e.g.,* 0–5% DV for added sugars across food groups), but considerable variation in RACC sizes in some food groups (*e.g.,* 5 g to 110 g in the grains food group). Other comments support having different criteria (*e.g.,* for NTL and food group contributions) for products with smaller RACCs. The comments note that small RACC foods contribute meaningfully to the diet, but, in many cases, the proposed food group requirements are not mathematically possible for smaller RACC individual/mixed foods because the RACC size is smaller than the minimum FGE requirement.

(Response 52) We agree that taking into consideration the characteristics of the different food groups, rather than using a ''one-size-fits-all'' approach, aligns with the framework of the *Dietary Guidelines, 2020–2025* and its emphasis that healthy dietary patterns are formed by choosing nutrient-dense foods across different food groups, which vary in the nutrients they provide and can work together to improve health. Different food groups consist of foods that vary in their nutrient content and setting the same limit for all food groups could result in foods with unnecessary excess saturated fat, sodium, or added sugars being able to bear the ''healthy'' claim or result in the unnecessary addition of NTL (*e.g.,* saturated fat or added sugars) to products in some food groups. For example, increasing the saturated fat limit across all food groups could result in the unnecessary addition of saturated fat for products in food groups such as vegetables, which are generally not sources of saturated fat, or result in the addition of added sugars to fruit products, which are generally already naturally sweet.

Therefore, we have maintained the proposed approach of adjusting NTLs across food groups and subgroups for individual foods (§ 101.65(d)(3)(iii)) based on considerations such as different nutrient profiles of the different food groups and subgroups; the *Dietary Guidelines, 2020–2025* recommendations for different food groups (*e.g.,* consuming fat-free and low-fat dairy) and for saturated fat, sodium, and added sugars; and current intakes of different food groups/subgroups and NTL; and our marketplace review of nutrient-dense foods (Ref. 2). We have, however, modified the NTL criteria for combination foods (*i.e.,* mixed products, main dishes, and meals) so that the limits for saturated fat, added sugars, and sodium are streamlined and are not dependent on the food groups that make up the combination foods (§ 101.65(d)(3)(iii), (iv) and (v)) (as further discussed in section V.E (''Combination Foods''). We also have included criteria specifically for foods with smaller RACCs (≤50 g) (§ 101.65(d)(3)(iii)) based on comments to the proposed rule that demonstrate that some nutrient-dense foods with smaller RACCs are not able to qualify based on the proposed criteria, which were also supported by our marketplace review of nutrient-dense foods across different food groups and categories (Ref. 2). The changes to the NTL criteria for individual foods, as well as the rationale for those changes, are discussed below in the individual NTL sections for saturated fat, sodium, and added sugars.

(Comment 53) Some comments support considering the ''food matrix'' (*e.g.,* nutrient and non-nutrient components of foods, as well as physical structure and form) as part of the ''healthy'' definition, and say that, without taking the food matrix into consideration, the proposed NTL could discourage the consumption of certain foods that contain beneficial nutrients but do not qualify for the claim (*e.g.,* full-fat dairy).

(Response 53) The description of nutrient-dense foods in the *Dietary Guidelines, 2020–2025* (*e.g.,* containing little or no added sugars, saturated fat, and sodium) does not change based on food matrix components such as physical structure and food form. Therefore, while we do adjust NTL based on unique considerations for the different food groups, including some components of the food matrix (such as overall nutrient profile), we decline to adjust NTL criteria based on other components of the food matrix such as physical structure, food form, and non-nutrient components because they do not characterize the nutrient levels of a food.

(Comment 54) Some comments believe that the approach used for calculating the criteria for NTL should be the same approach used for calculating FGE criteria. For example, some comments argue that the criteria for the NTL, such as added sugars, should be calculated by dividing the DV by four eating occasions—analogous to the approach used for calculating FGE criteria—arguing that there is more room for intake of added sugars, for example, in the daily diet (*i.e.,* without reaching the daily limit of 50 g for added sugars) than what would result with the proposed limits.

(Response 54) We decline to use the same approach for setting NTL as for calculating FGE criteria. FGE requirements are the *minimum* amounts of a food from a particular recommended food group that must be contained in a product for it to bear the ''healthy'' claim, and they are intended to help consumers identify foods that can help them reach recommendations for food groups to meet nutritional needs.

In contrast to FGE criteria, NTL criteria are the *maximum* amounts of saturated fat, added sugars, and sodium, that foods which bear the ''healthy'' claim can contain, based on recommendations to limit intake of these nutrients. For the NTL, the goal is to stay below, rather than achieve, the limit in order to avoid excess intake of saturated fat, added sugars, and sodium. Consumers eat a variety of foods throughout the day. This may include multiple foods, which may or may not meet the ''healthy'' criteria, at different eating occasions that provide saturated fat, added sugars, and sodium. Foods that do not qualify for the ''healthy'' claim that are consumed throughout the day also serve as sources of saturated fat, sodium, and added sugars, and may contain higher amounts of these nutrients (*e.g.,* if they do not meet the ''healthy'' NTL criteria). Consequently, it is not appropriate to calculate the baseline amounts for the NTL using the assumption that all foods consumed in a day are foods that qualify for ''healthy,'' and it is not appropriate to use the same approach for calculating the maximum amount of added sugars, saturated fat, or sodium as is used for calculating the minimum amount of FGEs (*e.g.,* dividing the DV by four) in order for a food to qualify for ''healthy.'' This approach would be unlikely to help consumers identify foods that are particularly useful for building a healthy dietary pattern recommended by the *Dietary Guidelines, 2020–2025,* and could result in consumers exceeding the recommended daily limits for these NTL. We therefore decline to change the approach for calculating the baseline amounts for the NTL (*e.g.,* by dividing the DVs for the NTL by four eating occasions) as suggested in the comments. We have, however, modified the proposed adjustments for NTL for some food groups and discuss these modifications in the saturated fat, sodium, and added sugars sections below.

(Comment 55) Some comments encourage FDA to set consistent limits for saturated fat, added sugars, and sodium (*i.e.,* the same percent DV limit for all three nutrients). For example, one comment suggests that the proposed baseline limits do not reflect the definition of nutrient density in the

Dietary Guidelines where all three nutrients are ''equally addressed.'' The comment suggests that consumers could interpret a higher limit for one nutrient as indicating that the one nutrient is less of a public health concern and offered alternative approaches for consideration, such as ≤5% DV for saturated fat, added sugars, and sodium; 8% DV for saturated fat, added sugars, and sodium; or 10% DV for saturated fat, added sugars, and sodium.

(Response 55) While we agree that the concepts of limiting saturated fat, sodium, and added sugars are all part of the definition of nutrient-dense foods in the Dietary Guidelines, we disagree that the definition implies that the limits for saturated fat, sodium, and added sugars must be the same in a nutrient-dense food. There are many factors that we considered when determining the limits for saturated fat, added sugars, and sodium, such as dietary recommendations and current scientific evidence for each, intake of each in the United States, inherent amounts of each in different foods, their respective functions in foods, and our marketplace review of nutrient-dense foods in the food supply (Ref. 2). These factors vary depending on the nutrient and the food group.

In setting the criteria for NTL, we proposed baseline values for each nutrient and adjusted the values, as warranted. Different food groups and subgroups each contain foods that provide a variety of nutrients, including important nutrients that are underconsumed, and some naturally contain higher amounts of nutrients that should be limited. For example, dairy foods provide vitamin D and calcium; however, they also may contain saturated fat. In contrast, fruits and vegetables contain minimal or no saturated fat. Using the same saturated fat criteria across all food groups could result in the exclusion of foods that provide important nutrients and that are recommended by the Dietary Guidelines. However, increasing the saturated fat limit across all food groups could result in the unnecessary addition of saturated fat for foods in food groups such as vegetables, which are generally not sources of saturated fat. Therefore, we decline to use the same percentages to set the saturated fat, added sugars, and sodium limits. See below for further discussion of the individual limits that we have determined for saturated fat, added sugars, and sodium.

2. Saturated Fat

(Comment 56) Several comments express support for the proposed limits on saturated fat, including the baseline of ≤5% of the DV per RACC and proposed adjustments for different food groups (*i.e.,* ≤10% of the DV per RACC for dairy products, game meats, seafood, and eggs). The comments support aligning the baseline level with the existing ''low in saturated fat'' nutrient content claim, and also support adjusting the limits for certain food groups to allow for naturally-occurring saturated fat in nutrient-dense foods recommended by the *Dietary Guidelines, 2020–2025* (*e.g.,* low-fat dairy products, lean proteins, eggs, nuts, seeds, seafood, and certain oils), while ''limiting the addition of saturated fats to other recommended foods, such as frozen vegetables in a butter sauce.'' In contrast, some comments express concern with the proposed saturated fat limits for individual foods of ≤5%, ≤10%, and ≤20% DV (depending on food group), asserting that the proposed saturated fat criteria are too strict. Some comments support the following alternative limits which they assert are largely in agreement with our proposed saturated fat limits but are based on RACC size rather than by food group: 5% DV per RACC for individual foods with a RACC ≤30 grams, 10% DV for individual/mixed foods per RACC with a RACC >30 grams, 15% DV per serving for main dishes, and 20% DV per serving for meals. The comments argue that the alternative limits would allow for inclusion of foods with intrinsic saturated fat (*e.g.,* protein foods, dairy, seafood, and avocado), while ''retaining a reasonable cap on overall saturated fat intake.'' Another comment states that the strict proposed saturated fat limits could deprive children of sufficient saturated fat, which is necessary for proper growth and brain development.

(Response 56) In the proposed rule (87 FR 59168 at 59178), we discuss that consensus reports, as well as the *Dietary Guidelines, 2020–2025,* recommend limiting saturated fat intake to no more than 10% of calories per day, based on risk of CVD. The baseline limit for saturated fat (≤5% DV per RACC) is consistent with the low saturated fat nutrient content claim (§ 101.62(c)(2)). The limits are further consistent with the limits for most of the individual foods in the original definition for ''healthy,'' and our marketplace review of nutrient-dense foods (Ref. 2), as well as comments that we received to the proposed rule, which did not suggest that the proposed saturated fat limits overall were too restrictive. As further discussed in Response 52, we have maintained the approach of adjusting limits for saturated fat, sodium, and added sugars for individual foods based on considerations for the different food groups and subgroups. Using a baseline limit of ≤5% DV for individual foods and adjusting the limit (*e.g.,* increasing the limit to ≤10% DV for some food groups and subgroups (*e.g.,* dairy) results in a variety of nutrient-dense foods recommended by the *Dietary Guidelines, 2020–2025* across food groups being able to qualify for the ''healthy'' claim, including those with some inherent saturated fat (*e.g.,* low-fat dairy). As discussed in Response 52, having the same saturated fat limit across different food groups could result in foods with unnecessary excess saturated fat being able to bear the ''healthy'' claim or result in the unnecessary addition of saturated fat to products in some food groups that are generally not sources of saturated fat (*e.g.,* fruits and vegetables). Therefore, we decline to change the baseline limit of ≤5% DV for saturated fat for individual foods, and we decline to adjust the limit based solely on RACC size for individual foods without incorporating food group adjustments. We have, however, adjusted the saturated fat criteria for some food groups and subgroups such that more nutrient-dense foods encouraged by the *Dietary Guidelines, 2020–2025* that contain inherent or intrinsic saturated fat will now qualify for the claim, as discussed below. We have also modified the saturated fat limits for combination foods (*i.e.,* mixed products, main dishes, and meals) so that the limits are streamlined and are not dependent on the food groups that make up the combination foods, as further discussed in section V.E (''Combination Foods''). In addition, we have modified the proposed criteria to include different criteria for smaller RACC foods, described in detail in Response 8. Categories based on RACC size are also incorporated in the criteria for main dishes and meals (weighing at least 6 oz and 10 oz per labeled serving, respectively).

Further, we disagree that the saturated fat limits for the ''healthy'' claim would deprive children of sufficient saturated fat for proper growth and development, as current saturated fat intakes in this population exceed recommendations. For example, data from the *Dietary Guidelines, 2020–2025* demonstrate that 82–88% of children (ages 2–13 years) in the United States exceed the recommended daily limit for saturated fat.

(Comment 57) Some comments agree with the proposal to limit saturated fat in general but express concern regarding the higher limit for dairy, game meats, eggs, oils and oil-based spreads and

dressings, and/or seafood. For example, some comments express concern that higher limits are allowed for foods that represent high sources of saturated fat in the diet, such as dairy and meat.

(Response 57) The proposed rule discusses our rationale for the proposed adjustments to the baseline saturated fat limit across the different food groups and subgroups (87 FR 59168 at 59178). Generally, adjustments were made based on specific considerations of the different food groups and subgroups, as further discussed in Response 52, to ensure that nutrient-dense foods across all food groups and subgroups could qualify for the ''healthy'' claim. This approach aligns with the *Dietary Guidelines, 2020–2025* approach for healthy dietary patterns, *i.e.,* incorporating a variety of nutrient-dense foods across all of the food groups and subgroups (Ref. 1). For example, the *Dietary Guidelines, 2020–2025* discusses that dairy is one of the core elements of a healthy dietary pattern and states that most individuals would benefit by increasing intake of dairy in fat-free or low-fat forms, whether from milk (including lactose-free milk), yogurt, and cheese, or from fortified soy beverages or soy yogurt. The *Dietary Guidelines, 2020–2025* also identifies protein foods, including lean meats, poultry, eggs, and seafood, as one of the core elements of a healthy dietary pattern. When selecting protein foods, the *Dietary Guidelines, 2020–2025* recommends shifting to nutrient-dense options, specifically lean and options that are low in saturated fat and shifting to add variety to the intake of protein foods. The Healthy U.S.-Style Dietary Pattern, as an example, includes daily amounts of lean protein and fat-free or low-fat dairy, because of the nutrients that these food groups provide (Ref. 1). Similarly, the adjustments to the saturated fat limits result in nutrient-dense forms of protein foods and dairy, for example, qualifying for the claim, thereby including a variety of foods that provide important nutrients to the diet while also limiting the amount of saturated fat that these foods contribute to the overall daily intake of saturated fat. These saturated fat criteria can help consumers identify products that can help them make shifts within the protein and dairy food groups. For example, one suggested shift in the *Dietary Guidelines, 2020–2025* is ''[w]hen cooking and purchasing meals, select lean meat and lower fat cheese in place of high-fat meats and regular cheese . . .'' (Ref. 1).

The adjustments in the saturated fat criteria are consistent with the *Dietary Guidelines, 2020–2025.* For example, for dairy, the saturated fat limit of ≤10% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) will result in fat-free and low-fat dairy products qualifying to bear the claim, which are more nutrient-dense forms of dairy recommended by the *Dietary Guidelines, 2020–2025,* but not dairy products with higher amounts of saturated fat (*e.g.,* 2% or full-fat milk). Fat-free and low-fat dairy products provide the same nutrients, but contain less saturated fat, than higher fat options such as 2% and full-fat milk and cheese. The saturated fat criteria will limit the contributions of qualifying foods to daily saturated fat intake, while still resulting in a variety of nutrient-dense forms across food groups, including dairy, game meats, eggs, seafood, and oils and oil-based spreads and dressings being able to meet the ''healthy'' definition, consistent with the *Dietary Guidelines, 2020–2025.* Therefore, we are finalizing the proposed saturated fat limit of ≤10% DV for game meats and eggs (see section V.D.5 (''Nutrients Not Included'') for discussion of comments on eggs and dietary cholesterol) and provide further discussion below of comments on nuts and seeds, soy products, seafood, dairy, and for oils and oil-based dressings and spreads.

(Comment 58) Some comments raise concerns that the saturated fat limits are inconsistent across different food groups and subgroups, asserting that plant-based foods, such as those in the beans, peas, lentils, and soy products subgroup, should have at least the same saturated fat limit (*i.e.,* ≤10% DV instead of ≤5% DV), or a higher limit, than animal-based foods on the grounds that: plant-based foods have beneficial nutrients that are lacking in animal-based foods (*e.g.,* dietary fiber); certain plant-based products, such as some soy-based foods, ''have a healthier fat profile overall'' (*e.g.,* higher amounts of unsaturated fats) than animal-based foods; plant-based foods also provide ''important nutrients,'' which is used as a basis in the proposed rule for animal-based foods having a higher saturated fat limit; and the reasons for the different saturated fat limits for animal- and plant-based foods are not consistent with nutrition science or Federal dietary recommendations. Some comments agree with the rationale in the proposed rule that many foods in the beans, peas, lentils, and soy products group are generally lower in saturated fat; however, the comments point out that some foods do contain saturated fat naturally. For example, some comments point out that soybeans contain higher amounts of saturated fat (2.88 g per 100 g) than most other legumes (except for peanuts), but their fatty acid profile is predominantly unsaturated fats (*e.g.,* 60% polyunsaturated fat and 15% saturated fat), similar to the fatty acid profile of nuts. In comparison, peanuts contain 6.28 g of saturated fat per 100 g, but they are placed in the nuts and seeds subgroup and their saturated fat is excluded from the saturated fat limit. Other comments discuss certain soy-based products (*e.g.,* plant-based patties, some tofu products) that would not be able to qualify due to their saturated fat content. Overall, these comments recommend: (1) excluding the naturally occurring saturated fat contained in soybeans from the saturated fat limit for soy products, similar to the nuts and seeds subgroup, because of their similar fatty acid profiles (*i.e.,* predominantly unsaturated fats) or (2) increasing the saturated fat limit for the beans, peas, lentils, and soy products subgroup to ≤10% DV to be consistent with other protein subgroups.

(Response 58) Because the protein foods group is diverse and contains varying amounts of saturated fat and different nutrients, we proposed adjustments to the baseline saturated fat limit for some protein foods subgroups (proposed § 101.65(d)(3)(ii)). For example, for game meat and seafood, the proposed saturated fat limits were increased from the ≤5% DV per RACC baseline limit to ≤10% DV per RACC (similar to the <2 g per RACC saturated fat limit for the ''extra lean'' nutrient content claim for game meat or seafood products). For nuts and seeds, we proposed that the saturated fat content inherent in nuts and seeds would not contribute to the 5% DV per RACC saturated fat limit for that subgroup. We explained the rationale for this exclusion. First, unsalted nuts and seeds are nutrient-dense foods and, while they contain saturated fat, they have a fat profile makeup of predominantly unsaturated fats. Second, scientific evidence, including the scientific evidence supporting multiple FDA-qualified health claims, demonstrate that replacing other sources of saturated fat in the diet with nuts has beneficial effects on risk of coronary heart disease, including nuts with higher saturated fat. Third, more than half of Americans do not meet the recommendation for nuts, seeds, and soy products, and the *Dietary Guidelines, 2020–2025* recommends consuming nuts without differentiating among types (even though the saturated fat content of nuts is variable). And fourth, the *Dietary Guidelines, 2020–2025* recommends reducing saturated fat by substituting certain ingredients with

sources of unsaturated fats, for example using nuts and seeds in a dish instead of cheese.

For beans, peas, lentils, and soy products, we proposed the baseline limit for saturated fat of ≤5% DV per RACC because these foods generally have low amounts of naturally occurring saturated fat. We also noted that the protein foods subgroups used in the proposed rule were slightly different than the protein subgroups in the *Dietary Guidelines, 2020–2025* due to consideration of animal sources of protein for which labeling is regulated by USDA's Food Safety and Inspection Service (*e.g.,* meat and poultry products, egg products, and catfish), and specific variation needed in FGE requirements and NTL across protein foods subgroups. For example, we proposed a subgroup for game meats and a subgroup for eggs instead of the meats, poultry, and eggs subgroup from the *Dietary Guidelines, 2020–2025.* In addition, we grouped ''beans, peas, lentils and soy products'' together as a subgroup and ''nuts and seeds'' as another subgroup. In contrast, the *Dietary Guidelines, 2020–2025,* which categorizes foods into food groups and subgroups based on similar nutrient profiles of different foods, groups ''beans, peas, and lentils'' together as one subgroup and ''nuts, seeds, and soy products'' as another subgroup (Ref. 1). The *Dietary Guidelines, 2020–2025* also explains that generally foods made from processed soybeans (*e.g.,* tofu, tempeh, and products made from soy flour) are part of the nuts, seeds, and soy products subgroup, while soybeans and edamame (soybean in the pod) are part of the beans, peas, and lentils subgroup.

After considering the comments received on this topic and the *Dietary Guidelines, 2020–2025* categorization of protein foods subgroups, which is based on groupings of protein foods with similar nutrient profiles, we modified the following proposed protein foods subgroups: ''beans, peas, lentils, and soy products'' and ''nuts and seeds.'' The final rule includes soy products with nuts and seeds (instead of with beans, peas, and lentils) in the ''nuts, seeds, and soy products'' subgroup and the proposed rule's subgroup of ''beans, peas, lentils, and soy products'' is now the ''beans, peas, and lentils'' subgroup in the final rule, which is in alignment with the *Dietary Guidelines, 2020–2025* subgroups. The saturated fat that is naturally occurring in foods in the nuts, seeds, and soy products subgroup will be excluded from the saturated fat limit of ≤5% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) for nuts, seeds, and soy products. The rationale for the exclusion of inherent saturated fat in nuts, seeds, and soy products is similar to the rationale discussed in the proposed rule, and above, for the exclusion of inherent saturated fat in nuts and seeds and is based on scientific evidence and the *Dietary Guidelines, 2020–2025,* and supported by our marketplace review (Ref. 2). Nuts, seeds, and soybeans (from which soy products are derived) generally have a fatty acid profile that is predominantly unsaturated fats, and there are multiple health claims based on scientific evidence supporting the beneficial relationship of fatty acids contained in these foods (*e.g.,* substitution of unsaturated fats for saturated fats) and/or these foods (*e.g.,* nuts, including nuts with relatively higher amounts of saturated fat) and reduced risk of coronary heart disease. Moreover, the *Dietary Guidelines, 2020–2025* does not differentiate between specific nuts or soy products based on saturated fat, whereas they do differentiate between foods in other food groups based on saturated fat (*i.e.,* lean or low-fat meats and fat-free and low-fat dairy). In addition, the *Dietary Guidelines, 2020–2025* discusses specific strategies for making shifts to reduce saturated fat intake by replacing it with unsaturated fat. We note that even the nuts that are the highest in saturated fat have fat profiles that are predominantly unsaturated fat (*e.g.,* Brazil nuts contain ~24% saturated fat and ~74% unsaturated fat) (Ref. 7). Our review of the products available in the current marketplace demonstrates that, if inherent saturated fat were not excluded, a majority of nut and seed products, without added sources of saturated fat, would not be able to meet the saturated fat limit even if it was increased to ≤10% DV (per 50 g due to their small RACC) (Ref. 2). Similar to nuts and seeds, soybeans also have fat profiles that are predominantly unsaturated fat (*e.g.,* soybeans, mature seeds, raw contains ~14.5% saturated fat and ~66% unsaturated fat) (Ref. 7), and therefore, the same rationale applies. However, as we do not consider coconut to be part of the nuts, seeds, and soy products subgroup, the inherent saturated fat in coconut is not excluded from the saturated fat limit. See Response 38 for discussion of why coconut is not considered part of the nuts, seeds, and soy products subgroup.

Foods such as soybeans and edamame are considered part of the beans, peas, and lentils subgroup, consistent with the Dietary Guidelines. These foods (without added ingredients), including different forms, such as frozen edamame, would qualify for the exemption for single-ingredient foods that are encouraged by the *Dietary Guidelines, 2020–2025.* Soy products that contain other sources of saturated fat, for example, a soy-based vegetable patty that contains added vegetable oil, would be subject to the saturated fat limit for the nuts, seeds, and soy products subgroup; however, the saturated fat inherent in soybeans would not contribute to the limit. As discussed in the *Dietary Guidelines, 2020–2025,* one strategy for reducing intake of saturated fat from protein foods is to replace processed or high-fat meats with beans, peas, and lentils. Shifts such as these are encouraged in part because of the lower saturated fat content of beans, peas, and lentils. Increasing the saturated fat limit for individual foods in the beans, peas, and lentils subgroup (*e.g.,* from ≤5% DV to ≤10% DV, as requested in some comments), which are generally lower in inherent saturated fat, would not reflect the recommended shifts in the *Dietary Guidelines, 2020–2025* for the protein foods group and for lowering saturated fat intake, and could result in foods in this subgroup with unnecessary excess saturated fat qualifying to bear the ''healthy'' claim. Further, our marketplace review demonstrates that a number and variety of nutrient-dense foods within the different protein foods subgroups, including the beans, peas, and lentils subgroup and the nuts, seeds, and soy products subgroup, are able to meet the saturated fat limits for the different protein foods subgroups (Ref. 2). For example, nutrient-dense soy products with naturally occurring saturated fat, such as different types of tofu, meet a saturated fat limit for nuts, seeds, and soy products of ≤5% DV, excluding the saturated fat inherent in nuts, seeds, and soybeans. Therefore, we decline to increase the saturated fat limit for the beans, peas, and lentils subgroup (see below for further discussion of comments on the saturated fat limit for nuts, seeds, and soy products).

Other changes that we have made to the final rule will result in more flexibility for products in the beans, peas, and lentils subgroup to qualify for the ''healthy'' claim. As discussed earlier, we have expanded the exemption for raw, whole fruits and vegetables to include single-ingredient foods recommended by the *Dietary Guidelines, 2020–2025* in other food groups and in other forms (*e.g.,* frozen edamame, unsalted roasted soybeans (soy nuts), and whole soybean flour). See below and Response 9 for further

discussion of the expanded exemption. In addition, we have modified the saturated fat limits for combination foods (*i.e.,* mixed products, main dishes, and meals), which varied in the proposed rule depending on the food group components, to a consistent amount regardless of the food groups or subgroups contained in the mixed product, main dish, or meal (see section V.E (''Combination Foods'') for further discussion). This provides more flexibility, compared to the proposed rule, for mixed products (*e.g.,* plant-based patties), main dishes, and meals made with components from food groups and subgroups such as fruits; vegetables; grains; beans, peas, and lentils; and nuts, seeds, and soy products to meet the saturated fat limits for ''healthy.'' The saturated fat inherent in nuts, seeds, and soy products would be excluded from the saturated fat limit for mixed products, main dishes, and meals. This will result in mixed products, main dishes, and meals that are made with nutrient-dense foods encouraged by the *Dietary Guidelines, 2020–2025* meeting the saturated fat criteria for ''healthy.'' For these reasons, we decline to increase the saturated fat limit for the beans, peas, and lentils subgroup. Further discussions of comments on nuts, seeds, and soy products, and on oils are below, and we did not receive comments on saturated fat and other plant-based food groups (*i.e.,* fruits, vegetables, and grains). Therefore, we are finalizing the proposed saturated fat limits of ≤5% DV for fruits, vegetables, and grains.

(Comment 59) We specifically asked for comment in the proposed rule on whether all nuts, regardless of saturated fat, should qualify for the ''healthy'' claim and whether the saturated fat content contained in nuts and seeds should not contribute to the saturated fat limit for nut and seed products. Many comments support the proposed approach—that the saturated fat contained in nuts and seeds should not contribute towards the saturated fat limit for nut and seed products—agreeing with the rationale detailed in the proposed rule. In contrast, one comment expresses concern with allowing foods with higher amounts of saturated fat, such as nuts, to qualify because of the Dietary Guidelines daily limit for saturated fat of 10% of calories. The comment requests that further education be done for products containing nuts and seeds, *i.e.,* language paired with a healthy icon label to help consumers understand healthy dietary patterns and saturated fat (''certain ''healthy'' nuts should be consumed in moderation due to their higher saturated fat content''). Another comment encourages FDA to eliminate the exemption for saturated fat from nuts, noting that the *Dietary Guidelines, 2020–2025* does not make reference to source of saturated fat with the recommendation to limit saturated fat intake, and that eliminating the exemption would encourage consumers to limit the consumption of nuts that are high in saturated fat. The comment uses the example that there are several dairy products that meet the current requirement of 1 g of saturated fat per RACC and serving, and that these current requirements that exist for dairy products should also apply to nuts.

(Response 59) In the preamble to the proposed rule (87 FR 59168 at 59178–59179), we proposed that the saturated fat inherent in nuts and seeds would not count towards the saturated fat limit for nut and seed products of ≤5% DV per RACC. We agree with comments supporting this proposal because, while nuts and seeds contain saturated fat, they have a fat profile makeup of predominantly monounsaturated and polyunsaturated fats, and numerous studies have demonstrated that replacing other sources of saturated fat in the diet with nuts has beneficial effects on CVD risk, including nuts with relatively higher amounts of saturated fat. FDA also has qualified health claims characterizing these relationships, and the *Dietary Guidelines, 2020–2025* recommends consuming nuts without differentiating among types. For these reasons, we are finalizing our proposal that the saturated fat inherent in nuts and seeds does not count towards the saturated fat limit for nuts and seed products.

The *Dietary Guidelines, 2020–2025* recommends reducing intake of saturated fat by substituting certain ingredients with sources of unsaturated fats, including using nuts and seeds in a dish instead of cheese. In addition to the multiple qualified health claims on nuts, there are also health claims based on the scientific evidence for the substitution of unsaturated fats for saturated fats. For example, as discussed above, we have authorized a health claim for the substitution of unsaturated fats for saturated fats and reduced risk of heart disease. The *Dietary Guidelines, 2020–2025* further recommends consuming nuts without differentiating among types, *i.e.,* does not specify that only lower saturated fat nuts should be consumed or that nuts with higher amounts of saturated fat should be limited. In contrast, different types of dairy products are encouraged in the *Dietary Guidelines, 2020–2025* when describing strategies for the dairy group and when describing strategies for reducing saturated fat in general. For example, one strategy that is discussed is to choose fat-free or low-fat milk instead of 2% or whole milk. The ''healthy'' criteria for the dairy food group and for the nuts, seeds, and soy products subgroup align with the *Dietary Guidelines, 2020–2025* because fat-free and low-fat dairy, as well as nuts and seeds (without differentiating among types), can qualify for the ''healthy'' claim. The fatty acid profile of nuts, seeds, and soybeans, which consists of predominantly unsaturated fats, is different than the fatty acid profile of dairy, which consists of predominantly saturated fats, and the comment did not provide any rationale for why the requirements for nuts should be the same for dairy, particularly since nuts are included in the protein foods group and not the dairy food group. Based on the reasons described above, we disagree that the exemption for saturated fat inherent in nuts and seeds should be eliminated. Further, for reasons described above, we disagree that current saturated fat requirements for dairy should apply to nuts or that some nuts should not be able to qualify for the ''healthy'' claim. As discussed above, the final rule excludes naturally occurring saturated fat inherent in nuts, seeds, and soybeans from the saturated fat limit for the nuts, seeds, and soy products subgroup. Any saturated fat that is added to products in the nuts, seeds, and soy products subgroup that is not inherent in nuts, seeds, and soybeans will count towards the saturated fat limit (see below for further discussion of the saturated fat limit for the nuts, seeds, and soy products subgroup).

We agree that consumer education is an important part of implementing the ''healthy'' final rule and intend to consider the issue of potential excess consumption of foods labeled as ''healthy'' in our education efforts to support implementation of the rule. However, we disagree that specific statements such as ''certain 'healthy' nuts should be consumed in moderation due to their higher saturated fat content'' on the label accompanying the ''healthy'' claim is the best approach. The updated ''healthy'' definition includes criteria for saturated fat, sodium, and added sugars, but provides exclusions for inherent saturated fat contained in food groups and subgroups (*e.g.,* nuts, seeds, and soy products) in which the fat profiles are made up of predominantly unsaturated fats. These exclusions are supported by scientific

evidence discussed above and result in nutrient-dense foods that are encouraged by the *Dietary Guidelines, 2020–2025* qualifying for the claim. Because these foods can be particularly useful in building a healthy dietary pattern, which aligns with the purpose of the updated ''healthy'' claim, it is not necessary to include additional language accompanying the ''healthy'' claim about the saturated fat content of nuts.

(Comment 60) Another comment requests that FDA consider whether the saturated fat criterion for nuts and seeds could increase the use of nuts as a source of saturated fat in combination foods that may not have previously included nuts, which could pose issues for individuals with nut allergies (*e.g.,* who may not be aware of changes to products to include nuts).

(Response 60) FDA takes several measures to protect those with food allergies and other food hypersensitivities. These measures include establishing regulatory requirements (*e.g.,* allergen labeling); providing guidance to the food industry, consumers, and other stakeholders on best ways to assess and manage allergen hazards in food; conducting surveillance; and taking regulatory actions when appropriate. For certain foods or substances that cause allergies or other hypersensitivity reactions, there are more specific labeling requirements. Under section 403(w)(1) of the FD&C Act, food labels must identify the food source of all major food allergens used to make the food. While it is possible that some manufacturers may choose to reformulate products in ways that increase the use of nuts to meet the ''healthy'' criteria, FDA cannot predict whether this rule will result in an overall increase in the use of nuts in products that previously did not include them, and we do not have any evidence that there will be a significant change in the foods available to consumers with food allergies. If there are changes made to ingredients that include the addition of major food allergens (*e.g.,* nuts and fish), these ingredients still must be declared on the food label in accordance with sections 403(i) and 403(w) of the FD&C Act. It is important that consumers with food allergies always read labels to identify foods that they are allergic to, which can also help them recognize any changes in the formulation of a product.

(Comment 61) Some comments recommend that we increase the limit for saturated fat from added oils in peanut butter (≤5% of the DV for nuts and seeds in the protein food subgroup in proposed § 101.65(d)(3)(ii)) to make it consistent with the proposed limit for some of the other protein food subgroups (*i.e.,* ≤10% of the DV), noting that oils may sometimes be added to peanut butter for stability and ease of spreading. The comments highlight the nutrient content of nuts and seeds (*e.g.,* sources of unsaturated fats), including peanut butter, and the health benefits associated with their consumption. Further, several comments assert that peanut butter is an economical way for people to consume important nutrients and protein. One comment states that it would be unfortunate if peanut butter were excluded from the final rule.

(Response 61) As discussed above, we described the rationale for adjusting the saturated fat baseline limit for different protein subgroups in the proposed rule (87 FR 59168 at 59178–59179). For example, for game meats and seafood, the proposed saturated fat limit was increased from ≤5% DV per RACC to ≤10% DV per RACC (similar to the <2 g per RACC saturated fat limit for the ''extra lean'' nutrient content claim for game meat or seafood products) because using the ≤5% DV baseline limit would prevent nutrient-dense foods in these subgroups from being able to bear the ''healthy'' claim due to their inherent saturated fat. In contrast, for the nuts and seeds subgroup, the proposed adjustment to the baseline saturated fat limit was to exclude the inherent saturated fat in nuts and seeds from counting towards the ≤5% DV per RACC saturated fat limit. This adjustment was proposed so that all nuts, which contain fat profiles that are predominantly unsaturated fats, could qualify for the ''healthy'' claim, consistent with scientific evidence and the *Dietary Guidelines,* as described above.

We agree that nut butters can be an economical way for people to consume protein and certain nutrients. Our review of the products available in the current marketplace demonstrates that many nut butters meet the proposed saturated fat criteria for nuts and seeds, including all nut butters that contain only nuts or only nuts and salt (Ref. 2). Therefore, we disagree that peanut butter would be unable to bear the ''healthy'' claim with a saturated fat limit of ≤5% DV (excluding the saturated fat inherent in nuts). As noted in some comments, oils may be added to some peanut butters for stability and ease of spreading. However, as mentioned, there are also nut butters that do not contain added oils. Many of the nut butters that do not meet the limit for saturated fat to bear the claim contain palm oil or fully hydrogenated vegetable oils, which have relatively higher amounts of saturated fat compared with other oils. Increasing the baseline saturated fat limit to ≤10% DV, in addition to providing an exclusion for saturated fat inherent in nuts and seeds, could result in additional saturated fat, including from oils that are higher in saturated fat such as palm oil, in products that already contain inherent saturated fat. The *Dietary Guidelines, 2020–2025* states that ''[t]he fat in some tropical plants, such as coconut oil, palm kernel oil, and palm oil, are not included in the oils category because they contain a higher percentage of saturated fat than do other oils'' (Ref. 1). Further, increasing the saturated fat limit to ≤10% DV (which could result in additional saturated fat in nut butters, for example from oils with higher amounts of saturated fat), would not be consistent with our basis for proposing a saturated fat limit for 100% oils of 20% of total fat—to align with the National Academies (*i.e.,* DRI macronutrient report description of dietary fats low in saturated fatty acids), the *Dietary Guidelines, 2020–2025,* and other labeling claims. Many nut butters, including peanut butter, are able to qualify for the claim with a saturated fat limit of ≤5% DV while excluding the saturated fat inherent in nuts.

For the reasons discussed above, we decline to further adjust the proposed saturated fat limit for nuts and seeds and are therefore finalizing the limit for the nuts, seeds, and soy products subgroup at ≤5% DV per RACC or per 50 g for RACCs ≤50 g or ≤3 Tbsp, with the exclusion of inherent saturated fat in nuts, seeds, and soy products (§ 101.65(d)(3)(iii)).

(Comment 62) Some comments assert that the saturated fat criteria for seafood are too stringent, despite seafood having a favorable fatty acid profile (*i.e.,* good sources of unsaturated fats) and providing other important nutrients (*e.g.,* calcium, potassium, and vitamin D). For example, some comments said that certain higher fat species of fish (*e.g.,* king salmon and halibut) would be disqualified with a ≤10% DV per RACC saturated fat limit, despite being high in nutrients such as beneficial fats. Similarly, some comments assert that certain higher fat fish that contain predominantly unsaturated fat, are higher in eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) than other fish, and are recommended by the *Dietary Guidelines, 2020–2025* would be excluded from bearing the ''healthy'' claim. Some comments note that the proposed saturated fat limit for seafood represents a regression of standard to pre-2016 (referring to the FDA enforcement discretion guidance that was issued for foods that are not low in

total fat but have a fat profile consisting of predominantly mono- and polyunsaturated fats and is discussed further in our response below). Another comment expresses concern regarding the proposed approach for allowing more ''nutrient flexibility'' for some food categories but not others—such as nuts and seeds, but not seafood—despite their similar fatty acid profiles with high mono- and polyunsaturated fat content, arguing that it is arbitrary and unjustified. Some comments, therefore, request that we either increase the saturated fat limit for seafood (*e.g.,* from ≤10% DV to ≤15% DV), use a framework similar to our 2016 guidance (*i.e.,* for foods that contain amounts of combined mono- and polyunsaturated fats that are greater than their saturated fat amount), or provide an exemption for saturated fat contained in seafood, similar to the exemption for saturated fat contained in nuts and seeds, because they all have similar fatty acid profiles. Other comments request that we expand the exemption for raw, whole fruits and vegetable to other single ingredient foods, to ensure that nutrient-dense foods recommended by the *Dietary Guidelines, 2020–2025,* such as seafood, can qualify for the claim.

(Response 62) As discussed in the *Dietary Guidelines, 2020–2025,* the seafood subgroup, which includes fish and shellfish, provides beneficial unsaturated fatty acids, such as EPA and DHA, as well as other important nutrients (*e.g.,* calcium, vitamins D and B_{12}, and heme iron). Despite the beneficial fatty acid and nutrient profiles of seafood, almost 90% of the U.S. population do not meet recommendations for seafood (Ref. 1). The *Dietary Guidelines, 2020–2025* encourages seafood choices that are higher in beneficial unsaturated fatty acids (*e.g.,* EPA and DHA), and does not distinguish between seafood based on saturated fat amounts, in contrast to dairy and meat (*i.e.,* fat-free or low-fat dairy, and lean or low-fat meat).

In 2016, we issued a guidance on the use of the term ''healthy,'' in part to advise food manufacturers of our intent to exercise enforcement discretion relative to foods that are not low in total fat but have a fat profile makeup of predominantly mono- and polyunsaturated fats. We explained in the guidance that the focus of the most recent dietary fat recommendations has shifted away from limiting total fat intake to encouraging intakes of mono and polyunsaturated fats and that foods that use the term 'healthy' on their labels that are not low in total fat should have a fat profile makeup of predominantly mono and polyunsaturated fats (*i.e.,* sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food). We advised manufacturers that we intended to exercise enforcement discretion with respect to the requirement at that time that any food bearing the nutrient content claim ''healthy'' meet the low fat criterion (§ 101.65(d)(2)(i)), provided that the amounts of monounsaturated and polyunsaturated fats in the product constituted the majority of the fat content, if certain conditions were met (Notice of Availability for a Final Guidance ''Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry'' September 28, 2016, 81 FR 66527). This exercise of enforcement discretion was important because the fat that is contained in these products is mostly the types that are encouraged by current dietary recommendations (*i.e.,* unsaturated fats).

We agree with the comments recommending that we expand the proposed exclusion for inherent saturated fat in nuts and seeds to seafood because seafood has fat profiles consisting of predominantly unsaturated fats similar to nuts and seeds and contains EPA and DHA as well as other important nutrients. The final rule, therefore, excludes the inherent saturated fat contained in seafood from the saturated fat limit for the seafood subgroup in § 101.65(d)(3)(iii), similar to the nuts, seeds, and soy products subgroup. Our marketplace review demonstrates that saturated fat amounts not only vary between types of seafood (*e.g.,* different types of fish and shellfish), but also within species (*e.g.,* different species of salmon) (Ref. 2). While single-ingredient seafood automatically qualifies for the ''healthy'' claim under the single-ingredient exemption (see Response 9), a saturated fat limit for the seafood subgroup of ≤10% DV could exclude products containing certain species of higher fat fish/seafood (*e.g.,* certain species of salmon) that are sources of beneficial unsaturated fatty acids and recommended by the *Dietary Guidelines,* from qualifying for the ''healthy'' claim if the products contain other ingredients (*e.g.,* sauce or seasoning). Further, the saturated fat limits for combination foods (*i.e.,* mixed products, main dishes, and meals) could restrict rather than encourage seafood from being incorporated into combination foods (see section V.E (''Combinations Foods'') for further discussion on the saturated fat limits for combination foods). Excluding individual foods that contain higher fat fish that are sources of unsaturated fatty acids (*e.g.,* EPA and DHA), but are not single-ingredient products, or causing manufacturers to avoid using certain seafood ingredients in combination foods, is not consistent with the *Dietary Guidelines, 2020–2025,* which specifically encourages consumption of fish that is higher in EPA and DHA (and lower in methylmercury) and does not distinguish between types of seafood based on saturated fat amounts.

The basis for the exclusion of inherent saturated fat in seafood is similar to that for the exclusion of inherent saturated fat in nuts, seeds, and soy products. The fatty acid profile of seafood is similar to nuts, seeds, and soybeans in that it is predominantly unsaturated fats and there is strong evidence that substituting unsaturated fats for saturated fat can lower the risk of CVD (for further discussion of this evidence, see Response 63). Further, there are health claims based on the evidence supporting the substitution of unsaturated fats for saturated fats and risk of coronary heart disease. For example, we have authorized a health claim for the substitution of unsaturated fats for saturated fats and reduced risk of heart disease. In addition, as previously noted, the *Dietary Guidelines, 2020–2025* does not emphasize or differentiate between certain seafood based on saturated fat, whereas it does for other food groups and subgroups (*i.e.,* lean or low-fat meats and fat-free or low-fat dairy). Instead, the *Dietary Guidelines, 2020–2025* encourages consumption of seafood, such as salmon, that is higher in the unsaturated fats EPA and DHA (and lower in methylmercury). Even fish with relatively higher amounts of saturated fat have fat profiles that are predominantly unsaturated fats (*e.g.,* salmon, chinook, raw contains ~30% saturated fat and ~69% unsaturated fat) (Ref. 7). The *Dietary Guidelines, 2020–2025* also discusses specific strategies for reducing saturated fat intake by replacing it with unsaturated fat and for adding variety to protein subgroup intakes—such as consuming seafood more often or replacing foods that are higher in saturated fat (*e.g.,* high-fat meats or regular cheese) with sources of unsaturated fat. Therefore, to ensure that nutrient-dense seafood products with a fatty acid profile of predominantly unsaturated fats are not excluded from bearing the ''healthy'' claim, we are excluding the inherent saturated fat in seafood from the saturated fat limit in § 101.65(d)(3)(ii) for the seafood subgroup.

In the proposed rule, we proposed an adjustment to the baseline saturated fat limit for seafood (*i.e.,* increasing the baseline saturated fat limit from ≤5% DV per RACC to ≤10% DV per RACC) to be consistent with the saturated fat limit for the ''extra lean'' nutrient content claim for seafood or game meat products (§ 101.62(e)(4)), as was used in the original criteria for ''healthy,'' and because using the baseline saturated fat limit would prevent nutrient-dense foods in this food group from being able to bear the ''healthy'' claim even though they contain important beneficial nutrients such as unsaturated fatty acids (*e.g.,* EPA and DHA) and can help consumers build a healthy dietary pattern as recommended by the *Dietary Guidelines, 2020–2025.* Because the inherent saturated fat in seafood will now be excluded from the saturated fat limit for the seafood subgroup, we have determined that the baseline saturated fat limit of ≤5% (with the exclusion of inherent saturated fat in seafood), rather than the proposed limit of ≤10% DV, will result in nutrient-dense seafood products qualifying for the ''healthy'' claim without resulting in the addition of unnecessary saturated fat to products that already contain inherent saturated fat. This approach is consistent with the saturated fat criteria for the nuts, seeds, and soy products subgroup. Moreover, the single ingredient exemption, discussed in Response 9, includes higher fat species of fish that are sources of beneficial unsaturated fatty acids such as EPA and DHA, among other nutrient-dense foods.

(Comment 63) Some comments contend that few dairy foods, other than non-fat and low-fat, unflavored, milk and yogurt, could bear the ''healthy'' claim despite dairy being good or excellent sources of three of the four nutrients of public health concern (*i.e.,* calcium, vitamin D, and potassium). Some comments support having higher saturated fat limits for foods such as dairy, or express opposition to any limit on saturated fat, asserting that FDA lacks credible evidence that saturated fats are harmful. Some comments object to FDA's interpretation of the effect of saturated fat on cardiovascular health and obesity, arguing that full-fat dairy products have ''neutral and positive attributes.'' Other comments recommend that we exclude milkfat from the saturated fat limit for the dairy food group when it is inherently present in a product (such as cheese), due to emerging science on benefits of milkfat, arguing that full-fat and reduced-fat dairy products (*e.g.,* 2% milk) should also be able to make ''healthy'' claims. Some comments state that all nutrition science should be considered, not just the science reflected in the *Dietary Guidelines, 2020–2025* and the updated Nutrition Facts label, and reference groups outside of the United States that have either provided exemptions for certain dairy products (*e.g.,* 2% milk, whole milk, and yogurt and cheese if they contain certain amounts of nutrients) from front-of-pack labeling requirements (Health Canada) or have changed their dietary recommendations to include dairy at all fat levels for the general population (Australian Heart Foundation). Further, some comments note that the 2025 Dietary Guidelines Advisory Committee is addressing a question on food sources of saturated fat, and that future iterations of the Dietary Guidelines may create additional food source-specific guidelines on saturated fat; therefore, they argue that flexibility should be provided for dairy products (*e.g.,* exempting milkfat from the saturated fat limit) to reduce delays in adjusting to the next Dietary Guidelines.

(Response 63) In the proposed rule (87 FR 59168 at 59172), we described the need to update the ''healthy'' definition so the claim would again accurately represent levels of nutrients in a food that may help consumers maintain healthy dietary practices, consistent with current nutrition science and Federal dietary guidance, as reflected in the *Dietary Guidelines, 2020–2025.* More closely aligning the ''healthy'' definition with the nutrition science underpinning the *Dietary Guidelines, 2020–2025* will better inform consumers and help them identify foods that are particularly useful in building a healthy dietary pattern. The Dietary Guidelines, which are updated every 5 years to reflect current nutrition science, are the foundation of Federal dietary guidance and are intended to inform policymakers when implementing federal policies and programs related to food, nutrition, and health. The Dietary Guidelines, as well as consensus reports from authoritative bodies, and their nutrition science underpinning, help FDA to shape regulations on nutrition-related claims and other information that is on a food label.

When developing regulations for nutrition-related claims and nutrition labeling, we review and consider many sources of scientific evidence, information, and dietary recommendations that may be relevant (*e.g.,* conclusions of other expert or international bodies), and findings or research that represent consensus of experts in the field or an entire body of scientific literature are generally more informative than individual studies. We have closely aligned the updated criteria with nutrition science underpinning federal dietary guidance, particularly the Dietary Guidelines, while also considering other sources of scientific evidence and information, for example, consensus reports from authoritative bodies; FDA health claims and the scientific evidence on which they are based; our marketplace review of nutrient-dense foods; public comments to the proposed rule, including studies and data submitted in comments; and U.S. consumption patterns for saturated fat, added sugars, sodium, and recommended food groups and subgroups.

Nutrient-dense foods are described in the *Dietary Guidelines, 2020–2025,* as providing important nutrients (*e.g.,* vitamins and minerals), while providing little or no saturated fat, added sugars, and sodium (Ref. 1). Fat-free and low-fat dairy products are considered to be more nutrient-dense forms of dairy because they provide the same important nutrients (*e.g.,* calcium, vitamin D, and potassium), but contain less saturated fat than higher fat options such as 2% and full-fat milk and cheese (Ref. 1). As discussed above, the *Dietary Guidelines, 2020–2025* states that it would be beneficial for most consumers to increase consumption of dairy in fat-free or low-fat forms and includes strategies to increase dairy intake, such as drinking fat-free or low-fat milk with meals or incorporating unsweetened fat-free or low-fat yogurt into meals or snacks. In the proposed rule, we proposed a saturated fat limit for the dairy group of ≤10% DV per RACC, an increase from the baseline saturated fat limit of ≤5% DV per RACC, so that fat-free and low-fat dairy products—more nutrient-dense forms of dairy recommended by the *Dietary Guidelines, 2020–2025*—could meet the saturated fat limit. Our review of the products available in the marketplace, in response to these comments, demonstrates that nutrient-dense forms of dairy, including fat-free and low-fat milk and yogurt, can meet the proposed ≤10% DV per RACC saturated fat limit (Ref. 2). Our marketplace review also indicates that many cheeses currently in the marketplace do not meet the proposed ≤10% DV per RACC saturated fat limit (*e.g.,* because fat-free and low-fat cheese products make up a low percentage of the overall cheese market) (Ref. 2). However, the *Dietary Guidelines, 2020–2025* emphasizes that most individuals would benefit by increasing intake of fat-free or low-fat

cheese (as well as other types of dairy such as fat-free or low-fat milk and yogurt), and we have determined that a saturated fat limit of ≤10% DV per RACC or per 50 g for RACCs ≤50 g or ≤3 Tbsp for the dairy food group will help consumers identify dairy products in more nutrient-dense forms (*i.e.,* fat-free and low-fat), consistent with the *Dietary Guidelines, 2020–2025,* and that these nutrient-dense dairy foods that qualify for the ''healthy'' claim can serve as a foundation for a healthy dietary pattern. Therefore, we decline to increase the saturated fat limit for dairy foods above ≤10% DV per RACC. We emphasize that dairy products that exceed the saturated fat limit can still be part of a healthy dietary pattern and their nutritional attributes can be conveyed with other labeling claims or other truthful and non-misleading statements in labeling.

The *Dietary Guidelines, 2020–2025* provides the following recommendation for limiting saturated fat: ''For those 2 years and older, intake of saturated fat should be limited to less than 10 percent of calories per day by replacing them with unsaturated fats, particularly polyunsaturated fats'' (Ref. 1). The recommended limit for saturated fat in the *Dietary Guidelines, 2020–2025* is based on the totality of the scientific evidence, including rigorous systematic reviews, examined by the 2020 DGAC for the relationship between saturated fat, particularly the replacement of saturated fat with unsaturated fats, and cardiovascular disease and blood cholesterol. For example, the 2020 DGAC review found that reducing intake of saturated fat in adults by substituting it with unsaturated fats, particularly polyunsaturated fat, lowers the incidence of CVD (Ref. 8). Specifically, the 2020 DGAC concluded in their report that: (1) there was strong evidence that replacing saturated fat intake with polyunsaturated fatty acids reduces CHD events and CVD mortality in adults and (2) there was strong and consistent evidence that replacing saturated with unsaturated fats, particularly polyunsaturated fats, in the diet reduces low-density lipoprotein (LDL) cholesterol in adults. The 2020 DGAC report emphasizes that shifts from saturated fat to unsaturated fats are best within the context of a healthy dietary pattern, which includes higher intake of fatty fish, nuts and seeds, and low-fat dairy (as well as other recommended food groups) (Ref. 8).

As discussed in detail above, the inherent saturated fat in seafood and in nuts, seeds, and soybeans are excluded from the saturated fat limits for the seafood subgroup and the nuts, seeds, and soy products subgroup because their fat profiles are predominantly unsaturated fats. Based on the evidence for unsaturated fats, particularly the substitution of unsaturated fats for saturated fat, there are Federal dietary recommendations and health claims for the substitution of unsaturated fats for saturated fat in the diet and for foods with fatty acid profiles that are predominantly unsaturated fats. Further, in contrast to what it does for dairy, the *Dietary Guidelines, 2020–2025* does not distinguish between or encourage different types of seafood based on saturated fat content, but rather encourages seafood choices that are higher in unsaturated fats, *i.e.,* EPA and DHA (and lower in methylmercury), and also does not distinguish between or encourage different types of nuts, seeds, and soy products based on saturated fat content. In contrast to the fat profiles of nuts, seeds, and soy products, and seafood, which are predominantly unsaturated fat, the fat profiles of full-fat dairy foods are predominantly saturated fat (*e.g.,* milk, whole, 3.25% milkfat, with added vitamin D contains ~67% saturated fat and 25% unsaturated fat; yogurt, plain, whole milk contains ~54% saturated fat and ~22% unsaturated fat) (Ref. 7). One of the characteristics of a healthy dietary pattern, as described in the *Dietary Guidelines, 2020–2025,* includes relatively higher amounts of low- or non-fat dairy. In addition, as mentioned previously, the *Dietary Guidelines, 2020–2025* encourages shifts to more nutrient-dense forms of dairy, *i.e.,* fat-free and low-fat dairy.

We are aware of relatively recent studies on the effects of different sources of saturated fat, such as dairy. The 2020 DGAC review focused on types of dietary fats rather than sources; however, the committee recognized the growing body of research on specific fatty acids, sources of fats (explicitly sources of saturated fat), and the food matrix in their report. As noted in some comments, the 2025 DGAC is currently examining a question on food sources of saturated fat and risk of cardiovascular disease. It would be premature to speculate about what the findings will be from the 2025 DGAC review related to food sources of saturated fat, or what future iterations of the Dietary Guidelines might include on this topic. Further, we are unaware of recommendations from other U.S. Federal entities, or consensus reports from authoritative bodies that include recommendations for the general U.S. population, that encourage full-fat dairy for the general U.S. population.

Based on these considerations, we decline to exempt the saturated fat inherent in dairy foods from the saturated fat limit for the ''healthy'' definition. We will continue to stay abreast of research in this area, including any future consensus reports or recommendations from federal bodies, such as the *Dietary Guidelines.* For discussion of comments expressing opposition to any limit on saturated fat for the ''healthy'' criteria, see section (a) below (basing the saturated fat limit on a ratio approach versus the % DV).

(Comment 64) Some comments support the proposed saturated fat limit of ≤20% of total fat for 100% oils, oil-based spreads, and oil-based dressings, asserting that this limit is consistent with what is used by the National Academies, grounded in the scientific literature, and ensures that oils, spreads, and dressings can be a part of a healthy dietary pattern because they are lower in saturated fat and higher in unsaturated fatty acids. One comment notes that FDA struck the right balance in determining which products should be considered ''healthy'' with respect to the ''oils and fats'' group. In contrast, some comments argue that the saturated fat limit of ≤20% of total fat poses a food design problem for oil-based spreads. Two comments assert that 25% of total fat is the lower limit for saturated fat in order for spreads to maintain their solid nature, and that a limit of 20% of total fat would only allow sprays and liquid margarine products to qualify. Further, these comments recommend that spreads be given the option of qualifying as a small RACC food and qualifying based on the actual amount of saturated fat per serving rather than the saturated fat oil component. One comment notes that a saturated fat limit of 25% of total fat is 5% lower than most spreads in the market. Another comment recommends increasing the limit to 33% of total fat asserting that this would be consistent with the World Health Organization's (WHO) recommendations for total fat and saturated fat of no more than 30% of caloric intake and 10% of caloric intake, respectively.

(Response 64) In the proposed rule (87 FR 59168 at 59189), we explained that we proposed a saturated fat limit for oils of 20% of total fat to ensure that only oils with a fat profile of predominantly monounsaturated and polyunsaturated fats, as recommended by the *Dietary Guidelines, 2020–2025,* meet the criteria for ''healthy.'' We discussed in the proposed rule that a saturated fat limit of ≤20% of total fat for the oils group is also consistent with both the percentage used in the National

Academies DRI macronutrient report to describe dietary fats low in saturated fatty acids (Ref. 9) and the saturated fat requirement for determining the type of foods, for example vegetable oils, spreads, and shortenings, that are eligible to bear the health claim for ''Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease'' (Ref. 13). Further, it aligns with the recommendations and strategies in the *Dietary Guidelines, 2020–2025* for the substitution of saturated fat with unsaturated fat, including specific shifts that are encouraged related to oils (*e.g.,* using oils that are higher in unsaturated fat instead of fats high in saturated fat, such as butter, shortening, lard, or coconut or palm oils). As noted above, the *Dietary Guidelines, 2020–2025* does not include coconut oil, palm kernel oil, or palm oil in the oils category because they contain a higher percentage of saturated fat compared to other oils.

We agree with comments that a saturated fat limit of ≤20% of total fat is supported by a body of scientific evidence, including evidence demonstrating reductions in LDL-cholesterol when plant-derived oils are substituted for fats or oils higher in saturated fat. We recognize that saturated fat is used in oil-based spreads for certain functions such as stability and texture. However, we disagree that 25% of total fat is the lower limit for saturated fat in order for oil-based spreads to maintain their solid nature, as our marketplace review demonstrates that there are oil-based spreads currently in the marketplace that contain saturated fat in amounts that are ≤20% of total fat (Ref. 2). Therefore, we also disagree that a saturated fat limit of ≤20% of total fat would only result in sprays and liquid margarine products qualifying. Increasing the limit for oil-based spreads, for example to ≤25% or ≤33% of total fat as requested in some comments, would result in use of the ''healthy'' claim on oil-based spreads with higher amounts of saturated fat which would be inconsistent with the claim's objective of helping consumers to identify products that are particularly useful for creating a healthy diet consistent with dietary recommendations. We note that the WHO recommended limits of ≤30% of total calories from total fat and ≤10% of total calories from saturated fat are based on percentages of total caloric intake and are not on a per product basis. Therefore, we disagree that the WHO recommendations for total fat and saturated fat as a percentage of total calorie intake warrant a saturated fat limit of 33% of total fat for oil-based spreads in this rule regarding the ''healthy'' claim.

For the reasons discussed above, we decline to increase the saturated fat limit for oil-based spreads and are finalizing the saturated fat limit of ≤20% of total fat for 100% oils, oil-based dressings, and oil-based spreads. While oil-based spreads are a small RACC food, the saturated fat limit for the oils food group, including 100% oil, oil-based dressings, and oil-based spreads, is based on a percentage of total fat rather than the amount of saturated fat per serving, for the reasons discussed above.

a. Request for Comment on Limits Based on Ratio of Saturated Fat to Total Fat (Alternative Approach)

In the preamble to the proposed rule, we explained that we were also considering alternatives to the proposed limits on saturated fat, including an approach using a ratio of saturated fat to total fat, such as a ratio based on current DVs for saturated fat and total fat, which are based on 10% and 35% of daily calorie intake, respectively (87 FR 59168 at 59179). We explained that the intent of this approach would be to apply a single ratio across all food groups, thereby reducing the variation in the proposed limits, while still providing some flexibility for foods that supply monounsaturated and polyunsaturated fats (see 87 FR 59168 at 59179). We invited comment on this approach.

(Comment 65) Some comments argue that a ratio of unsaturated fat to saturated fat is a more favorable approach than the proposed approach for saturated fat limits based on percent DV, asserting that current Dietary Guidelines focus ''on the type of fat, rather than the amount of fat or specific subtypes of fat.'' Similarly, some comments argue that a ratio-based approach (*e.g.,* a ratio of saturated fat to total fat of <1:3.5 derived from the DVs for saturated fat and total fat) would ensure that foods such as fish products, which contain high levels of mono- and polyunsaturated fats, are able to bear the ''healthy'' claim, as well as other foods like cooked soybeans, cooked edamame, dried chickpeas, and boiled or canned potatoes. In contrast, numerous comments express support for the current proposal of using a limit of saturated fat alone, and not for the alternative approach of using a ratio of saturated fat to total fat, reasoning that the current proposed approach is simpler and aligns better with the Dietary Guidelines, which do not focus on achieving a particular ratio of saturated fat. The comments argue that a ratio approach is also not generally used in other dietary guidance and that any type of ratio-based approach that would place emphasis on overall fat content is not consistent with Federal policy recommendations and could create confusion for consumers. However, one comment indicates support for a ratio approach if the Dietary Guidelines were updated to include a recommended ratio of saturated to total fat. Some comments also discuss that an alternative approach like a ratio of saturated fat to total fat would be harder to understand and possibly misleading—specifically, it could allow manufacturers to manipulate their ratios and achieve ''healthy'' claims on products with high saturated fat. Similarly, other comments express opposition to the use of a ratio for saturated fat to total fat on the grounds that it could encourage manipulation of dairy foods to decrease the ratio, it would not contribute to greater consumer understanding of ''healthy'' diets, and it could lead to a greater intake of saturated fats. In addition, one comment says that a ratio approach would exclude foods with small amounts of saturated fat (*e.g.,* 1 gram) if those foods did not contain at least a certain amount of total fat (*e.g.,* 3.5 grams).

(Response 65) We agree that the Dietary Guidelines focus on types of fat, rather than the amount of total fat or specific subtypes of fat. However, this does not support a ratio approach for saturated fat. In fact, this supports the proposed approach for saturated fat as a percentage of the DV, as the *Dietary Guidelines, 2020–2025* provides a recommended daily limit amount for saturated fat, but does not provide recommendations for specific ratio amounts (*e.g.,* ratio of saturated fat to total fat or ratio of unsaturated fat to saturated fat). Therefore, we agree that the approach of a saturated fat limit based on the percent DV, and not on a ratio, is more consistent with the *Dietary Guidelines, 2020–2025*'s recommended quantitative limit for saturated fat. We also note that removal of the total fat limit as part of the ''healthy'' criteria also supports the shift to focus on the types of fat rather than total fat, as we discuss in the proposed rule (87 FR 59168 at 59178–59179). We agree that using saturated fat limits based on the percent DV is simpler than using limits based on a ratio and emphasize that a ratio approach does not distinguish between products that have low amounts of saturated fat and low amounts of other fat versus products that have high amounts of

saturated fat and high amounts of other fat. Therefore, we share the concern that a ratio approach could allow manipulation of fats to allow for more saturated fat in a product by increasing other fat sources in the product, which goes against the intent of having a saturated fat limit. In addition, a ratio approach could result in manipulation to add more fat sources in order for a product that contains even a small amount of saturated fat to qualify (*e.g.,* if the product contained a small amount of saturated fat, but not enough total fat to meet the specified ratio).

We note one exception in the ''healthy'' criteria, for oils and oil-based spreads and dressings, where the limit for saturated fat is based on a percentage of total fat. The composition of oils is unique (primarily made up of fatty acids) compared to the other food groups, and we proposed a limit for saturated fat of ≤20% total fat for this category. See Response 64 for further discussion about the saturated fat limit for oils and oil-based dressings and spreads.

Regarding seafood, we have adjusted the proposed criteria to provide more flexibility for nutrient-dense foods that are recommended by the Dietary Guidelines (see Response 62 for discussion of saturated fat and seafood). For example, all varieties of fish, including fish that is high in mono- and polyunsaturated fats but also contains saturated fat, can qualify for the ''healthy'' claim based on the single-ingredient exemption. A majority of other examples provided in comments in support of a ratio can also meet the updated definition (*e.g.,* cooked soybeans, cooked edamame, dried chickpeas). See Response 58 on saturated fat and beans, peas, lentils, and soy products and Response 9 for the expanded exemption for single-ingredient nutrient-dense foods.

(Comment 66) One comment states that saturated fat, as a single amount or a ratio, should not be included as a nutrient to limit as it could result in reduced intake of nutrient-dense foods. The comment asserts that limiting saturated fat as a class, or single nutrient, is too simplistic, noting for example that it does not take into consideration individual saturated fatty acids that can have different effects. Another comment recommends that careful consideration be given when grouping all saturated fatty acids under the general term ''saturates'' because not all saturates have the same physiological effects.

(Response 66) We disagree that saturated fat should not be included as a nutrient to limit and that including it as a nutrient to limit would prevent nutrient-dense foods from bearing the ''healthy'' claim. As discussed in the proposed rule (87 FR 59168 at 59178), several consensus reports reviewing the scientific evidence related to saturated fat intake, as well as the *Dietary Guidelines, 2020–2025,* include recommendations to limit saturated fat based on CVD risk. Further, dietary recommendations continue to recognize the well-established relationship between consumption of saturated fat and effects on blood cholesterol (87 FR 59168 at 59178). Despite these recommendations, 76% of males and 71% of female adults (ages 19–30 years) in the United States exceed recommended limits for saturated fat (Ref. 8). It is important, therefore, to continue to include a limit for saturated fat as part of the ''healthy'' definition, while still ensuring that there are nutrient-dense foods containing some inherent saturated fat that can qualify. The updated ''healthy'' criteria framework includes adjustments and exemptions to ensure that nutrient-dense foods recommended by the Dietary Guidelines can qualify for the claim. In the proposed rule, we made adjustments to the baseline saturated fat limit for some food groups and subgroups, such as increasing the saturated fat limit to ≤10% per RACC for dairy products to ensure that low-fat dairy could qualify, as recommended by the *Dietary Guidelines, 2020–2025,* and excluding the inherent saturated fat in nuts and seeds from the saturated fat limit for that subgroup. Further, as discussed above, we have expanded the exemption for raw, whole fruits and vegetables to single-ingredient foods recommended by the Dietary Guidelines and made adjustments to the proposed criteria so that the inherent saturated fat in soybeans and seafood are excluded from the saturated fat limit for their respective subgroups. As a result, a variety of nutrient-dense foods can qualify for the updated ''healthy'' claim, particularly when compared to the original ''healthy'' definition.

We further disagree that the saturated fat limit is too simplistic and does not take into consideration individual saturated fatty acids that can have different effects. The *Dietary Guidelines, 2020–2025* provides a quantitative intake recommendation for saturated fat, which relates to intake of all saturated fatty acids. The comments did not provide details on a suggested alternative grouping or provide data or information to support the rationale for an alternative grouping for saturated fat, and therefore FDA does not have a basis on which to consider alternative groupings. For these reasons, we decline to change the classification of the saturated fat group and all individual saturated fatty acids are included within the saturated fat group for the purposes of the ''healthy'' nutrient content claim criteria.

(Comment 67) One comment asserts that the Dietary Reference Intake (DRI) values for saturated fat, on which the DV is based, were issued in the early 2000s and that methodology for developing evidence-based guidance has evolved since that time. The comment also states that DRIs are predicated on essentiality, and it is unclear if saturated fat is an essential nutrient given that humans can synthesize saturated fatty acids de novo. Therefore, the comment asserts that the approach used to establish a saturated fat DV may not be appropriate and supports a ratio approach instead.

(Response 67) While DRIs are one consideration when determining DVs, DVs do not have to be solely or directly based on DRI values. For example, there is not a DRI value for saturated fat, and the DVs for macronutrients—total fat, total carbohydrate, and protein—are not solely based on DRI values. We also note that the DRI framework has been expanded to now include chronic disease risk reduction (Refs. 10 and 11), therefore a DRI value does not need to be based on essentiality.

In the proposed rule (87 FR 59168 at 59178), and the NFL Final Rule (81 FR 33742), we provide examples of consensus reports, as well as the *Dietary Guidelines, 2020–2025,* which have reviewed the scientific evidence related to saturated fat intake, and recommended saturated fat intakes of no more than 10% of calories based on CVD risk. In 2016, we reaffirmed in the NFL Final Rule that the 20 g DV, which is 10% of calories for a 2,000 calorie reference intake level, is consistent with scientific evidence based on CVD risk for the general population (81 FR 33742 at 33786). Therefore, the DV for saturated fat is not related to whether or not saturated fat is an essential nutrient. Similarly, the recommendations in consensus reports, as well as in the Dietary Guidelines, to limit daily intake of saturated fat are not based on whether saturated fat is essential, but rather on the scientific evidence for saturated fat as it relates to CVD risk. The 2020 DGAC Report explains that humans do not have dietary requirements for saturated fats because they ''synthesize them from other dietary substrates''; intake of saturated fat is associated with risk of CVD; and the Committee recommends ''saturated fat intake be

limited to less than of 10 percent of total energy intake, as recommended by the *2015–2020 Dietary Guidelines for Americans*'' (Ref 8). While we agree that methodology for developing evidence-based guidance has evolved since the early 2000s, we disagree that the DV is based on methodology from that time, as the 2020 DGAC, for example, used current methodologies to evaluate the body of evidence for saturated fat and CVD risk.

Basing nutrient limits for the use of the ''healthy'' claim on a percentage of the DV for saturated fat, added sugars, and sodium, instead of on gram amounts (the approach used in the original ''healthy'' criteria), allows for flexibility and helps ensure longevity if DVs are updated in the future. If the DV for saturated fat were to change in the future, it would be reflected in the ''healthy'' criteria because the limits for the NTL are based on the % DV.

Lastly, when we asked for comment on an alternative ratio approach, the example that we provided in the proposed rule (*i.e.,* a ratio based on current DVs for saturated fat and total fat) was based on DVs, including the DV for saturated fat. The comment did not provide input specifically on that example nor did it suggest, or provide information or evidence for, an alternative ratio amount that would not be based on DVs. For the reasons described above, we do not have a basis to change to a ratio approach and will maintain the overall approach of basing the saturated fat limit on a percentage of the DV rather than on a ratio (with the exception of the oils group as discussed above).

3. Sodium

(Comment 68) Many comments agree that sodium should be included as a nutrient to limit in the ''healthy'' claim. Some comments agree that the proposed ≤10% of the DV per RACC baseline limits for individual foods, including fruit, vegetable, grain, and dairy products and protein foods, are an appropriate step towards curtailing sodium consumption. These comments note that most sodium consumed in the United States comes from salt added during commercial food processing and preparation and that sodium consumption in the United States far exceeds the recommended daily intake limit—average intake (ages 1 and older) is 3,393 mg/day and the recommended daily limit from the current *Dietary Guidelines, 2020–20205* is 2,300 mg/day for most ages. A few comments argue that the sodium limits should be more restrictive, for example, that the baseline limit should be lowered to ≤5% DV. Other comments agreed with a ≤10% DV limit instead of a ≤5% DV limit based on the functional role that sodium plays in many foods, asserting that a sodium limit of ≤5% DV is not feasible or practical at this time. One comment acknowledges that, while lower sodium limits would be preferable, aiming to lower daily intake to 2,300 mg is a more realistic goal; however, it also notes that foods that exceed the voluntary sodium reduction targets should not be eligible for the ''healthy'' claim.

(Response 68) In the proposed rule (87 FR 59168 at 59179), we explained that a lower sodium limit for the updated ''healthy'' definition should be feasible due to reductions in sodium in certain foods in response to consumer support for policies to limit sodium content in manufactured foods and technological progress since the original definition was issued in 1994. For example, in 2021, FDA published short-term (2.5 year) voluntary sodium reduction targets for the food industry, as part of a gradual, iterative approach to help reduce sodium in the food supply and support reducing sodium intakes over time (Ref. 12). In 2024, we issued new, voluntary targets for sodium reduction in foods in a draft guidance that serve as Phase II of the Agency's ongoing work. The new targets build on the final, voluntary sodium reduction goals issued in 2021, now referred to as Phase I (Ref. 47). When determining the proposed sodium limit for the ''healthy'' claim, we considered the many functions of sodium in food, including taste, texture, microbial safety, and stability. The sodium limit of ≤10% DV (currently ≤230 mg for adults and children 4 years of age and older) is ~50% less than the sodium limit in the original criteria for ''healthy'' (480 mg or ~20% DV). As noted, we proposed a lower limit (≤10% DV) than the limit in the original criteria because of the technological advances and progress that have been made since 1994 in reducing sodium in foods. We are concerned that a limit of ≤5% of the DV for sodium would not be practical at this time. Having limits that are too restrictive would prevent a variety of nutrient-dense foods across foods groups and subgroups from being able to qualify for the ''healthy'' claim.

Compared to the sodium limit in the original definition (480 mg per RACC or per 50 g for RACCs ≤30 g for individual foods), the lower limit of ≤10% DV (currently 230 mg) per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) will allow the updated ''healthy'' claim to help consumers identify more nutrient-dense foods that can help them achieve a healthy dietary pattern, which is consistent with the *Dietary Guidelines, 2020–2025.* Further, our marketplace review of nutrient-dense foods demonstrates that a ≤10% DV limit permits a variety of nutrient-dense foods to qualify across food groups and subgroups, while allowing some sodium for processing, preservation, or taste (*e.g.,* low sodium canned vegetables) (Ref. 2). For the reasons discussed above, we decline to lower the baseline limit for sodium to ≤5% DV per RACC. See the discussion in Response 69 for a comparison of the sodium reduction targets and the criteria for the ''healthy'' nutrient content claim.

(Comment 69) Some comments raise concerns that the proposed limits for sodium are too restrictive and would exclude products encouraged by the *Dietary Guidelines, 2020–2025,* including whole grain tortillas and most nutrient-dense low/reduced sodium canned products (*e.g.,* canned vegetables). The comments assert that the proposed limits are significantly lower (25–50%) than the original ''healthy'' criteria and suggest that food products could contain more sodium and still align with the *Dietary Guidelines, 2020–2025.* Some comments state that the proposed limits undermine the functional purposes of sodium. The comments also assert that sodium is crucial to ensuring the flavor of foods that are promoted by the rule and the *Dietary Guidelines, 2020–2025,* reasoning that compliance with the ≤10% DV limit would result in a lack in taste that would discourage consumption of such products, even if they bear the ''healthy'' claim.

Some comments assert that the proposed sodium limits would not encourage reformulation and that there is more room to accommodate greater amounts of sodium, suggesting different options as alternative sodium criteria across food categories, for example:

1. Individual foods: 0–10% DV per RACC or per 50 g for foods with small RACCs; mixed products: 460 mg (20% DV) per RACC and labeled serving or per 50 g for foods with small RACCs; main dishes: 600 mg or less per labeled serving; and meals: 600 mg or less per labeled serving; or

2. Individual or mixed foods, small RACC (RACC ≤30 g/2 Tbsp): 10% DV per RACC; individual or mixed foods, RACC >30 g/2 Tbsp: 20% DV per RACC; main dishes: 25% DV per serving; and meals: 30% DV per serving.

The comments argue that the alternative criteria would allow more options in the marketplace to be labeled as ''healthy,'' including foods that are encouraged by the Dietary Guidelines

and MyPlate, and those that are affordable, accessible, and culturally relevant choices, that do not meet the proposed sodium criteria (*e.g.,* canned vegetables, 100% whole grain tortillas, some Special Supplemental Nutrition Program for Women, Infants and Children (WIC) eligible cereals, and reduced sodium/light soups). A few comments advocate for increasing the sodium limit to ≤15% DV for individual foods because it would provide additional enticements for reformulation efforts to lower the sodium levels for foods. One comment, in support of keeping the sodium limits for the original ''healthy'' definition, notes that when the sodium limit for the original ''healthy'' definition of 600 mg is applied to a main dish weighing 270 g (222 mg sodium/100 g), it is well below the category target mean of 270 mg/100 g for the ''frozen meals'' category from the short-term sodium reduction targets. In contrast, another comment advocates for a sodium limit lower than the proposed limit for meals (30% DV) because meals lower in sodium are more consistent with the 2016 draft long-term voluntary sodium reduction goals, for example, a typical 9 oz. (255 g) frozen meal had a target mean of 460 mg (180 mg/100 g) compared with the proposed sodium limit of 690 mg (30% DV) for meals.

(Response 69) Based on evidence showing a beneficial effect of reducing sodium intake on risk of CVD and hypertension, including on systolic and diastolic blood pressure, the National Academies established the following Chronic Disease Risk Reduction Intake (CDRR) values: 1,200 mg/day, ages 1 through 3; 1,500 mg/day, ages 4 through 8; 1,800 mg/day, ages 9 through 13; and 2,300 mg/day, ages 14 and above (Ref. 11). Data from the *Dietary Guidelines, 2020–2025* demonstrates that 90% of the U.S. population exceeds recommended limits for sodium intake (Ref. 1). In the United States, most sodium consumed comes from salt added during commercial processing and preparation of foods (including foods that are prepared in restaurants). The *Dietary Guidelines, 2020–2025* notes that the nutrient-dense choices in the Healthy U.S.-Style Dietary Pattern contribute approximately 60–100% of the CDRR (for different ages across calorie levels). As a result, there is very little room for food choices that are high in sodium in a healthy dietary pattern that meets the daily recommended limit for sodium, for most calorie levels and at most ages. To reduce sodium intake, the *Dietary Guidelines, 2020–2025* recommends implementing multiple strategies, for example, consuming foods with less sodium in all food groups, by using food labels to choose products with no-salt-added, less sodium, or reduced sodium.

We explained in the proposed rule (87 FR 59168 at 59179) that we expect that it is feasible to lower the sodium limit for the new ''healthy'' criteria, as compared to the original definition, due to reductions in sodium in certain foods and food categories, in response to consumer support for policies to limit sodium content in manufactured foods (Refs. 17 and 18) and technological progress since the original definition of ''healthy'' was finalized in 1994. We disagree that the proposed sodium limits do not take into consideration the function of sodium in foods. As mentioned above, when determining the limits for the ''healthy'' claim, we considered the many functions of sodium in food, including taste, texture, microbial safety, and stability. We proposed a limit for sodium of ≤10% per RACC to allow for these considerations. Furthermore, as we stated in the proposed rule, while a baseline limit for sodium of ≤5% of the DV per RACC would be consistent with the proposed saturated fat and added sugar baseline limits, we were concerned that a limit of ≤5% of the DV per RACC for sodium would not be practical.

Lowering the ''healthy'' sodium limit to ≤10% DV also aligns with recent FDA initiatives related to sodium reduction in foods. For example, these include our 2021 final guidance with voluntary targets for reducing sodium in foods (Phase I targets) (Ref. 12), our 2024 draft guidance with voluntary targets for reducing sodium in foods (Phase II targets) (Ref. 47), our 2023 proposed rule to permit safe and suitable salt substitutes to reduce sodium in standardized foods (Ref. 15), and our 2020 enforcement discretion guidance related to use of an alternate name for potassium chloride in food labeling (''potassium salt'') (85 FR 82332, December 18, 2020). Technological progress and efforts such as these, as well as our marketplace review of nutrient-dense foods, support lowering the sodium limits for the updated ''healthy'' definition compared to the limits in the original ''healthy'' definition that were issued in 1994.

As referenced in some comments to the ''healthy'' proposed rule, the 2021 final guidance included 2.5-year voluntary targets for commercially processed, packaged, and prepared food. While the sodium reduction targets and ''healthy'' criteria are complementary to one another and support the same overarching goal—reducing intake of sodium in the United States—the purpose, approach, and rationale for the limits for the updated ''healthy'' criteria are different than those for the sodium reduction targets. The 2021 final guidance for industry provides voluntary 2.5 year sodium reduction targets, with target mean and upper bound concentrations for 163 categories of food that are commercially processed, packaged, and prepared. The 2024 draft guidance for industry contains 3-year voluntary sodium reduction targets for 163 categories of food that aim to help reduce Americans' average sodium intake to about 2,750 mg/day. The ''healthy'' claim, and underlying criteria, seeks to help consumers identify foundational foods that can help them build a healthy dietary pattern, which would consist of intake of less than 2,300 mg of sodium per day, consistent with the *Dietary Guidelines, 2020–2025*.

We decline to adopt the recommendations in some comments that suggest alternative sodium limits. Setting a sodium limit of 20% DV for individual foods would not be consistent with the *Dietary Guidelines, 2020–2025,* as it would not help consumers identify foods that are particularly useful in creating healthy dietary patterns because they are nutrient-dense, *e.g.,* containing little or no sodium. Instead, products that contain 20% DV of sodium per serving would be considered to be high in sodium based on our regulations. Our nutrient content claims regulations at § 101.54(b) allow for the use of claims indicating that a food is an ''excellent source of,'' ''high,'' or ''rich in'' a nutrient if it contains 20% or more of the DV per RACC. According to current nutrition science and Federal dietary guidance, consumers should strive to limit sodium in their diets as part of building healthy dietary patterns rather than to get enough of it. Therefore, it would not be appropriate or consistent with current dietary recommendations to set a sodium limit for the use of the ''healthy'' claim that is equal to the amount required for the use of claims indicating that a food is ''an excellent source of,'' ''high in,'' or ''rich in,'' a nutrient.

The intent of the updated sodium limits for the ''healthy'' claim is to ensure both a sufficient number and variety of nutrient-dense foods, across different food groups and subgroups recommended by the *Dietary Guidelines, 2020–20205,* can bear the ''healthy'' claim, while also being rigorous enough to distinguish foods that are particularly useful in building a healthy dietary pattern. The sodium

limits may also result in industry innovation, which can increase the availability of lower sodium nutrient-dense foods in the marketplace and help consumers build healthier dietary patterns.

Our marketplace review demonstrates that a sodium limit of ≤10% DV, combined with other permitted exemptions (see Response 9), results in a variety of nutrient-dense individual foods across all food groups qualifying for ''healthy'' (including nutrient-dense foods included in the Dietary Guidelines and MyPlate website) without resulting in foods that contain unnecessary excess sodium to bear the claim (Ref. 2). For example, it shows that different forms of food products across food groups, including affordable, accessible, and culturally relevant nutrient-dense foods could qualify to bear the ''healthy'' claim because they can meet a sodium limit of ≤10% DV, such as canned, dried, frozen, and other shelf-stable or packaged products (*e.g.,* options for canned vegetables and 100% whole grain tortillas) and also accommodates some of the functional purposes of sodium.

Accordingly, we have determined that a baseline sodium limit of ≤10% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) for individual foods results in a variety of nutrient-dense foods across recommended food groups qualifying for the ''healthy'' claim while ensuring that foods that can qualify for ''healthy'' do not contain unnecessary excess sodium, and we therefore decline to increase the sodium limit. See Response 8 for further discussion of criteria for small RACC foods. Also see section V.E (''Combination Foods'') for discussion of specific criteria for combination products, including mixed products, main dishes, and meals.

(Comment 70) Some comments supporting the alternative criteria described in the previous comment summary suggest that such alternative criteria would help consumers adapt to a stepwise reduction of sodium. Similarly, some comments suggest that a stepwise approach imposes flexible sodium limits on a product-by-product basis, while accounting for products' contributions to healthy dietary patterns. For example, some comments recommend that the small RACC (≤30 g) individual and mixed food category have their own limit (*e.g.,* ≤10% DV) on the grounds that these changes would reflect the smaller consumption of these foods in a diet. Some comments suggest that the most effective approach to lower sodium in foods is to use a stepwise, gradual reduction of sodium in line with FDA's 2021 voluntary sodium reduction targets guidance, reasoning that the guidance ''involves a level of precision with respect to sodium targets for specific products within a category/RACC that the 'healthy' sodium criteria would not be able to reach.'' One comment asserts that the ''healthy'' sodium limits are not consistent with and are ''unusually dramatic'' compared with other federal dietary policy and references a USDA proposed rule from February 2023, ''Children's Nutrition Program: Revisions to Meal Patterns Consistent With the 2020 Dietary Guidelines for Americans'' (88 FR 8050, February 7, 2023) in which the USDA proposed a gradual reduction in school meal sodium limits.

(Response 70) We agree that there should be a stepwise approach across food categories (*i.e.,* gradual or incremental increases in sodium for individual foods with a smaller RACC, individual foods with larger RACCs, mixed products, main dishes, and meals). As discussed in Response 8, we have decided to modify the criteria by providing specific criteria for foods with smaller RACCs as recommended in many comments. In addition, in section V.E (''Combination Foods'') we discuss our incremental or stepwise approach for setting the NTL for mixed products, main dishes, and meals.

In the previous response, we described the differences in the specific aims, approaches, and rationales for the voluntary sodium reduction targets and the sodium limits for the updated ''healthy'' definition. Accordingly, while these two efforts align in their support of the role of lower sodium foods in healthy dietary patterns, we disagree that the limits for sodium for foods that bear the ''healthy'' nutrient content claim should match the sodium reduction targets that are for 163 categories of food commercially processed, packaged, and prepared by industry.

Similarly, there are differences in the specific aims, approaches, and rationales between the sodium limits in the 2023 USDA child nutrition meal patterns proposed rule, and the recently issued 2024 final rule, and the sodium limits for the updated definition for the voluntary ''healthy'' nutrient content claim. As an example of one of the key differences, the sodium limits in the USDA final rule apply, on average, to school meals offered during a particular school week (89 FR 31962). The sodium limits for ''healthy'' are based on a per RACC or per labeled serving basis, whereas the USDA sodium limits for school meals apply, on average, to lunches and breakfasts offered during a school week and do not apply per meal or per menu item. For example, under the USDA final rule, specific products are not held to specific sodium limits, but meals need to fit in the overall weekly limit. As a result, meals, menu items, or products with higher sodium can be offered if they are balanced out with products with lower sodium throughout the school week. In contrast, the ''healthy'' claim, when voluntarily used on a food label or in food labeling, is intended to help consumers identify foods that are particularly useful, because of their nutrient levels, for serving as a foundation for a healthy dietary pattern. While there were multiple proposed sodium reduction dates in the USDA proposed rule, the USDA final rule has a single sodium reduction for both school lunch and breakfast, to occur in school year 2027–2028. The USDA final rule gives schools and the school food industry an endpoint to work toward in the near-term, while still providing time to gradually reduce sodium prior to implementation. We disagree that the ''healthy'' proposed sodium limit of ≤690 mg per labeled serving for meals is unusually restrictive compared to the sodium limits in the USDA final rule for school meals (see section V.E (''Combination Foods'') for more information on sodium limits for mixed products, main dishes, and meals). Further, as noted in their final rule, USDA used FDA's sodium reduction targets from the 2021 final guidance (now being referred to as Phase I) to inform the proposed weekly sodium limits for the school lunch and breakfast programs. As discussed in Response 69 and above, there are differences in the specific aims, approaches, and rationales for the FDA voluntary sodium reduction targets and the sodium limits for the updated ''healthy'' definition—which seeks to help consumers identify foundational foods that can help them build a healthy dietary pattern consistent with the *Dietary Guidelines, 2020–2025* (*e.g.,* consisting of sodium intake of less than 2,300 mg per day). Similarly, while the sodium limits for school meals and the sodium limits for the ''healthy'' claim both support the role of lower sodium foods in healthy dietary patterns, these efforts have different purposes and considerations, and they use different approaches.

(Comment 71) Other comments reference ''Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term 'Healthy' '' (70 FR 56828, September 29, 2005) (''2005 sodium final rule''), specifically the decision to eliminate the ''second tier''

(more restrictive) sodium limits, corresponding to ~15% of the DV, from the 1994 ''healthy'' definition, based in part on concerns from industry regarding the feasibility of reformulating products to meet reduced sodium limits.

(Response 71) The intent of the two-tiered sodium levels established by the 1994 final rule was to encourage industry to be innovative and further lower sodium levels in foods bearing the claim ''healthy.'' In 2005, we decided to retain the higher ''first-tier'' sodium limits, in part, because of the challenges related to the feasibility at that time of meeting the lower limits, including technological barriers to reducing sodium in foods that were in the marketplace at that time. In the 2005 sodium final rule (70 FR 56828 at 56834), we stated that we had anticipated that phasing in the lower second-tier sodium level requirement for the term ''healthy'' would allow the food industry time to develop technically and commercially viable alternatives to salt. We said at that time that, although it is unfortunate that no viable alternative has been found, we understand the manufacturing difficulties that are presented by the absence of a suitable substitute for salt and has taken them into consideration in deciding how to regulate the sodium content of foods bearing the ''healthy'' claim. We also stated that: ''[w]hen FDA issued the 1994 final rule providing for a phased-in second-tier sodium level . . . [we] had anticipated that with the passage of time, there would be sufficient technological progress to make it feasible to implement this lower sodium level requirement for foods labeled as 'healthy' '' (70 FR 56828 at 56836). Since 2005, there have been some substantial sodium reduction efforts, including technological advances such as development and usage of safe and suitable salt substitutes to help manufacturers reduce sodium in foods. Taking into account the compliance date for this final rule for updating the ''healthy'' definition, over 30 years will have passed since the original ''healthy'' definition was issued and over 20 years will have passed since the 2005 sodium final rule on defining sodium levels for the ''healthy'' claim. While we have provided some flexibility for mixed products (compared to the proposed rule) and for meals (compared to the original ''healthy'' definition), (see discussion of combination foods in section V.E), the lower sodium limits for individual foods and main dishes, compared with the original ''healthy'' definition, are consistent with the progress that has been made over this time. Additionally, we expect that progress in these areas will continue going forward, consistent with sodium reduction efforts such as those described above.

(Comment 72) Some comments raise concerns that the proposed sodium limits of ≤10% DV are too restrictive for certain food groups, subgroups, or types of products. In, brief, the comments identified the following products as possibly not being able to meet the proposed sodium limits:

- Many frozen foods (*e.g.,* seafood products), including frozen foods that meet the original ''healthy'' criteria (*e.g.,* frozen vegetables in a tomato sauce).
- Canned foods (*e.g.,* vegetables).
- Some fresh seafood, without added ingredients, that typically have a sodium content above the proposed limit.
- Soup, including reduced sodium/light soups. One comment points out that soups have a RACC of 245 g or approximately 8 ounces, larger than the RACC for main dishes, which must weigh a minimum of 6 ounces; however, soups qualify as an individual/mixed product with a proposed limit of ≤10% DV, while main dishes have a proposed sodium limit of ≤20% DV.
- Many plant-based products, such as those made with soy (*e.g.,* plant-based patties).
- Liquid oil-based dressings.
- Many whole grain products, including bread and tortillas.
- Cheeses.

One comment argues that four eating occasions per day allows for consumption of 25% DV for sodium at each occasion and that the proposed limits only allow ''healthy'' grain products to contain 10% DV for sodium. Other comments discuss the different functions of sodium in foods and note that the feasibility of lowering sodium in certain products is challenging (*e.g.,* soups and cheeses). Specifically, one comment suggests that FDA allow ''formulation flexibility'' related to standards of identity, *e.g.,* for cheeses that are required by their standards of identity to use salt, so that more cheese products can qualify for the ''healthy'' claim. The comment asserts that permitting the use of salt alternatives in standardized cheeses will allow further innovation by the dairy industry and allow more cheeses to qualify for the ''healthy'' claim while meeting standards of identity. The comment further recommends that FDA issue enforcement discretion or a direct-to-final rule, simultaneously with the ''healthy'' final rule, to allow the use of salt alternatives in standardized cheeses.

Many comments request more flexibility in the sodium limits for specific food groups, subgroups, or products, so that more of products listed above can bear the healthy claim, noting that a moderate amount of sodium increases palatability of foods that provide important nutrients, such as seafood (*e.g.,* frozen fish) and dairy (*e.g.,* cheese). In contrast, one comment concurs with the proposed limit on sodium for the dairy food group. For frozen foods, comments highlight the importance of availability of affordable, frozen products to low-income families. Some comments suggest increasing the limits for both sodium and added sugars to ≤20% DV for grain products.

(Response 72) As explained above, the *Dietary Guidelines, 2020–2025* suggests that consumers use food labels to choose products with no-salt-added, less sodium, or reduced sodium. The *Dietary Guidelines, 2020–2025* describes nutrient-dense foods and beverages as products that provide vitamins, minerals, and other health-promoting components, while having little or no saturated fat, sodium, and added sugars. Along with our consideration of the Dietary Guidelines, we used our marketplace review to demonstrate whether nutrient-dense foods across food groups could meet the ≤10% DV sodium limit for individual foods, including products mentioned in comments such as whole grain breads, tortillas, and English muffins; frozen and fresh seafood; reduced/light sodium soups; reduced sodium/low sodium canned vegetables, frozen vegetable blends in sauces, and plant-based patties (Ref. 2).

Frozen vegetable blends and plant-based patties. Certain frozen vegetable blends in sauces could qualify as a mixed product depending on the individual components of the food (*i.e.,* if they meet the FGE requirements for mixed products). We have provided more flexibility for sodium in mixed products by increasing the limit from ≤10% DV to ≤15% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp), which is discussed in section V.E.2 (''Mixed Product''). The higher sodium limit for mixed products could also provide more flexibility for products mentioned in the comments, for example plant-based patties, such as those made with soy, depending on the individual components of the product. There are other vegetable blends with sauces and plant-based patties that will not qualify for the ''healthy'' claim because their sodium amount exceeds the ≤15% DV limit for mixed products, or because

they do not meet the minimum FGEs for a mixed product and their sodium exceeds the ≤10% DV limit for individual foods.

Canned vegetables. For canned vegetables, amounts of sodium vary widely, including in reduced-sodium canned vegetables. An individual food labeled as ''low sodium'' would need to contain 140 mg or less per RACC (or per 50 g for foods with RACC ≤30 g) (§ 101.61(b)(4) (21 CFR 101.61(b)(4))). Therefore, all ''low sodium'' foods, including all ''low sodium'' canned vegetables would meet the 10% DV sodium limit, which is currently 230 mg. For a food labeled as ''reduced sodium,'' the food needs to contain at least 25% less sodium per RACC than an appropriate reference food (see § 101.61(b)(6)). Therefore, the amount of sodium can vary for reduced-sodium canned vegetables depending on the sodium amount in the reference food (which is also similar for foods labeled as ''light''), and these products could still contain higher amounts of sodium. Our marketplace review demonstrates that many canned vegetables, including low-sodium canned vegetables and some reduced-sodium vegetables, can meet a ≤10% DV sodium limit (Ref. 2). Canned vegetable products that meet the ''healthy'' claim are products that are particularly useful, because of their nutrient content (including sodium amounts), in helping consumers identify foods that can be the foundation of a healthy dietary pattern. Canned vegetable products that have sodium in excess of 10% DV are not necessarily unhealthy (*e.g.,* they can still be part of a healthy dietary pattern) and their beneficial nutritional attributes can be communicated in other ways that are not false or misleading. Therefore, we have decided to finalize the ≤10% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) sodium limit for individual foods for the vegetable food group and for the beans, peas, and lentils subgroup.

Seafood. The expanded exception for whole, raw fruits and vegetables to other forms (*e.g.,* frozen) and to other foods recommended by the *Dietary Guidelines, 2020–2025,* in other food groups (*e.g.,* seafood), will result in fresh and frozen seafood without added ingredients qualifying for the ''healthy'' claim without being subject to FGE or NTL requirements, including the sodium limit (see Response 9). Our marketplace review indicates that there are additional seafood products, *i.e.,* besides single-ingredient seafood (including some frozen seafood products), that can also meet the ≤10% DV limit (Ref. 2). Seafood products that qualify for the ''healthy'' claim are products that are particularly useful, because of their nutrient levels (including sodium amounts), for helping consumers identify foods that are foundational for a healthy dietary pattern. As emphasized in the *Dietary Guidelines, 2020–2025,* there is little room in most healthy dietary patterns for excess sodium. Therefore, we have decided to finalize the sodium limit of ≤10% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) for individual foods for the seafood group. Seafood products that are not able to meet the sodium limit are not necessarily unhealthy and can still be included as part of a healthy dietary pattern. Further, their beneficial nutritional attributes can be communicated with other label statements and claims, provided they are not false or misleading.

Soup. For soup, sodium content varies widely, with most soups containing a high amount of sodium (≥20% DV). A majority of soups do not meet the sodium limits for the original ''healthy'' claim. While some dry soup mixes can meet the updated sodium limits for ''healthy,'' most ''wet soups'' cannot. Wet soups are those that contain liquid (*i.e.,* they exclude dry soup mixes). Our marketplace review of wet soups, including reduced sodium and light soups, demonstrates that over 70% of wet soups contain a high amount, at least 460 mg (≥20% DV), of sodium per RACC, with numerous containing ≥1,000 mg of sodium per RACC (Ref. 2). As mentioned above, an individual food labeled as ''low sodium'' would need to contain 140 mg or less per RACC (or per 50 g for foods with RACC ≤30 g) (§ 101.61(b)(4)). Low-sodium foods, including low-sodium soups, would therefore meet the ≤10% DV sodium limit for individual foods, which is currently 230 mg. We note that there are also some soups with no added salt, which only contain small amounts of sodium, that also meet the sodium limit for individual foods. As mentioned above, foods labeled as ''reduced sodium'' contain at least 25% less sodium per RACC than an appropriate reference food (§ 101.61(b)(6)). The nutrient content claim ''light'' may be used on a food if the sodium is reduced by 50% or more compared to the reference food, and other requirements are met (*e.g.,* the reference food contains ≤40 calories and ≤3 g of fat per RACC) (21 CFR 101.56). Because the amount of sodium varies for reduced sodium and light soups depending on the sodium amount in the reference food, these products could still contain higher amounts of sodium. As previously mentioned, we have increased the sodium limit for mixed products to ≤15% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp). This change will provide more flexibility for products, such as certain soups, to meet the sodium limit for mixed products compared to the proposed limit of ≤10% DV. Based on their ingredients, it is possible that certain soups could meet the FGE requirements for a main dish and in those cases the sodium limit would be ≤20% DV per labeled serving. We recognize, however, that most soups currently in the marketplace will exceed the sodium limits for individual foods, mixed products, and main dishes and that sodium reduction in soups can be challenging. As discussed, foods that qualify to bear the ''healthy'' claim are foods that, because of their nutrient levels (including amounts of sodium), are particularly useful in building healthy dietary patterns. Soups that cannot bear the ''healthy'' claim are not necessarily unhealthy, nor does the absence of a ''healthy'' claim indicate that these soups are unable to provide any nutritional benefits. Soups, such as reduced sodium or light soups, can be part of a healthy dietary pattern, and their beneficial attributes can be conveyed to consumers in other ways that are not false or misleading (*e.g.,* other nutrient content claims).

Oil-based dressings oil-based spreads, and 100% oils. In the proposed rule, we proposed lowering the baseline sodium limit to ≤5% DV for oil-based dressings and oil-based spreads because of their small RACC sizes. However, as previously discussed, we have now provided different criteria for smaller RACC foods (*i.e.,* qualifying on a 50-gram basis instead of per RACC for foods with RACCs ≤50 g or ≤3 Tbsp). As a result, and as supported by our marketplace review (Ref. 2), it is not necessary to reduce the sodium limit to ≤5% DV for oil-based dressings and oil-based spreads due to their small RACC since their criteria will be based on 50 grams. Therefore, the final rule has a sodium limit of ≤10% DV per 50 g for oil-based dressings and oil-based spreads. In addition, we are finalizing the proposed sodium limit of 0% DV for 100% oils.

Grain products. Nutrient-dense forms of whole grains, including whole grain bread and cereal products, can qualify for the claim. Several comments grouped their comments about sodium together with added sugars (*e.g.,* asserting that the proposed added sugar and sodium limits for grain products would prevent a vast majority of whole grain breads, buns, tortillas, and cereals

from qualifying from ''healthy''). In those cases, it is difficult to distinguish between the specific concerns with the sodium limits versus the specific concerns with the added sugars limits for some of the example products mentioned in the comments. However, we disagree that a ≤10% DV sodium limit would prevent a ''vast majority'' of whole grain bread products from qualifying, as our marketplace review shows that there are many whole grain bread products (including several English muffin products) that already meet a ≤10% DV limit (Ref. 2). We note that we have provided more flexibility for the added sugars limit for whole grain products by increasing the limit from ≤5% DV to ≤10% DV for the grains group, which is discussed in section V.D.4 (''Added Sugars''). We further disagree that 100% whole grain tortillas would be unable to qualify for the updated ''healthy'' claim as indicated in some comments. Our marketplace review demonstrates that some 100% whole grain tortillas are currently able to meet the sodium limit for the updated ''healthy'' criteria (Ref. 2). We also note that most tortillas are not able to qualify for the original ''healthy'' definition (*e.g.,* do not contain 10% of a specified beneficial nutrient, with the exception of those with added fiber). The *Dietary Guidelines, 2020–2025* points out that the grains that are typically consumed in the United States are forms with higher amounts of sodium and lists tortillas as one of the examples. They discuss that shifts to more nutrient-dense forms of grains will help in building healthy dietary patterns. Therefore, the sodium limit of ≤10% DV (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) for individual foods results in nutrient-dense options in the grains group qualifying for the claim, and can consequently help consumers identify foods that are particularly useful for building a healthy dietary pattern that is consistent with current nutrition science and Federal dietary guidance. Therefore, we have decided to finalize the ≤10% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) sodium limit for the grains group.

We also disagree with the comments asserting that the sodium limit for grains will impact consumers' ability to access whole grain products. Setting a sodium limit of 20% DV for individual foods, as suggested by some comments, would not be consistent with the Dietary Guidelines as it would not help consumers identify whole grain foods that are nutrient-dense, *e.g.,* containing little or no sodium. As noted above, products that contain 20% DV or more of sodium per serving would be considered high in sodium. We note that the ''healthy'' criteria do not prevent products that cannot qualify to bear the claim from being sold, and, as stated previously, the absence of a ''healthy'' claim on a food does not mean that the food is ''unhealthy.'' Foods that do not qualify for the ''healthy'' nutrient content claim can still be part of a healthy dietary pattern. In contrast, foods that can bear the ''healthy'' claim are foods that, because of their nutrient content, including amounts of sodium, are particularly useful in building a healthy dietary pattern.

Dairy. We acknowledge the different functions of sodium in foods, and, as discussed in the proposed rule and above, the functions of sodium were a consideration when allowing additional flexibilities for the proposed baseline limits for sodium compared to those for saturated fat and added sugars. We also understand that sodium reduction can be more challenging for certain foods, such as cheeses, and that sodium varies widely across different cheese products. Our marketplace review of nutrient-dense foods demonstrates that there are numerous foods that meet a ≤10% DV sodium limit in the dairy food group, including different nutrient-dense milk and yogurt products (Ref. 2). The *Dietary Guidelines, 2020–2025* notes that dairy is usually consumed in forms that contain higher amounts of sodium, such as cheese (*e.g.,* cheese in mixed dishes, including sandwiches, pizza, and pasta dishes). While some cheeses can meet a ≤10% DV sodium limit per RACC, or per 50 g for RACCs ≤50 g, most cheeses will not meet a ≤10% DV sodium limit and 10% DV saturated fat limit per RACC, or per 50 g for RACCs ≤50 g or ≤3 Tbsp. We agree that allowing more flexibility for manufacturers to use salt substitutes in standardized foods would help reduce sodium content of standardized foods, including standardized cheeses and related cheese products. As noted above, in 2023 we issued a proposed rule, ''Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods'' (Ref. 15). In the proposed rule, we propose to amend our standard of identity regulations that specify salt (sodium chloride) as a required or optional ingredient to permit the use of salt substitutes in standardized foods.

We agree that allowing salt substitutes in standardized foods would provide food manufacturers with new flexibility to use salt substitutes and would support further innovation by food manufacturers that could lead to a greater number of products that can meet the sodium limits for the ''healthy'' claim, including dairy, grain, and canned vegetable products.

Therefore, we have decided to finalize the sodium limit of ≤10% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) for individual foods for the dairy food group.

Other. We also disagree with the rationale that having four eating occasions per day equates to 25% DV for sodium at each eating occasion, which supports a sodium limit of 20% DV for individual foods, such as grain products. The sodium limits in the ''healthy'' definition are intended to ensure that the foods that bear the claim are those that can help consumers stay below the daily limit of sodium. Consumers do not eat a diet composed entirely of foods that qualify as individual foods for the ''healthy'' claim, and multiple foods containing sodium could be eaten at one eating occasion. Therefore, basing the sodium limit on this type of calculation could result in foods bearing the ''healthy'' claim that would not help consumers stay beneath the daily sodium limit.

We did not receive comments that the proposed sodium limits of ≤10% DV were too restrictive for fruits, game meats, eggs, and nuts and seeds (see ''Frozen vegetable blends and plant-based patties'' section above for discussion of soy products), and are finalizing a sodium limit of ≤10% DV per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp) for fruits, game meats, eggs, and nuts, seeds, and soy products.

(Comment 73) One comment recommends that FDA evaluate the possibility of incorporating the ratio of sodium to potassium as an alternative criterion that would apply to products that exceed the proposed limit of 230 mg sodium per RACC. Another comment requests that we either adopt higher sodium limits in general—individual or mixed foods, small RACC (RACC ≤30g/2 Tbsp): ≥10% DV per RACC; individual or mixed foods with RACC >30g/2 Tbsp: ≥20% DV per RACC; main dishes: ≥25% DV per serving; and meals: ≥30% DV per serving, or adopt these higher sodium limits for food products that contain at least as much potassium as sodium (*i.e.,* a ratio of 1:1 or <1) and allow NTE as an alternative option to FGEs. The comment discusses the importance of potassium in cardiovascular and bone health; the low intake of potassium in the United States; the relationship of potassium and sodium on blood pressure; the 2019 National Academies report on Dietary Reference Intakes (DRI) for Sodium and Potassium; FDA actions related to potassium labeling,

including potassium salt; and that public health efforts to reduce sodium intake may also inadvertently reduce potassium intake.

(Response 73) We previously explained why including sodium as one of the NTL for the updated ''healthy'' definition is consistent with dietary recommendations, and the underlying scientific evidence on which they are based, which support the relationship between sodium and blood pressure and risk of CVD. The 2020 DGAC Report mentions the relationship between sodium and potassium and the association with blood pressure and CVD (Ref. 8). However, the *Dietary Guidelines, 2020–2025* does not discuss potassium in relation to sodium recommendations, nor does it include a specific recommendation for potassium (besides the inclusion of the DRI values in Appendix 1) or recommendations for a specific ratio of sodium to potassium (Ref.1). Other organizations and consensus reports from authoritative bodies have also not adopted a sodium-to-potassium ratio recommendation instead of, or in addition to, individual recommendations for sodium limits (and individual potassium limits in some cases). For example, the 2019 National Academies DRI report for sodium and potassium concluded that there was insufficient evidence to characterize the relationship between the ratio of sodium to potassium and health outcomes (Ref. 11). Therefore, the National Academies DRI authoring committee was unable to establish the sodium and potassium DRIs based on a ratio and unable to assess the behavioral implications of recommending a ratio (Ref. 11). The National Academies DRI committee expressed concern in the DRI report that establishing a DRI value as a sodium-to-potassium ratio might lead to the misimpression that using a potassium supplement to modify the ratio would be beneficial, which has not yet been evaluated. They noted that further investigation into the interactions of sodium and potassium is needed.

We agree that potassium is an underconsumed nutrient and that it is important for health, including because (among other things) of its role in lowering blood pressure, as we discussed in the NFL Final Rule in support of the mandatory declaration of potassium on the label (81 FR 33742). We also agree that use of potassium chloride can help lower sodium in the food supply and that the substitution of potassium chloride for sodium chloride can have beneficial impacts on public health by reducing intake of sodium, which is overconsumed, and increasing intake of potassium, which is underconsumed. Recent efforts, such as our 2020 final guidance on naming of potassium chloride in food labeling and our 2023 proposed rule to permit salt substitutes in standardized foods, support the use of salt substitutes like potassium salts in foods to help reduce sodium in the food supply (Refs. 14 and 15). We agree that use of potassium salts is one tool that could be used to reduce sodium in foods that could then potentially bear the ''healthy'' claim. However, we disagree that our positions and actions about potassium and the use of potassium chloride as a salt substitute in foods is reason to include potassium as part of the sodium limit for the updated ''healthy'' definition, or reason to include NTE as part of the updated definition (see section V.D.6 (''Nutrients to Encourage'') for discussion of NTE). The *Dietary Guidelines, 2020–2025* notes that if individuals consume healthy dietary patterns, they can meet recommendations for potassium, calcium, and dietary fiber, and that consumers should be encouraged to make shifts to increase intakes of vegetables, fruits, beans, whole grains, and dairy to increase intakes of potassium, calcium, and dietary fiber closer to recommendations. The approach for the updated ''healthy'' definition, which incorporates food group requirements (*i.e.,* minimums) and includes multiple flexibilities for underconsumed food groups and subgroups (*e.g.,* adjustments to FGE requirements for vegetable and dairy products and adjustments to NTL for whole grain, seafood, and dairy products), is intended to help consumers identify foods that are particularly useful in building healthier dietary patterns—which help them get closer to or meet recommended intakes of food groups and subgroups and, as a result, achieve adequate intake of beneficial nutrients, including potassium.

The comment stating that reducing sodium-containing foods may also inadvertently reduce potassium-containing foods did not provide any data besides referencing shared food sources that are commonly consumed. In fact, the comment included a report that suggested a potential strategy to prevent an inadvertent reduction in potassium intake is the use of potassium salts to partially replace sodium in foods. The report summarized a modeling study showing that the substitution of sodium with potassium salts in the top sources of sodium resulted in an estimated decrease of sodium intake of 9% with an accompanying increase in potassium intake of 16% (Ref. 16). The use of potassium salt in the food supply has increased in recent years, and we anticipate that its usage may continue to increase. Additionally, because potassium is required on the Nutrition Facts label (§ 101.9(c)(8)), consumers can use that label to determine and compare amounts of potassium in different foods.

Similar to the discussion in section V.D.2 (''Saturated Fat'') related to a ratio approach for saturated fat, a ratio approach for sodium (*e.g.,* using a ratio of sodium to potassium for products that exceed the proposed limit of 230 mg sodium per RACC, as recommended in the comment) would add complexity to the ''healthy'' definition and does not distinguish between products that have low amounts of sodium and low amounts of potassium versus products that have high amounts of sodium and high amounts of potassium. Similarly, having higher sodium limits for products that contain a certain amount of potassium (as requested in the comment) would also result in foods that are high in sodium qualifying for ''healthy,'' which is not in alignment with the *Dietary Guidelines, 2020–2025.* For the reasons discussed above, we decline to include a ratio of sodium to potassium as an alternative to the sodium limit or adopt higher sodium limits for foods that contain at least as much potassium as sodium in the food and allow NTE. We also decline to adopt the specific sodium limits for individual/mixed products with small RACCs, individual/mixed products with RACC >30 g/2 Tbsp, and main dishes that were mentioned in the comment that requested higher sodium limits in general. The sodium limit for small RACC foods in the updated ''healthy'' definition is similar to the sodium limit suggested in the comment for individual foods and mixed products with small RACCs (except it will be applied to foods with a RACC ≤50 g or ≤3 Tbsp and determined on a 50 g basis) and the ''healthy'' sodium limit for meals is the same as that suggested in the comment for meals (≤30% DV per serving). We have also increased the sodium limit for mixed products (≤15% DV per RACC or per 50 g for RACCs ≤50 g or ≤3 Tbsp) and oil-based dressings and spreads (≤10% DV per 50 g) (see section V.C (''Food Group Equivalents'') for individual foods and section V.E. (''Combination Foods''). Our rationale for not adopting the sodium limits suggested in the comment for individual foods with RACCs ≥30 g (20% DV per RACC) and main dishes (25% DV per

serving) is also discussed in sections V.C (''Food Group Equivalents'') and V.E (''Combination Foods'').

4. Added Sugars

(Comment 74) Many comments support added sugars limits for products bearing a ''healthy'' claim, citing national and international recommendations to limit added sugars and research on the association between added sugars consumption and increased risk of weight gain and chronic diseases. The comments also note that added sugars are overconsumed in the United States, accounting for almost 270 calories, or more than 13% of total calories per day in the United States population (Ref. 1). However, some comments question the need for an added sugars limit, suggesting that sugar has been ''unduly vilified.'' The comments state that, in the NFL Final Rule, FDA ''conceded that the scientific evidence does not establish an independent relationship between added sugars and a disease'' and further assert that the scientific evidence linking added sugars to chronic illness remains inconclusive. The comments suggest that limiting ''healthy'' foods to those with no more than 5% of the DV for added sugars is not supported by scientific or marketplace evidence or by a regulatory rationale because we have not established a ''low'' added sugars nutrient content claim.

(Response 74) As discussed in the proposed rule (87 FR 59168 at 59178), the *Dietary Guidelines, 2020–2025* recommends choosing nutrient-dense foods across and within food groups while limiting foods and beverages higher in added sugars. 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 identified as nutrient-dense foods (Ref. 1). As noted in some comments, limiting added sugars intake is also supported by a number of other national and international health and health professional organizations. The proposed NTL criteria for added sugars help to ensure that foods bearing the ''healthy'' claim are the nutrient-dense foods that are particularly useful in creating a healthy dietary pattern, as described in the Dietary Guidelines, and do not contain excess added sugars, which can have negative health implications.

Although we stated in the NFL Final Rule that there is not an independent association between added sugars and risk of disease (81 FR 33742 at 33844), there was nevertheless ample scientific justification for requiring the mandatory declaration of added sugars. That determination was based on evidence related to healthy dietary patterns and a reduced risk of chronic disease as well as on evidence showing that consumption of higher amounts of added sugars makes it difficult to meet nutrient needs within calorie limits. More specifically, we required the mandatory declaration of added sugars on the Nutrition Facts label due, in part, to strong evidence showing that dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a decreased risk of CVD (Ref. 19). In addition, Americans continue to overconsume added sugars (Ref. 8), which can make it difficult to meet nutrient needs within calorie limits. Thus, consumption of added sugars, in excess, has direct implications on whether individuals can consume a healthy dietary pattern, which is associated with reduced risk of diet related disease, without exceeding the amount of calories they need. Given that the purpose of the ''healthy'' nutrient content claim is to help consumers identify foods that are particularly useful in helping them create a healthy dietary pattern, it is important that foods bearing the ''healthy'' claim not contribute amounts of added sugars to the diet that would make it difficult to construct a healthy dietary pattern within calorie limits.

We disagree that the proposed baseline limit of ≤5% of DV per RACC for added sugars in individual foods (currently ≤2.5 g for adults and children 4 years of age and older) is arbitrary. While there is no ''low added sugars'' nutrient content claim, we have established requirements for the use of ''low in'' claims for other nutrients consistent with the 5% DV limit, making this criterion generally consistent with other ''low in'' nutrient content claims. We have also reviewed a variety of nutrient-dense products across different food groups and subgroups that are recommended by the Dietary Guidelines available in the marketplace to compare their added sugar levels with the proposed limits (Ref. 2). We are finalizing added sugars limits for ''healthy'' based on considerations for specific food groups and subgroups recommended by the *Dietary Guidelines for Americans, 2020–2025* and supported by our marketplace review.

(Comment 75) Some comments argue that the proposed added sugars limits are inconsistent with the Dietary Guidelines recommendation to consume less than 10% of calories per day from added sugars. The comments note that the Dietary Guidelines recommend shifts toward choosing foods and beverages with less added sugars, but our proposal allows no added sugars for some food categories. The comments suggest that there is room within a healthy dietary pattern that includes no more than 50 g added sugars to accommodate slightly higher amounts of added sugars. The comments argue that, with limits of 10–20% of the added sugars DV in certain categories, and four eating occasions per day, consumers would consume only a portion of the Daily Reference Value for added sugars, and it would also leave room in a dietary pattern to consume other foods that may not meet the ''healthy'' definition.

(Response 75) We disagree with comments suggesting that the proposed added sugars limits are inconsistent with the Dietary Guidelines. Since the Dietary Guidelines were first issued in 1980, the Dietary Guidelines have included recommendations to limit intake of sugars. Since the *Dietary Guidelines for Americans, 2015–2020,* a recommendation has been included in the Dietary Guidelines to limit intake of added sugars to less than 10% of calories per day (Refs. 20–26, 4, and 1).

We also disagree that it would be appropriate to apply the quantitative intake recommendation for added sugars from the Dietary Guidelines to individual food products because the recommended limit from the Dietary Guidelines is meant to be applied across the diet for the entire day rather than to individual foods that make up the diet. As previously noted in section III. (''Background''), the ''healthy'' claim is used to identify foods that have nutrient content that makes them foundational foods for a healthy dietary pattern. Furthermore, the recommendation in the Dietary Guidelines is a limit not to be exceeded rather than an amount to achieve in the diet. An added sugars limit of ≤10% of the DV for individual food products across all food categories would not help consumers to identify the most nutrient-dense forms of many foods recommended by the Dietary Guidelines and would be inconsistent with the recommendation to consume *less than* 10% of calories from added sugars per day.

(Comment 76) Some comments support the ≤5% DV per RACC baseline limit for added sugars, with adjustments to the added sugars limits for certain food categories. The comments suggest that ''healthy'' claims on foods loaded with added sugars confuse consumers

and are out of step with the Dietary Guidelines' advice to limit added sugars to achieve a healthy dietary pattern. Some comments say that the adoption of stricter limits on added sugars for products making ''healthy'' claims will help restore consumer confidence in the integrity of the claim and prevent misleading ''healthy'' claims on products like sugary granola bars, frozen meals, shakes, cereals, and other foods and beverages with excess added sugars.

Other comments raise concerns that nutrient-dense foods recommended by the Dietary Guidelines (*e.g.,* whole grain cereals, fruit and vegetable products, and nuts) would not be able to meet the ''healthy'' criteria due to the added sugars requirements. Comments note that sugars are added to nutrient-dense foods for several reasons, including palatability, food preservation, and functional attributes (*e.g.,* viscosity, water activity, texture, bulk, and browning). The comments say that establishing a limit of 0% of calories from added sugars for some categories could eliminate some nutrient-dense products from qualifying as ''healthy'' and be counterproductive to the goal of improving the nutritional quality of Americans' diets. The comments suggest that strict limits for added sugars could discourage reformulation, and even cause manufacturers to make products that are less healthy because the ''healthy'' limits are not attainable.

Some comments also raise concerns that the proposed added sugars limits lack consistency across product categories, with some product categories having minimal amounts of either 0% or 2% of the DV for added sugars. They indicate that the lack of consistency in added sugars limits across food categories could confuse consumers.

Many comments suggest higher limits for added sugars. The comments recommend a baseline limit of at least 5% DV and up to 20% of the DV for added sugars for individual foods and mixed products to accommodate development of more and better product options that consumers would incorporate into their diets. Some comments support a 30% DV added sugars limit for meals, 25% DV for main dishes, and proportionally smaller amounts for individual foods/mixed products.

(Response 76) In setting added sugars limits for individual foods, we considered several factors, including variability in the need for added sugars based on how certain products are typically consumed, whether the food category is underconsumed, as well as availability of foods in the marketplace with varying amounts of added sugars. As discussed in the proposed rule (87 FR 59168 at 59178), applying the same added sugars limit across all food groups could result in unnecessary addition of sugars to foods. For example, nutrient-dense foods, such as eggs, nuts, fruits, and vegetables, are often not consumed with the addition of sugar, so setting a limit for these foods that is consistent with foods from other food groups that more commonly have sugars added to increase palatability, such as whole grain cereals and fat-free and low-fat dairy, could result in foods with unnecessary excess added sugars qualifying for the ''healthy'' claim'' or the unnecessary addition of added sugars to protein foods, fruits, and vegetables. We disagree that consumers would be confused by varying added sugars limits across food groups. The ''healthy'' nutrient content claim acts as a quick signal to consumers that a food, because of its nutrient composition, is particularly useful in creating a healthy dietary pattern. The added sugars limits for different food categories are geared towards manufacturers so they can determine whether their products qualify to bear the claim. Therefore, we decline to set one added sugars limit for individual food products across food categories and are finalizing our approach of setting nutrient limits based on considerations for different food categories.

We also disagree that the added sugars limit for individual foods and mixed products should be set at 20% or more of the DV for added sugars. Our nutrient content claim regulations allow for the use of claims indicating that a food is an ''excellent source of,'' ''high,'' or ''rich in'' a nutrient if it contains 20% or more of the DV per RACC (§ 101.54(b)). As discussed, the *Dietary Guidelines, 2020–2025* recommends choosing nutrient-dense foods while limiting foods and beverages higher in added sugars. Therefore, it would not be appropriate to set an added sugars limit for the use of the ''healthy'' claim that is equal to or greater than the level required for the use of claims indicating that a food is ''an excellent source of,'' ''high in,'' or ''rich in,'' a nutrient, as that limit would result in foods bearing the ''healthy'' claim that are not particularly useful in creating a diet that is consistent with current dietary recommendations.

As for the comments expressing concern that some nutrient-dense foods recommended by Federal dietary recommendations would not meet added sugars limits, we have adjusted some of the added sugars limits which results in more nutrient-dense foods encouraged by the *Dietary Guidelines, 2020–2025* being able to bear the claim. As further discussed below, we are increasing the added sugars limit for fruits, vegetables, and protein foods as well as for grains. We have also adjusted added sugars limits for mixed products, meals, and main dishes to provide more flexibility for recipes and the formulation of such foods (see section V.E (''Combination Foods''). These changes will permit manufacturers to formulate foods with some added ingredients, such as seasonings and sauces containing small amounts of added sugars, and still qualify for the ''healthy'' claim. Our review (Ref. 2) of products available in the marketplace and their added sugars content provided additional support for these changes.

(Comment 77) Some comments note that foods made from recipes on the USDA MyPlate Kitchen website (Ref. 27), which provides recipes intended to help Americans put the recommendations of the Dietary Guidelines into practice, contain levels of added sugars that are greater than the proposed limits for the ''healthy'' claim. Other comments assert that the proposed added sugars limits for ''healthy'' are inconsistent with USDA's recent proposed rule to revise the school nutrition standards. The comments say that USDA's proposed rule includes added sugars limits that provide significantly more flexibility than FDA's proposed ''healthy'' criteria, and in some cases 4–5 times the amount of added sugars permitted in our proposal. One comment also refers to a 2021 analysis of the most cost-effective way to follow a dietary pattern consistent with the *Dietary Guidelines for Americans, 2020–2025* that was conducted by the USDA Center for Nutrition Policy and Promotion. The analysis of USDA's Thrifty Food Plan (TFP) gives examples of higher nutrient density, lower cost foods (Ref. 28). The comment states that many of the food sources identified in the TFP report would not meet the proposed ''healthy'' criteria.

(Response 77) Most of the recipes provided on the MyPlate website are for mixed products, meals, and main dishes, which have higher added sugars limits than individual foods. While all MyPlate recipes contain nutrient-dense ingredients and the finished product can be a part of a healthy diet, some recipes are for foods, such as desserts (*e.g.,* recipes for apple crisps, chocolate squash cake, and banana cupcakes), that are not foundational to a healthy dietary pattern. Therefore, we disagree that all foods in recipes on the MyPlate website should be able to meet the added sugars

limits for the ''healthy'' nutrient content claim (Ref. 27).

We also disagree that limits we set for use of the healthy claim should be consistent with added sugars limits in the recently issued USDA rule that revises meal patterns for the Child Nutrition Programs. The ''Child Nutrition Programs: Meal Patterns Consistent With the 2020–2025 Dietary Guidelines for Americans'' rule (89 FR 31962) updates standards in an effort to further improve the nutritional quality of school meals.

It would not be appropriate to align requirements for the ''healthy'' claim with those of USDA programs, such as the National School Lunch Program (NSLP) and WIC, as they serve different purposes. The ''healthy'' rule provides criteria for use of a voluntary nutrient content claim suggesting that a food, because of its nutritional content, is particularly useful in building a healthy dietary pattern. However, NSLP requirements are designed to provide age-appropriate meals to specific age/grade groups and set minimum standards for school meals that schools must follow to receive cash subsidies and USDA foods for reimbursable meals served at the school. The NSLP requires five meal components, each with daily and weekly minimums, and the current requirements provide limits for calories, saturated fat, and sodium. In addition, new added sugars limits for school meals will be gradually phased in over the next several years. Considerations, such as food and labor costs, student participation, and plate waste, are taken into account when developing the meal patterns for the NSLP. The WIC food packages provide supplemental foods designed to meet the special nutrient needs of low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, infants and children up to 5 years of age who are at nutritional risk. Because these programs serve a subset of the U.S. population—*i.e.,* students (NSLP) or persons with specific nutritional needs (WIC)—it would not be appropriate to base requirements for the ''healthy'' nutrient content claim, which is applicable to the general U.S. population and based on a healthy dietary pattern (*i.e.,* total diet), on USDA requirements for these programs.

The purpose of USDA's TFP is more closely aligned with the purpose of the ''healthy'' nutrient content claim in that it is made up of specific amounts of various food categories that together comprise a practical, cost-effective diet that meets dietary guidance. Furthermore, the TFP Market Basket for a reference family of four is also based on recommended food group and subgroup amounts in the *Dietary Guidelines for Americans, 2020–2025* Healthy U.S.-Style Dietary Pattern and FNDDS data that we used for our marketplace review (Ref. 2). However, there are important differences. The modeling categories used in the 2021 USDA Center for Nutrition Policy and Promotion analysis referenced in comments were designed to prioritize higher nutrient-density foods (*i.e.,* those with less added sugars, saturated fat, and/or sodium) and consider prices while allowing for food diversity in the Market Basket. Cost is an important factor in determining the TFP Market Basket, and while we have given consideration to whether nutrient limits would exclude low-cost, nutrient-dense foods, selecting nutrient limits for the ''healthy'' claim that help consumers identify foods that are foundational to a healthy dietary pattern is our primary consideration. We also note that the examples provided of foods that are deemed to be in the ''higher nutrient-density'' category are placed in that category based on whether they contain 21.2g/100g of total sugars rather than being based on their added sugars content. Furthermore, several examples of nutrient-dense whole grain cereals that are part of the TFP provided in the comment would be above the 20% or more DV per RACC (the level at which FDA permits ''high'' claims under our nutrient content claim regulations), which is not consistent with setting a limit that ensures that the ''healthy'' claim identifies foods that are particularly useful in constructing a healthy dietary pattern. While the limits for added sugars may exclude some foods from the TFP from bearing the ''healthy'' claim, the flexibilities we are providing in the rule with the ''single-ingredient exemption'' (see Response 9), as well as adjustments to the added sugars limit for grains, fruits, vegetables, and protein foods, as discussed below, will result in more nutrient-dense products included in the TFP being able to bear the ''healthy'' claim, consistent with the purpose of the claim.

a. Added Sugars Limits for Food Groups and Certain Food Products

(Comment 78) Some comments support the proposed limit of 0% of the added sugars DV (0 grams) for vegetable, fruit, and protein products, while others say the proposed limits for those food groups are too restrictive. The comments that oppose the proposed limit say that it would not allow for the addition of small amounts of sugars to these foods in recipes and by seasonings and other ingredients. The comments also note that sugars may be added when formulating recipes to align with culinary flavor profiles. In addition, some comments assert that small amounts of sugar (1–2 g per serving) may be added to certain canned beans, peas, and lentils (*e.g.,* kidney beans) to enhance the texture or palatability due to the bitter taste. The comments provide examples of foods, such as bagged salads with dressings, frozen fruit and grain bowls, frozen vegetable burgers, and canned vegetables that could not bear the healthy claim due to the proposed added sugars limits. Some comments argue that, by setting a 0% DV added sugars limit for fruit, vegetables, and protein food groups, FDA is creating a barrier to innovation in these categories. The comments suggest that a 0% DV limit for added sugars in the fruit, vegetables, and protein groups is inconsistent with food pattern modeling used to develop the *Dietary Guidelines for Americans, 2020–2025* because the nutrient-dense reference foods for fruit, whole grains, nuts, and dairy all had low amounts of added sugars and were able to be combined within the ''Healthy US Dietary Pattern.'' Further, some comments state that consumers should not be misled to believe that recommended foods, such as nuts and seeds, must contain zero added sugars to be ''healthy,'' asserting that this is not consistent with Federal dietary policy.

Some comments also note that recipes in MyPlate Kitchen containing fruits and vegetables have between 5–10% of the DV for added sugars. The comments refer to the proposed added sugars allowance for oil-based dressings of ≤2% of the DV to improve palatability of vegetables, but note that vegetables, as an individual food product, would not be able to contain any added sugars. Further, the comments assert that FDA provided no explanation to support its conclusion that whole grain or dairy-based foods are ''healthy'' when containing ≤5% DV added sugars, but fruits, vegetables, and nut and seed-based products are not.

Other comments state that products such as nuts and seeds are often consumed as components of mixed products and express concern regarding the proposed 0% DV limit for added sugars for certain protein foods, including nuts and seeds. The comments urge FDA to revise the added sugars limit for protein foods to ≤5% DV to accommodate nuts and seeds, which are commonly consumed as a snack food. The comments state that the ≤5% DV baseline limit, in conjunction with the 0% DV limit on nuts and seeds, would force producers to either exclude

nuts and seeds from products or make other fundamental alterations. The comments express concern that some nutrient-dense protein foods, like peanut butter, which may contain small amounts of added sugars for palatability, could be excluded as a result of the strict 0% DV added sugars restriction. The comments note that nut butters are a nutritious, sustainable, shelf-stable, and economical source of protein. Some comments recommend that the added sugars limit for nuts and seeds should be ≤5% of the DV for added sugars, consistent with the proposed limits for dairy products because dairy products are also sweetened to increase palatability.

The comments suggest that that such stringent added sugars limits for fruits, vegetables, and protein foods could have unintended consequences. The comments suggest that the proposed 0% DV limit for these foods could promote increased use of ingredients such as polyols and other low or no calorie sweeteners, stating that a growing proportion of people are trying to avoid these types of ingredients. Furthermore, they argue that the proposed limits for these recommended foods could discourage their consumption or confuse consumers about the relative health value of these foods.

(Response 78) We disagree that the proposed added sugars limit for fruits, vegetables, and protein foods would discourage their consumption since these foods are often consumed in their natural state without the addition of any sugars. For many years, dietary recommendations, including the Dietary Guidelines, have consistently recommended fruits, vegetables, and certain protein foods and limiting the consumption of sugar, so we also disagree that the proposed added sugars limit would be confusing to consumers. However, we recognize that small amounts of added sugars that are added to recommended foods through recipes and seasonings can enhance the flavor of fruits, vegetables, and protein foods and can have functional properties that go beyond palatability. Small amounts of sugars may also be added to fruits and vegetables for flavor standardization because of the variability in sugar content due to growing conditions. We are increasing the added sugars limit for fruits, vegetables, and protein foods to provide some flexibility for products containing foods from these food groups that are foundational to a healthy dietary pattern.

We conducted a review of the products available in the marketplace to determine how much added sugars are typically included in individual fruit, vegetable, and protein foods, such as canned and frozen fruits and vegetables, and nut products, including different types of nut butters (Ref. 2). While we agree that requiring fruits, vegetables, and protein foods to contain no added sugars to qualify for the ''healthy'' claim would prevent some individual food products from these categories from bearing the claim, we disagree that a limit of 5% of the DV is appropriate. Many individual food products in these categories contain no added sugars and setting a limit of 5% of the DV per RACC could result in foods that contain more added sugars than necessary bearing the ''healthy'' claim, when the ''healthy'' limits are intended to help consumers identify foods that are particularly useful in achieving a healthy dietary pattern. Small amounts of added sugars contributed by different foods in the diet add up over the course of the day and can make it difficult for an individual to meet nutrient needs without exceeding the amount of calories they need in a day for weight maintenance (81 FR 33742 at 33759). We looked at the added sugars content of specific fruit, vegetable, and protein food products mentioned in comments (*e.g.,* nut butters and fish with seasonings) and found that there are products of this type currently in the marketplace with less than or equal to 5% of the DV for added sugars.

Furthermore, many of the MyPlate kitchen recipes incorporating fruits and vegetables with amounts of added sugars of 5–10% of the DV are mixed products, meals, and main dishes rather than individual foods. As previously mentioned, we are increasing the added sugars limits for mixed products, meals, and main dishes to provide more flexibility in the formulation of those products. Based on our consideration of the different purposes and functions of added sugars in different foods, including texture, flavor standardization; use in seasonings, sauces, and other ingredients in the formulation of recipes; consistency with the *Dietary Guidelines, 2020–2025;* and our marketplace review of nutrient-dense foods, we are finalizing an added sugars limit for individual fruits, vegetables, and protein foods of ≤2% of the DV (currently ≤1 g for adults and children 4 years of age and older) per RACC (or per 50 g for foods with RACCs 50 g or less or 3 Tbsp or less), which will provide for the addition of small amounts of added sugars without resulting in products that contain unnecessary amounts of added sugars being able to bear the ''healthy'' claim.

Many products mentioned in comments, such as frozen fruit and grain bowls, frozen vegetable grain bowls, frozen plant-based patties, and some fresh, bagged salads with dressing and toppings, could be considered mixed products or main dishes, depending on their formulation. Products that only contain enough of one of the recommended food groups to bear the claim (*e.g.,* a bag of salad with only salad dressing) would be considered to be individual foods. The increased added sugars limit for individual fruits, vegetables, and protein foods, as well as the increased limit for grains (discussed below), provide more flexibility for the types of products mentioned in comments that contain small amounts of added sugars but can still be foundational to a healthy dietary pattern. The increased added sugars limit also decreases the likelihood that manufacturers will add polyols and low- and no-calorie sweeteners to fruits, vegetables, and protein foods.

(Comment 79) One comment provides that, while the DGAC Report recommended a limit for added sugars in foods, there was acknowledgement that foods containing small amounts of added sugars can be part of a healthy diet. The comment supports FDA's proposal that 100% juices eligible to bear the ''healthy'' claim contain 0% added sugars, but also advocates that juice drinks containing a small amount of added sugars should be considered ''healthy.''

(Response 79) We disagree that, in general, juice drinks containing small amounts of added sugars should qualify to bear the ''healthy'' claim. The Dietary Guidelines consider juice drinks to be sugar-sweetened beverages. Sugar-sweetened beverages are one of the major sources of added sugars in the typical U.S. diet, contributing approximately 24% of added sugars to the diets of adults and children 1 year and older (Ref. 1 Figure 1–10). The Dietary Guidelines includes 100% fruit juices, but not juice drinks containing added sugars, in the fruit group. Furthermore, the *Dietary Guidelines for Americans, 2020–2025* says that when juices are consumed, they should be 100% juice or 100% juice diluted with water (without added sugars). Juice drinks often contain juices from fruits that are naturally sweet, and therefore, allowing juice drinks to contain added sugars could result in juice drinks with unnecessary excess sugars qualifying to bear the ''healthy'' claim. In addition, as stated above, small amounts of added sugars contributed by different foods in the diet add up over the course of the day and can make it difficult for an individual to meet nutrient needs

without exceeding the amount of calories they need in a day for weight maintenance (81 FR 33742 at 33759). For these reasons, we decline to revise the rule so that juice drinks containing even small amounts of added sugars could qualify for the ''healthy'' claim.

(Comment 80) A number of comments raise concerns that the added sugars limit of zero g for the fruit group would prevent tart fruit products, (*e.g.,* dried cranberries, dried tart cherries, and cranberry juice drinks), and, in particular, cranberries and tart cherries, from bearing the ''healthy'' claim. The comments explain that cranberries and tart cherries have a lower natural sugar content than most other fruits, necessitating added sugars for palatability. The comments assert that the proposal unfairly disadvantages tart fruit products and would discourage Americans from consuming these nutrient-dense fruits. The comments also posit that the added sugars limit, in conjunction with the proposed FGE criteria, would mislead consumers to believe that such products are unhealthy because they do not bear a ''healthy'' claim. One comment argues that, from a First Amendment perspective, FDA has ignored a number of less restrictive means to achieve its goals, including the comment's proposed modified criteria for lower sugar fruits such as cranberries. The comments also express concern over the financial impact on cranberry and tart cherry farmers if such products are not eligible to bear the ''healthy'' claim due to their added sugars content.

The comments note that products that compete with cranberry and tart cherry products in the marketplace, such as raisins and dried apples, have a similar or higher total sugar content and would be permitted to make the claim. The comments state that the added sugars in dried cranberries and tart cherries do not result in more total calories than comparable foods. They assert that the body's response to sugars does not depend on whether they are naturally present or added to foods. The comments also note that reduced sugar dried cranberries have less sugar and more fiber compared to other dried fruits.

The comments assert that cranberry and tart cherry products are nutritious and contain bioactive components. The comments explain that such products are high in nutrients, such as vitamins A and C as well as in copper and flavanoids. The comments highlight that USDA currently promotes consumption of cranberry products, despite their added sugar content, and raise concerns that the proposed added sugars limit undercuts the nutritional contribution that dried cranberries, cranberry juice, and tart cherry products make to healthy dietary patterns.

Some comments advocate for a framework that would allow cranberry products, including sweetened dried cranberries, that meet fruit FGE criteria and sodium and saturated fat limits, but contain added sugars for palatability in an amount that does not exceed the total sugar content of similar fruit products, to bear the ''healthy'' claim. The comments similarly support either an exemption for tart cherries from the added sugars limit or say that the added and natural sugar limits should be standardized for all fruits without exception. The comments ask that, if we do not change our position on the added sugars limits for tart fruits, we delay implementation of the final rule for 5 years to give the industry time to use its inventory of previously printed labels and work to procure new labeling as well as to conduct research regarding added sugars in tart cherries.

Some comments also oppose the exclusion of cranberry and tart cherry juice products from using the ''healthy'' claim simply because they do not meet fruit equivalent requirements and contain added sugars. The comments provide information about the health benefits of 27% cranberry juice drink and argue that consumers need to consume less cranberry content compared to the content of other fruit juices to receive the healthful benefits from polyphenol bioactives contained in cranberries. The comments also note that FDA issued a letter of enforcement discretion for a qualified health claim regarding the relationship between cranberry juice beverages containing at least 27% cranberry juice (8 fluid oz) and risk reduction of recurrent urinary tract infections in healthy women. The comments suggest that if we proceed with the proposed definition of ''healthy,'' it could lead consumers to switch to apple juice, orange juice, or grape juice from cranberry juice.

(Response 80) We agree that cranberries and tart cherries are examples of naturally tart fruits to which manufacturers often add sugar to increase palatability. The comments and our review of products in the marketplace demonstrate that many cranberry and tart cherry products provide amounts of total sugars that are less than or equivalent to comparable fruit products. We recognize that cranberry and tart cherry products, because of their nutrient composition, are particularly useful in building a healthy dietary pattern (although the qualified health claim and any other health benefits not directly related to nutrient content mentioned by the comments are not relevant here). Therefore, we intend to consider the exercise of our enforcement discretion for the added sugars limit for cranberry and tart cherry products that meet fruit FGE criteria and meet the nutrient limits 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 endogenous (inherent) sugars but no added sugars (*e.g.,* unsweetened raisins, 100% grape juice). We consider a ''comparable product'' to be one that is in the same food category (*e.g.,* fruit), that is in the same form (*e.g.,* dried), and that has the same usage (*e.g.,* snack). For example, we consider unsweetened raisins to be comparable to sweetened dried cranberries and sweetened dried cherries and unsweetened 100% grape juice to be comparable to a sweetened 27% cranberry juice drink.

Additionally, we intend to exercise enforcement discretion for the inclusion of the added sugars contribution from cranberry and tart cherry ingredients in mixed products that meet the FGE criteria and the nutrient limits for sodium and saturated fat, but the cranberry and tart cherry ingredients contain added sugars for palatability in an amount that is no greater than the amount of total sugars in comparable products, as previously described. For example, under this enforcement discretion policy, the added sugars contributed by dried cranberries in a trail mix that meets the FGE criteria and nutrient limits for mixed products would not count towards the added sugars limit for the product when the added sugars in the dried cranberries are in an amount that is no greater the amount of total sugars in a comparable product with endogenous sugars (*e.g.,* raisins).

At this time, we do not intend to exercise enforcement discretion for other tart fruit products. Based on the information that we have received in response to the requirement for mandatory declaration of added sugars on the Nutrition Facts label and the proposed added sugars limits for the use of the ''healthy'' implied nutrient content claim, cranberry and tart cherry products are uniquely impacted by the added sugars labeling requirements. They are at a competitive disadvantage in the marketplace compared to other comparable foods that naturally have the same amount of total sugars (*e.g.,* raisins, grape juice).

We are not aware that there are other tart fruits that are at a competitive

disadvantage because products made with those fruits require sugars for palatability at an amount that is comparable to other fruit products with natural sugars. Furthermore, many products made with other tart fruits (*e.g.,* lemonade and limeade) are made with far less juice or fruit and more sugar and water than cranberry and tart cherry products.

For the reasons previously mentioned, we are only providing enforcement discretion for cranberry and tart cherry products at this time, but could consider remedies for other tart fruit products if we become aware of additional information demonstrating that they are similarly situated. As with any intent to exercise enforcement discretion, FDA may update the exercise of enforcement discretion, consistent with FDA's good guidance practices (21 U.S.C. 371(h), 21 CFR 10.115).

(Comment 81) Many comments express concern that the proposed limit on added sugars for grains would prevent many whole grain foods from bearing a ''healthy'' claim and generally make it difficult for consumers to make healthy dietary choices. The comments say that added sugars are used to make nutrient-dense foods, including whole grains, more palatable. They suggest that the addition of moderate amounts of added sugars can increase consumption of whole grains, which are currently underconsumed in the United States, and promote more healthful dietary patterns. The comments suggest increasing the added sugars limit for grains (*e.g.,* to 10%, 20% or 25% of the DV for added sugars).

The comments say that more than 95% of the major ready-to-eat breakfast cereal products on the market and most whole grain breads will not qualify due to the added sugars criteria. The comments note that, among the general population, ready-to-eat cereal eaters have higher intakes of several nutrients, including the nutrients of public health concern, such as calcium, vitamin D, and fiber, than those who do not eat ready-to-eat cereal. In addition, the comments cite data from the National Health and Nutrition Examination Survey 2017–2018, which they say shows that ready-to-eat cereal is the number one contributor of fiber in children's diets and ready-to-eat cereal is a top source of whole grain for all Americans 2 years of age and older. The comments note that ready-to-eat cereal is an affordable and accessible choice because it is a shelf-stable food that can be found in small stores in big cities, large supermarkets, and online. The comments cite data showing that the intake of nutrients of public health concern was significantly higher among low-income ready-to-eat cereal eaters compared to low-income non-eaters. Some comments argue that the proposed ≤5% DV added sugars limit for breakfast cereal is too low and suggest that consumers will add more sugars on their own if limits are set too low. Some comments recommend increasing cereal products' added sugars limits from 5% of the DV to 10% of the DV to reflect their delivery of whole grains and essential nutrients and their typical consumption as a main dish.

(Response 81) Most Americans meet recommendations for total grain intakes, but 98 percent fall below recommendations for whole grains and 74% exceed limits for refined grains (Ref. 1). The *Dietary Guidelines for Americans, 2020–2025* recommends that grain-based foods in nutrient-dense forms limit the additions of added sugars, saturated fat, and sodium. It also notes that that limited amounts of added sugars can be used to make some grain-based foods more palatable while staying within calorie and nutrient limits, but most grains should be eaten in their most nutrient-dense forms.

In response to these comments, we conducted a review of the products available in the marketplace to look more closely at the added sugars content of whole grain products, such as ready-to-eat cereals, hot cereals, whole grain breads, and whole grain crackers (Ref. 2). Our marketplace review of the added sugars content of whole grain breads and crackers showed that there are many whole grain breads and crackers that contain ≤5% of the DV for added sugars, including whole grain options for breads, pita bread, English muffins, hotdog and hamburger rolls, naan, flatbreads, pizza crusts, tortillas, and crackers, and therefore, would qualify to use of the ''healthy'' claim. While we did not find that 95% of ready-to-eat cereals would be ineligible for the ''healthy'' claim based on the proposed added sugars limit, the proposed added sugars limit does significantly limit the number of whole grain cereal products, as well as the variety of whole grain foods that would qualify for the claim. There is a wide distribution in terms of the added sugars content of whole grain breakfast cereals (ranging from 0 g/serving to 22 g/serving). Increasing the added sugars limit from ≤5% of the DV for added sugars to ≤10% of the DV for added sugars would result in more, and a wider variety of, whole grain cereals, which are encouraged in the Dietary Guidelines as sources of important nutrients, as well as a wider variety of whole grain foods being able to bear the claim.

However, increasing the added sugars limit to ≥10% of the DV for added sugars would not reflect the Dietary Guidelines recommended shifts towards nutrient dense forms of all grains, including ready-to-eat breakfast cereals, that are recommended in the Dietary Guidelines, and could result in whole grain foods, such as breads and crackers, with excess added sugars, qualifying to bear the ''healthy'' claim. We recognize that ready-to-eat cereals can be an important source of nutrients to the diet because most are fortified. However, the *Dietary Guidelines for Americans, 2020–2025* notes that grains are generally consumed in forms with higher amounts of sodium and added sugars (*e.g.,* grain-based desserts, many ready-to-eat breakfast cereals) rather than the nutrient-dense forms and recommend shifting to more nutrient-dense forms of grains, such as ready-to-eat breakfast cereals with less sugar to help meet healthy dietary patterns.

After further consideration of the added sugars limit for grain products and the comments received on this topic, we find, based in part on the recommendations in the *Dietary Guidelines, 2020–2025* for whole grains that suggest that limited amounts of added sugars can be included to increase palatability and the availability of nutrient-dense whole grain cereals in the marketplace, that increasing the added sugars limit from ≤5% of the DV to ≤10% of the DV would result in more nutrient-dense whole grain products encouraged by the Dietary Guidelines, such as whole grain cereals with less sugar, being able to bear the claim, and would allow manufacturers to use the ''healthy'' claim on a wider variety of whole grain products, which are underconsumed in the United States. Therefore, we are finalizing an added sugars limit of ≤10% of the DV per RACC for added sugars (currently ≤5 g for adults and children 4 years of age and older) for whole grains.

With respect to comments that suggest that consumers will add more sugars on their own if the added sugars limits for the ''healthy'' claim are too low and that the added sugars limits need to be increased to 10% of the DV for added sugars because cereal products are typically consumed as a main dish, the ''healthy'' claim is a voluntary nutrient content claim that does not prescribe how or when a consumer would consume a food or what they would add to their food. Regardless of what the added sugars limit is for products bearing the claim, consumers may choose to add sugars to their food, and they may choose to consume cereal alone or with other foods as part of a

snack or meal. Main dishes must contain foods from at least two qualifying food groups with no less than ½ FGE from either of the two food groups and a total of two FGEs. If a cereal product meets the FGE requirements and other requirements for the use of the ''healthy'' claim as a main dish, it could also qualify based on the added sugars limit for main dishes (≤15% of the DV for added sugars), which is higher than the limit for individual foods, which are now able to contain ≤10% of the DV for added sugars.

(Comment 82) Specifically referring to dairy, some comments support the proposed added sugars limit for dairy of ≤5% of the DV. The comments say that dairy products should not be permitted to have higher limits because dairy products are often sweetened. The comments also say that, although sugars are often added to dairy products, many dairy products do not contain added sugars and do not need them for palatability. The comments recommend against allowing any flavored milk to bear the ''healthy'' claim, citing data from the School Nutrition and Meal Cost Study showing the main source of added sugars in both school breakfasts and school lunches was flavored fat-free milk. The USDA School Nutrition and Meal Cost Study is a nationally representative assessment of the school meal programs (Ref. 40). The comments say that encouraging children to drink beverages with no added sugars is a goal of the Dietary Guidelines, which would be supported by only allowing the ''healthy'' label to be used on unflavored rather than flavored milk.

Conversely, other comments urge FDA to consider allowing a reasonable increase in sugar content because a moderate amount of sugar increases palatability of dairy foods that provide essential nutrients. The comments suggest a 10% added sugars limit for dairy products, because they assert that the addition of added sugars is necessary to increase the palatability of dairy and encourage consumption of nutrient-dense dairy products. The comments argue that flavored milks and yogurts are a nutrient-dense source of vitamins, minerals, and protein and that flavored varieties of dairy products encourage more consumption of these foods across the population that is underconsuming dairy. The comments note that companies have already been working to reformulate their products to include lower sugar options following the publication of the NFL Final Rule; however, if the added sugars limit for products to qualify for the ''healthy'' claim is set too low, the comments state that further reformulation will be impractical and undesired by consumers, and therefore, companies will be less likely to undertake reformulation.

The comments also argue that, according to the *Dietary Guidelines 2020–2025,* nearly two-thirds of all energy from added sugars in the average American diet is coming from sugar-sweetened beverages, sweetened coffees and teas, desserts and sweet snacks, and candies and sugars. In contrast, dairy foods contribute only 4% of total added sugars to the average American diet, and yogurt contributes less than 2%. The comments argue that beverages make up a large proportion of a child's caloric intake and, therefore, the current Dietary Guidelines recommend that beverages also need to be evaluated in light of both overall calories and available nutrient content. The comments suggest that milk can help fulfill these two elements while other beverages cannot.

Other comments suggest that FDA has not provided adequate scientific rationale to support or justify the proposed added sugar limit for dairy foods at 5% of the DV/RACC. The comments assert that the proposed limits for dairy would encourage the use of alternative, non-nutritive sweeteners that have not been proven to aid in weight management in the long term. The comments recommend increasing the added sugars limit to at least 10% DV per c-eq for dairy products.

Many comments urge FDA to increase the added sugars limit for yogurts, stating that a certain amount of sweetness is needed to offset the naturally tart taste of yogurt. One comment says that, according to their analysis of Nielson Label Insight data, the proposed added sugars limit would prevent 72% of yogurts, including low-fat and fat free yogurts from bearing the ''healthy'' claim. The comment argues that disqualification of most low-fat and fat-free yogurts with moderate amounts of added sugar from bearing the ''healthy'' claim will further jeopardize Americans' consumption of dairy foods and may engender a false perception that yogurts are not healthy. Another comment asserts that the science does not support limiting intake of core foods that contain added sugars, such as flavored yogurt and milk. The comment points to a recent study showing that yogurt consumers had higher diet quality and higher percent of the population meeting recommended intakes for calcium, magnesium, and potassium than non-consumers (Ref. 29). The comments say that such a low limit for added sugars would force more yogurt manufacturers to sweeten their yogurts with low and no calorie sweeteners.

(Response 82) The definition of nutrient-dense foods and beverages provided in the *Dietary Guidelines for Americans 2020–2025* includes fat-free and low-fat dairy products, when prepared with no or little added sugars, saturated fat, and sodium (Ref. 1). The *Dietary Guidelines for Americans, 2020–2025* note that most Americans are not consuming enough dairy and suggest that strategies to increase dairy intake include drinking fat-free or low-fat milk or a fortified soy beverage with meals or incorporating unsweetened fat-free or low-fat yogurt into breakfast or snacks. There is no mention of flavored milks, flavored yogurts, or other flavored dairy products or plant-based dairy alternatives as recommended foods. Further, the *Dietary Guidelines for Americans, 2020–2025* recommend that beverages that contain no added sugars should be the primary choice for children and adolescents. It notes that consuming beverages with no added sugars is particularly important for young children ages 2 through 8, when only a small number of calories remains for other uses after meeting food group and nutrient needs with nutrient-dense choices. Unsweetened fat-free and low-fat milk, including low-lactose or lactose free options or fortified soy beverages are among the beverages recommended for children and adolescents in the Dietary Guidelines.

We disagree that the study cited in the comment is sufficient to determine that science does not support limiting intake of added sugars from dairy products such as yogurt and flavored milk. As discussed previously, the Dietary Guidelines, as well as consensus reports from authoritative bodies, and their nutrition science underpinning, help FDA to shape regulations on nutrition-related claims and other information that is on a food label. We rely on these sources of information because the reflect expert review and recommendations based on the body of nutrition evidence rather than findings from one individual study, which may not reflect the larger body of evidence.

While we are including dairy products with small amounts of added sugars added to increase their palatability in the foods that qualify for the ''healthy'' claim, including dairy products with significant amounts of added sugars would not be consistent with the *Dietary Guidelines for Americans, 2020–2025,* which recommends consumption of the most nutrient-dense forms of foods and specifically encourages consumption of

unsweetened fat-free and low-fat dairy products (*e.g.,* milk and yogurt) as nutrient-dense options in the dairy group. In response to the comments, we conducted a marketplace review to look at added sugars content of dairy products, including milk products, yogurts, and plant-based dairy alternatives (Ref. 2). Unlike the grains group, where relatively few products in certain product categories, such as ready-to-eat cereals, would meet the proposed added sugars limit, we found that the majority of dairy products (approximately 73%) contained 0 g of added sugars per serving and most unflavored dairy products across all dairy product categories, as well as approximately 32% of yogurts and 9% of flavored milks, could meet the proposed limit of ≤5% of the DV for added sugars. Given that there are many dairy products currently on the market that could meet the proposed added sugars limit, including a significant number of yogurts and even some flavored milk products, and in keeping with the recommendations and strategies for reducing consumption of added sugars discussed in the *Dietary Guidelines, 2020–2025,* including the specific recommendation encouraging consumption of unsweetened dairy products, as well as the purpose of the ''healthy'' nutrient content claim, we are finalizing the added sugars limit of ≤5% of the DV per RACC (currently ≤2.5 g/RACC for adults and children 4 years of age and older) for dairy products.

(Comment 83) Some comments express concern about the application of the proposed added sugars limit to plant-based dairy alternatives. The comments say that, to approximate the natural sweetness of dairy or to feed the microbes responsible for creating yogurt, sugar is sometimes required in modest amounts to create alternative dairy products with similar culinary attributes to conventional dairy products. The comments also say that the enzymatic hydrolysis process used to create some oat milk products breaks down starches naturally occurring in oats into sugars. Some comments support added sugars limits for plant-based dairy alternatives that are consistent with those of cow's milk dairy products. Some comments suggested that higher levels of added sugars are necessary in plant-based dairy alternatives in comparison to other dairy products while others suggested that the same added sugars limits should be applied for dairy and plant-based dairy alternatives. The comments also argue that plant-based dairy alternatives, such as oat beverages, must declare sugars created through enzymatic hydrolysis as added sugars on the Nutrition Facts label, and, therefore, the proposed added sugars limits would prevent such products from bearing the ''healthy'' claim, while cow's milk products that contain added sugars could bear the claim. Some comments suggest that, in the case of alternative dairy products containing sugars solely as a result of enzymatic or microbial activity and no other added sugar, such products should be eligible to bear a ''healthy'' claim if they contain less sugar than 1 cup of unsweetened cow's milk, contribute significant nutrients of value, and do not exceed the saturated fat and sodium limits per RACC for dairy.

(Response 83) With respect to sugars added to plant-based milk alternative products through enzymatic hydrolysis, we said in our guidance regarding declaration on the Nutrition Facts label (Ref. 30) that, for the added sugars declaration on the label, we consider sugars created through the hydrolysis of starch or other complex carbohydrates inherent to grains, such as oats or rice, to be the same as sugars created through the hydrolysis of starch in the production of ingredients, such as maltodextrins, because in both cases, sugars are created through controlled hydrolysis. Because the hydrolysis process is controlled, manufacturers can determine the amount of sugars created and present in the final product. We said that we considered the sugars created through controlled hydrolysis in the production of plant-based beverages to provide empty calories to the diet. Although many plant-based beverages created through controlled hydrolysis contain sugars created through that process (that are considered added sugars for the purposes of the Nutrition Facts label) in amounts similar to the total sugars content of unflavored cow's milk, we are aware that there are such products in the marketplace that are unsweetened, contain no added sugars, and therefore do not contribute empty calories from added sugars to the diet. We do not have data or information about whether and how much added sugars may be necessary in plant-based dairy alternatives to approximate the taste of dairy, to feed microbes in the creation of plant-based yogurt alternatives, or to break down starches into sugars, and the comments that argued for this adjustment did not provide such data or information. Therefore, we do not have a basis to set a different added sugars limit for plant-based dairy alternatives, and so we also decline to provide an exemption from the added sugars limit for the sugars created through controlled enzymatic hydrolysis in the creation of plant-based beverages.

(Comment 84) One comment urges us to permit liquid oil-based dressings containing up to 6% of the DV (3 g) of added sugars per RACC rather than the proposed limit of ≤2% (currently ≤1 g for adults and children 4 years of age and older). The comments say that the sugars in oil-based dressings play a role in making nutritious leafy greens and other vegetables in salads tastier. The comments also note that the *Dietary Guidelines for Americans, 2020–2025* states that a limited amount of added sugars can be included as part of an overall healthy eating pattern that includes healthy choices from each of the food groups.

(Response 84) The comment did not provide any data or other information to support changing the added sugars limit for oil-based dressings from 2% of the DV for added sugars to 6% of the DV for added sugars. There are many ingredients in oil-based dressings that can enhance the flavor of foods (*e.g.,* the oil itself, herbs, and other seasonings) besides sugar. We reviewed products available in the marketplace and found that approximately 26% of oil-based dressings can meet the added sugars limit of 2% of the DV per 50 g. The *Dietary Guidelines for Americans, 2020–2025* recommends limiting added sugars to no more than 10% of calories per day. As discussed in the NFL Final Rule, small amounts of added sugars add up throughout the course of the day (81 FR 33742 at 33759). Because oil-based dressings can contain multiple ingredients that can enhance the flavor of foods such as leafy green vegetables, there are many such products in the marketplace that meet the added sugars limit. Further, we are not aware of any data or information that would support a different limit that is greater than ≤2% of the DV for added sugars. Therefore, we decline to change the added sugars limit for oil-based dressings and are finalizing the added sugars limits of 0% of the added sugars DV per RACC (or per 50 g if 50 g or less or 3 Tbsp or less) for 100% oil and oil-based spreads and ≤2% of the DV per RACC (or per 50 g if 50 g or less or 3 Tbsp or less) for oil-based dressings.

b. Low- and No-Calorie Sweeteners

In the proposed rule (87 FR 59168 at 59180), we noted that we do not consider high-intensity (low- and no-calorie) sweeteners to be added sugars. Although we used the term ''high intensity sweeteners'' to describe sweeteners other than sugars and syrups

that are added to foods for sweetening purposes in the proposed rule, high intensity sweeteners are a subset of sweeteners that are many times sweeter than table sugar (sucrose). The comments discuss sweeteners that provide less calories than sucrose more broadly. Therefore, for the purpose of this final rule, we will refer to all sweeteners (*e.g.,* ''high intensity sweeteners,'' ''nonnutritive sweeteners,'' ''sugars metabolized differently than traditional sugars,'' ''zero calorie sweeteners,'' sugar alcohols, etc.) that provide less calories than sucrose as ''low- and no- calorie sweeteners'' throughout rather than ''high intensity sweeteners.''

(Comment 85) Some comments agree with FDA's position in the proposed rule that low-and no-calorie sweeteners are not a factor in determining whether a product meets the requirements for the use of the ''healthy'' claim and support foods qualifying for the ''healthy'' claim that contain these ingredients. The comments note that the *Dietary Guidelines for Americans, 2020–2025* emphasize that a healthy dietary pattern is one that is flexible and allows individuals the ability to adjust the recommendations to meet their personal preferences, cultural traditions, and budgetary restrictions. The comments state that allowing products containing low-and no-calorie sweeteners to bear the ''healthy'' claim will allow companies to offer a variety of healthy foods that appeal to consumers and help the reduce the amount of added sugars in their diets. The comments also state that science has determined the safety of low- and no-calorie sweeteners.

Many comments opposing a ''healthy'' claim on products containing low- and no-calorie sweeteners express concern about the safety of low- and no-calorie sweeteners, including specific products such as aspartame, saccharin, sucralose, and acesulfame. They also question the validity of studies professing the safety of low- and no-calorie sweeteners, arguing that while sweeteners may have neutral effects on physical health, low- and no-calorie sweeteners can negatively impact health. They discuss individual studies on the impact on the microbiome, the association with neurophysiological symptoms such as headaches, migraines, and irritability, and suggest that low- and no-calorie sweeteners are addictive and foster cravings that lead to the overconsumption of foods that are associated with metabolic diseases. Similarly, the comments argue that these sweeteners are metabolically active and lead to a number of complications including glucose intolerance.

The comments express particular concern about the use of low- and no-calorie sweeteners in products marketed to children. The comments refer to a citizen petition from the Sugar Association (FDA–2020–P–1478) regarding the labeling of products containing low- and no-calorie sweeteners, including requests related to the labeling of these sweeteners in foods and beverages consumed by children, which are outside the scope of this rule. The comments discuss statements from health professional organizations such as the American Academy of Pediatrics (Ref. 31) and the American Heart Association (Ref. 32) suggesting that the long-term safety of low- and no-calorie sweeteners in children has not been established.

(Response 85) As explained in the preamble to the proposed rule, since 1994, we have recognized that labeling that describes a food product as ''healthy'' in a nutritional context is making an implicit claim of the level of nutrients in the product. This implied claim can be used to identify foods that are particularly useful in creating a diet that is consistent with current dietary recommendations. Based on current nutrition science and Federal dietary guidelines, we have included the NTL that further this goal—added sugars, saturated fat, and sodium. We agree that the ability of foods using the ''healthy'' claim to contain low- and no-calorie sweeteners can give manufacturers more flexibility in formulating foods to meet the requirements for the use of the claim and can provide consumers with more options to meet their needs and preferences.

Further, we note that significant scientific evidence has shown that low- and no-calorie sweeteners are safe for consumption. Under the FD&C Act, such evidence is required to establish the safety of any substance intentionally added to food, whether it is a food additive requiring pre-market approval or is excepted from the definition of a food additive because it is generally recognized as safe (GRAS) under the conditions of its intended use. For every food additive petition for a low- or no-calorie sweetener, FDA assesses its safety under its intended conditions of use. When GRAS notices have been submitted for a low- or no-calorie sweeteners, FDA conducted an initial evaluation to determine whether to file it as a GRAS notice for evaluation of whether the notified substance (a low- or no-calorie sweetener in this case) is GRAS under the conditions of its intended use (see 21 CFR 170.265(a)(1)). FDA also stays abreast of published literature and is aware that there are some new studies regarding consumptions of sweeteners by children and adolescents, but notes these studies have methodological challenges and are not conclusive. Based on the evaluation of existing evidence, including studies on the association of consumption of sweeteners in children and adolescents on various health outcomes, FDA has determined that the uses of sweeteners that are authorized by regulation are safe, and FDA had no questions regarding notifiers' GRAS conclusions for a variety of sweeteners. For more information about FDA's position on low- and no-calorie sweeteners, see FDA's published information about food additive petitions and GRAS notices (Ref. 33).

Thus, to the extent that comments argue that low- and no-calorie sweeteners should not be permitted in foods bearing the ''healthy'' claim based on their health effects and their perceived impact on maintaining healthy dietary practices, based on the FDA determinations of safety, we do not have a basis for concluding that products bearing the ''healthy'' claim should not contain low- or no-calorie sweeteners due to any perceived impact on consumers' ability to maintain healthy dietary practices. We intend to continue to monitor the use of low- and no-calorie sweeteners and evidence related to their impact on health and, as appropriate, will update the nutrient content claim ''healthy'' as nutrition science evolves.

(Comment 86) Some comments note the language in the Dietary Guidelines regarding the lack of certainty about the effectiveness of replacing added sugars with low- and no-calorie sweeteners as a long-term weight management strategy and refer to guidance issued by the WHO on the use of non-sugar sweeteners that was based on a systematic review and meta-analysis on the health effects of non-sugar sweeteners conducted by the WHO (Refs. 1, 34, and 41). The comments claim that the guidance states that ''there is no clear consensus on whether non-sugar sweeteners are effective for long-term weight loss or maintenance, or if they are linked to other long-term health effects at intakes within the Acceptable Range.'' The comments call for more studies on the long-term effects of low- and no-calorie sweeteners before it can be determined whether they contribute to a healthy dietary pattern. They also recommend that FDA monitor the marketplace to determine if manufacturers reformulate products

with low- and no-calorie sweeteners to meet the ''healthy'' criteria.

(Response 86) Our determination that products containing low- and no-calorie sweeteners may use the ''healthy'' claim is not based on their association with weight loss or weight maintenance. Products may contain low- and no-calorie sweeteners for a variety of reasons, including to replace sugars, which can cause dental caries and impact blood glucose levels. We previously discussed that we have determined that low- and no-calorie sweeteners evaluated by FDA are safe, and we do not have a basis to exclude products containing low-and no-calorie sweeteners from bearing the claim. However, we do intend to monitor the use of low- and no-calorie sweeteners and evidence related to their impact on health.

(Comment 87) Some comments recommend that sugars, such as D-tagatose and isomaltulose, are metabolized differently than traditional sugars, and should be excluded from the definition of added sugars for the purpose of the ''healthy'' claim. One comment notes that many foods in which traditional sugars are replaced with isomaltulose may bear a health claim about the reduction in risk of dental caries, and it could be confusing to consumers if such a product could not bear the ''healthy'' claim yet another food containing a similar amount of traditional sugar that does promote dental caries could bear the ''healthy'' claim.

(Response 87) We disagree with comments asserting that FDA should not consider D-tagatose and isomaltulose as added sugars for the purpose of the ''healthy'' nutrient content claim. We concluded in the NFL Final Rule that because D-tagatose and isomaltulose are chemically sugars, and other substances are included or excluded from the definition of sugars and added sugars based on whether they are free, mono-, or disaccharides rather than on their physiological effects. Including D-tagatose and isomaltulose in the declaration of added sugars is consistent with how we have characterized other sugars (81 FR 33742 at 33837).

With respect to the comment suggesting that consumers would be confused if a product containing traditional sugars can bear a ''healthy'' claim yet a product bearing the health claim related to isomaltulose and a reduced risk of dental caries is not able to bear the claim, we disagree. As discussed in section V.H (''Nutritional Context''), the ''healthy'' nutrient content claim is different from a health claim. The ''healthy'' nutrient content claim suggests that a food, because of its nutrient content, is particularly helpful in building a healthy dietary pattern, whereas a health claim discusses the relationship between a substance and a disease or health related condition. The fact that a food may bear a health claim about a specific relationship between a substance and a disease or health related condition does not mean that the food is particularly useful in building a healthy dietary pattern consistent with dietary recommendations. As such, products containing D-tagatose or isomaltulose must meet the added sugars limit to bear the ''healthy'' claim.

(Comment 88) Some comments suggest that American consumers would be unlikely to trust a ''healthy'' label on products that include low- and no-calorie sweeteners and request that the definition of ''healthy'' include a required disclosure that products contain low- and no-calorie sweeteners on the front of the label.

(Response 88) As for the comments claiming that consumers will not trust products containing low- and no-calorie sweeteners bearing a ''healthy'' claim, we do not have evidence to suggest that this outcome is possible or likely. We do note, however, that the criteria for a ''healthy'' claim are based on the foods' contribution of nutrients to a healthy dietary pattern that help consumers in maintaining healthy dietary practices. Therefore, we decline to change our position on low- and no-calorie sweeteners.

(Comment 89) Some comments suggest that restrictive added sugars limits could incentivize the increased use of low- and no-calorie sweeteners in fruits, vegetables, protein food groups (including the nuts and seed subgroup) and express opposition to nutrition policy that would expand broad use of these ingredients. Likewise, the comments express concern with the growing number of new products containing low- and no-calorie sweeteners and suggest that the proposed rule could result in the increased use of low- and no-calorie sweeteners and other highly processed ingredients, instead of natural products such as honey.

Similarly, some comments assert that an allowance for low- and no-calorie sweeteners would lead consumers away from choosing products with naturally occurring sugars. These comments argue that allowing sweetener-enriched products to bear the ''healthy'' claim would lead to increased use of ''highly processed'' low- and no-calorie sweeteners, which would negatively impact the sugar industry.

Some comments also oppose including any products with low- and no-calorie sweeteners in the ''healthy'' definition on the grounds they would train consumers' palates to expect unhealthy food more often that could lead to overconsumption. They say that a main driver of excessive food intake is the desire to experience reward, even when calorically satiated, and sweet taste, whether caloric or not, is highly rewarding. The comments also argue that children are particularly sensitive to the rewarding effects of sweet taste, asserting that taste preferences are formed at an early age.

(Response 89) We do not know whether and how manufacturers may voluntarily reformulate their products to meet the requirements for the use of the ''healthy'' claim, and we also do not have evidence regarding how consumers will respond to any such changes in the marketplace. ''Healthy'' is a voluntary nutrient content claim that is used to identify foods that are foundational to a healthy dietary pattern, and products containing low- and no-calorie sweeteners would be an even smaller subset of the foods in the market that qualify to bear the ''healthy'' claim. Consumers are motivated by a variety of factors when choosing foods to purchase and consume (*e.g.,* taste, appearance, mouthfeel, etc.). We are not aware of any evidence that the ability of products bearing the ''healthy'' claim to contain low- and no-calorie sweeteners would lead consumers away from choosing products with naturally occurring sugars.

The added sugars limits are set to help consumers to identify foods that are particularly useful in helping the build healthy dietary patterns—nutrient-dense foods with limited amounts of added sugars. However, as discussed above, we have increased the added sugars limits for many individual food groups and subgroups, as well as for mixed products, main dishes, and meals (see section V.E (''Combination Foods'')), which will result in more nutrient-dense products sweetened with some traditional sugars being able bear the claim. (See Response 78 for additional discussion about the added sugars limit and low- and no-calorie sweeteners in the fruits, vegetables, and protein food groups.)

Thus, the final rule does not prevent the use of low- and no-calorie sweeteners in products bearing the ''healthy'' claim. However, we intend to continue to monitor the use of low- and no-calorie sweeteners and the evidence related to their impact on health.

5. Nutrients Not Included

a. Total Fat

(Comment 90) Some comments support FDA's proposal that total fat not be included in the ''healthy'' criteria and confirmed our assertion that this approach would be consistent with current nutrition science, the *Dietary Guidelines, 2020–2025,* and the updated Nutrition Facts label. One comment also notes that not having a total fat limit is consistent with FDA's 2016 enforcement discretion guidance for the ''healthy'' nutrient content claim, relative to foods that are not low in total fat but have a fat profile consisting predominantly of mono- and polyunsaturated fat. Some comments discuss the adverse consequences of having a total fat limit in the original definition, such as the exclusion of foods that are high in unsaturated fats. The comments noted that, by not having a total fat limit, the rule would allow the claim on foods (*e.g.,* fish, avocados, nuts and seeds, and certain oils) that are sources of mono- and polyunsaturated fats, which are important components of healthy dietary patterns.

(Response 90) We agree that not including a total fat limit, while maintaining a saturated fat limit, is consistent with current nutrition science, the *Dietary Guidelines, 2020–2025,* and the updated Nutrition Facts label. This approach will also result in foods that are sources of unsaturated fats being able qualify for the claim.

b. Trans Fat

(Comment 91) Several comments agree with our proposal to not include *trans* fat limits as part of the updated criteria for the ''healthy'' nutrient content claim, noting that the primary dietary source of industrially-produced *trans* fat, PHOs, are no longer considered to be GRAS and have largely been removed from the food supply and the saturated fat limits should adequately address other sources of *trans* fat aside from PHOs (*e.g., trans* fat from ruminant products). One comment states that the science does not support an additional limit for *trans* fat on top of the saturated fat limit. In contrast, another comment recommends having a *trans* fat limit as part of the updated criteria for the claim; the comment mentions that studies have shown a positive association between *trans* fat intake and CVD risk and expresses the view that *trans* fat provides little to no nutritional benefit.

(Response 91) We agree that *trans* fat has adverse effects on CVD risk; however, the comment does not provide any data or information showing that the proposed saturated fat limits would not adequately address products in the marketplace containing *trans* fat, particularly since PHOs are no longer considered GRAS and have largely been removed from the food supply. We note that, in the **Federal Register** of December 14, 2023 (88 FR 86580), FDA published a notice confirming the effective date of a direct final rule amending our regulations to no longer provide for the use of PHOs in food given our determination that PHOs are no longer GRAS. The rule also revokes prior sanctions (*i.e.,* pre-1958 authorization of certain uses) for the use of PHOs in margarine, shortening, and bread, rolls, and buns based on our conclusion that these uses of PHOs may be injurious to health. Therefore, we decline to change our approach for *trans* fat, and the final rule does not include a limit for *trans* fat as part of the updated ''healthy'' criteria.

(Comment 92) One comment requested that FDA require any amount of *trans* fat to be listed on food labels.

(Response 92) The amount of *trans* fat required for the declaration of *trans* fat on food labels is outside of the scope of this rule. We note, however, that the NFL Final Rule and our label regulation at § 101.9(c)(2)(ii) does require disclosure of *trans* fat as part of the Nutrition Facts label.

c. Dietary Cholesterol

(Comment 93) In the proposed rule (87 FR 59168 at 59181), we tentatively concluded that it was unnecessary to include limits for dietary cholesterol as part of the updated ''healthy'' criteria because, similar to our approach with *trans* fat, dietary cholesterol would already be sufficiently limited by the proposed limits for saturated fat. We invited comment on our proposed approach, including any data showing that the saturated fat limit would not adequately limit dietary cholesterol or any data indicating that foods with both lower amounts of saturated fat and higher amounts of dietary cholesterol (*i.e.,* seafood and eggs) should not be able to qualify for the ''healthy'' claim.

Several comments agree that we should not include a limit for dietary cholesterol for the ''healthy'' claim, noting that limits on dietary cholesterol would be redundant given the limits for saturated fat, and that dietary cholesterol limits would also deter consumption of nutrient-dense foods, particularly eggs and other protein products. One comment explains that replacing saturated fat with unsaturated fat is more important for lowering LDL-cholesterol and that scientific evidence does not support limiting dietary cholesterol to lower LDL-cholesterol. The comment agrees that the saturated fat limits would adequately address dietary cholesterol because dietary cholesterol and saturated fat are often found in the same foods, noting that the exceptions of eggs and shellfish are nutrient-dense foods that can be incorporated into a healthy dietary pattern.

(Response 93) We agree that the saturated fat limits adequately address dietary cholesterol. As noted in the proposed rule (87 FR 59168 at 59181), the *Dietary Guidelines, 2020–2025* does not make any recommendations regarding intake of dietary cholesterol, but the National Academies recommend that dietary cholesterol consumption be as low as possible without compromising the nutritional adequacy of the diet. We also noted in the proposed rule that the 2020 DGAC Report stated that it is difficult to assess the independent effects of dietary cholesterol on blood lipids and CVD because dietary cholesterol is found in sources that are also typically sources of saturated fat. A dietary pattern that is low in saturated fat is typically low in dietary cholesterol. Thus, the saturated fat limits for the definition of the ''healthy'' claim will adequately address dietary cholesterol because of their common food sources.

(Comment 94) Two comments support the inclusion of a dietary cholesterol limit, noting that studies show an adverse association with dietary cholesterol and blood cholesterol or cardiovascular health. One of these comments states that the proposed rule ignores the role of cholesterol on cardiovascular health by not including a dietary cholesterol limit. The comment also notes that an average-sized egg contains 186 milligrams of cholesterol and that some sub-groups of the population (*i.e.,* those with high cholesterol, diabetes, or cardiovascular disease) are advised to limit their intake of cholesterol to less than 200 mg/day.

(Response 94) As explained in the previous response and discussed in the 2020 DGAC Report, it is difficult to assess the independent effects of dietary cholesterol on blood lipids and CVD because dietary cholesterol is found in sources that are also typically sources of saturated fat (Ref. 8). In the proposed rule, we explained that we expect that the saturated fat limits would sufficiently limit most foods that contain more than 60 mg of cholesterol, with a few exceptions such as eggs and some shellfish (87 FR 59168 at 59181). In the *Dietary Guidelines, 2020–2025,* eggs and seafood (which includes fish and shellfish) are listed as examples of

nutrient-dense foods and are identified in the Key Recommendations as examples of one of the core elements—protein foods—in a healthy dietary pattern. While some sub-groups of the population who are considered at-risk for certain chronic diseases (*e.g.,* those with high blood cholesterol) or who have certain chronic diseases (*e.g.,* those with CVD) may aim to lower their intake of dietary cholesterol, the ''healthy'' claim is intended to help the general population identify foods that are particularly useful in helping them build a healthy dietary pattern. Individuals with specific health conditions or concerns can use the Nutrition Facts label to identify foods that contain higher amounts of dietary cholesterol. For these reasons, and the reasons discussed in the previous response, we decline to change our approach for dietary cholesterol and a limit for dietary cholesterol is not included as part of the updated criteria.

(Comment 95) One comment discusses the importance of consumer education and data monitoring related to dietary cholesterol. The comment explains the importance of providing information to help consumers interpret how to use the ''healthy'' claim, particularly in the context of amounts of foods consumed, so that foods such as eggs, as well as other foods labeled as ''healthy,'' are not overconsumed. The comment also recommends that FDA monitor the impact of the updated ''healthy'' claim on dietary cholesterol intake.

Other comments ask that we perform data monitoring to evaluate the impact of the updated ''healthy'' claim on the presence of different nutrients or ingredients in the marketplace or on the dietary intake of different nutrients or ingredients.

(Response 95) We agree that excessive consumption of foods labeled as ''healthy'' is an important topic and that consumer education may help consumers use the ''healthy'' claim to help build healthy dietary patterns. We plan to undertake consumer education efforts, which could address, for example, the importance of both staying within calorie limits and choosing a variety of nutrient-dense foods within and across different food groups and subgroups—two concepts that are an integral part of the *Dietary Guidelines, 2020–2025.* We also plan to monitor and evaluate the impacts of the updated ''healthy'' definition after its implementation.

d. Other Comments on Nutrients Not Included

(Comment 96) One comment recommends that we consider an absolute calorie limit—such as 200 calories, 400 calories, and 600 calories per labeled serving or RACC (whichever is larger) for individual foods, main dishes, and meals, respectively—as part of the ''healthy'' criteria to discourage the consumption and development of high calorie foods.

(Response 96) We included FGE criteria and NTL criteria in the updated definition for the ''healthy'' nutrient content claim to help consumers identify foods that are particularly useful in building a healthy dietary pattern, which are nutrient-dense foods. Nutrient-dense foods are described in the *Dietary Guidelines, 2020–2025,* as providing vitamins, minerals, and other health-promoting components while having little or no added sugars, saturated fat, and sodium (Ref. 1). Because nutrient-dense foods contain little or no excess calories, and/or are prepared with little or no excess calories, from added sugars or saturated fat, they tend to have a higher amount of nutrients per calorie. While we did not include a specific calorie limit in the proposed criteria, calories are taken into consideration indirectly in the ''healthy'' definition by including criteria for NTL for saturated fat and added sugars (which provide calories) as well as FGE criteria. FGE criteria were determined based on a 2,000 calorie diet; therefore, the amount of nutrient-dense foods needed to meet the FGEs are based on recommended nutrient amounts within that calorie limit. The comment did not provide any data or information demonstrating why an absolute calorie limit would be necessary or that the FGE and NTL criteria were not sufficient in limiting calories, nor did it explain how calorie limits were calculated or determined. Therefore, we decline to include a limit for calories on top of the FGE and NTL criteria.

(Comment 97) One comment requests that we exempt foods that qualify for the ''healthy'' claim from § 101.13(h), which requires a disclosure statement for foods with certain levels of cholesterol. The comment says that, without an exemption, foods might give consumers mixed messages about dietary cholesterol.

(Response 97) Disclosure statements are required when ''a food that bears a nutrient content claim contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related'' (see section 403(r)(2)(B) of the FD&C Act). The nutrients that require disclosure statements include total fat, saturated fat, cholesterol, and sodium (§ 101.13(h)). These nutrients are also included as NTL in the original definition of ''healthy'' (§ 101.65(d)). As discussed earlier in this section, total fat and dietary cholesterol are no longer included as NTL in the definition. The *Dietary Guidelines, 2020–2025,* does not include a key recommendation for intake of total fat or dietary cholesterol (see Response 93) (Ref. 1). Thus, disclosure statements for total fat or cholesterol are not required for use of the claim ''healthy.'' The saturated fat limits we are finalizing will help ensure that foods with higher amounts of total fat that use a ''healthy'' claim are predominantly comprised of unsaturated fats, and that cholesterol-containing foods are limited. There are situations where foods that qualify for the claim may contain saturated fat in amounts that exceed the disclosure level for saturated fat. The updated ''healthy'' definition provides exclusions for inherent saturated fat contained in certain food groups and subgroups (*e.g.,* nuts, seeds, and soy products and seafood) that have fat profiles that are predominantly made up of unsaturated fat. As discussed in the saturated fat section above, these exclusions are supported by current nutrition science and result in nutrient-dense foods that are encouraged by the *Dietary Guidelines, 2020–2025* being able to qualify for the claim. Because these foods, which may contain saturated fat that exceeds the disclosure level, are nutrient-dense foods encouraged by the *Dietary Guidelines, 2020–2025* and are foundational for healthy dietary patterns, we conclude that disclosure statements highlighting these levels of saturated fat are unnecessary and foods that bear the ''healthy'' claim are exempt from the requirement for disclosure statements for saturated fat in § 101.13(h).

(Comment 98) Several comments discuss certain ingredients or chemicals, besides nutrients, that can be present in foods and whether they should be considered as part of the criteria for the ''healthy'' claim. Some comments argue that the proposed rule's focus on sodium, saturated fats, and added sugars leaves open the possibility for products to bear ''healthy'' labels despite containing ''unhealthy'' compounds not covered by the rule.

(Response 98) As explained in the preamble to the proposed rule (87 FR 59168 at 59169), since 1994, we have recognized that labeling that describes a

food product as ''healthy'' in a nutritional context is making an implicit claim of the level of nutrients of the product. The presence or absence of ingredients other than nutrients in a food product (*e.g.,* preservatives, colorings, contaminants (including toxic elements), pesticides, oxalate) is outside of the scope of the ''healthy'' nutrient content claim. Similarly, information about the production method of a food (*e.g.,* genetically engineered or organic) is beyond the scope of the ''healthy'' nutrient content claim as it does not characterize the level of nutrients in a food.

7. Nutrients To Encourage

(Comment 99) Some comments support eliminating the NTE (*i.e.,* nutrients that are underconsumed and whose low intake in the general population or in individual subpopulations raise public health concern) requirement. The comments assert that the NTE requirement has allowed food manufacturers to fortify non-nutrient-dense foods for the sole purpose of qualifying as ''healthy'' without improving the healthfulness of the products. The comments provide that the ''healthy'' claim should not appear on heavily processed, non-nutrient-dense foods that have been fortified to meet the claim's criteria. Many comments say the food group-based approach we proposed by FDA, noting that it is consistent with dietary recommendations for healthy dietary patterns and may minimize the unintended consequences of focusing solely on individual nutrients. Other comments support the shift away from the NTE requirement by noting that certain foods would not qualify as ''healthy'' if there were NTE requirements, despite evidence in support of the health benefits of these foods (*e.g.,* mushrooms).

Other comments oppose the exclusion of the NTE criteria from the rule. The comments assert that nutrients, such as vitamins, minerals, fiber, and protein, should continue to be part of the ''healthy'' nutrient claim criteria. One comment supports FDA's food group-based approach as an effective way to encourage consumers to eat a variety of foods as part of a balanced diet, but believes it is still important to retain some additional nutrient requirements for certain food categories to help ensure that these foods provide a similar nutrient profile to comparable foods, including for plant-based alternatives to dairy products.

(Response 99) The *Dietary Guidelines, 2020–2025* (Ref. 1) focuses on the importance of a healthy dietary pattern as a whole and its role in promoting health, reducing risk of chronic diseases, and meeting nutrient needs. The original definition for the ''healthy'' nutrient content claim was based solely on individual nutrients, including a minimum amount of a beneficial nutrient and specific allowable limits for other nutrients, and is inconsistent with current nutrition understanding of healthy dietary patterns and their effect on health and development of chronic disease. Foods that contain certain NTE, such as vitamins, minerals, or fiber, can be beneficial to consumers. However, requiring that foods contain a certain amount of individual NTE in order to qualify for the ''healthy'' claim would not necessarily help consumers identify foods that are particularly useful, based on their overall nutrient profile, for building healthy dietary patterns. Additionally, as we explained in the proposed rule, including criteria for NTE could spur fortification to allow foods that are low in saturated fat, sodium, and added sugars to qualify for the ''healthy'' claim, despite these foods not contributing to a meaningful amount of a food group (87 FR 59168 at 59176). Including requirements for specific amounts of foods from across all of the recommended food groups better reflects how nutrients work together and make up the food groups and subgroups that are part of a healthy dietary pattern. We conclude that the criteria of the ''healthy'' claim should include FGE requirements instead of requirements for individual NTE in the definition. Furthermore, we decline to revise the definition to include any requirements for NTE in addition to the FGE requirements, considering that consumption of the recommended amounts of food across all of the recommended food groups enables consumers to create healthy dietary patterns and achieve nutrient adequacy. For more on how we are ensuring that alternative dairy foods provide the same nutrient profile as traditional dairy in order to qualify in the dairy food group to bear the ''healthy'' claim, please see Response 32.

(Comment 100) One comment suggests that, if FDA decides to keep the NTE requirement, we should require foods to meet the nutrition criteria without fortification. The comment suggests that FDA would also need to create exemptions for certain fruits, vegetables, and nuts that do not meet the NTE requirement.

(Response 100) As discussed in the previous response, we decline to retain or add any requirements for NTE in place of or in addition to FGE requirements. Instead, the ''healthy'' definition includes criteria of FGEs for the food groups encouraged by the *Dietary Guidelines, 2020–2025.* Therefore, considerations regarding fortification or exemptions based on NTE are not necessary.

(Comment 101) Some comments assert that both inherent and fortified nutrients should be allowed. One comment provides that the body does not discern whether a nutrient comes from an intrinsic or fortified source and that nutrients from either an intrinsic or fortified source contribute equally toward the overall nutrient intake. The comments mention that the Dietary Guidelines recognize that, in some cases, fortified foods may be useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts. The comments contend that, because manufacturers are already subject to FDA's existing fortification policy, exclusion of the NTE criteria is unnecessary. A number of comments mention that the Dietary Guidelines make reference to the value of choosing fortified foods to help meet nutrient needs for certain vitamins and minerals. One comment cites as an example the Dietary Guidelines' reference to Vitamin D being harder to acquire through natural sources from the diet alone, thus requiring the consumption of foods and beverages fortified with Vitamin D in order to achieve nutrient adequacy. Another comment mentions that, given ''healthy'' is a nutrient content claim, the inclusion of positive nutrients and food groups is prudent.

(Response 101) As previously stated, we decline to amend the definition to include any requirements for NTE in addition to the FGEs. FGE criteria based on the consumption of food across all of the recommended food groups will help consumers in identifying foods that are particularly useful in constructing healthy dietary patterns. Because requirements for NTE are not included in the definition, we do not need to address issues related to inherent or fortified nutrients. The presence of individual nutrients in a food, and knowledge about the benefits, however, may be useful to consumers, and, as previously discussed, manufacturers may communicate such information in many different ways. While highlighting foods with significant levels of a nutrient may be useful to some consumers, we reiterate that helping consumers identify nutrient-dense foods from the recommended food groups, which better reflects the overall nutrient content of foods, can better help consumers in creating healthy dietary patterns to maintain healthy dietary

practices, which is the primary purpose of the ''healthy'' claim.

(Comment 102) Some comments recommend a first ingredient approach combined with a NTE requirement as an alternative option to the proposed FGE requirements, such that the FGE criteria would be considered to be met if a food's first ingredient (or for foods other than beverages, the second ingredient if the first ingredient is water or broth) is in one of the food groups to encourage and a NTE requirement is met. Other comments recommend that, as an alternative option to food group requirements, FDA allow a food to qualify for the ''healthy'' claim if, in addition to meeting the NTL criteria for sodium, saturated fat, and added sugars, the food also meets NTE thresholds of nutrients such as dietary fiber, protein, vitamin D, calcium, potassium, or iron. The comments distill this recommendation as allowing foods to qualify for healthy if they meet both: (1) NTL criteria and (2) either the minimum amount for an inherent or fortified positive nutrient or the food group criteria. Another comment recommends an alternative approach of including a target of 10% DV for nutrients identified by the Dietary Guidelines as being at risk of underconsumption as a way to qualify for the ''healthy'' claim. Another comment recommends an approach involving a scaled percentage DV of NTE for different food groups, regardless of FGE content.

(Response 102) We decline to adopt a first ingredient approach to determine FGEs because, as discussed in Response 11, it is not a reliable way to help consumers identify foods that can help them meet recommended food group amounts. As discussed in Response 99, we conclude that the criteria for the ''healthy'' claim should include FGE requirements instead of requirements for individual NTE in the definition because requiring foods to contain a certain amount of individual nutrients to qualify for the ''healthy'' claim would not necessarily help consumers identify foods that are particularly useful for building healthy dietary patterns. Furthermore, combining an NTE requirement with a ''first ingredient'' approach would not be more effective than an FGE requirement. Because a ''first ingredient'' approach would lead to uncertainty about the specific amount of a food group in a product, such an approach combined with the presence of a single NTE in the product would not help consumers identify foods that are particularly useful for building healthy dietary patterns.

(Comment 103) The comments assert that, with the proposed limitations on saturated fat, sodium, and added sugars, the exclusion of NTE criteria would lead to underconsumption of nutrients that are necessary for healthy dietary patterns. The comments recommend that FDA include NTE criteria for nutrients identified as dietary components of public health concern by the Dietary Guidelines, including calcium, dietary fiber, potassium, and vitamin D. One comment contends that the proposed rule would exclude many foods that are nutrient-dense, for example, foods containing meaningful amounts of NTE, based solely on their nominal added sugars content; foods having slightly less than the precise amounts of food groups required by the proposal; or foods containing slightly more sodium than the proposal would require.

(Response 103) We disagree that excluding NTE criteria would lead to underconsumption of nutrients of public health concern. As discussed above, and per the *Dietary Guidelines, 2020–2025,* if a healthy dietary pattern is consumed, *i.e.,* a diet that meets the recommended daily amount of food from across the recommended food groups, the intake of nutrients of public health concern such as calcium, dietary fiber, potassium can meet the daily requirements (Ref. 1). The requirements for vitamin D can be met as well, except in specific cases, such as situations where climate and sunlight exposure become an issue. A ''healthy'' claim can help consumers identify the foods that are particularly useful in constructing healthy dietary patterns and thus meeting nutrient requirements, including nutrients of public health concern. It is for this reason that the ''healthy'' claim definition includes requirements for FGEs. We recognize, though, that, for some specific individuals and situations, nutrients in dietary supplements and/or fortified foods could be useful, and those benefits can continue to be communicated to consumers through various truthful and non-misleading label statements.

(Comment 104) One comment notes the health benefits of antioxidants and omega fatty acids and recommends that FDA devise a system that reflects the relationship of a specific foods' overall essential nutrient content in relation to the caloric space that the food takes up in a person's daily diet.

(Response 104) As discussed previously, the original definition for ''healthy'' reflected an individual nutrient-centric approach, but nutrition science and dietary recommendations have evolved since the time the original definition was developed. The construction of overall healthy dietary patterns, and not the identification of foods with specific individual nutrient amounts, is most associated with promoting health and reducing chronic disease risk in the general public (Ref. 1). For the reasons previously discussed, we conclude that the criteria of the ''healthy'' claim should include FGE requirements, along with nutrient limits, instead of requirements for individual NTE in the definition. FGE requirements better reflect the overall nutrient content of a food and the array of nutrients that are contained in the different food groups, including examples mentioned in the comment. Further, we made other adjustments to the criteria to support the use of the ''healthy'' claim on certain nutrient-dense foods from the recommended food groups. For example, we have made adjustments to exclude the inherent saturated fat in nuts, seeds, and soy products, and seafood from the saturated fat criteria, because their fat profile is predominantly unsaturated fat (*e.g.,* omega-3 and omega-6 fatty acids), and an adjustment so that nutrient-dense single-ingredient foods encouraged by the *Dietary Guidelines* can automatically qualify for the claim. The presence and benefits of individual nutrients can still be communicated in many different ways and through many different types of truthful and non-misleading statements on the label.

E. Combination Foods (i.e., Mixed Products, Main Dish Products, and Meal Products)

1. General Comments

(Comment 105) Many comments object to FDA's proposed requirement that at least one FGE from one, two, or three different food groups must be present in every individual product/mixed product, main dish, or meal, respectively. The comments note that the proposed framework is not reflective of the practical realities of recipe design and that recipes do not always contain a full FGE from one, two, or three food groups. They request that FDA instead allow for aggregation of any volume or fractions of defined food groups to contribute to the total FGE requirements for mixed products, main dishes, and meals. The comments mention that permitting aggregation of any volume or fractions of defined food groups in meeting FGEs in combination foods will allow for more flexibility in recipes while still promoting intake of underconsumed food groups.

One comment mentions that pasta products can be made with a variety of nutrient-dense ingredients, such as

vegetables and legumes, and that, under the proposed requirements, such pasta products would require either one full FGE of grains or vegetables, or ½ FGE of grains and ½ FGE of vegetables. The comment requests that FDA revise the FGE requirements so that an individual food or mixed product would qualify if it contains a total of 1 FGE from one or more different food groups, so that, for example, products containing ⅓ FGE vegetable and ⅔ grain, or ¼ FGE vegetable and ¾ FGE grain could qualify. According to the comment, this would better reflect the overall food group contribution of, for example, a pasta product that contains a meaningful contribution to both the whole grains and vegetable food groups.

(Response 105) As described in the proposed rule, combination foods are foods that contain a meaningful amount of more than one food group. The proposed rule required that a mixed product needed to contain at least ½ FGE each of two different foods groups per RACC to meet the FGE criteria (87 FR 59168 at 59190). The requirement that mixed products contain ½ FGE from two different food groups effectively provides one total FGE, similar to individual foods, since mixed products are similar in size to an individual food. As the comments note, however, the components of mixed products are not always divided into exactly ½ FGE of different food groups. For example, a mixed food may have ⅔ FGE of one food group and ⅓ FGE of a different food group. Although the proportions would not be exactly ½ FGE for each food group, the total amount of FGE would still be one FGE. We recognize that requiring at least ½ FGE from two different food groups could restrict formulations of foods that could otherwise contribute meaningful FGE amounts to the diet and manufacturers could potentially be limited in the types of healthful food offerings they could provide to consumers. For this reason, we have revised the criteria for mixed products at § 101.65(d)(iv). The final rule allows for two or more food groups to contribute to the 1 FGE total for mixed products; the food groups contributing to the 1 FGE (''qualifying food groups'') must be present in amounts of at least ¼ FGE. We are setting this threshold because setting the level lower than ¼ FGE would not provide meaningful amounts of the required food groups in mixed products and therefore not be as effective in helping consumers meet the daily recommended amounts for the food groups. Similarly, for main dish products and meal products, we conclude that flexibility should be provided by allowing varying proportions of the FGE amounts required for the food. We acknowledge that main dish products might not contain at least 1 FGE each of two different food groups and that meal products might not contain at least 1 FGE each of three different food groups. Rather, the foods may have less of one food group and more of another and still be nutrient-dense. With these changes, the total amount of FGE required for main dish products and meal products would still be the same as proposed, but the required minimum contributions of each of the individual components FGEs is reduced. Although a minimum of one full FGE from each qualifying food group component will not be required, the rule will require the product to have no less than ½ FGE from each of the two qualifying food group components for main dishes, or each of three qualifying food group components for meals, so that the product provides a meaningful amount of the respective food groups (see § 101.65(d)(iv) and (v)). For example, a main dish could contain ½ FGE of vegetables and 1 ½ FGE of whole grains, totaling two full FGEs. As another example, a meal product could contain ½ FGE of dairy, ¾ FGE of protein foods, and 1 ¾ FGE of whole grains, combining for 3 full FGEs.

Pasta products, which are most commonly made of wheat, would typically fall under the individual foods criteria for grain products. The comments, however, discuss pasta products that might be made from both grain ingredients and vegetable ingredients. With the updated FGE criteria for mixed products, these type of pasta products could qualify for use of the ''healthy'' claim as a mixed product if the product contained a total of one full FGE from whole grain and vegetable ingredients, with a minimum FGE amount for the qualifying food groups of ¼ FGE. For example, the whole grain ingredients could contribute ¾ of the whole grain FGE and the vegetable ingredients could contribute ¼ of the vegetable FGE. The adjustments in the required minimum FGE amounts provides flexibility in the qualification of combination foods while also providing consumers with meaningful amounts of food groups recommended for building healthy dietary patterns.

(Comment 106) In the proposed rule, we proposed specific NTL criteria for combination foods, and many comments address these proposed limits for sodium, added sugars, and saturated fat.

Some comments express that the proposed criteria for combination foods are difficult to follow. Some comments request that FDA provide more examples of these types of products to help with understanding the final criteria.

Some comments note that, while they agree that nutritious dietary patterns should contain less sodium and added sugars and more whole foods, the rule for combination foods products places limits on added sugars, sodium, and saturated fat, without providing a scientific rationale regarding why some products have different limits than others (*i.e.,* depending on the food groups contained in the product). The comments request more information about the rationale for the distinction and request that FDA standardize the requirements for added sugars, sodium, and saturated fat among combination foods that contain different food groups.

One comment suggests an alternative framework and several comments refer to and express support for this alternative framework. The alternative framework would combine FDA's proposed individual foods and mixed products food categories into one category, and further delineate the combined individual/mixed food category by RACC size to include a small RACC subcategory, as defined in § 101.13, as individual foods with RACCs that are 30 g or less or 2 Tbsp or less. The alternative framework would retain the original food categories of main dishes and meals. The comment requests that the limits for sodium, added sugars, and saturated fat increase in a stepwise manner based on RACC/serving size that correlate to specific food categories and do not vary based on food groups. The comment suggests the following limits for sodium:

- 10% DV sodium per RACC for the individual and mixed food category with small RACCs;
- 20% DV sodium per RACC for individual and mixed foods with a RACC >30g;
- 25% DV sodium per serving for main dishes; and
- 30% DV sodium per serving for meals.

With respect to added sugars, the comment questions why there is not a sliding scale for added sugars limits based on the proportional RACC/serving size. The comment recommends the same percentage limits for added sugars as it does for sodium limits. The comment also suggests a stepwise increase in saturated fat limits, as follows:

- 5% DV saturated fat per RACC for the individual and mixed food category with small RACCs;

- 10% DV saturated fat per RACC for individual and mixed foods with a RACC >30g;
- 15% DV saturated fat per serving for main dishes; and
- 20% DV saturated fat per serving for meals.

(Response 106) We calculated the proposed NTL criteria for combination foods based on the criteria for the individual component food groups. For mixed products, we calculated the limits by finding the average of the NTL criteria for their component food groups (87 FR 59168 at 59191). For main dishes and meal products, we calculated the NTL criteria by adding together the nutrient limits for the two or three individual food groups, respectively, that make up the food product (id. at 59192 to 59193). For example, for a whole grain vegetable lasagna main dish, the sodium limit as proposed would be ≤20% DV (≤10% DV for whole grains plus ≤10% DV for vegetables). We explained in the proposed rule that, because there is variation in the saturated fat limits for different subgroups of protein foods, the proposed saturated limit for combination products containing protein varied depending on the type of protein in the product. Similarly, because there was variation in the proposed added sugars limits for different food groups, the proposed added sugars limits for combination products also varied depending on the food groups (or subgroups) in the product.

Due to the different proposed limits for the individual food groups and subgroups, however, the resulting criteria for all of the possibilities of combination foods were numerous and complicated. Additionally, as some comments explain, combination foods are not typically formulated by only adding the foods from two or three different food groups together, but, rather, are formulated to include foods from the different food groups along with other ingredients (*e.g.,* sauces and seasonings). To simplify and streamline the criteria and also to provide some flexibility in formulations and recipes for combination foods, the final rule, at § 101.65(d)(3)(iii) through (v), revises the NTL criteria for combination foods.

Sodium. We agree with comments that support an incremental or stepwise approach for the NTL across food categories. In the proposed rule, the sodium limits for most individual foods and for mixed products, which typically have RACCs similar in size to individual foods, were set at the baseline limit of ≤10% of the DV (currently ≤230 mg for adults and children 4 years of age and older) per RACC (87 FR at 59192). In determining the baseline sodium limit, we considered many factors, such as the effects of sodium on health and chronic disease as well as the many functions of sodium in food, including taste, texture, microbial safety, and stability (see section V.D.3 for further discussion of sodium limits for individual foods). As mentioned previously, some comments provide information that explain that combination foods, such as mixed products, are not necessarily formulated by just adding foods from two different food groups together, such as a vegetable and a grain product. Rather, recipes and formulations can include foods from different food groups along with other ingredients to create particular taste profiles, flavors, etc. Additional components to the recipes could include ingredients such as seasonings and sauces and some additional sodium is often present in the formulations of mixed products in the additional ingredients, such as a sauce or seasonings. For this reason, we determine that it is reasonable for mixed products to have a sodium limit that is incrementally higher (≤15% DV per RACC) than the sodium limit for individual foods. Providing additional flexibility to the sodium limit for mixed products could also allow manufacturers to provide a greater variety of healthful options to consumers. However, considering the health effects of sodium consumption and the recommended total sodium limits in the diet, we conclude that mixed products should not exceed 15% of the DV for sodium (currently ≤345 mg for adults and children 4 years of age and older) per RACC (or per 50 g for RACCs ≤50 g or ≤3 Tbsp). The ≤15% DV mixed product sodium limit at § 101.65(d)(3)(iv) increases the mixed product sodium limit from what we proposed by 50% without bringing the limit up to those of larger combination foods (*i.e.,* main dish products and meal products).

For main dish and meal products, we proposed sodium limits of ≤20% and ≤30% of the DV per labeled serving, respectively (87 FR at 59192 and 59193), and we are finalizing these limits at § 101.65(d)(3)(v) and (vi). These limits reflect the stepwise increase in size and number of food group components of these larger food products. At ≤30% of the DV per labeled serving, a meal product, which contains FGEs from at least three different food groups, will have three times the allowable sodium limit of an individual food. As previously discussed, main dish products are required to contain FGEs from two different food groups. To scale the sodium limit proportionate to the FGE requirements, the sodium limit is set at ≤20% of the DV per labeled serving for main dish products. This limit is twice the amount of the limit for an individual food. It is also ⅔ the value of the meal products limit, which is appropriate due to the number of food group components required of main dishes compared to meal products. We conclude that the range of values from ≤10% to ≤30% of the DV for sodium, across the categories of foods (*i.e.,* individual foods, mixed products, main dishes, and meals), appropriately reflects the increasing sizes and number of food group components in each food category, while still helping consumers identify foods across different food categories that can serve as a foundation for healthy dietary patterns and help stay below the daily recommended limit for sodium. Increasing the limits beyond those finalized in this rule, for example limits higher than ≤10% for individual foods, ≤15% for mixed products, and ≤20% for main dishes, as requested in some comments, would not help consumers in identifying foods that can help them build healthy dietary patterns by staying below the daily recommended limit for sodium.

Added Sugars. We are revising the limits for added sugars in the rule to be ≤10% of the DV per RACC (or per 50 g for RACCs ≤50 g) for all mixed products, regardless of their food group components (see § 101.65(d)(3)(iii)). Setting the limit at ≤10% DV simplifies and provides one standard value for all mixed products. Similar to the limits for sodium for combination foods, we agree that added sugars limits should incrementally increase across the different types of combination food products. Further, based on the comments that we received to the proposed rule and supported by our review of products available in the marketplace (Ref. 2), we find that it is reasonable to accommodate added sugars content that is higher than the range that we had proposed for mixed products, main dishes, and meals. Even though certain individual food group components may not contain many added sugars, some additional added sugars may be included in developing recipes and formulations for combination foods. While the proposed sodium limits for main dish and meal products were a single value for their individual categories (≤20% and ≤30% of the DV per RACC), the proposed limits for added sugars for these categories varied depending on the

specific food groups that contributed to the FGEs. (See 87 FR 59168 at 59192 to 59193.) For both main dishes and meal products, the added sugars limits ranged from 0% of the DV to ≤10% of the DV depending on the food group components (id.). To simplify the requirements, we revised the rule to provide a single added sugars limit value for each combination food category that incrementally increases across the combination food categories in a way that reflects their sizes and number of food group components (see § 101.65(d)(3)(iii)–(v)). Additionally, the rule increases the added sugars limits above the highest proposed levels for each of the combination food categories, which may allow for flexibility in formulations and recipes for combination foods.

For main dish products, we are setting the added sugars limit incrementally higher than mixed products at ≤15% of the DV per labeled serving (see § 101.65(d)(3)(v)). The rule's limit of ≤15% DV added sugars for main dish products is an increase from the highest proposed added sugars limit for mixed products of ≤10% of the DV, which may provide for flexibility in formulations and recipes of healthy main dish options that manufacturers can provide to consumers while still helping consumers to identify foods that help them stay within the daily recommended intake limit for added sugars. Likewise, the rule increases the proposed limit for added sugars for meal products to ≤20% of the DV per labeled serving (see § 101.65(d)(3)(v)). Meal products must have one more food group component than main dishes and are larger products that constitute the entirety of a meal. Thus, the increase to ≤20% of the DV represents an incremental increase of added sugars from the ≤15% of the DV limit for main dish products. As with the other combination foods, increasing the added sugars limit for meals may result in manufacturers' being able to provide a wider variety of healthy food product options to consumers while still helping consumers identify foods that can help them build healthy dietary patterns by staying within daily recommended intake limits.

Saturated Fat. The final rule also streamlines and simplifies the criteria for saturated fat. Similar to the proposed limits for added sugars, the proposed limits for saturated fat for combination foods varied depending on the specific food groups that contributed to the FGEs (see 87 FR at 59192 to 59193). For combination foods, the proposed saturated fat limits ranged from ≤5% of the DV to ≤25% of the DV, depending on the food group components (id.). As with the other nutrient criteria, the different possibilities for saturated fat limits of combination foods were numerous and resulted in complicated calculations. Therefore, to simplify the requirements, the final rule sets a single saturated fat limit value for each combination food category (mixed products, main dish products, meal products) (see § 101.65(d)(3)(iii)–(v)). Similar to the limits for sodium and added sugars, the limits for saturated fat for combination foods increases incrementally across combination food categories. For mixed products, we are setting one limit for saturated fat of ≤10% of the DV per RACC or per 50 g for RACCs ≤50 g (see § 101.65(d)(3)(iii)). In determining the saturated fat limit for mixed products, we found that some considerations were different than those for added sugars and sodium. For example, there are already modifications to the saturated fat criteria to allow flexibility for inherent saturated fat for some food groups (*i.e.,* where the fat composition is made up of predominantly unsaturated fat). In addition, there are options to use other types of fat, specifically unsaturated fats, to replace saturated fat in foods (*e.g.,* using vegetable oils higher in unsaturated fat instead of palm oil or butter). Therefore, unlike for added sugars and sodium, we did not make additional adjustments for mixed products above the highest saturated fat limit for individual foods and the rule sets the limit for saturated fat at ≤10% of the DV per RACC or per 50 g for RACCs ≤50 g (see § 101.65(d)(3)(iii)). As described for determination of the added sugars and sodium limits, the nutrient limits across combination foods should appropriately reflect the increasing sizes and number of food group components in each food category. Thus, for main dish products which consist of two full FGEs, we are setting the saturated fat limit at ≤15% of the DV per labeled serving (see § 101.65(d)(3)(iv)). For meal products, we are setting the limit at ≤20% of the DV per labeled serving (see § 101.65(d)(3)(v)). As with the other criteria, the saturated fat limits increase across the food categories. The limits range from ≤5% DV for some individual foods to ≤20% DV for meal products. The saturated fat limits for the original ''healthy'' definition aligned with the ''low saturated fat'' nutrient content claim. Depending on the weight of the main dish or meal product, the saturated fat limits in the final rule are the same or higher than the original limits. Increasing the saturated fat limits, compared to the original definition, results in different nutrient-dense foods being able to contribute towards FGEs for combination foods. For example, certain nutrient-dense foods that contain higher amounts of saturated fat, such as low-fat dairy or eggs, are recommended by the Dietary Guidelines as core elements of healthy dietary patterns. Combination foods that have these nutrient-dense foods as contributors to the FGE requirements are useful in building healthy dietary patterns and the saturated fat limits reflect this. The streamlined and simplified criteria for combination foods are provided in the table below.

Table 1.--Criteria for Combination Foods

	Minimum Total FGE Requirement	Sodium Limit (%DV)	Added Sugars Limit (%DV)	Saturated Fat Limit (%DV)
Mixed Products (per RACC)	1	15%	10%	10%
Main Dish Products (per labeled serving)	2	20%	15%	15%
Meal Products (per labeled serving)	3	30%	20%	20%

(Comment 107) One comment claims that FDA provided very few examples of food products that would or would not meet the ''healthy'' criteria. The comment asserts that the lack of examples makes it difficult to evaluate the proposed definition, especially for combination foods. The comment mentions it is difficult to determine if a combination product on the market meets the minimum FGE requirements without access to the product's recipe. The comment urges FDA to conduct testing of the proposed definition with a variety of combination products to gain a better understanding of what products would or would not qualify, provide additional examples to the public, and determine what modifications to the proposed criteria are needed.

(Response 107) The NTL calculations for combination foods are based on the FGE and NTL criteria for various individual foods and the level of nutrients present in a particular food is readily available from the Nutrition Facts label. We used our marketplace review to compare products available in the current marketplace against the limits for saturated fat, sodium, and added sugars for combination foods. For example, we reviewed the increases to the proposed added sugars limits for mixed products, main dishes, and meals, and the increase to the proposed sodium limit for mixed products that are discussed in Response 106. Our marketplace review indicates that these increased limits provide more flexibility for nutrient-dense combination foods to be able to meet the NTL requirements, for example, certain bagged salads with dressing, plant-based patties, frozen grain and vegetable bowls, and frozen meals with sauces and seasonings, depending on their formulations (Ref. 2). Whether a particular combination food product will qualify for the ''healthy'' claim depends on the ingredients and recipe for the particular product (*e.g.,* for determining which category a product would fall under—an individual food, mixed product, main dish, or meal—and therefore which nutrient to limit and FGE requirements apply); thus, it is difficult for FDA to provide extensive examples of combination food products that would qualify. However, manufacturers, who have access to all information necessary to determine a products eligibility, will be able to determine if their own foods, formulations, and recipes meet the requirements of the ''healthy'' definition to label their foods appropriately.

(Comment 108) One comment disagrees with FDA's proposal to count multiple equivalents of beans, peas, and lentils as either a protein food or a vegetable for combination foods, but not both, unless multiple types of food (*e.g.,* both split peas and black beans) are present.

The comment asserts that an FGE in excess of one does not lose nutritional value simply because only one member of the subgroup is present. The comment says such a restriction may lead to decreased product innovation on the part of manufacturers, who may choose to avoid using any volumes of such foods in excess of one equivalent if such volumes do not provide a potential labeling advantage via the ''healthy'' claim.

(Response 108) Under FDA's proposed framework, if a combination food has more than one type of food from the beans, peas, and lentils subgroup, in amounts such that each food meets the food group requirements individually, the amount of one food from the beans, peas, and lentils subgroup could meet the vegetable group requirement while another food from the same subgroup could be used to meet the protein food requirement. If, however, the food product consists of only one type of food from the beans, peas, and lentils subgroup, the one type could not count toward both the vegetable and protein food group requirements in the same combination food. (See 87 FR 59168 at 59191).

Although we proposed that beans, peas, and lentils may individually count as either a vegetable or a protein food in a combination food for purposes of FGE criteria, this requirement does not prevent combinations of bean, peas, and lentils from qualifying for the claim. There are many scenarios where these combinations can meet the ''healthy'' requirements. For example, a food that has beans and peas (or any combination of beans, peas, and lentils) could qualify as mixed products or main dishes depending on the amount of FGEs contained. A mixed product food would need the amount of beans and peas to total one full FGE (*e.g.,* ½ FGE beans plus ½ FGE peas). A main dish food would need the amount of beans and peas to total two full FGEs (*e.g.,* 1 FGE beans plus 1 FGE peas). Foods that are solely a mixture of these protein foods without other ingredients would also be able to qualify for the claim under the single-ingredient exemption. For example, a dry mix of black beans and peas could qualify under the single-ingredient exemption because both dry black beans and dry peas are single-ingredient protein foods. Similarly, mixtures of solely one of the subgroup foods could fall under the single-ingredient exemption, such as a mixture of a dry black beans and dry red beans, which are both in the beans subgroup and single-ingredient protein foods. Foods that have just a single type of subgroup foods, such as only black beans, in excess of one FGE, could also qualify for the claim. The food could be considered as an individual food, a black bean food, and could fall under the requirements for individual protein foods. Having a food group ingredient in excess of the FGE does not automatically place the food into a combination food category. The criteria for ''healthy,'' including the single-ingredient-exemption, provides many different opportunities for beans, peas, and lentils, both in combination with each other or individually, to qualify for the claim.

2. Mixed Product (§ 101.65 (d)(3)(iii))

(Comment 109) One comment requests additional clarification regarding the criteria for mixed products. The comment questions whether products that contain sufficient amounts from two different protein food subgroups, for example, a product that contains ½ FGE of both seafood and nuts, would be eligible to bear the ''healthy'' claim.

(Response 109) Consideration under the criteria for combination foods, including mixed products, requires that the food contain components of more than one food group, such as protein foods and whole grains (see § 101.65(d)(3)(iv)–(vi)). Foods that contain multiple food components from the same food group, such as a food containing a mixture of fruit or a food that contains seafood and nuts, could qualify for the claim, but would be considered individual foods, rather than combination foods. As discussed in a previous response, the components of a mixed product can occur in varying proportions provided that the total FGE effectively is still one FGE and the FGE amount from each food group is not less than ¼ FGE.

(Comment 110) One comment expresses concern that blended 100% juice products would be unfairly penalized under the proposed rule. The comment notes that, to qualify under the proposed rule, a 100% juice would either need to have ½ cup fruit and ½ cup vegetables, or ¼ cup fruit and ¼ cup vegetables. The comment notes that, under this proposed framework, a blended 100% juice product with ⅓ cup fruit and ⅙ cup vegetables would have ½ cup total fruit and vegetables but would not have ¼ cup each of fruit and vegetables and would thus be ineligible to bear the ''healthy'' claim. The comment asserts that 100% blended

juices should qualify as ''healthy'' if they contain at least ½ c-eq of 100% juice, regardless of the proportion of fruit juice and vegetable juice. The comment also notes that, in a combination food containing fruit equivalents and protein equivalents, it will be challenging to meet the combination food requirements for FGEs. The comment provides that generally, 100% juice blends with protein contain protein isolates rather than whole protein sources. The comment urges FDA to allow combination foods to contain one FGE rather than both or allow protein isolates to be included in the protein subgroup.

(Response 110) As proposed, blends of juices containing both fruit juices and vegetable juices that did not contain at least ½ FGE of each would not have been able to qualify for the ''healthy'' claim. However, as discussed in Response 9, the final rule expands the proposed exemption for raw, whole fruits and vegetables to individual foods or mixed products that are comprised of one or more nutrient-dense foods encouraged by the *Dietary Guidelines, 2020–2025* (with no other added ingredients except for water). Therefore, a juice that is a blend of 100% fruit juice (a single-ingredient fruit product) and 100% vegetable juice (a single-ingredient vegetable product) now qualifies for the ''healthy'' claim without needing to meet the FGE criteria or NTL criteria (see § 101.65(d)(3)(i)). In addition, as described in Response 106, the rule provides additional flexibility for mixed products by allowing varying proportions of the qualifying food groups provided that the total FGE is still one FGE and the FGE amounts from each of the qualifying food groups is not less than ¼ FGE (*i.e.,* minimum of ⅛ c-eq each of fruit or vegetable) (see § 101.65(d)(3)(iii)). Therefore, a blended 100% juice product with ⅓ cup-eq fruit and ⅙ cup-eq vegetables (that meets the NTL criteria) would now qualify for the ''healthy'' claim.

Likewise, a juice blend of 100% juice and a single-ingredient food from other food groups, such as a single-ingredient protein food, would also be included in the exemption for single-ingredient foods and mixtures of single-ingredient foods. The juice blend could not have any other ingredients except water to qualify for the exemption. If other ingredients were included in the product, then the product would need to meet all requirements for a standard mixed product, specifically the FGE requirements and the NTL criteria. As discussed in the earlier section on protein foods, however, ingredients such as soy protein concentrates and soy protein isolates would not count toward meeting protein FGEs and would also not be considered a single-ingredient protein food (see Response 36). Therefore, a juice blend with 100% juice and soy protein isolates would not be eligible for the single-ingredient exemption for ''healthy'' but could still qualify for use of the claim as an individual food if the applicable criteria were met.

3. Main Dish (§ 101.65 (d)(3)(iv))

(Comment 111) One comment asserts that the proposed FGE requirements are misaligned with the regulatory definitions for main dishes and meals and are not consistent with the Dietary Guidelines. The comment provides that main dishes are defined, in part, as two 40 g food portions from at least two food groups and meals are defined, in part, as three 40 g food portions from at least 2 food groups. The comment notes that a meal, pursuant to FDA's regulatory definition of ''meal,'' could be comprised of 80 g of vegetables and 40 g of protein and, even though nutrient-dense, would not qualify for the healthy claim as proposed because it is not comprised of 3 full FGEs from three different food groups. The comment asserts that FDA should allow for the calculation of composite FGEs that take into account meaningful contributions to multiple food groups.

(Response 111) For the purposes of making a nutrient content claim, a main dish product contains not less than two 40 g portions of foods from at least two food groups and a meal product contains not less than three 40 g portions of foods from two or more food groups (§ 101.13(l)–(m)). The final rule requires that a main dish product contain a total of two FGEs from two food groups and meal products contain a total of three FGEs from three food groups (see § 101.65(d)(3)(iv)). The requirements for the ''healthy'' claim do not conflict with the definitions of main dish and meal products in § 101.13, they are more limited, consistent with the purpose of the claim. While not all main dish and meal products will meet the criteria for the ''healthy'' claim, those that contain the required minimum FGE amounts and qualify for use of the claim will be products which are particularly useful in meeting the recommended food group amounts and, therefore, in building a healthy dietary pattern. See Response 105 and § 101.65(d)(3)(iv) and (v) for the additional flexibility we are providing in the proportions of individual FGEs required for main dishes and meal products.

(Comment 112) A comment asks that FDA establish saturated fat limits based on food categories that reflect the serving size of the food, rather than being dependent upon which food groups are present in the product. The comment notes that, for plant-based products, the proposed saturated fat levels would disqualify soy-based products, such as plant-based burgers, due to the levels established for saturated fat. The comment asserts that higher limits for saturated fat are warranted to account for their role on the plate.

(Response 112) The final rule streamlines the criteria for saturated fat in combination foods, so that the limits are not dependent upon which food groups are present in the product. Whereas under the proposed rule, the saturated fat limits varied depending on the food group components, the final rule modifies the saturated fat limits for combination foods to a consistent amount, regardless of the food groups or subgroups contained in the mixed product, main dish, or meal (see § 101.65(d)(3)(iv)–(vi)). Additionally, the saturated fat inherent in soybeans does not contribute to the saturated fat limit (see § 101.65(d)(3)(ii)). These changes provide more flexibility (*e.g.,* higher saturated fat limits), compared to the proposed rule, for soy-based products such as plant-based patties. (See Response 59.)

4. Meal Product (§ 101.65 (d)(3)(v))

(Comment 113) One comment opposes the proposed increase in the sodium limit for meal products. The comment notes that, under current FDA regulations, a meal product or main dish making a ''healthy'' claim must contain no more than 26% of the DV for sodium per labeled serving, but, under the proposed criteria, a meal product would be allowed to contain 30% of the DV for sodium per labeled serving. The comment asserts that FDA should not increase the limit for sodium, as meals lower in sodium are healthier for consumers and more consistent with FDA's 2016 draft long-term Voluntary Sodium Reduction Goals.

(Response 113) One of the objectives for updating the ''healthy'' definition is to ensure that the foods that are able to bear the ''healthy'' claim are those that are recommended by dietary guidance, such as the Dietary Guidelines, as being particularly useful in building healthy dietary patterns. Therefore, individual foods such as grains, dairy, and vegetables that meet the individual sodium limit of ≤10% of the DV per RACC are able to qualify for the claim. It follows that combinations of those

individual foods that qualify for the claim should be able to be eligible to bear the ''healthy'' claim as well. Setting the sodium limits at ≤20% DV and ≤30% DV per labeled serving, respectively, allows two full FGEs of individual foods that qualify for ''healthy'' to be combined into one ''healthy'' main dish product and three full FGEs of individual foods that qualify for ''healthy'' to be combined into one ''healthy'' meal product. Setting the limits at lower amounts would prevent some products that are combinations of ''healthy'' individual foods from using the ''healthy'' claim, thus preventing consumers from identifying combination foods that are consistent with the recommendations in the Dietary Guidelines and healthy eating patterns. The limits we are setting for sodium for the ''healthy'' claim, however, are upper limits, and combination foods are not required to contain sodium at that amount. The sodium limits for main dish products and meal products in the rule are ≤20% and ≤30% of the DV per labeled serving, respectively (§ 101.65(d)(3)(iv) and (v)).

(Comment 114) A number of comments request that meal replacement shakes be allowed a higher added sugar limit. One comment notes that meal replacement products are intended to replace one or more conventional meals per day for weight management. The comment recommends that the rule contain a higher limit for added sugars of up to 30% DV in meal replacement products. The comment asserts that the change would increase palatability and could reduce the overall daily sugar intake for consumers compared to the current average.

(Response 114) Meal replacement products typically fall under the RACC categories for dairy, specifically the sub-category for shakes and shake substitutes, and would need to meet the criteria for those types of individual food products in order to bear the ''healthy'' claim. Depending on the ingredients, these shakes could also be mixed products if there were FGE contributions from different food groups and the FGE amounts met the mixed product requirements. In this case, the mixed product would have higher added sugars limits (≤10% of the DV) than would individual dairy foods (≤5% of the DV). For foods that serve as a full meal, the criteria for the meal product category could apply. The criteria for meal products are higher than those for individual foods and mixed products due to their role in the daily diet as the entirety of a meal. For example, meal products have an added sugar limit of 20% of the DV. If a shake product is consistent with an entire meal, the shake could fall under the meal product category and be subject to the higher threshold for added sugars and the other NTL provided that the products also met the size and food group requirements for meal products. We also note that this a voluntary claim and meal replacement products are not limited in how much added sugar they can contain based on this rule.

F. Beverages

(Comment 115) Many comments support FDA's proposal to allow plain water and plain, carbonated water without any flavoring or additional ingredients to automatically qualify as ''healthy.'' Comments highlight that the *Dietary Guidelines, 2020–2025* recommends water as a primary beverage to be consumed as part of a healthy dietary pattern and explain that FDA's proposal reinforces Federal guidance that water is an overall healthy choice to maintain hydration and reduce consumption of sugar-sweetened beverages. Other comments note the proposal's consistency with recommendations in a 2021 Federally commissioned report that the National Clinical Care Commission submitted to Congress on ''Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications'' that encourages the consumption of water, including in place of sugar-sweetened beverages. Some comments also state that labeling bottled water as ''healthy'' would generally remind consumers of the benefits of drinking plain water from any source.

One comment opposes including calorie-free carbonated beverages like carbonated water in the definition asserting that carbon dioxide induces a hunger stimulating hormone that can lead to increased food consumption and faster weight gain in rats. Another comment states that, while sparkling and still water fall into the definition of ''healthy,'' labeling bottled water ''healthy'' is unnecessary, and FDA should focus on foods that are processed or have additives instead. Some comments discourage use of the ''healthy'' claim on bottled water, raising concerns it could be perceived as claiming bottled water is healthier than tap water or potentially take emphasis away from ensuring access to safe tap water. The comments voice concerns about promoting bottled water due to negative climate and environmental impacts resulting from plastic use and bottled water production and distribution.

(Response 115) We agree that plain water and plain carbonated water should automatically qualify to bear the ''healthy'' claim. Water automatically qualifying for the ''healthy'' claim is appropriate as water is necessary for proper functioning of the human body and helps consumers choose beverages that fit in a healthy dietary pattern within calorie needs. Current nutrition science and Federal dietary guidance, as reflected in the *Dietary Guidelines, 2020–2025,* recommend limiting consumption of foods higher in added sugars, which provide excess calories to the diet without contributing significant amounts of essential nutrients and identify water and sparkling water as beverages that are part of a healthy dietary pattern. Bottled plain water and plain carbonated water provide calorie-free alternatives to sugar-sweetened beverages in the marketplace, and bottled water bearing the ''healthy'' claim can help consumers identify beverages with no added sugars and calories.

As discussed in section V.D.2. (''Saturated Fat''), when developing regulations for nutrition-related claims and nutrition labeling, we review and consider many sources of scientific evidence, many sources of information, and dietary recommendations that may be relevant (*e.g.,* conclusions of other expert or international bodies). Findings or research that represent consensus of experts in the field or an entire body of scientific literature are generally more informative than individual studies. We are updating the definition for the claim to help consumers maintain healthy dietary practices consistent with the current nutrition science and Federal dietary guidance, as reflected in the *Dietary Guidelines, 2020–2025.* The *Dietary Guidelines, 2020–2025* recommend calorie-free beverages, such as carbonated or sparkling water, to help people adopt healthy dietary patterns. We disagree that calorie-free carbonated water should not qualify to bear the ''healthy'' claim due to the reported effects of carbon dioxide from a single study in rats. We view the *Dietary Guidelines, 2020–2025* and its many sources of underlying scientific evidence as being more informative than a single study in rats for establishing criteria to bear the ''healthy'' claim. The comments discouraging use of the ''healthy'' claim on bottled water due to concerns about the possible perception of bottled water as healthier than tap water or potential to take emphasis away from ensuring access to safe tap water did not provide evidence to support their assertions and do not

change our view. Comments regarding the environmental impacts of bottled water are outside the scope of this rulemaking.

(Comment 116) Many comments recommend including unsweetened coffee (including whole, ground, and roasted coffee beans) and unsweetened tea (derived from the *Camellia sinensis* plant) as beverages that automatically qualify to bear the ''healthy'' claim. The comments assert that, consistent with the *Dietary Guidelines, 2020–2025,* these products play a role in providing consumers with hydration but will not contribute to calories or added sugars intake. The comments assert there is strong and consistent research on the health benefits and antioxidant content of coffee and tea and also note the products include other compounds that the comments characterize as potentially beneficial, such as caffeine. The comments cite the 2015 DGAC scientific report's conclusion that drinking coffee is associated with a reduced risk of cardiovascular disease, diabetes, multiple cancers, and all-cause mortality. The comments mentioning tea refer to evidence for tea, derived from *Camellia sinensis,* supporting a beneficial effect of flavonoids, specifically flavan-3-ol on cardiometabolic outcomes. Some comments distinguish ''herbal tea,'' also referred to as ''herbal infusions'' or ''tisanes'' from tea, derived from the *Camellia sinensis* plant. Comments describe ''herbal teas'' and ''herbal infusions,'' hereafter referred to as herbal infusions, as a diverse category of beverages with about 400 different parts of plants from 300 different plants. The comments note that herbal infusions could be from a single plant species (*e.g.,* camomile or peppermint) or a mixture of different plants that could include tea (*Camellia sinensis).* These comments support allowing unsweetened herbal infusions (flavored or unflavored, caffeinated or decaffeinated) to be eligible for the ''healthy'' claim, stating that this would incentivize companies to offer additional products without added calories or added sugars that can contribute to a balanced diet. Some comments note that coffee or tea without added ingredients may contain intrinsic calories depending on the nature of the coffee bean or tea leaf and the brewing process, but request that FDA include such products regardless of intrinsic calorie content.

(Response 116) We agree that including unsweetened coffee and tea, in addition to plain and carbonated water, as beverages that automatically qualify to bear the ''healthy'' claim align with beverage choices recommended by the *Dietary Guidelines, 2020–2025.* According to the Dietary Guidelines, beverages that are calorie-free, such as water, coffee, or tea without added sugar or cream, should be the primary beverages consumed. We view evidence submitted by comments on health outcomes of coffee and tea to further support the *Dietary Guidelines, 2020–2025* beverage recommendations. Allowing coffee and tea to automatically qualify for ''healthy'' could expand consumer choice of beverages that help maintain a healthy dietary pattern within calorie limits.

We agree that tea is derived from the plant *Camellia sinensis.* For example, we previously recognized that green tea is made from *Camellia sinensis* in our response to a qualified health claim petition regarding the relationship between green tea and certain cancers (Ref. 43). The comments state that herbal infusions are derived from an unspecified and broad range of plants and plant parts and also include mixtures. It is currently unclear how this vast category of beverages from single and combinations of unnamed plants and plant parts could help consumers maintain healthy dietary practices. At this time, we do not have sufficient information to determine whether herbal infusions should automatically qualify for the ''healthy'' claim. We therefore extend automatic qualification for the ''healthy'' claim to tea—derived from *Camellia sinensis*—and not to herbal infusions.

While the *Dietary Guidelines, 2020–2025* recommends coffee and tea, it also highlights some concerns about consuming caffeinated beverages (Ref. 1). Caffeine is a stimulant that can occur naturally in foods such as tea and coffee or that can be added to beverages. According to the *Dietary Guidelines, 2020–2025,* many people consume caffeine during pregnancy or lactation. Caffeine passes to the infant in small amounts through breast milk, but usually has no adverse impacts when the mother consumes low to moderate amounts (about 300 milligrams or less per day, which is about 2 to 3 cups of coffee) (Ref. 1). Those who could be or are pregnant should consult their healthcare providers for advice concerning caffeine consumption. For healthy adults, FDA has cited 400 mg/day of caffeine as an amount not generally associated with dangerous, negative effects. However, due to general concerns about adults consuming over 400 mg/day and concerns about potential negative health effects of caffeine for those who may be pregnant or lactating, we are not permitting any beverages, including coffee and tea, with added caffeine as an ingredient to automatically qualify to bear the ''healthy'' claim. We view overconsumption of foods labeled as ''healthy'' as an important topic. We intend to educate consumers to help understand how to use the ''healthy'' claim to help build healthy dietary patterns and the importance of choosing a variety of nutrient-dense foods and beverages across all food groups, in recommended amounts, while staying within calorie limits, to build a healthy dietary pattern consistent with the Dietary Guidelines.

We decline to allow coffee or tea without added ingredients that contain 5 or more intrinsic calories to automatically qualify for the ''healthy'' claim, as it would be inconsistent with the *Dietary Guidelines, 2020–2025* recommendations for calorie-free beverages and our existing definition of the nutrient content claim ''calorie free.'' Our regulations at 21 CFR 101.60(b), state that the terms, ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' may be used on the label or in the labeling of foods, provided that the food contains less than 5 calories per RACC and per labeled serving. Thus, given that the recommendation in the Dietary Guidelines that is the basis for our inclusion of coffee and tea is limited to ''calorie free'' beverages and given our regulatory definition of the nutrient content claim ''calorie free,'' only those coffees and teas that contain less than 5 calories per RACC and per labeled serving may automatically bear the ''healthy'' claim.

(Comment 117) Many comments support expanding the automatic qualification to bear the ''healthy'' claim beyond plain water and plain carbonated water to other beverages such as carbonated or noncarbonated waters, coffee, and tea that contain certain added ingredients such as flavors, non-nutritive sweeteners, vitamins, minerals, and electrolytes. The comments posit that these additional beverages should be treated the same as plain water and plain carbonated water because Federal dietary recommendations encourage consumption of these beverages, in part, because they contain no added sugars. The comments assert there is no distinction for excluding waters with added flavors or non-nutritive sweeteners that are added for taste, which do not contribute calories or sugar, but make drinking water easier

and more enjoyable. The comments assert that, by recognizing flavored carbonated or noncarbonated waters (including those with non-nutritive sweeteners) as ''healthy,'' FDA would be aligning its healthy definition with those beverages that are recommended choices under the Dietary Guidelines.

One comment notes the potential for confusion if a healthy claim were included on plain and plain carbonated water but not on other calorie-free beverages. The comment provides that, to avoid consumer confusion, FDA might consider either not permitting water or any calorie-free beverages to carry a ''healthy'' claim as they do not provide nutrients or a food group, or permit all calorie-free beverages, including coffee, tea, flavored waters, and diet sodas, to carry a ''healthy'' claim.

Another comment argues that flavor extracts are exempt from nutrition labeling and this exemption supports the use of flavors in the definition of ''healthy'' as it shows that we view the significant function is for flavoring and is not nutritional. The comment suggests that recognizing calorie-free flavored water as ''healthy'' would allow companies to offer a variety of beverages with consumer appeal. The comments support extending the automatic qualification to these other non-caloric beverages asserting it would help people reduce calorie and sugar intake, is essential to combatting obesity in the United States, would foster hydration, and, in some cases, enhance nutrient intake, while allowing for flexibility and the ability for consumers to customize their beverage choices to align with a healthy dietary pattern.

Some comments assert that the addition of ''lawful food ingredients,'' such as flavors, carbonation, vitamins, minerals, and electrolytes to water for taste should not disqualify beverages from qualifying as ''healthy'' if they do not add significantly to their caloric or sugar content. The comments note that these added minerals or electrolytes include potassium, calcium, magnesium, and others, and are present at low levels—typically no more than 0.5% of the formulation—so their addition does not meaningfully affect the composition of the product, other than to slightly affect the taste of the water, and it does not affect the calorie or sugar content.

Some comments request that FDA allow beverages containing at least 10% of the DV of calcium, potassium, dietary fiber, Vitamin D, or iron to qualify as ''healthy.'' Another comment states that FDA should include high-fiber beverages without excessive amounts of harmful nutrients in the definition of ''healthy,'' suggesting that such beverages could be useful in helping Americans meet their recommended fiber intake.

One comment asserts the Dietary Guidelines does not recognize fortified bottled waters or beverages such as coffee or tea or beverages sweetened with non-nutritive sweeteners as key components of a healthful dietary pattern. The comment asserts that such products may be formulated in a manner that enables other types of nutrition-related claims (*e.g.,* zero calories, sugar-free) but should not be eligible for the ''healthy'' claim based on the rationale developed by FDA to link the use of this claim more closely to the recommendations in the *Dietary Guidelines, 2020–2025.* Another comment supports such beverages being able to bear other types of nutrition-related claims but not the ''healthy'' claim. The comments assert that other calorie-free beverages like soft drinks with artificial sweeteners should not qualify for a ''healthy'' claim because they do not contribute to nutritional needs.

(Response 117) We agree with the comments that support expansion of the automatic qualification to bear the ''healthy'' claim to non-caloric beverages, such as carbonated or noncarbonated waters, coffee, and tea, containing non-caloric ingredients such as flavors, no- or low-calorie sweeteners, vitamins, and minerals. We consider vitamins and minerals to include electrolytes or essential minerals such as sodium, calcium, and potassium that play a role in many body functions. As discussed in section V.D.4 (''Added Sugars''), we consider no- or low-calorie sweeteners to include the terms artificial sweeteners, high-intensity sweeteners, non-nutritive sweeteners, and non-calorie or non-caloric sweeteners. We view the inclusion of certain calorie-free ingredients such as flavors, no- or low-calorie sweeteners, vitamins, and minerals in waters, coffee, and tea that bear the ''healthy'' claim to be consistent with current nutrition science, Federal dietary guidance, and our food additive regulations. Allowing certain calorie-free ingredients such as flavors, no- or low-calorie sweeteners, vitamins, and minerals in beverages that may bear the ''healthy'' claim can help consumers identify foods that help them to maintain healthy dietary practices by providing consumers variety in their beverage choices to align with a healthy dietary pattern. We decline to amend the rule to permit diet soft drinks or sodas to automatically qualify for the ''healthy'' claim. The *Dietary Guidelines, 2020–2025* recommends non-caloric beverages such as water, coffee, and tea, but does not include diet soft drinks or sodas. The *Dietary Guidelines, 2020–2025* explains that both the calories and nutrients that non-caloric beverages provide are important considerations. According to the Dietary Guidelines, beverages that are calorie-free, such as water, coffee, or tea without added sugar or cream, or that contribute beneficial nutrients, such as fat-free and low-fat milk and 100% juice, should be the primary beverages consumed. Diet soft drinks or sodas do not contribute beneficial nutrients and, as mentioned, are not included in the *Dietary Guidelines, 2020–2025* as recommended calorie-free beverage options.

We decline to modify the criteria to bear the ''healthy'' claim to contain a certain amount of the DV for specific vitamins and minerals and fiber. In section V.C (''Food Group Equivalents'') and section V.D (''Nutrients to Limit''), we discuss our basis for updating the ''healthy'' claim to be a food group-based approach in addition to NTL criteria.

(Comment 118) Some comments express concerns about water containing non-caloric flavors and ingredients and state that if such beverages are allowed, FDA should set standards for the types of beverages that should qualify (*e.g.,* how much flavoring or sweetener would be allowed, which types of non-nutritive or high-intensity sweeteners would be allowed).

Some comments oppose the inclusion of beverages containing low- or no-calorie sweeteners, citing research and global public health guidance warning against their use. Additionally, some comments state that safety data is lacking in children and recommend that children under 5 years old avoid low- or no-calorie sweeteners. One comment cites a state's prohibition on use of low- and no-calorie sweeteners for products served to children and recommends the exclusion of waters containing low- or no-calorie sweeteners because there is no way to distinguish between child and adult consumption in a retail setting. Some comments attribute possible adverse health impacts such as cravings for sweet or high-calorie foods and overconsumption of sweeteners such as aspartame to consumption of low- or no-calorie sweeteners. The comments express concern about the lack of evidence on the long-term impacts of low- or no-calorie sweeteners and cite that further research is needed to determine the observed associations between its consumption and risk for outcomes such as obesity, type 2

diabetes, cardiovascular diseases, mortality, and unfavorable impacts on birthweight and adiposity in offspring. Other comments oppose allowing the ''healthy'' claim on calorie-free beverages such as soft drinks with artificial sweeteners asserting the proposed rule did not discuss the topic of high intensity sweeteners and quote the *Dietary Guidelines, 2020–2025* when stating ''questions remain about their effectiveness as a long-term weight management strategy.''

(Response 118) We discuss issues of safety and health impacts of consuming low- or no-calorie sweeteners in children and adults in section V.D.4 (''Added sugars'').

(Comment 119) Another comment asserts that juice beverages (*i.e.,* those containing less than 100% juice) can help contribute to a healthy dietary pattern by providing beneficial nutrients and requests we develop a more expansive ''healthy'' beverage category. The comment recommends we permit juice beverages to bear the ''healthy'' claim if they meet the following criteria: (1) contain no added sugar; (2) meet the proposed NTL criteria, and (3) contain either a full FGE (including products that contain half 100% juice and half water with ½ cup of 100% juice or one full FGE of fruit) or 10% of the DV per RACC of certain nutrients (such as vitamin C, calcium, iron, potassium, vitamin D, etc.). The comment also recommends requiring juice beverages must meet the fortification policy to bear a ''healthy'' claim, so foods for which fortification is discouraged could not qualify.

(Response 119) We agree that there are beverages other than water or 100% juice that can contribute to healthy dietary patterns. Although we decline to adopt the specific criteria recommended by the comment, in principle, we agree that 100% juices with only the addition of water and no added sugars can be part of a healthy dietary pattern. Water automatically qualifies for the ''healthy'' claim, and 100% juices with only the addition of water (*e.g.,* 100% juices that have been diluted with water such that they are 50% juice and 50% water) automatically qualify under the single-ingredient exemption (see Response 9). We discuss in section V.C (''Food Group Equivalents'') that we are no longer requiring that foods bearing the ''healthy'' claim provide certain levels of NTE because there has been a shift in nutrition science toward overall healthy eating patterns and away from focusing on the amounts of individual nutrients consumed that led to the corresponding shift in the definition of the ''healthy'' claim. Including requirements for minimum amounts of foods from the recommended food groups better reflects the overall nutrient content of foods and how nutrients in the food groups and subgroups may work together as part of a healthy dietary pattern. Similarly, with this focus on food groups, the fortification policy is no longer relevant to the ''healthy'' claim and we decline to incorporate it into this rule (see Response 100).

(Comment 120) As bottled water will qualify to bear the ''healthy'' claim, some comments request that FDA exempt bottled water from requiring nutrition labeling if a nutrient content claim such as ''healthy'' is used. The comments argue that most bottled water is exempt from nutrition labeling under § 101.9(j)(4) because it contains insignificant amounts of the mandatory nutrients. However, this exemption is contingent upon the product not bearing any nutrient content claims on its label or in labeling. The comments state that a bottled water product that bears the term ''healthy,'' even if otherwise exempt from nutrition labeling, would then be required to bear nutrition labeling despite the fact that the nutrition information would only convey ''zero'' of the mandatory nutrients. The comments request that FDA provide enforcement discretion from nutrition labeling when a bottled water product that otherwise is exempt from nutrition labeling under § 101.9(j)(4) bears a ''healthy'' claim in cases where they do not contain calories or other significant levels of nutrients.

(Response 120) We recognize that bottled water as well as certain coffee and tea products bearing the nutrient content claim ''healthy'' would no longer qualify for the exemption from nutrition labeling requirements at § 101.9(j)(4). Although we asked for comment in the proposed rule about the eligibility of calorie-free beverages, coffee, and tea to bear the ''healthy'' claim, we did not ask for comments specifically about the continued applicability of the exemption from nutrition labeling provisions under § 101.9(j)(4) and the proposed ''healthy'' claim. Until such time as we have had the opportunity to address this directly in a future rulemaking, we intend to consider the exercise of our enforcement discretion with respect to mandatory nutrition labeling on waters, coffee, and tea containing less than 5 calories per RACC that bear the ''healthy'' claim on their labels or labeling.

G. The Term ''Healthy'' and Related Terms or Derivatives of ''Healthy''

(Comment 121) Many comments support finalizing use of the term ''healthy'' or related terms as an implied nutrient content claim and strongly oppose expanding the list of related terms. The comments ask that the final rule reaffirm that the definition of ''healthy'' applies only to those terms currently defined as derivatives for a ''healthy'' nutrient content claim, *i.e.,* ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness,'' and only in those circumstances where the requisite ''nutritional context'' (*i.e.,* an explicit or implicit characterization of the level of a nutrient) is present on the label. The comments request that, if additional synonyms are included, FDA identify the reliable consumer perception evidence upon which it relied sufficient to establish that a term is viewed as synonymous with ''healthy'' to restrict the use of additional terms, adding that without such consumer research and an opportunity for public notice and comment, FDA lacks authority to regulate the use of other terms under the implied nutrient content claim for ''healthy.''

Some comments request that FDA reconsider permitting any derivatives of ''healthy'' and argue that claim should be limited only to the term ''healthy'' to further standardize the claim and ensure consumer understanding. Some comments recommend removing the terms ''healthier'' and ''healthiest,'' suggesting these terms are hierarchical and comparative and thus not aligned with the original intent of demonstrating the ''healthful'' properties of a certain food. The comments assert that the terms ''healthier'' and ''healthiest'' could cause confusion for consumers, leading them to believe that products bearing such terms may meet a higher nutritional threshold when this is not the case. One comment recommends we emphasize the healthiness of single-ingredient products by establishing a further designation, such as ''healthiest'' that is exclusively reserved for whole, single-ingredient nuts, nut butters, whole grains, beans, legumes, seeds, fruits, and vegetables.

Some comments urge FDA to include a complete list of related or derivative terms in the codified language and clearly state that other potentially synonymous terms not otherwise codified will not be considered implied ''healthy'' claims such that they can be used without meeting the criteria laid out in § 101.65(d). The comments assert that, although the proposed rule provides examples of related terms for ''healthy,'' the list of examples appears to be without limitation and arguably

could include other terms (*e.g.,* ''wholesome,'' ''nutrient-dense,'' or ''nutritious''), causing confusion for both manufacturers and consumers absent a complete list.

One comment states that if FDA also regulates terms that are synonymous with healthy, restaurants will be constrained in their communications to consumers, which will lead to less education and access to nutritionally beneficial foods and beverages by inadvertently limiting a restaurants ability to communicate to customers through menus, menu boards, and other channels.

(Response 121) As discussed in the 1994 final rule to establish the ''healthy'' nutrient content claim (59 FR 24232 at 24235), we determined that the regulatory definition of ''healthy'' should apply to the use of any of its derivatives in a nutritional context. Derivatives of ''healthy'' have the same general meaning and connotation as this term and, thus, when used in food labeling, may be construed by consumers to imply that the products on which they appear will be helpful in maintaining healthy dietary practices. After nearly 30 years of experience with the ''healthy'' nutrient content claim, we still conclude that it is appropriate to require that any of the derivatives of ''healthy,'' when used in a nutritional context in food labeling, must be in accordance with the definition of ''healthy'' in § 101.65(d). Accordingly, the final rule, at § 101.65(d)(3), provides that the term ''healthy'' or derivative terms ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'' can be used as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if the food meets the criteria to bear the claim. We are amending § 101.65(d)(3) to clarify that the derivatives of ''healthy'' are ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness.'' We agree with the comments requesting that we codify the complete list of derivatives for ''healthy'' to make clear that other terms not otherwise codified will not be considered derivatives of the ''healthy'' implied nutrient content claim under § 101.65(d).

With regard to the comments concerning potential consumer confusion over use of the terms ''healthier'' and ''healthiest,'' which suggest these terms are hierarchical and comparative and thus not aligned with the original intent of demonstrating the ''healthful'' properties of a certain food, the comments did not provide any data or other information to support such concerns, and we are therefore unpersuaded to change our position. Moreover, after nearly 30 years of experience with the ''healthy'' nutrient content claim, we have not been made aware of any consumer confusion resulting from any use of these derivative terms. As discussed, since the 1994 final rule, we have determined that it is appropriate to apply § 101.65(d) to the use of the derivatives of ''healthy'' in a nutritional context.

The comments regarding communications with consumers in restaurants are outside the scope of this rulemaking.

(Comment 122) Some comments argue that FDA should regulate additional terms as ''healthy'' claims, suggesting that there are several terms other than ''healthy'' and its derivatives that consumers may interpret as indicating that the levels of nutrients in a food are such that the food may help maintain healthy dietary practices. The comments assert that all words that characterize a food's general healthfulness, for example, ''nutritious,'' ''nourishing,'' ''wholesome,'' ''nutritive,'' and ''good for you,'' should be held to the uniform criteria as that of the final ''healthy'' definition. The comments express concern that such terms could otherwise be unduly confusing to consumers if not held to the same standards in the final rule. The comments assert that the most obvious of these terms is ''nutritious'' and its derivatives, such as ''nutrition,'' ''nutritional,'' ''nutritiously,'' and ''nutritionally'' and additional terms include ''nutrient-dense,'' ''good for you,'' ''nourishing'' and ''wholesome.'' The comments further assert that consumers likely perceive these claims as synonymous with ''healthy'' and the claims should be regulated as implied ''healthy'' claims and request that FDA expressly add ''nutritious,'' ''nourishing,'' ''wholesome,'' and their derivatives, and any other equivalent terms, to the final rule as examples of terms that are synonymous with ''healthy.'' The comments claim that these kinds of terms are relatively pervasive in marketing and advertising messages for food products and extending eligibility criteria for ''healthy'' to apply to these phrases may help prevent replacement of ''healthy'' on food labels with similar terms that are not regulated. The comments claim such additional regulation is necessary given the public skepticism of the government's regulation of food labels and mistrust of some food label claims. The comments assert that this, in turn, may help prevent consumer confusion and strengthen the consistency and utility of these terms in differentiating foods that are most useful in promoting achievement of recommended dietary patterns and urge FDA to conduct research to help it determine whether to recognize these terms as synonymous with ''healthy'' or to establish separate definitions for their use.

Other comments specifically oppose incorporating additional terms, such as wholesome, nutritious, or other similar terms, as synonyms for healthy, claiming consumers view those terms differently and that FDA has not provided any information or consumer research to establish that these terms should be viewed as synonyms for healthy. The comments assert that defining ''healthy'' is complex enough without expanding the reach of the rule to include other terms that might have competing or misaligned meanings.

(Response 122) As discussed in the 1994 final rule (59 FR 24232 at 24235), while we recognize that terms such as ''nutritious,'' ''wholesome,'' and ''good for you'' can be implied nutrient content claims when they appear in a nutritional context on a label or in labeling, we do not believe that they are necessarily synonymous with ''healthy.'' We do not have sufficient information to determine whether definitions for the terms mentioned in these comments are needed, and what those definitions should be. The comments did not provide sufficient information on which to develop definitions or to establish these terms as synonyms for the term ''healthy.'' Thus, we are not extending the definition of ''healthy'' to these terms. However, we note that when these terms appear on labels or labeling, they may be subject to regulation under the general misbranding provision of section 403(a) of the FD&C Act.

H. Nutritional Context

(Comment 123) Some comments support our proposal to broaden our interpretation of when a ''healthy'' claim constitutes a nutrient content claim. Other comments express concern that evaluating the use of ''healthy'' only in a nutritional context could be exploited by companies who would use the word in other contexts to mislead consumers. The comments state that if the word ''healthy'' is in the brand name or on the front of a food package, the product should meet the healthy definition and that anything different is deceptive.

(Response 123) In the proposed rule (87 FR 59168 at 59181 through 59183),

we discuss, among other things, that ''healthy'' is a broad term that can have connotations beyond the nutritional properties of a food. We proposed to define ''healthy'' as a nutrient content claim only when it is used in a nutritional context; in other words, the proposed criteria would only apply when ''healthy'' is used on a label or in labeling, and other information, such as other claims, images, or vignettes, about the nutrition content of the food is also present somewhere on the labeling. If the term ''healthy'' is used in a nutritional context on a label or in labeling, it is an implied nutrient content claim which highlights that a food, because of its nutrient content, is particularly useful in constructing a diet that is consistent with current dietary recommendations. Therefore, such use of the term ''healthy'' would be subject to the updated ''healthy'' criteria set forth in this rule.

With regard to comments that suggest we regulate all uses of the term ''healthy'' as an implied nutrient content claim, we decline to do so. The preamble to the 1994 rule explains the reasons for which FDA determined that the term ''healthy'' should not be regulated as an implied nutrient content claim when not used in a nutritional context. Since that time, FDA has not received information on which to conclude that consumers would not be able to understand when ''healthy'' is used in a context in which it is not an implied nutrient content claim. Consequently, we have no reason to believe that consumers would infer that the term ''healthy,'' when used outside of a nutritional context, would signal that the food has a nutrient profile that would be helpful to consumers in structuring a diet that conforms to current dietary guidelines. Rather, such inferences are likely to be drawn only if the term ''healthy'' is accompanied by additional language or graphic material or is otherwise presented in a context that explicitly or implicitly suggests that the food has a particular nutrient profile (see 59 FR 24232 at 24234 to 24235). Accordingly, this regulation covers labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices because of its nutrient content. However, we note that, even outside of the nutritional context, FDA has the authority to ensure that ''healthy'' is not used in a misleading manner under section 403(a)(1) of the FD&C Act.

(Comment 124) Some comments recommend that ''healthy'' (and related terms) be considered an implied nutrient content claim even when used as part of a health claim (*e.g.,* ''heart healthy'') or structure-function claim (*e.g.,* ''brain health''). The comments assert that any use of the term ''healthy'' on food labeling should be considered an implied nutrient content claim if the product's labeling also includes voluntary information about the nutrition content of the food (*e.g.,* if another nutrient content claim appears on the package or product website) because the average consumer will not understand that the term ''healthy'' is regulated differently when used as part of a health claim, structure/function claim, or implied nutrient content claim. To address the potential for consumer confusion, some comments assert that all products using the term ''healthy'' as part of a labeling claim in any context should be held to the same nutrient criteria.

In contrast, other comments state that the requirements of the rule should not apply to other labeling claims, such as structure/function claims, health claims, or other nutrient content claims that use the term ''healthy'' and FDA should explicitly state this in the rule. The comments note that, for example, structure/function claims often reference specific nutrients, however, use of the term ''healthy'' in such claims does not characterize the level of nutrient in the food; rather, it generally describes the role of the nutrient on the structure or function of the body. Some comments recommend FDA clarify it does not view compliance with ''healthy'' as a prerequisite for making other nutrient content claims, health claims, or structure/function claims that are subject to different nutritional requirements and regulations, or else it could negatively impact use of other labeling claims and lead to consumer confusion.

(Response 124) Section III.A (''Background'') provides a brief overview of different types of claims and statements commonly made on food labels or in food labeling. While we generally agree with comments stating that not all claims that use the term ''healthy'' should be subject to requirements of this rule, we note that use of the term ''healthy'' in a claim or statement on a food label or labeling may place the term into a nutritional context, and therefore, would make ''healthy'' an implied nutrient content claim. We further note that, while different nutrition labeling claims have different purposes and criteria for their use, a term or statement may be considered to be more than one type of claim (*e.g.,* a structure/function claim and a nutrient content claim), depending on the context of the use of the term or statement in light of the label and labeling as a whole. Additionally, other types of claims may be implied or explicit information about the nutrient content of the food, and therefore could be accompanying material that could put the use of ''healthy'' into a nutritional context. As stated in multiple parts of this rule, and consistent with FDA's approach to labeling regulation in other contexts, FDA considers whether a food product bears a claim, such as the ''healthy'' claim, on a case-by-case basis by looking at the claim in the context of the label and labeling as a whole.

(Comment 125) One comment requests that the updated definition of ''healthy'' expressly exclude trademarks that are registered on the Principal Register of the U.S. Patent and Trademark Office (USPTO) that include the word ''healthy'' and that FDA confirm that such registered trademarks do not misbrand a food product. The comment notes that the intent of the rule is to define ''healthy'' as a nutrient content claim only when it is used in a nutritional context and asserts that use of ''healthy'' in a trademark registered on the USPTO's Principal Register is used outside of a nutritional context because it is intended to signify that the product came from a specific source and not to describe the product's nutrient levels.

The comment also states that FDA lacks statutory authority to restrict labeling references to trademarks registered on the Principal Register that include the word ''healthy,'' and that the term ''healthy'' when used in registered trademarks is not false or misleading labeling under sections 201(n) and 403(a) of the FD&C Act because it does not misrepresent the characteristics or content of the food product itself, and its predominant meaning is a source identifier. Further, the comment argues that the update to the claim would represent a regulatory taking of the intellectual property of firms that have been using ''healthy'' in their product brand name.

(Response 125) We intend to examine whether the use of the term ''healthy'' on labels and labeling could be considered an implied nutrient content claim if any other information on the label or labeling, such as other claims, images, or vignettes, puts the term into a nutritional context. We disagree that a brand name using the term ''healthy'' is primarily a source identifier. As we stated in the 1994 rule establishing the ''healthy'' claim, nutritional context is established ''when the term appears in a brand name that by virtue of its use implies that the product is useful in

achieving dietary recommendations'' (59 FR 24232 at 24235). As we have also stated in response to similar comments since 1993, registering a trademark with the USPTO does not automatically place the use of ''healthy'' outside of a nutritional context. (See 58 FR 2372 at 2375, specifically stating ''One comment stated that the proposed definition for general nutrition claims could have an impact on many proprietary trademarks or slogans . . . FDA disagrees that terms such as those cited in the comments should be excluded from regulation under section 403(r) of the act. The agency believes that these terms can be implied nutrient content claims when they appear in a nutritional context on a label or in labeling.'')

As stated in other parts of this rule, we will consider the context of the use of the term by looking at the label and labeling as a whole. This approach is consistent with how FDA considers product or brand names on food labels or labeling in other contexts to determine whether a food product bears a claim.

We also disagree that the rule would constitute a taking. The Fifth Amendment to the U.S. Constitution prohibits the government from taking private property for public use without just compensation. The Supreme Court has held that the government effects a ''per se'' taking when it physically appropriates property, which is the ''clearest sort of taking.'' *Cedar Point Nursery* v. *Hassid,* 141 S. Ct. 2063, 2071 (2021). It is not clear that trademarks constitute ''private property'' within the meaning of the Fifth Amendment's Takings Clause. *See, e.g., Clemente Props., Inc.* v. *Urrutia,* 693 F. Supp. 3d 215, 247 (D.P.R. 2023) (''A question raised by the motions before the Court is whether a trademark is the type of private property protected by the Takings Clause. The question is debatable and far from settled.''). Even assuming trademarks do constitute private property under the Takings Clause, a regulatory taking occurs where regulations that ''restrict an owner's ability to use his own property'' go ''too far.'' *Cedar Point Nursery* at 2071–72. In such cases, a taking may be found based ''on a complex of factors, including: (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action.'' *Murr* v. *Wisconsin,* 582 U.S. 383, 393 (2017) (cleaned up) (referred to as the ''Penn Central factors'' after *Penn Central Transp. Co.* v. *New York City,* 438 U.S. 104, 124 (1978)). The force of any one of these three Penn Central factors may be ''so overwhelming . . . that it disposes of the taking question.'' *Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1005 (1984).

Regarding the character of the governmental action, it has long been established that the government may regulate products in the interests of public health and safety and such regulation ''cannot, in any just sense, be deemed a taking.'' *Mugler* v. *Kansas,* 123 U.S. 623, 668 (1887). The takings doctrine is based on the concept that, when the government seizes property for the public benefit, such as land for a road or a dam, the public should compensate the owner. But that is a different scenario from where the government limits the use of property to protect public health and safety. *See id.* at 669. As the Supreme Court has elaborated, ''[l]ong ago it was recognized that all property in this country is held under the implied obligation that the owner's use of it shall not be injurious to the community, and the Takings Clause did not transform that principle to one that requires compensation whenever the State asserts its power to enforce it.'' *Keystone Bituminous Coal Ass'n* v. *DeBenedictis,* 480 U.S. 470, 491–92 (1987) (cleaned up). As a result, restrictions on ''uses of personal property'' that are ''directed at the protection of public health and safety'' are ''the type of regulation in which the private interest has traditionally been most confined and governments are given the greatest leeway to act without the need to compensate those affected by their actions.'' *Rose Acre Farms, Inc.* v. *United States,* 559 F.3d 1260, 1281 (Fed. Cir. 2009). As we have stated throughout this rule, here the updated definition of ''healthy'' directly advances our substantial government interests in providing information to consumers to indicate that the nutrient content of a food may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims. Updating the ''healthy'' definition to ensure that it is aligned with current nutrition science and Federal dietary guidance promotes public health by providing consumers with information about foods that, because of their nutrient content, are particularly useful in constructing a diet that is consistent with current dietary recommendations. Because the term ''healthy'' can lead consumers to believe a food will help them maintain healthy dietary practices when that term is used as an implied claim in a trademarked brand name, the same public health purposes are at issue.

The other Penn Central factors also weigh in favor of finding no taking here. With regard to economic impact, the comment asserts that the value of the property of food manufacturers with brand names that contain the term ''healthy'' will be diminished because some of their products bearing the name may no longer qualify for the ''healthy'' claim. However, many changes in government laws, regulations, and policies have economic consequences, and the Supreme Court has long recognized that ''[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.'' *Pennsylvania Coal Co.* v. *Mahon,* 260 U.S. 393, 413 (1922). The Supreme Court has explained that ''mere diminution in the value of property, however serious, is insufficient to demonstrate a taking.'' *Concrete Pipe & Prods.* v. *Constr. Laborers Pension Trust,* 508 U.S. 602, 645 (1993). Similarly, a ''loss of profit'' does not establish a taking. *74 Pinehurst LLC* v. *New York,* 59 F.4th 557, 566 (2d Cir. 2023). And courts have rejected regulatory takings claims even where the government's actions ''impose considerable costs on private actors in the regulated industry.'' *Mobile Relay Assocs.* v. *FCC,* 457 F.3d 1, 12 (D.C. Cir. 2006). Instead, in evaluating the economic impact of a regulation, courts have explained that the ''touchstone'' is ''proportionality'': ''the size of a liability only weighs in favor of finding a taking insofar as it is out of proportion to the legitimate obligations society may impose on individual entities.'' *B&G Constr. Co.* v. *Dir., OWCP,* 662 F.3d 233, 260 (3d Cir. 2011) (cleaned up). Here, especially given the revisions from the proposed rule, we anticipate that some products that include ''healthy'' in their brand name would continue to qualify for the claim, and some others could qualify with appropriate modifications. While there may be changes to which products can qualify under the updated definition, it is unlikely that any trademarked brand name would be destroyed or even substantially restricted. These changes would, at most, constitute diminution in the value of property—and the comment does not provide evidence regarding how large any diminution in the value of the property would be. The comment further acknowledges that FDA could make changes to the nutrient and food group levels that were specified in the

proposed rule that would result in more products that currently bear a brand name containing the term ''healthy'' continuing to qualify to bear the claim. As noted elsewhere in this final rule, FDA made multiple changes that increased flexibility from the proposed to the final rule, including increasing the added sugar limits for mixed dishes, main dishes, and meal products and providing for aggregation of food group equivalents.

With respect to the last Penn Central factor, a ''reasonable investment-backed expectation must be more than a unilateral expectation or an abstract need.'' *Ruckelshaus,* 467 U.S. at 1005 (cleaned up). Courts have held that those who do business in highly regulated fields are on notice that changes are possible. *Connolly* v. *Pension Ben. Guar. Corp.,* 475 U.S. 211, 226–27 (1986) (''Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end'') (cleaned up). As described at the beginning of this comment response, food manufacturers have been on notice since 1994 that their brand names, if making an implied claim, would need to comply with the ''healthy'' claim definition. As the claim definition is based on nutrition science, it is reasonable to expect that the definition would be updated over time to match updates in nutrition science and that the scope of products that would be able to bear the claim may shift to some extent.

(Comment 126) Many comments oppose our proposal to broaden the interpretation of nutritional context, arguing that what they perceived to be an overly broad interpretation of nutritional context could cause confusion and limit consumer access to relevant information when choosing a variety of foods within an overall healthy eating pattern. The comments assert that FDA acknowledged in the 1994 rule that the various uses of the term ''healthy'' demonstrate the need for us to take a flexible case-by-case approach in deciding whether a claim that uses the term ''healthy'' is an implied health claim or nutrient content claim, and we determined there was insufficient evidence to conclude consumers would not be able to discern the context in which the ''healthy'' claim appears on the label or labeling of a product. The comments state they believe this continues to be the case today and that more work and data (*e.g.,* consumer studies) would be needed by FDA to justify an expanded definition of nutritional context.

The comments support what they state is FDA's longstanding position that ''healthy'' claims are only implied nutrient content claims when made ''in connection with an explicit or implicit claim or statement about a nutrient (such as 'healthy, contains 3 grams of fat')'' and assert that this original standard provides clear parameters for determining whether a ''healthy'' claim is an implied nutrient content claim, *i.e.,* by requiring a direct nexus between the ''healthy'' claim and the nutrient statement. The comments argue that this original standard also aligns with FDA's statutory authority under the FD&C Act, which authorizes FDA to establish nutrient content claim requirements only for claims that characterize the level of any nutrient which is of the type required by the FD&C Act to be in the label or labeling of the food (section 403(r) of the FD&C Act (21 U.S.C. 343(r)). The comments assert that industry has relied upon this standard for more than two decades and has developed product portfolios based on these established principles and disagree with FDA's proposal to alter this standard, arguing that the proposed changes to the interpretation of nutritional context would divert from FDA's current standards and would treat a broader class of ''healthy'' claims as implied nutrient content claims. The comments raise concerns about whether a brand name on the front of a label that uses the term ''healthy'' and a separate, back-of-pack claim that a product ''provides essential vitamins and minerals'' would be treated as an implied nutrient content claim by FDA. Some comments argue that only manufacturers who use the term ''healthy'' when describing the product's nutritional value should be required to comply and that manufacturers who simply use ''healthy'' as a term in the product's name-brand, slogan and/or logo/mascot, and who are not describing the nutritional content should be allowed to use the term without complying with this rule. The comments argue that the proposed interpretation of nutritional context would not only exceed FDA's statutory authority, but also would fail to advance FDA's policy aim, *i.e.,* to ensure that consumers have access to truthful and non-misleading information to inform healthy dietary choices.

(Response 126) The minor revisions we are making to § 101.65(d)(1) defining implied nutrient content claims are consistent with FDA's longstanding approach to consider whether a food product bears a claim, such as the ''healthy'' claim, on a case-by-case basis by looking at the claim in the context of the labels and labeling as a whole. The revisions merely clarify that information on the label or labeling that puts ''healthy'' into a nutritional context need not be immediately adjacent to the implied nutrient content claim. Under the rule, we intend to continue using a flexible, case-by-case approach in evaluating and considering labeling claims, by placing the use of the term ''healthy'' into the context of the overall label or labeling.

Such revisions are also consistent with FDA's statutory authority under the FD&C Act. As explained in section IV. (''Legal Authority''), section 403(r) of the FD&C Act specifies that claims made in the label or labeling of the food that expressly or by implication characterize the level of any nutrient which is the type required by section 403(q)(1) or (q)(2) of the FD&C Act to be in the label or labeling of the food are permitted only if they are made in accordance with FDA's authorizing regulations. As early as the 1994 rule, FDA determined that, when used in a nutritional context, the term ''healthy'' is making an implied claim that the levels of the nutrients in the food are such that the food would be useful in achieving a total diet that conforms to current dietary recommendations (59 FR 24232 at 24234). Consequently, it is squarely within FDA's authority to define implied nutrient content claims, such as ''healthy,'' by regulation, to clarify when a claim implies that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. We therefore disagree with the comments that imply that the revisions to § 101.65(d)(1), which state that ''healthy'' is a nutrient content claim where it is used to characterize the food itself and ''where there is also implied or explicit information about the nutrient content of the food,'' are no longer aligned with FDA's statutory authority under the FD&C Act.

Furthermore, as explained in the proposed rule, the minor revisions made to § 101.65(d)(1) bring that provision in line with the updated criteria for the ''healthy'' claim. The updated criteria incorporate food group requirements in addition to individual NTL criteria. Therefore, § 101.65(d)(1) no longer requires that the accompanying material be a ''claim or statement about a nutrient,'' but instead requires that it be ''information about the nutrient content of the food.'' This change recognizes that material that states or implies that the nutrient content of the food would be useful to consumers in structuring a diet that is supported by current dietary

recommendations is not limited to statements about the presence/level of one specific nutrient and reflects that the updated ''healthy'' criteria, along with current nutrition science and Federal dietary guidance, emphasize food groups and the overall nutrient content of the food, rather than one individual nutrient in isolation.

Additionally, we disagree with comments stating that FDA should not consider use of the term ''healthy'' in a slogan, product name, logo, or mascot a nutrient content claim because it is not describing nutritional content. As stated above, under the rule, we intend to continue applying a flexible, case-by-case approach that considers the overall content of the food label and labeling when determining if a product label uses the ''healthy'' claim in a nutritional context. Contrary to what this comment asserts, this approach furthers FDA's goals to help ensure that consumers receive information that may help them maintain healthy dietary practices to promote public health, prevent misleading labeling, and reduce potential confusion caused by the use of inconsistent definitions for nutrient content claims. We address additional comments about the statutory authority to expand the nutritional context and about whether the requirements of the final rule directly advance FDA's asserted interests in section V.K (''Legal Comments'').

(Comment 127) Many comments request that FDA reconsider its position that the inclusion of voluntary front-of-pack nutrition icons such as Facts Up Front, MyPlate, or other symbols on the label, that do not reference nutrients, would be considered ''nutritional context'' that would render the term ''healthy'' on the label being subject to the ''healthy'' nutrient content claim definition. The comments disagree that these labeling elements create a nutritional context. The comments assert that the Facts Up Front program represents the standardized and factual display of nutrient information about a food and does not create any sort of nutritional or health halo for the product and that other claims, such as those about whole grain or fruit content, do not characterize the nutrient content. The comments note that FDA referenced a MyPlate logo as creating nutritional context for a ''healthy'' nutrient content claim; however, the comments argue that there are a variety of MyPlate symbols, including icons providing an overview of food group contributions on a plate (*i.e.,* half fruit and vegetables) but also other icons that can be used to signal the food groups present (fruits, vegetables, grains, dairy, protein, oils), or foods to limit, and even physical activity. The comments suggest that, provided they are used with appropriate context and not in a misleading manner, these icons do not create the nutritional context for ''healthy'' to be viewed as an implied nutrient content claim. The comments state that FDA has cited no consumer research or evidence to suggest that consumers view this type of information as creating a nutritional context.

Some comments state that FDA should acknowledge that mandatory label elements, such as a statement of identity, or corporate, company, or subsidiary name in a distribution statement, or the Nutrition Facts label does not provide the requisite nutritional context for a ''healthy'' nutrient content claim, provided that the mandatory label elements appear on the label in a way consistent with FDA's labeling requirements. According to the comments, a company name, which is often a mandatory label component, should be able to appear anywhere on pack, including the front panel, without being viewed as nutritional context for an implied ''healthy'' nutrient content claim. The comments argue that corporate and company names are not easily changed, and in most cases, represent a large portfolio of products. As such, the comments request FDA to include a provision in the final regulation that expressly exempts corporate and/or company names from triggering the criteria for a ''healthy'' implied nutrient content claim provided that the corporate or company name is not otherwise false and misleading in the context of the entire label.

(Response 127) With regard to the use of MyPlate and other related graphic icons, we discussed in the proposed rule (87 FR 59168 at 59182) that there may be instances where the use of a graphic on the label of a food bearing ''healthy'' would place the term in a nutritional context; for example, if the label on a can of beans labeled ''healthy'' also used the MyPlate symbol (which graphically puts the food groups together in the context of an overall dietary pattern, as a translation of the Dietary Guidelines) or other voluntary front of pack labeling (such as the Facts Up Front labeling program) to imply that the product meets nutritional needs. We reiterate that FDA considers food labels and labeling as a whole and will consider the context of statements made in labels and labeling to determine whether a product bears a ''healthy'' implied nutrient content claim. For certain graphics mentioned by the comment, such as an ''activity'' button icon referring to physical activity, such an icon likely would not provide the requisite nutritional context to establish a ''healthy'' claim; however, many of the MyPlate graphic representations are voluntary information about the food groups present in a food and thus would provide the requisite nutritional context to establish an implied nutrient content claim. While we are not aware of specific studies regarding consumer understanding of whether these specific icons create nutritional context, such findings are not necessary to this particular determination, as the information contained in the graphic images of food groups or a plate with multiple food groups is consistent with our stated parameters for limiting our consideration of the term ''healthy'' as an implied nutrient content claim to instances in which it is used in a nutritional context. However, we agree that mandatory label elements, such as the statement of identity, corporate name of the manufacturer, or the Nutrition Facts label, do not place the use of the term ''healthy'' elsewhere on the product into a nutritional context.

(Comment 128) Some comments argue that it is inadequate to only consider nutrition criteria when labeling foods ''healthy,'' stating that FDA should fully ''repeal'' the ability for companies to use the word ''healthy'' until FDA reviews and requires further criteria for when foods can be labeled ''healthy.'' The comments suggest, at a minimum, that we consider the safety of food additives when determining whether a food is ''healthy'' by including requirements that such foods do not contain food additives that have been associated with health risks. Some comments discuss FDA's ''Closer to Zero'' plan for reducing dietary exposure of babies and young children to toxic elements and express concern about juice products being eligible for the ''healthy'' claim using only ''nutrition-based criteria, without accounting for the levels of toxic elements where an FDA action level applies to them.'' Similarly, other comments, noting that ''healthy'' will act as a nutrient content claim only when used in a nutritional context, recommend the inclusion of an accompanying statement such as ''based on nutritional content only'' to avoid consumer misconception.

(Response 128) This final rule defines ''healthy'' as a nutrient content claim only when it is used in a nutritional context. As explained in the preamble to the proposed rule, since 1994, we have recognized that labeling that describes a food product as ''healthy'' in a nutritional context is making an implicit claim of the level of nutrients in the

product. The presence or absence of ingredients other than nutrients in a food product, as described in the comments (*e.g.,* toxic elements and non-nutrient food additives), is outside of the scope of the ''healthy'' nutrient content claim. However, as the comments note, our ''Closer to Zero'' plan describes the activities we are currently undertaking for reducing dietary exposure of babies and young children to contaminants from food (Ref. 35).

As stated above, we have no reason to believe that consumers would infer that the term, ''healthy,'' when used outside of a nutritional context, would signal that the food has a nutrient profile that would be helpful to consumers in achieving a diet that is consistent with current dietary recommendations, and such inferences are only likely to be drawn if the term ''healthy'' is accompanied by additional material or is otherwise presented in a context that explicitly or implicitly suggests that the food has a particular nutrient profile. For this reason, it is not necessary to require an accompanying statement to the ''healthy'' nutrient content claim, such as ''based on nutritional content only.''

I. Records Requirements

(Comment 129) Many comments agree with our proposed requirement that food manufacturers of products (other than raw, whole fruits, raw whole vegetables, water, and individual foods where the standard information required on the food label provides sufficient information to verify that the food meets the FGE requirements) that bear the ''healthy'' claim make and keep written records to verify that the food meets the FGE requirements where the FGE contained in the product is not apparent from the label of the food. These comments express support for the flexibility we proposed for manufacturers to demonstrate compliance using records they believe best meet the requirements rather than being required to produce any specific form or documents. The comments note that such an approach is similar to FDA's recordkeeping system for nutrition labeling of added sugars and other nutrients for which no analytical test methods exist. The comments agree that updating the definition of ''healthy'' and requiring each manufacturer to make and keep written records to verify the food meets the definition supports the overall goal of promoting a healthier food supply for all. However, some comments argue that FDA does not have legal authority to access proprietary information, such as complete product formulation, and state that FDA should clarify that records kept to verify the food group contributions are limited in nature and need only include the specific information regarding the food group contribution information, rather than the full recipes or formulations that are confidential and trade secret information.

(Response 129) We disagree with the assertion that FDA does not have legal authority to access proprietary information such as complete product formulation. As discussed in section IV. (''Legal Authority''), the authority granted FDA under sections 701(a), 403(r), 403(a)(1) and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without access to such records, FDA would not know whether the food meets the requirements to bear the ''healthy'' claim consistent with section 403(r) of the FD&C Act, and whether the use of the claim is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether a food that is voluntarily bearing a ''healthy'' nutrient content claim is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring to be kept under § 101.65(d)(4). Failure to make and keep records and provide the records to FDA, as described in § 101.65(d)(4), would result in the food bearing the ''healthy'' claim being misbranded under section 403(r) and 403(a)(1) of the FD&C Act.

However, as discussed in the preamble to the proposed rule (87 FR 59168 at 59194), manufacturers will be responsible for the type of records they maintain and are not required to produce any specific form or document. We proposed that records be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records in accordance with 21 CFR part 11 and the records must be accurate, indelible, and legible. The manufacturer is in the best position to know which records provide the documentation required to determine compliance. In the preamble to the proposed rule (87 FR 59168 at 59194), we note that compliance with the requirements for NTL will be verifiable for all food products using the Nutrition Facts label; that is, it will be apparent from the Nutrition Facts label whether a food meets the applicable criteria for saturated fat, sodium, and added sugars content, and thus no additional records are required. In addition, for some foods, we will be able to use the product label (including the Nutrition Facts label, the ingredient list, the statement of identity, and any other information) to verify compliance with the food group requirements. Other foods will not need to provide records to document compliance because the single ingredient exemption in the final rule expands the types of foods that can automatically qualify for the ''healthy'' claim without needing to meet criteria for FGEs and NTL (see Response 9). Records used to verify that a food meets the FGE requirements for ''healthy'' could include recipes or formulations, batch records providing data on the weight of certain ingredient contributions to the total batch, certificates of analysis from ingredient suppliers, or other appropriate verification documentation that provides the needed assurance that a food bearing the ''healthy'' claim complies with the FGE requirements.

We expect that manufacturers choosing to use the ''healthy'' claim will have the type of records needed to verify that the food meets the requirements, given that they will have to analyze their product to determine whether it meets the requirement to bear the claim. The records requirement is intended to provide flexibility in what records the manufacturer makes available to FDA to verify the claim. The records provided to FDA during an inspection would only need to provide information on the FGEs because, as discussed above, the information on NTL will be available on the food package. Most importantly, other information about the food can be redacted to ensure confidentiality of a food product formulation as long as the information provided can adequately verify compliance with the requirements to bear the ''healthy'' claim. Furthermore, even if a manufacturer's records contained confidential commercial information or trade secret information or a manufacturer believes that certain information should be protected from public disclosure, there are safeguards to protect against public disclosure of that information and mechanisms that a manufacturer can use to assert that certain information should be protected from disclosure. We protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C.

1905, and part 20 (21 CFR part 20). For example, our regulations pertaining to disclosure of public information, at part 20, include provisions that protect trade secrets and commercial or financial information which is privileged or confidential. If a manufacturer keeps proprietary recipe information in its records, it should mark the information as such before providing the records to FDA upon request.

(Comment 130) Some comments request that we recognize that records may be stored centrally and need not be physically available at the manufacturing facility and that allowing for central storage of records would be consistent with the approach FDA has taken in numerous other situations, citing 21 CFR 117.315(c).

(Response 130) Records must be made available to us upon request, during an inspection, for official review and photocopying or other means of reproduction (§ 101.65(d)(4)). As discussed in the proposed rule (87 FR 59168 at 59196), the records would need to be reasonably accessible (access to records within 24 hours can be considered reasonable) to FDA during an inspection at each manufacturing facility (even if not stored onsite) to determine whether the food meets the requirements for bearing the ''healthy'' claim. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

(Comment 131) Some comments request clarification regarding which party is responsible for keeping records in a situation where a contract manufacturer produces a product on behalf of another party and maintains the product recipe as confidential and proprietary, suggesting that it should be sufficient if the manufacturer provides to the distributor/own-brand company a signed statement confirming that the product is eligible for the ''healthy'' definition.

(Response 131) Companies using the ''healthy'' claim on their products may maintain the required records however they choose, including whatever arrangements they have with manufacturing partners, provided they are aware that they are responsible for ensuring that the products they introduce into interstate commerce are not misbranded under the FD&C Act. As discussed in the previous response, if FDA inspects a manufacturer or manufacturing facility, the relevant records to demonstrate that a food meets the requirements for bearing the ''healthy'' claim would need to be provided within a reasonable time, such as someone providing the records electronically to FDA, if appropriate. As described above, redacted records are also potentially appropriate to maintain, provided the redacted records are able to demonstrate that the food meets the requirements for bearing the ''healthy'' claim. A signed statement confirming that the product is eligible for the ''healthy'' claim would not be sufficient to provide to FDA during an inspection to demonstrate that a food product qualifies to bear the ''healthy'' claim.

In the preamble to the proposed rule (87 FR 59168 at 59195), we also discussed how manufacturers should be able to obtain the necessary information from ingredient suppliers to demonstrate that any foods they manufacture that bear the ''healthy'' claim meet the requirements for the claim.

(Comment 132) Some comments suggest that FDA provide further clarity around calculating values for the designated thresholds, stating in instances where the requirements cannot be verified with the label and manufacturers have to maintain information in records to determine whether the product meets the FGE requirements, food formulators/food companies need clarification regarding whether unrounded values would need to be at or above thresholds and to what decimal place. Some comments urge FDA to clarify that either unrounded or rounded nutrient values may be used to determine compliance, suggesting that this would be consistent with FDA's approach for other absolute nutrient content claims such as ''fat free,'' where FDA indicated that ''because there is no nutritional difference between rounded and unrounded values of a nutrient in a food, [FDA] does not see a need to specify which value should be used in determining whether or not a food qualifies to make a nutrient content claim'' (see 58 FR 44020 at 44024 (August 18, 1993).) The comments claim that the same standard should apply to the updated ''healthy'' nutrient content claim definition because ''healthy'' is an absolute claim, where either the rounded or unrounded value could be used to assess compliance.

(Response 132) We agree with the comments and our previously stated position that because there is no nutritional difference between rounded and unrounded values of a nutrient in a food, we do not see a need to specify which value should be used in determining whether a food qualifies to bear the ''healthy'' nutrient content claim. As the comments note, this is consistent with our position in the final rule ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods; Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term; Technical Amendment'' (58 FR 44020, August 18, 1993).

(Comment 133) The comments assert that the rule should be accompanied by mechanisms to ensure food manufacturers adequately keep records and catalog the nutritional components of their foods to abide by the updated ''healthy'' standards. Some comments argue that the proposed recordkeeping requirements to ensure manufacturers are following the regulations seem to leave enforcement and compliance in a state of ambiguity and call for increased transparency regarding enforcement of compliance from food manufacturers. Some comments claim that the proposed rule involves limited recordkeeping requirements that entails non-standardized forms of evidence showing that combination foods and grains labeled as ''healthy'' meet FDA standards but there is no explicit information on how often inspections take place or how these records are verified for accuracy. Similarly, some comments argue that there is also no indication of what consequences are for failing to be compliant, claiming that with evidence that manufacturers have intentionally misrepresented labels in the past, it is essential for this action to be transparent regarding enforcement and consequences for lack of compliance.

(Response 133) As discussed in the proposed rule (87 FR 59168 at 59194), where the requirements cannot be verified using the label, the manufacturer will have or should have the information required to determine whether the product meets the criteria for bearing the ''healthy'' claim. The information contained in manufacturers' records must be accurate for ensuring that the nutrient content claim is used in accordance with § 101.65(d) and that the food labeling complies with section 403(r) of the FD&C Act. We conclude that the records will provide FDA with the necessary means to determine compliance with the criteria for bearing the ''healthy'' nutrient content claim. We are requiring that records be made available to us for examination or copying during an inspection upon request; this is consistent with our other recordkeeping regulations (see, *e.g.,* 21 CFR 111.605 and 111.610). The records would need to be reasonably accessible (access to records within 24 hours can be considered reasonable) to FDA during an inspection at each

manufacturing facility (even if not stored onsite) to determine whether the food meets the requirements for bearing the ''healthy'' claim. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible. We note that having a false declaration on the label is a violation of section 403(a)(1) of the FD&C Act. In addition, providing false information in records to FDA may also be a potential criminal violation under 18 U.S.C. 1001. Under 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully: (1) Falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry may be subject to a fine or imprisonment.

J. Effective and Compliance Dates

(Comment 134) Many comments support the proposed compliance date that is 3 years after the effective date (*i.e.,* 60 days after the date the final rule publishes in the **Federal Register**) stating that this would provide adequate time for compliance. Some comments recommend that FDA revise the effective date to make it the same as the date the final rule is published in the **Federal Register** rather than 60 days after to allow manufacturers already in compliance with the rule to voluntarily label their products ''healthy'' as soon as possible. Similarly, some comments suggest that FDA provide enforcement discretion for products that elect to use the ''healthy'' term in compliance with the new definition prior to the compliance date. Some comments request an effective date that is the same at the compliance date (*i.e.,* 3 years after issuance of the final rule), stating that this is allowed under FDA's administrative regulations, which require that the effective date be at least 30 days after publication of the final rule, but do not restrict longer effective dates. Some comments urge FDA to confirm that ''healthy'' may be used during the compliance period consistent with the original regulation and that providing an effective date that is the same as the compliance date would reinforce that the original ''healthy'' definition may appropriately be used in the period after the final rule is issued and before the compliance date.

Some comments request that FDA recognize the compliance date as applying to the date a product is manufactured and labeled rather than the date it is introduced into interstate commerce, arguing that this is less confusing for distribution systems and easier to implement. The comments state that this would be consistent with how FDA has approached other labeling changes (*i.e.,* considering the compliance date to apply to the date a food was labeled).

(Response 134) The comments suggest there may be some confusion with regard to the meaning of the effective date. The effective date is the date on which the Office of the Federal Register amends the *Code of Federal Regulations* in § 101.65(d) to reflect the new requirements for the ''healthy'' implied nutrient content claim as promulgated by this final rule. The effective date for this final rule is 60 days after the date of the final rule's publication in the **Federal Register**. The compliance date—meaning the date on which we would begin enforcing the rule—is 3 years after the effective date. As explained in the proposed rule, a compliance date that is 3 years after the effective date is intended to provide industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to have the information in a timely manner. However, although companies are not required to be in compliance with the new requirements for the ''healthy'' implied nutrient content claim until the date that is 3 years after the effective date, a company is free to choose to relabel in accordance with the new requirements sooner, as discussed further in section V.K (''Legal Comments'').

With regard to the comments requesting that we recognize the compliance date as applying to the date a product is labeled rather than the date it is introduced into interstate commerce, we agree. Compliance with the updated definition of ''healthy'' in § 101.65(d) will be assessed for products that are labeled (*i.e.,* when the label is placed on the product) with the ''healthy'' implied nutrient content claim on or after the compliance date (3 years after the effective date). We will not begin to enforce the updated final rule requirements before the compliance date. We evaluate the date the food product was labeled for purposes of determining whether the product must meet the updated requirements.

Further, as discussed in response to comment 161 below, manufacturers would not be required to comply with requirements of the final rule until the compliance date. Thus, once any new requirements for the definition of the nutrient content claim ''healthy'' are in effect, manufacturers could either comply with the new requirements or continue to use the original definition of ''healthy'' until the compliance date.

(Comment 135) One comment asserts that the compliance date would be difficult to meet due to the workload and costs associated with the rule. One comment argues that the time period before the rule takes effect should allow food manufacturers time to update their packaging and change their recipes to comply with the ''healthy'' definition to avoid damage to their brand. One comment suggests that FDA set a compliance date for small businesses that is 2 years after the proposed compliance date and use that period to educate small businesses on the rule and associated compliance issues, arguing that small businesses are at a disadvantage compared to large companies. One comment asserts the rule would benefit large consumer packaged goods companies that have the financial means to accommodate relabeling their products, thus placing small businesses at a competitive disadvantage because the rule would have disproportionate impacts on small businesses, and requests accommodations for small businesses relating to compliance and the provision of education resources.

(Response 135) FDA has gone through an extensive and transparent rulemaking process to update the definition of the ''healthy'' claim and has established a generous compliance period for manufacturers to come into compliance. Although one comment did suggest an additional 2 years (or a total of 5 years) is needed, we do not have information that would enable us to determine whether all or merely some small businesses need additional time to comply with the rule, nor do we have information that would enable us to determine how much, if any, additional time is needed for small businesses generally. If we were to extend the compliance date for all small businesses to 5 years, consumer confusion could result because different versions of the ''healthy'' claim would exist in the market for a longer period of time. The differences could frustrate, rather than enhance, the consumer's ability to maintain healthy dietary practices and potentially undermine public confidence in use of the claim. We also note that businesses may choose to include a ''healthy'' claim on food product labeling that meets the criteria in this rule, but are not required to do so, and that our estimates indicate that only a small number of products will need to relabel or reformulate their

products to comply with the new definition (see Ref. 39).

K. Legal Comments

1. Statutory Authority

(Comment 136) One comment agrees that FDA has the authority to make changes to the ''healthy'' definition according to the most recent science. While some comments acknowledge that the FD&C Act ''allows FDA to define terms that expressly or implicitly characterize the nutrient content of a food,'' where the nutrients are those required to be labeled within the Nutrition Facts label, other comments argue that the statute does not give FDA authority to require foods bearing nutrient content claims to have a minimum amount of food group equivalents. Another comment asserts that FDA knew or agreed it did not have authority to include food groups in this context because we have not done so in the past. Another comment states that FDA's food group criteria are ''nutrient-agnostic'' and therefore outside of the scope of section 403(r) of the FD&C Act.

(Response 136) We disagree with the comments that included an overly narrow reading of section 403(r)(1)(A) of the FD&C Act. As discussed above, the statutory language describes nutrient content claims as claims in the label or labeling of a food that ''expressly or by implication'' ''characterize[ ] the level of any nutrient which is of the type required . . . to be in the label or labeling of the food.'' (section 403(r)(1)(A) of the FD&C Act). FDA regulations define ''implied nutrient content claims,'' in part, as claims that ''suggest[ ] that [a] food, because of its nutrient content, may be useful in maintaining healthy dietary practices,'' (§ 101.13(b)(2)(ii)). As we stated in the 1993 final rule establishing this claim, ''a claim that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrient in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health'' (58 FR 2302 at 2375, January 6, 1993). Therefore, the ''healthy'' claim by implication characterizes the level of nutrients in a food, and as such, the claim must be made in accordance with FDA regulations under section 403(r) of the FD&C Act.

Although the comments advocate for a narrow interpretation of the statute, the Supreme Court has embraced broad constructions of the FD&C Act based on the Court's understanding of its text, congressional intent, and remedial purpose. See, *e.g., United States* v. *Bacto-Unidisk,* 394 U.S. 784, 798 (1969) (''Congress fully intended that the [FD&C] Act's coverage be as broad as its literal language indicates.''); *United States* v. *Dotterweich,* 320 U.S. 277, 280 (1943) (''The purposes of [the FD&C Act] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.''). Moreover, Congress may ''expressly delegate to an agency the authority to give meaning to a particular statutory term'' and to ''prescribe rules to 'fill up the details' of a statutory scheme.'' *Loper Bright Enters.* v. *Raimondo,* 144 S. Ct. 2244, 2263 (2024) (cleaned up). The best reading of the NLEA is that Congress ''delegate[d] discretionary authority'' to FDA. *Id.* Relevant provisions appear throughout section 403(r) and specifically in section 403(r)(2)(A)(i) of the FD&C Act, which requires nutrient content claims to ''use[ ] terms which are defined in regulations of the Secretary.'' Therefore, the best reading of sections 403(r)(1)(A) and 403(r)(2)(A)(i) of the FD&C Act is that they delegate discretionary authority to FDA to decide, as appropriately informed by its technical expertise and within the limits of its statutory authority, how particular claims may characterize the level of any nutrient in a food.

The food group equivalent criteria included in the updated definition of ''healthy'' help ensure that foods bearing the ''healthy'' claim have a nutrient profile that may help consumers maintain healthy dietary practices, in line with the definition and purpose of this implied nutrient content claim. Each food group that is part of the food group equivalent requirements represents the inclusion of multiple important nutrients. The use of food groups better accounts for how all these nutrients contribute to, and may work synergistically to create, a healthy dietary pattern and improve health outcomes, consistent with current nutrition science. By requiring products to contain a certain amount of a food group, the rule will help ensure foods bearing the ''healthy'' claim contain a variety of important beneficial nutrients and, therefore, that their labeling provides non-misleading information that assists people who wish to choose foods that will meet recommended nutrient intakes and maintain healthy dietary patterns.

Accordingly, consistent with Congress's objectives to provide appropriate nutritional information to consumers, the statutory phrase ''characterize[ ] the level of any nutrient which is of the type required . . . to be in the label or labeling of the food'' is best understood in light of current science to encompass both limits on certain individual nutrients and food group criteria that more broadly incorporate a variety of nutrients from nutrient-dense foods. The updated ''healthy'' claim implicitly characterizes the level of a number of nutrients that are of the type required to be declared on the Nutrition Facts label. As we explained in the proposed rule and elsewhere in this final rule, the updated definition of this implied claim, consistent with current dietary guidelines, includes food groups that represent a number of different nutrients and the claim is thus characterizing the overall nutrient content of the food, rather than focusing on one individual nutrient in isolation, for example, as with an express nutrient content claim.

Thus, we also disagree that our previous definition of, or examples regarding, the ''healthy'' claim indicate that FDA did not believe it had the authority to go beyond individual nutrients in the context of the implied ''healthy'' claim to focus on food groups in addition to specific nutrient levels. The changes made by this rulemaking are due to evolving science, not a change in FDA's understanding of its legal authority. For years, FDA has defined ''healthy'' in the context of the overall characteristics of foods as they contribute to building a healthy dietary pattern and the definition has used a number of nutrient levels. In the 1994 definition of the claim, levels for nine different individual nutrients were discussed: fat, saturated fat, cholesterol, vitamin A, vitamin C, calcium, iron, protein, and fiber (previously § 101.65(d)(2)(i)). As discussed elsewhere in this document, in recent years the Dietary Guidelines have shifted from focusing on such individual nutrients to recommending healthy dietary patterns and the consumption of food groups in certain quantities to achieve adequate nutrient intake, based on the understanding that each food group contributes an array of important nutrients to the diet (Ref. 1). Thus, the way various nutrients are counted for the definition of the ''healthy'' claim has been updated to account for that evolution in nutrition science. The reference in the statute to

''characteriz[ing] the level of any nutrient'' and the reference in the regulation to ''maintaining healthy dietary practices'' incorporate a scientific component because both the characterization and the assessment of healthy dietary practices involve an evaluation of the impact of diet on health. And, as science has evolved over time, the understanding of an implied claim that a food contains levels of nutrients that aid in maintaining healthy dietary practices should also evolve. To ensure that such a claim is not misleading, avoids consumer confusion, and continues to assist people who wish to choose foods whose nutritional content contributes to good health, FDA has concluded that the definition of the claim should be updated to match the current scientific understanding of the underlying facts. Thus, it is appropriate and consistent with the statutory and regulatory framework, including Congress's express delegation of rulemaking authority to the Agency to define terms in nutrient content claims, for FDA to update definitions related to implied nutrient content claims based on current science, including the ''healthy'' claim, which FDA has long regulated as an implied nutrient content claim. To the extent that this rulemaking entails a change in the exercise of our statutory authority, it is justified by these advances in nutrition science that have led to broader recommendations, including in the Dietary Guidelines and as discussed in greater detail throughout this final rule and the proposed rule, to explicitly refer to food groups as a way to build a healthy dietary pattern (see *Home Care Ass'n of Am.* v. *Weil,* 799 F.3d 1084 (D.C. Cir. 2015) (stating the Administrative Procedure Act (APA) imposes ''no special burden when an Agency elects to change course'' and the ''reasoned explanation'' under the APA for an alternative approach includes an Agency awareness of the change in position and good reasons for the change (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)).

(Comment 137) One comment argues that the use of the phrase ''maintain healthy dietary practices'' is outside of the FD&C Act's nutrient content claim authority, as section 403(r) of the FD&C Act only focuses on levels of specific nutrients in a food.

(Response 137) This comment misunderstands the implied nutrient content claim scheme that has been in place since 1993 and the statutory basis for it. First, as we quoted above, the 1993 final rule stated that ''a claim that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrient in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health'' (58 FR 2302 at 2375). Therefore, the comment is incorrect in asserting that this standard is irrelevant for nutrient content claims, especially implied claims. Additionally, section 403(r) of the FD&C Act itself uses the phrase ''. . . will assist consumers in maintaining healthy dietary practices'' to describe the basis for certain types of nutrient content claims (see, *e.g.,* section 403(r)(2)(A)(ii)(II) and (r)(2)(A)(iii)(I) of the FD&C Act). Moreover, we have found that ''Congress was clearly concerned with such claims. The October 24, 1990, proceedings in the Senate show that one purpose of the 1990 amendments was to regulate the use of nutrient content claims that appear on food labels and labeling to help consumers make appropriate dietary choices (136 Congressional Record S16610 (October 24, 1990))'' (see 58 FR 2302 at 2375). Ensuring that the information presented to consumers on food labels can help consumers identify foods that will help them maintain a healthy diet has been a part of our authority under both sections 403(q) and 403(r) of the FD&C Act since the passage of the 1990 NLEA Amendments.

Further, the original definition of the ''healthy'' claim at § 101.65(d)(1)(i) has specifically included language about helping consumers maintain healthy dietary practices since it was finalized in 1994. This is not new language, but instead aligns with the statutory and regulatory framework that has been applied for almost 30 years since the inception of the claim.

(Comment 138) One comment argues that by broadening the basis on which the ''healthy'' claim can be put in a nutritional context and focusing on the overall characteristics of a food, rather than a tie to a specific level of an individual nutrient, FDA no longer has the statutory authority to regulate the ''healthy'' claim.

(Response 138) We disagree that the minor changes to the description of how FDA assesses, on a case-by-case basis, whether a claim ''expressly or by implication'' characterizes the level of any nutrient, places ''healthy'' outside the scope of a nutrient content claim as described in section 403(r) of the FD&C Act. As discussed above in Response 136, under section 403(r) of the FD&C Act, nutrient content claims include both express and implied claims that characterize the level of any nutrient which is of the type required to be in the label or labeling of a food. Additionally, claims that characterize the level of nutrients in the food include claims about the overall nutrition profile of the food. This is especially true for defined implied nutrient content claims like ''healthy,'' where, since the relevant regulations were issued, FDA's focus has been on foods that are useful in creating a diet consistent with dietary recommendations because of their nutrient content. Nothing in the FD&C Act requires a reference to a specific level of one individual nutrient to impliedly characterize the level of any nutrient in the food as directed by section 403(r) of the FD&C Act (see Response 136 for further discussion).

(Comment 139) One comment discusses our statutory authority in setting nutrient to limit thresholds, asserting that, in setting these thresholds, we must ground the types and levels of such nutrients on a ''permitted'' statutory basis, specifically referring to either section 403(r)(2)(A)(vi) or 403(r)(2)(B) of the FD&C Act.

(Response 139) This comment misstates the statutory authority for setting the nutrient to limit thresholds within the definition of the ''healthy'' claim. The statutory basis, as discussed in previous responses (*e.g.,* Response 136), is section 403(r)(1)(A) of the FD&C Act as well as section 403(r)(2)(A)(i) of the FD&C Act. Section 403(r)(2) of the FD&C Act sets out specific requirements for making defined claims and states that a claim, such as ''healthy,'' may be made only in accordance with FDA regulations defining the term. The limitations for added sugars, sodium, and saturated fat are part of the definition of the term ''healthy.'' In contrast, the limitations on nutrients described in section 403(r)(2)(A)(vi) and 403(r)(2)(B) of the FD&C Act, referenced by the comment, refer to ''another nutrient in the food'' rather than the nutrients actually incorporated into the definition of the claim, and are not relevant here.

(Comment 140) Some comments say that we did not present support for the added sugars limits set forth in the proposed rule to demonstrate that added sugars amounts above those limits would reflect the amounts at which a ''healthy'' claim would become ''misleading.'' Furthermore, some comments suggest that we could only set limits for added sugars if there was a determination by the Secretary of HHS that these limits reflect the levels at which added sugars increase the risk of a disease or health-related condition

that is diet related in the general population.

(Response 140) We disagree that FDA must demonstrate that added sugar amounts above the limits set forth in the rule would reflect the amounts at which a ''healthy'' claim would become ''misleading'' or that a level of added sugars has a direct link to chronic disease under section 403(r) of the FD&C Act. The primary purposes behind section 403(r) of the FD&C Act and FDA's nutrient content claim regulations are to provide information to consumers that may help them maintain healthy dietary practices, to help prevent misleading labeling, and to reduce consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims. Preventing misleading labeling is only one of these purposes. The updated regulation for the ''healthy'' claim defines the claim with standardized criteria, such as the added sugars limit, for use on foods that useful in creating a diet that is consistent with dietary recommendations, to ensure that consumers are adequately informed and not misled. Furthermore, there is no requirement, under the statute or First Amendment jurisprudence, that limits FDA's authority over nutrient content claims to only regulating claims shown to be inherently or actually misleading. Nor is there any legal requirement that FDA determine that a nutrient increase the risk of a disease or health-related condition that is diet related in the general population in order to include limits for such nutrients as part of the regulatory definition for a nutrient content claim. While section 403(r)(2)(B) of the FD&C Act does refer to a nutrient at a level that increases the risk of diet-related diseases or health-related conditions in the general population, this provision is in the context of a required disclosure statement regarding a nutrient that is not the subject of the nutrient content claim and is therefore not relevant to FDA's authority to set criteria as part of a nutrient content claim definition.

(Comment 141) Several comments argue that we have statutory direction to follow the Dietary Guidelines, with one comment citing 7 U.S.C. 5341(a)(1) FD&C Act, and argue that FDA is not authorized to implement rules that deviate from the Dietary Guidelines' recommendations, including in setting the added sugars and sodium limits.

(Response 141) We disagree with the comments that FDA is deviating from the Dietary Guidelines in a way that is not permitted by statute. The provision cited by the comment, 7 U.S.C. 5341(a)(1) of the FD&C Act, states that the Dietary Guidelines ''shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.'' The cited provision, 7 U.S.C. 5341(a)(1) of the FD&C Act, does not elaborate on what it means for Agencies to successfully promote the Dietary Guidelines through their work and, further, there is nothing in 7 U.S.C. 5341(a)(1) of the FD&C Act that states that an Agency may not make any independent scientific considerations in rulemaking. Because we relied on and incorporated the recommendations in the current edition of the Dietary Guidelines in developing the final rule, as a result, the ''healthy'' rule promotes the Dietary Guidelines. The entire focus of the healthy rule is identifying foods that can be the foundation of building a healthy dietary pattern as specified in the *Dietary Guidelines, 2020–2025.* For example, modifications to the NTL thresholds were made for foods that are identified as underconsumed and promoted by the *Dietary Guidelines, 2020–2025,* such as nuts and seeds and seafood.

Beyond this one citation to a general provision about ''promoting'' the overall Dietary Guidelines, the comments that raise this issue do not point to any statutory requirement, such as in section 403(r) of the FD&C Act, that FDA follow the Dietary Guidelines or statutory language that states that FDA is not authorized to deviate from any individual recommendation in the Dietary Guidelines. Overall, the changes made to update the ''healthy'' criteria are consistent with current nutrition science and Federal dietary guidance, including the Dietary Guidelines. We have made certain adjustments to the baseline criteria to provide additional flexibility, to reflect practical realities (*e.g.,* marketplace conditions), consistent with the purpose of the ''healthy'' claim. Thus, there is no violation of any statutory directive regarding the Dietary Guidelines in the rule.

(Comment 142) One comment questions whether added sugar is a ''nutrient'' as the basis for an argument that FDA may not have the authority to include added sugars levels as part of a nutrient content claim definition. While acknowledging that there is no regulatory definition of ''nutrient,'' the comment states that other nutrients used in section 403(r) of the FD&C Act are ''chemically and structurally distinct from each other and have different physiological effects on the body.''

(Response 142) We disagree that FDA does not have the authority to include added sugars levels as part of a nutrient content claim definition. First, section 403(r) of the FD&C Act states that nutrient content claims ''characterize'' the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) [of section 403 of the FD&C Act] to be in the label or labeling of the food.'' Added sugars, thus, are a nutrient as described in section 403(r) of the FD&C Act because, pursuant to regulation, the amount of added sugars is required to be declared under section 403(q)(2)(A) of the FD&C Act (see 81 FR 33742 at 33801 through 33803 adding added sugars to the list of required nutrients to be declared on the Nutrition Facts label under section 403(q)(2)(A) of the FD&C Act). Therefore, limiting the amount of added sugars in a food is an appropriate criterion for a nutrient content claim under section 403(r) of the FD&C Act.

Given the statutory language in section 403 of the FD&C Act, whether other nutrients that are the subject of section 403(q) of the FD&C Act are chemically and structurally distinct from each other and have different effects on the body is not relevant to the analysis of whether added sugars is a nutrient as described in section 403(r) of the FD&C Act. Additionally, even if it were relevant, FDA does not agree that all the other nutrients are distinct in this way. For example, the listed section 403(q) of the FD&C Act declarations include broad categories (like total carbohydrates and total fat) and subsets of those categories (like fiber and saturated fat), which are clearly not entirely distinct. Thus, this argument is not persuasive.

2. Administrative Procedure Act (APA)

(Comment 143) One comment argues that it was arbitrary for FDA to incorporate FGEs into the definition of ''healthy'' because consumers will not be able to determine why the food qualifies for the claim or if the claim was made in error.

(Response 143) The purpose of the ''healthy'' claim is to help manufacturers provide information to consumers so that they can easily and quickly identify foods that are particularly useful in helping them build a healthy diet. The comment does not provide any explanation of why consumers need to be able to determine the basis for qualification for the ''healthy'' claim at the point of decision-making about a food. The basis for the ''healthy'' criteria is explained in the rule, which will help consumers understand what foods qualify for the ''healthy'' claim and whether foods are labeled with the claim when they should not be. We also plan to conduct consumer education regarding the

updated definition of the ''healthy'' claim to support consumers in their use of the claim to identify foods with which to build their healthy diets.

Although the rule will help consumers be better informed about which foods can help form the basis of a healthy diet, FDA recognizes that consumers may not have access to all documentation supporting the healthy claim for each individual product that they purchase. This is similar to many labeling requirements, and the fact consumers may lack some kinds of information does not mean that the rule is arbitrary or does not serve the goals of better informing consumers and preventing them from being misled (see *Home Box Office, Inc.* v. *FCC,* 567 F.2d 9, 36 n. 58 (D.C. Cir. 1977), *cert. denied,* 434 U.S. 829 (1977) (''In determining what points are significant, the 'arbitrary and capricious' standard of review must be kept in mind . . . only comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule or cast doubt on the reasonableness of a position taken by the agency.'')).

(Comment 144) A comment suggests that FDA's rationale for allowing food groups to have different baseline nutrient thresholds is an ''arbitrary inconsistency'' that should be addressed by making the baseline thresholds the same for all food groups. Several comments argue that FDA setting different baseline threshold limits for different nutrients, ''not having a consistent methodology'' for calculating the thresholds and providing flexibility for some food categories and not others made FDA's approach to NTL arbitrary and capricious. One comment asserts that we have failed to satisfy the arbitrary and capricious standard that has been described in the case law.

Several comments argue specifically that the nutrient limits for whole grains are lower than and do not provide the same flexibility as the limits for certain meats, nuts, eggs, and seafood, resulting in an arbitrary difference without an adequate rationale. Another comment argues that allowing added sugars in dairy and whole grain products, but not in fruit and vegetable products, is an arbitrary difference.

(Response 144) We note at the outset that arbitrary and capricious claims under the APA are reviewed under the APA's ''narrow'' and ''deferential'' arbitrary and capricious standard. *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983); *FCC* v. *Prometheus Radio Project,* 141 S. Ct. 1150, 1158 (2021). The court ''simply ensures that the agency has acted within a zone of reasonableness'' and ''has reasonably considered the relevant issues and reasonably explained the decision.'' *Prometheus Radio Project,* 141 S. Ct. at 1158. In addition, courts should ''give[ ] a high level of deference to [FDA's] scientific judgments.'' *Pharm. Mfg. Rsch. Servs., Inc.* v. *FDA,* 957 F.3d 254, 262 (D.C. Cir. 2020). In this rulemaking, FDA has provided a thorough explanation of its scientific judgment on these issues (see sections V.C. (''Food Group Equivalents'') and V.D. (''Nutrients to Limit'')).

We disagree with the characterization in the comments that we did not have a consistent methodology for establishing the nutrient to limit amounts in the rule. As described in section V.D (''Nutrients to Limit''), we started with a ≤5% DV limit for each nutrient to limit based on the amount that has historically been associated with the nutritional advice of what is considered to be ''low'' in any nutrient, as well as, in some cases, what would qualify the food for a ''low'' nutrient content claim, such as saturated fat. Some minor adjustments to the established baseline limits were made as necessary to help consumers maintain healthy dietary practices and for consistency with the Dietary Guidelines, such as increasing the saturated fat limit to ≤10% DV for fat-free and low-fat dairy so that those foods could qualify for ''healthy'' as they are recommended by the Dietary Guidelines (see section V.D.2 (''Saturated Fat'')). As explained further in section V.D.3 (''Sodium''), it was determined that a ≤5% DV limit would be too low for sodium given the functions of sodium in foods and current levels of sodium in the food supply, so an adjustment was made to have a baseline sodium limit of ≤10% DV. Accordingly, we have provided a reasoned scientific basis for each decision in the rulemaking and these adjustments were thoroughly reasoned and consistent with the statutory purpose.

Further, contrary to the comment's assertion, the difference between how meat, eggs, seafood, and nuts as compared to how whole grains were treated in the proposed rule was carefully explained, including based on consistency with the Dietary Guidelines (see sections V.D.2 (''Saturated Fat'') and V.D.4 (''Added Sugars'') for further discussion). The final rule provides additional flexibilities for other products after additional information was provided about adjustments that would help consumers maintain healthy dietary practices. Similarly, FDA has explained the reasons why some amounts of added sugars were able to be included in certain products and not others. We also note that some of the added sugars limits have been adjusted in the final rule, such as accommodating small amounts of added sugars in fruit and vegetable products, thus minimizing the difference noted by the comment. See section V.D.4. (''Added Sugars'').

(Comment 145) One comment asserts that the nutrient to limit thresholds are arbitrary because FDA did not demonstrate their connection to chronic disease risk or any other level at which a food becomes unhealthy. Another comment asserts that because the amount of added sugars is not directly related to chronic disease risk, there is no reason for the added sugars limit to be lower than that of sodium.

(Response 145) The comment's references to chronic disease risk or the level at which an individual food becomes ''unhealthy'' are misplaced. Determining a level at which individual foods become ''unhealthy'' would be inconsistent with current nutrition science and our numerous previous statements in a variety of contexts that all foods can be incorporated into a healthy dietary pattern. As discussed, this implied nutrient content claim describes a food that, because of its nutrient levels, will help consumers maintain healthy dietary practices. The NTL thresholds are used to identify foods that will be the foundation or building blocks of a healthy dietary pattern and are specifically not designed to be a level at which a particular food becomes ''unhealthy.'' See section III. (''Background'') for more on this issue. Determining a level at which foods become ''unhealthy'' would be inconsistent with current nutrition science and our numerous previous statements in a variety of contexts that all foods can be incorporated into a healthy dietary pattern. Claims like ''healthy'' help consumers identify which foods are the foundation of building a healthy dietary pattern.

Similarly, impact on chronic disease risk is not the basis for the ''healthy'' claim. While maintaining healthy dietary practices will likely lead to reduced chronic disease risk in the case of diet-related diseases, the purpose of labeling, such as the ''healthy'' claim, is to provide information to help consumers choose foods that can help them build a healthy dietary pattern. This recognition does not make FDA's position arbitrary—far from it, FDA has made reasoned, rational choices for the limits for each nutrient included in the definition based on current nutrition science and Federal dietary guidance.

We further note that the rationales for the added sugars and sodium limits are discussed at length in both the proposed rule (87 FR 59168 at sections VI.A.2.C. and VI.A.2.B) and elsewhere in this final rule (see sections V.D.4 (''Added Sugars'') and V.D.3 (''Sodium'')) and, as stated above, the definitions of nutrient content claims are not related to chronic disease risk, but to expressly or impliedly characterizing the levels of the nutrients in the food.

(Comment 146) One comment argues that the added sugars thresholds are arbitrary because we failed to articulate a consistent rationale for them. Another comment asserts that FDA lacked justification for its added sugars limit and therefore had not met the ''reasoned basis'' required by the APA.

(Response 146) We provided a reasoned scientific rationale for the added sugars limits in the proposed rule (87 FR 59168 at section VI.A.2.C) and in the final rule (see section V.D.4 (''Added Sugars'')). The proposed rule explained that while there is not a nutrient content claim for added sugars on which to begin to base our determination of the threshold levels for added sugars in the ''healthy'' claim, we were instead able to draw justification for the baseline level from consistency with how we were treating the other NTL like saturated fat.

The proposed rule explained that while there is not a nutrient content claim for added sugars on which to begin to base our determination of the threshold levels for added sugars in the ''healthy'' claim, we were instead able to draw justification for the baseline level from consistency with how we were treating the other NTL like saturated fat.

Once we had established an appropriate baseline limit, we went on to describe our reasoning each time a variation from the proposed baseline level of added sugars was determined to be appropriate based on market conditions, consumption patterns, or how added sugars are used in certain food groups. For example, while the baseline amount of added sugars to qualify for the ''healthy'' claim was proposed at 5% DV, we described in the proposed rule how added sugars usually are not present in vegetable, fruit, and protein products. We also stated our rationale for the variation in the section regarding fruit, that we did not want the addition of added sugars to such otherwise nutrient-dense food products (87 FR 59186).

We also note that, in response to comments, the final rule raises the added sugar limits for the vegetable, fruit, and protein food groups to accommodate small amounts of added sugars, which comments explained can be used to balance flavors when there is variation in natural sweetness of crops, or in sauces, seasonings and other recipe components. We also raised the added sugar limit for the whole grain food group based in part on comments that described the current market conditions such that a majority of recommended whole grain cereal products were unable to qualify to use the claim as proposed. Each of these adjustments were carefully considered and reasoned in crafting the final rule.

(Comment 147) One comment argues that a frozen vegetable product with a sauce and 300 mg of sodium being unable to qualify for the ''healthy'' claim because the amount of sodium is more than 230 mg is an arbitrary result when the foods (vegetables) are ones that consumers should be encouraged to select.

(Response 147) As stated previously, the goal of updating the criteria for a food being labeled with the ''healthy'' claim is to provide consumers with information to help them identify foods that are the foundation of a healthy eating pattern and the DGAs recommend nutrient-dense forms of foods to build a healthy dietary pattern. Although frozen vegetables can be nutrient-dense, including sodium in excess of the limits set in the rule makes a food one that may not be able to be used routinely in a foundational way. Labeling such a product as ''healthy,'' accordingly, would not serve the purposes of this rule—to help consumers have information to build healthy dietary patterns. This is particularly so when consumers have options for nutrient-dense forms of frozen vegetables that do not contain sodium in excess of the limits established for the ''healthy'' claim. Thus, that frozen vegetable products with sauces that exceed the sodium threshold do not qualify for the ''healthy'' claim is not arbitrary but is based on the scientific evaluation of how much sodium can be accommodated in a healthy dietary pattern and in the foundational foods that can be used to build such a diet. Additionally, as noted elsewhere in the rule, such products could be marketed with other claims describing their benefits that are not false or misleading.

(Comment 148) One comment asks FDA to market test the revised requirements to ensure they do not arbitrarily exclude nutrient-dense foods, such as small RACC foods, in violation of the APA. Another comment specifically argues that applying added sugars limits across a wide range of RACCs/serving sizes establishes arbitrary and overly restrictive requirements for foods with larger RACCs/serving sizes and would disqualify many nutrient-dense foods, including those that are encouraged by the Dietary Guidelines, from bearing the ''healthy'' claim.

(Response 148) Although we disagree with any assertion that the proposal was arbitrary in how the requirements were constructed, we have revised the final rule in light of a number of comments that raised concerns about the inability of foods with small RACC sizes to qualify for the claim under the proposed criteria because such foods would not have enough FGEs. In the final rule, we revised the requirements regarding the way small RACC foods can calculate FGEs, as discussed in Response 8, as well as expanding the exemption for raw fruits and vegetables to all single-ingredient foods, which will result in a number of small RACC foods qualifying without needing to address FGE requirements at all. These changes address the concern that this comment is expressing and result in more nutrient dense foods with small RACCs qualifying for the claim. We note that we also conducted a review of products currently available in the marketplace to help support our decisions to make changes to address issues such as this one raised in comments.

The application of the added sugar limits to foods with different serving sizes is also not arbitrary under the APA. Regardless of the size of the food product, it is the amount of added sugars being contributed to the diet that is the subject of the claim definition. Therefore, there is a reasoned basis for the added sugar limit, consistent with the stated purpose of the claim, to help consumers identify foods that are useful in creating a diet consistent with dietary recommendations. An added sugars limit for foods to qualify for the claim will help consumers stay under the recommended daily limit for this nutrient. Regardless of the size of the food product, it is the amount of added sugars being contributed to the diet that is the subject of the claim definition. Further, nutrient-dense foods, as described by the Dietary Guidelines, by definition have limited amounts of added sugars, so it is not likely that a nutrient-dense food that is recommended by the Dietary Guidelines would not be able to meet the NTL amounts specified in the final rule.

(Comment 149) Several comments argue that the proposed rule deviates from the Dietary Guidelines and nutrition science without a ''convincing'' justification and that such

a deviation violates the APA. One comment further asserts that there are ''scant'' explanations for the deviations from the Dietary Guidelines in the proposed rule. Another comment opines that the different levels of added sugars allowed in different food categories are arbitrary and deviate from the Dietary Guidelines.

(Response 149) FDA disagrees that we did not provide justification or explanations for the requirements set forth in this rule that differ from the recommendations in the Dietary Guidelines. As a preliminary matter, and as discussed further in response 140, FDA is not required to precisely follow the Dietary Guidelines. Consistent with 7 U.S.C. 5341(a)(1) of the FD&C Act, the definition of ''healthy'' established in this rule ''promote[s]'' the Dietary Guidelines. But it is true that, as explained elsewhere in this rule, in certain instances FDA determined that a deviation for the recommendations in the Dietary Guidelines was warranted to serve the purposes of this rule.

FDA provided a reasoned justification for each of the criteria for bearing the claim ''healthy'' that differ from the recommendations in the Dietary Guidelines. The APA only requires that Agencies provide ''a rational connection between the facts found and the choice made.'' (*Motor Vehicles Mfrs. Ass'n of the United States Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983)). While current nutrition science and the Dietary Guidelines have provided the foundation for the revisions to the definition of ''healthy,'' FDA determined that certain deviations from the Dietary Guidelines were appropriate based on various considerations, such as consumer consumption patterns, our marketplace review of nutrient-dense foods encouraged by the Dietary Guidelines, or consistent evidence of beneficial health effects (*i.e.,* that underlie qualified health claims or health claims) (see, *e.g.,* sections V.C. (''Food Group Equivalents'') and V.D.2 (''Saturated Fat'')). For each such deviation, FDA provided a justification. For example, as discussed in Response 32, the *Dietary Guidelines, 2020–2025* discussed alternatives to dairy and, at the time the Dietary Guidelines was published, the only beverage that it identified as having a nutritional profile similar to cow's milk was soy-based, so the Dietary Guidelines specifically recommended the example of soy-based dairy alternative beverage products. In this rule, we include other plant-based beverages that have a similar nutrition profile to cow's milk in the beverage alternatives that can qualify for the ''healthy'' claim in the dairy category. While the Dietary Guidelines did not specifically recommend these other products, we found no reason to exclude these other beverages when they have the same nutrient profile as cow's milk, as the focus here is on the nutrient levels present, and they can serve as useful choices to maintain healthy dietary practices consistent with the purpose of the claim.

(Comment 150) One comment argues that FDA has not provided an adequate basis for its proposal to depart from the NTE approach that has been in place for decades, by basing this decision on reducing indiscriminate fortification. Another comment asserts that eliminating the NTE criteria was arbitrary, that there were internal inconsistencies in the limits FDA set for the NTL, and that FDA failed to justify those limits and the FGE requirements for combination products, citing *Dist. Hosp. Partners, L.P.* v. *Burwell,* 786 F.3d 46, 59 (D.C. Cir. 2015) (agency action arbitrary and capricious if it is '' 'internally inconsistent and inadequately explained' ''); *Bus. Roundtable* v. *SEC,* 647 F.3d 1144, 1153 (D.C. Cir. 2011) (vacating rule that was ''internally inconsistent and therefore arbitrary'').

(Response 150) We disagree that we did not provide an adequate basis for eliminating the NTE as part of the definition of the ''healthy'' claim. The comment asserts incorrectly that FDA based this decision solely on reducing indiscriminate fortification. FDA recognizes that it is aware of and discussed the concern with indiscriminate fortification, but the comment ignores the explanation provided above and in the proposed rule regarding the reasons for changing the definition of the ''healthy'' claim—namely the shift in nutrition science toward overall eating patterns and away from focusing on the amounts of individual nutrients consumed. That definitional changed involved, in part, replacing specific NTE with FGEs, as already addressed in section V.C (''Food Group Equivalents'').

The comment does not specify how it believes the levels for the NTL are internally inconsistent, but in both the proposed rule and here in the final rule, FDA has provided lengthy discussion and justification for the qualifying levels set for the NTL for all types of products. Specifically for combination products, FDA has laid out the basis for how each limit was determined and how foods can satisfy the criteria if those foods can serve as a mixed product, main dish, or meal product. For example, after detailing how the sodium limit for individual foods was set at 10% DV and how that baseline level is consistent with sodium reduction efforts and the current status of the food supply, the proposed rule explained each time there was a variation from the baseline level for a particular food group or subgroup why the value was adjusted from the baseline (*e.g.,* 5% instead of 10% DV for salad dressings and oil-based spreads because of their small RACC size). Then, for combination products, the proposed rule further explained how the NTL levels for each of the food groups in the product would be averaged together for mixed products and added together for main dishes and meal products. This consistent approach was taken for each of the NTL in the proposed rule. In this final rule, FDA streamlined and further standardized these requirements so that manufacturers do not need to consider as many different nutrient levels when looking to calculate whether they meet the NTL criteria for their products. This change was made in response to a number of comments that requested more simplicity (see section V.E (''Combination Foods'')). The final rule is internally consistent and has a reasoned basis for each of the values.

Additionally, the citations to the two cases regarding internal inconsistency are misplaced for the reasons provided above. Every decision about the nutrient limits and FGEs was consistently made to further the goal of helping consumers identify foods that are particularly useful in building a healthy dietary pattern consistent with current dietary recommendations. In certain cases, different levels for different nutrients or different food groups were determined to best further this goal because of factors like current market conditions and consumer consumption patterns. This difference in nutrient levels does not make the rule or its justifications internally inconsistent, but rather makes them narrowly tailored to achieving the rule's goals.

(Comment 151) Several comments assert that the APA prohibits FDA from implementing the proposed rule because of its overly narrow definition of the word ''healthy'' and arbitrarily restrictive labeling standards.

(Response 151) The comments do not explain the basis for the assertion that the ''narrowness'' and ''restrictiveness'' of the definition of the claim ''healthy'' is arbitrary or capricious under the APA. Elsewhere in the rule, for example, in Response 143, we have explained why the definition is not arbitrary or capricious under the APA. As we have stated previously, the ''healthy'' claim is voluntary and has

been defined by regulation since 1994 for use when it suggests that the food is useful in creating a diet consistent with dietary recommendations. It is not arbitrary to restrict the use of this claim to foods that meet nutritional parameters consistent with current dietary recommendations in nutrition science and Federal dietary guidance and it is not overly narrow to tailor the definition to ensure that the claim only appears on the labels of foods that will help consumers achieve these dietary recommendations, given the current food marketplace and consumption patterns.

(Comment 152) One comment argues that it is illogical that an ingredient could be used in an authorized health claim but at the same time disqualify a food from bearing the ''healthy'' claim.

(Response 152) Health claims provide information about a specific food substance and a specific disease, while the ''healthy'' nutrient content claim provides information to help consumers identify foods that are foundational to establishing and maintaining healthy dietary practices consistent with current nutrition guidance. These are different purposes and there may be times where a health claim discusses a specific benefit, such as reducing dental caries, but the food may not meet the broader criteria for the ''healthy'' claim due to nutrient levels that are not consistent with the purpose of the ''healthy'' claim.

3. First Amendment

(Comment 153) Some comments say that the use of the ''healthy'' claim on products that do not meet the updated regulatory criteria to bear the claim are truthful, non-misleading commercial speech that is protected by the First Amendment. One comment asserts that FDA cannot narrowly define a term and then conclude that any other use of that term is misleading. Another comment says that the use of the ''healthy'' claim on non-compliant products cannot be false or misleading because a large number of products that would be excluded from the proposed definition of ''healthy'' are products that are currently promoted by the Dietary Guidelines. Other comments say that FDA has not provided evidence that using the ''healthy'' claim for foods that comply with the original regulations is false or misleading.

(Response 153) We disagree with these comments to the extent that they suggest that updating the definition of ''healthy'' will restrict truthful and non-misleading speech. The intention behind the statutory and regulatory requirements for nutrient content claims on food labels or labeling, including any ''healthy'' claims, is to help ensure that consumers are adequately informed and not misled by such claims so that they can identify foods that may help them maintain healthy dietary practices. It is appropriate and consistent with the statutory and regulatory framework for FDA to update the definition of ''healthy'' based on current science to help ensure that the claim remains truthful and non-misleading. As we have explained since 1994, the use of ''healthy'' constitutes an implied claim that a food, ''based on [its] nutrient levels, [is] particularly useful in constructing a diet that conforms to current dietary guidelines'' (see 59 FR 24232 at 24233). When dietary guidelines change, a formerly truthful and non-misleading ''healthy'' claim can become misleading if it no longer accords with those guidelines. Thus, contrary to the suggestions in the comments, updating the ''healthy'' definition in light of that current science is necessary to ensure that the use of the claim does not lead consumers astray. Indeed, Congress' purpose in enacting this legislation was to help ensure that consumers are not misled and that they can make informed nutritional choices without confusion caused by the use of claims with inconsistent meanings.

Through the Nutrition Labeling and Education Act (NLEA) of 1990, Congress granted FDA the authority to regulate nutrient content claims because it recognized that consumers were being misled by the use of inconsistent and confusing terms on food labeling. See, *e.g.,* 136 Cong. Rec. H5836, H5840 (July 30, 1990) (statement of Rep. Waxman) (''[Under the NLEA,] content claims would have to be consistent with terms defined by . . . the Food and Drug Administration. Today, companies use terms such as 'low' and 'light' differently and inconsistently. . . . The bill would correct this deceptive and misleading state of affairs by requiring that terms such as 'light' have a single meaning.'') and id. at H5843 (statement of Rep. Madigan) (''Consumers today are confronted with a variety of labels that provide them with disjointed and confusing information. . . . In the past few years, important scientific evidence has been repeatedly reported that clearly links dietary habits to good health. For this reason, the need to provide consumers with better information about the foods they eat is important.''); see also 136 Cong. Rec. H12951, H12953–54 (October 26, 1990) (statement of Rep. Madigan) (''[T]he bill requires that content claims such as light, low, et cetera, would have to be consistent with terms defined by the FDA. This is to address the current problem of companies using these terms differently and inconsistently.''). As discussed at length in the preamble to the proposed rule and in section IV (''Legal Authority''), the NLEA created section 403(r) of the FD&C Act, which provides specifications for a claim made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is the type required by section 403(q)(1) or (2) of the FD&C Act to be in the label or labeling of the food. The statute permits the use of these label and labeling claims that expressly or by implication characterize the level of any nutrient in a food, but only if the claims are made in accordance with FDA's authorizing regulations (section 403(r)(1)(A) and (r)(2)(A) of the FD&C Act). Such claims are referred to as ''nutrient content claims'' (87 FR 59168 at 59174). By taking this approach in the NLEA, Congress permitted only those nutrient content claims that FDA defines or approves. 58 FR 2302, 2392 (January 6, 1993); see also 136 Cong. Rec. S06607, S16608 (October 24, 1990) (statement of Sen. Metzenbaum) (''[FDA] is required to define in regulations the terms which may be used to characterize the level of a nutrient in food. In determining which terms to allow, the Secretary should consider the different ways such terms are used today. . . . By considering current uses and current consumer understanding, the Secretary can best decide how to define the term under this bill.''). To assist consumers in maintaining healthy dietary practices, and to ensure that claims in food labeling do not mislead them, Congress granted FDA broad authority to develop appropriate definitions for nutrient content claims. See id. at S16609 (statement of Sen. Metzenbaum).

Shortly after the NLEA was passed, in 1994, FDA issued an implementing regulation in which we defined ''healthy'' when the term is used as an implied nutrient content claim. We explained that we determined that, when used in a nutritional context, the term ''healthy'' is making an implied claim about the levels of the nutrients in the food; that is, that these levels are such that the food would be useful in maintaining healthy dietary practices and achieving a total diet that conforms to current dietary recommendations (56 FR 60421 at 60423). Therefore, since 1994, our regulations have included an established definition for the ''healthy'' nutrient content claim, which highlights that a food, because of its nutrient content, is particularly useful in

constructing a diet that is consistent with to current dietary guidelines.

In line with its statutory authority, FDA has given the nutrient content claim ''healthy'' a definition with a ''special and particular meaning'' (*Am. Acad. of Pain Mgmt* v. *Joseph,* 353 F.3d 1099, 1108 (9th Cir. 2004)). As such, the use of the nutrient content claim ''healthy'' without meeting the established criteria is at least potentially misleading, because it may convey to consumers and the public that FDA's established definition for the term has been met, which it has not (see id.). As we have said previously, ''because nutrition claims are of great importance to the public,'' they have ''a greater potential to be deceptive,'' and they are ''difficult for consumers to verify independently'' (58 FR 2302 at 2394). FDA's efforts to establish and update the criteria for the ''healthy'' nutrient content claim are reflective of its statutory mandate to standardize nutrition and health-related terms on food labels or labeling, by regulation, for the benefit of consumers.

To the extent that these comments suggest that FDA did not provide evidence demonstrating the need to update the definition for the ''healthy'' nutrient content claim, we also disagree. FDA provided evidence throughout the proposed rule that the existing definition of ''healthy'' is outdated and in some ways inconsistent with current nutrition science and Federal dietary guidance (see, *e.g.,* 87 FR 59168, 59172 at section IV.B., ''Need to Update 'Healthy' ''). The proposed rule provides, among other things, that the existing definition relies on nutrients that were of sufficient public health significance to warrant their inclusion on the nutrition label in 1994, when the final rule was published, and FDA has issued final rules updating the nutrition information on food labels in various ways since then to be consistent with nutrition science over time. It also discusses how the Dietary Guidelines have changed to focus on the importance of dietary patterns as a whole and replacement of less healthy food choices with nutrient-dense foods and provided examples of certain foods that are encouraged by the *Dietary Guidelines* that cannot bear the ''healthy'' claim under the existing definition (id.). The proposed rule explained that, in light of evolving nutrition science and Federal dietary guidance, changes to the criteria for the ''healthy'' claim are important to ensure that the claim is consistent with the longstanding purpose of this type of implied claim to indicate that the nutrient levels in a food may help consumers maintain healthy dietary practices (87 FR 59168 at 59172 through 59173). As explained throughout this section, such changes also advance FDA's goals of preventing misleading labeling and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims.

Moreover, we disagree that the use of the ''healthy'' claim on non-compliant products cannot be false or misleading because a large number of products that would be excluded from the proposed definition of ''healthy'' are products that are currently promoted as healthy by the *Dietary Guidelines.* Dietary recommendations can change and evolve over time as scientific evidence develops, and therefore, a food that was recommended to be consumed as the foundation of a healthy dietary pattern years ago could no longer be considered a foundational food. We explain throughout this rule that the updated ''healthy'' criteria are consistent with the Dietary Guidelines recommendations to consume nutrient-dense foods (*e.g.,* containing little or no added sugars, saturated fat, and sodium) and we provide examples of specific foundational foods promoted by the Dietary Guidelines that would qualify to bear the ''healthy'' claim based on the updated criteria (*e.g.,* certain varieties of fruits and vegetables, whole grains, fat-free and low-fat dairy, lean meat, eggs, beans, peas, lentils, nuts, seeds, water, etc.). However, where possible and consistent with current dietary recommendations, FDA has adjusted certain criteria to provide greater flexibility for foods to qualify to bear the ''healthy'' claim in this final rule. Our response to comments raising similar concerns can be found in Response 155.

(Comment 154) Several comments say that the proposed updated criteria for the ''healthy'' claim is a restriction on commercial speech and question whether it would satisfy the First Amendment test set forth in *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557, 563–66 (1980). One comment asserts that FDA does not have a substantial government interest as required by *Central Hudson* because government lacks ''an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information,'' citing *Thompson* v. *W. States Med. Ctr.,* 535 U.S. 357, 374 (2002). Other comments argue that the proposed criteria for the ''healthy'' claim do not directly and materially advance FDA's substantial interest in reducing chronic disease. Some of these comments cite the proposed rule to support this assertion because its quantifiable benefits calculation estimated that ''a small number (0 to 0.4% of people that try to follow current dietary guidelines) of . . . consumers would use the 'healthy' implied nutrient content claim to make meaningful, long-lasting food purchasing decisions'' (87 FR 59168 at 59168, 59195).

(Response 154) As a preliminary matter, as discussed in Response 153, the intention behind the statutory and regulatory requirements for nutrient content claims on food labels or labeling, including any ''healthy'' claims, is to help ensure that consumers are adequately informed and not misled by such claims so that they can identify foods that may help them maintain healthy dietary practices. The use of the ''healthy'' claim on products that do not meet the updated criteria for ''healthy'' may be misleading for several reasons, including that such use may imply that the definition and regulatory requirements have been met when they have not. The use of ''healthy'' on food labels or labeling could be shown to be misleading for a myriad of other reasons based on the particular product and circumstances. Because, under the threshold step of the *Central Hudson* framework, the government can restrict speech that is false or inherently or actually misleading, at least some ''healthy'' claims would not be entitled to First Amendment protection because they are false or misleading.

However, on a facial challenge, it may not be possible to categorically determine whether the universe of hypothetical claims is false or misleading. Under the *Central Hudson* framework, if commercial speech is truthful and is not inherently or actually misleading, the government must establish that the regulation directly advances a substantial government interest, and the regulation is no more extensive than necessary to serve that interest (*Central Hudson,* 447 U.S. at 563–66). That means that government regulation of speech that is *potentially misleading* is subject to review under these remaining *Central Hudson* steps. See, *e.g., Pearson* v. *Shalala,* 164 F.3d 650, 655 (D.C. Cir. 1999); *Public Citizen, Inc.* v. *La. Atty. Disciplinary Bd.,* 632 F.3d 212, 218 (5th Cir. 2011). Under the *Central Hudson* framework, ''there is no question'' that the government's interest ''in ensuring the accuracy of commercial information in the marketplace is substantial,'' *Edenfield* v. *Fane,* 507 U.S. 761, 769 (1993), including ''undoubtedly'' the ''[p]rotection of health and prevention of consumer fraud.'' *Bellion Spirits, LLC* v. *United*

States, 393 F. Supp. 3d 5, 24 (D.D.C. 2019), *aff'd,* 7 F.4th 1201 (D.C. Cir. 2021).

Here, the substantial government interest is in providing information to consumers to indicate that the nutrient content of a food may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims. Courts have long recognized that the government has a significant interest in promoting or protecting public health by regulating the information in food labeling. See, *e.g., Rubin* v. *Coors Brewing Co.,* 514 U.S. 476, 485 (1995); *see also Am. Meat Inst.* v. *U.S. Dep't Agric.,* 760 F.3d 18 (D.C. Cir. 2014) (en banc) (finding individual health concerns related to food products to be one of several substantial government interests underlying USDA labeling disclosures); *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 134 (2d Cir. 2009) (recognizing ''informed consumer decision-making so as to reduce obesity and the diseases associated with it'' through posting of calorie content information on menus as a substantial government interest); *Bellion Spirits, LLC* v. *United States,* 393 F. Supp. 3d at 25 (stating that the Alcohol and Tobacco Tax and Trade Bureau preventing a company from labeling and advertising its alcohol product to promote its biological benefits is directly connected to the substantial government interests of promoting health and preventing potential consumer deception). Moreover, we disagree that the Court's rationale in *Western States* is applicable to this rulemaking. In that case, the Court explained that, in general, the government should not restrict product advertising for the sole purpose of preventing members of the public from making bad decisions based on the advertising information. However, as described above, the interests here do not involve preventing members of the public from making bad decisions. To the contrary, the updated requirements to use the ''healthy'' claim support consumer choice. The requirements advance government interests related to providing consumers with important product information at the point of sale so that they can identify foods that may help them maintain healthy dietary practices if they choose, and preventing misleading labeling and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims.

The updated definition directly advances our substantial government interests in providing information to consumers to indicate that the nutrient content of a food may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims. Updating the ''healthy'' definition to ensure that it is aligned with current nutrition science and Federal dietary guidance promotes public health by providing consumers with information about foods that, because of their nutrient content, are particularly useful in constructing a diet that is consistent with current dietary recommendations. Consumers may then use that information, at the point of decision-making, to identify foods that are foundational to a healthy diet. As explained in the preamble to the proposed rule, advancements in nutrition science have provided a greater understanding of, and focus on, the importance of healthy dietary patterns, and how dietary components may act synergistically to affect health. Other regulations, such as those updating the Nutrition Facts label and serving size information for packaged foods, have been updated to reflect new scientific information, including the *Dietary Guidelines, 2015–2020,* consensus reports, national survey intake data, and research regarding consumer use and understanding of the label. 87 FR 59172. Likewise, the updated criteria for the ''healthy'' claim, outlined in this rule, reflect the recommendations of the *Dietary Guidelines, 2020–2025,* which have shifted to recommending healthy dietary patterns and the consumption of food groups in certain quantities to achieve adequate nutrient intake, based on the understanding that each food group contributes an array of important nutrients to the diet. Specifically, the updated ''healthy'' criteria include food group requirements instead of requirements for NTE (as in the original ''healthy'' definition) to reflect current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025,* which describes a healthy dietary pattern as consisting of ''nutrient-dense forms of foods and beverages, across all food groups, in recommended amounts, and within calorie limits.'' As stated previously, the food group approach better accounts for how nutrients contribute to, and may work synergistically to create, a healthy dietary pattern and improve health outcomes (see sections V.C. ''Food Group Equivalents'' and V.D.6 ''Nutrients to Encourage'' for further discussion about FGE requirements and NTE). Moreover, as explained further in other parts of this rule, the updated criteria also change the NTL requirements, for example, by incorporating limits on added sugars and removing limits on total fat and cholesterol. These changes reflect current nutrition science and the *Dietary Guidelines, 2020–2025,* which now emphasize limiting added sugars intake and have moved away from recommending a specific intake for total fat. Rather, current dietary recommendations emphasize replacement of saturated fats in the diet with unsaturated fats, particularly polyunsaturated fats, and a dietary pattern that is low in saturated fat is typically low in dietary cholesterol (rendering a cholesterol limit unnecessary). (See section V.D.4 ''Added Sugars'' for further discussion of the added sugars limits and section V.D.5 ''Nutrients Not Included'' for further discussion of the elimination of total fat and dietary cholesterol limits in the updated ''healthy'' criteria).

As demonstrated by these examples, and by others throughout the rule, this rule ensures that the criteria for ''healthy'' are harmonized with current regulations, nutrition science, and Federal dietary guidelines, and therefore that the ''healthy'' claim accurately indicates to consumers that a food, based on its nutrient levels, may help them maintain healthy dietary practices. Providing this information to consumers enables them to make more informed choices about the foods that can be the foundation of a healthy dietary pattern. It also comports with the legislative objectives of the NLEA to empower FDA to standardize nutrient content claims to ensure that they are accurate, not misleading, and can help consumers identify foods that can help them maintain healthy dietary practices.

In addition, the updated definition prevents misleading labeling and reduces consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims by requiring that foods bearing the ''healthy'' claim meet standardized nutritional criteria that reflects current, up-to-date, nutrition science and dietary recommendations. As discussed in Response 153, the need for consistent labeling claims on foods to prevent the public from being misled was an explicit motivation of Congress when it passed the NLEA's nutrient content claim provisions. See, *e.g.,* 136 Cong. Rec. H12954 (October 26, 1990) (statement of Rep. Moakley) (''The

current format for nutrition labeling on foods is often inadequate for today's consumer needs. In many cases the information is confusing and, in some cases, very misleading. Terms such as lite, high fiber, and low cholesterol, which now have little or no guidelines, will be defined and their use restricted to the FDA definition. This bill will help curb misleading claims . . .''). As such, the updated definition directly advances the goals of preventing misleading labeling and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims by ensuring that the term, ''healthy,'' when used in a nutritional context, has a consistent meaning that is supported by current nutrition science and Federal dietary guidance. Moreover, an updated, consistent definition for ''healthy'' enables consumers to identify foods that, based on current nutrition science and Federal dietary guidance, are particularly useful in building a healthy eating pattern, and to make more informed food selections and comparisons.

We further disagree that the updated criteria for the ''healthy'' claim do not directly advance FDA's asserted government interests due to the quantifiable benefits calculation included in the proposed rule. This calculation considers numerous factors to estimate all of the potential benefits of the rule, such as a reduction in all-cause morbidity and mortality stemming from consumers selecting and consuming more healthful foods. However, as explained throughout this rule, the longstanding purpose of FDA's definition of the ''healthy'' nutrient content claim is to provide information to consumers that indicates that the nutrient levels of a food may help consumers maintain healthy dietary practices. Achieving specific changes in rates of chronic disease are not the government interests we assert, and the law therefore does not require that such changes be demonstrated.

(Comment 155) One comment states that, while FDA does have a substantial interest in promoting public health through lawful restrictions on food labeling, the proposed added sugars and sodium limits for grain products would not directly advance that objective and would prohibit a broad range of nutrient-dense whole grain products from bearing ''healthy,'' which is in conflict with FDA's public health objectives and the Dietary Guidelines.

(Response 155) We disagree that the added sugars and sodium limits, as applied to grain products, do not advance FDA's asserted interests, and that the sodium limit for grain products in this final rule would prohibit a broad range of nutrient-dense, whole grain products from bearing the ''healthy'' claim. The *Dietary Guidelines, 2020–2025* emphasizes that there is little room in most dietary patterns for excess sodium and state that shifts to more nutrient-dense forms of grains will help consumers to build healthy dietary patterns. Whole grain products that meet the established criteria for sodium are particularly useful, because of their nutrient content (including sodium amounts), in helping consumers identify foods that are the foundation of a healthy dietary pattern. As explained in section V.D.3 (''Sodium''), the sodium limits for grain products are consistent with the *Dietary Guidelines, 2020–2025,* which recommends that consumers limit sodium in their diets as part of building healthy dietary patterns. Our marketplace review conducted in response to comments on this topic demonstrates that there are many whole grain products, including whole grain bread products (*i.e.,* English muffin products and some whole grain tortillas) and cereals, that meet the ≤10% DV limit for sodium.

We note that after considering comments received, this final rule has increased the added sugars limit for whole grain products from ≤5% DV to ≤10% DV. FDA has determined that increasing the added sugars limit for whole grain products to ≤10% DV aligns with the *Dietary Guidelines, 2020–2025* by resulting in more whole grain cereal products, which can be important sources of nutrients based on their high likelihood of fortification, being able to qualify for the ''healthy'' claim. This increase is supported by our marketplace review that examined the added sugars content of whole grain products, including ready-to-eat cereals, hot cereals, and whole grain breads and crackers.

In alignment with the *Dietary Guidelines, 2020–2025* the framework of this rule emphasizes healthy dietary patterns and nutrient density by incorporating both FGE criteria and NTL criteria in the definition for the ''healthy'' claim. The FGE criteria combined with the added sugars and sodium limits ensure that grain products are nutrient-dense and contain levels of those nutrients that will help consumers identify foods that can be the foundation for a healthy dietary pattern, consistent with current nutrition science and Federal dietary guidance. Accordingly, such limits directly advance FDA's government interests in providing information to consumers that indicates that a food's nutrient content may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent definitions for nutrient content claims.

(Comment 156) Several comments state that the updated criteria are unduly restrictive and are therefore unconstitutional under *Central Hudson.* Some comments say that FDA is required to demonstrate that the updated criteria are the least restrictive means to achieve our goals, which the comments assert it cannot do. Other comments state that the criteria are more extensive than necessary to serve FDA's substantial government interest and are thus constitutionally impermissible under *Central Hudson.* One comment argues that FDA failed to consider less restrictive alternatives for the updated criteria because FDA could run a public education campaign to discourage consumers from eating food with added sugars or encourage them to eat foods that contain large servings from multiple food groups, which would lead consumers to eat food that FDA prefers. Some comments assert that FDA could engage in its own affirmative speech by running advertisements or distributing literature promoting its own vision of what constitutes a healthy diet and that Supreme Court precedent requires FDA to consider whether it can achieve its goals through its own informational efforts.

(Response 156) We disagree that the rule is unduly restrictive. As an initial matter, more than one comment mischaracterizes the relevant inquiry under the *Central Hudson* standard, stating that the rule must be the least restrictive means to achieve the asserted government interest. The standard does not require the government to adopt the least restrictive means of advancing its goal (*Bd. of Trustees of the State Univ. of New York* v. *Fox,* 492 U.S. 469, 480 (1989)). Instead, the relevant inquiry is whether the fit between the government's ends and the means chosen to accomplish those ends ''is not necessarily perfect, but reasonable'' (Id.). Put another way, the question is not whether there is ''no conceivable alternative'' but instead whether the ''regulation [does] not burden substantially more speech than is necessary to further the government's interests.'' *Fleminger, Inc.* v. *U.S. Dep't of Health & Hum. Servs.,* 854 F. Supp. 2d 192, 196 (D. Conn. 2012), citing *Clear Channel Outdoor, Inc.* v. *City of New York,* 594 F.3d 94, 104 (2d Cir. 2010); *Bd. of Trustees,* 492 U.S. at 478.

FDA's approach to updating the definition for ''healthy'' is no more extensive than necessary to serve our interests in providing information to consumers to indicate that a food's nutrient content may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent nutrient content claims. The ''healthy'' nutrient content claim is voluntary. As we have discussed previously, nutrient content claims are not prohibited, but are permitted by statute and regulation under a range of circumstances. See section 403(r) of the FD&C Act and part 101, subpart D, ''Specific Requirements for Nutrient Content Claims.'' Nutrient content claim regulations prescribe that the information be presented in standardized form, using uniform terms defined by the Agency, so that consumers will not be misled (58 FR 2302 at 2394). Moreover, nutrient content claims are just one type of claim permitted on food labeling. As stated in multiple parts of this rule, there are many other avenues available for manufacturers to promote the benefits, including the nutrition- or health-related benefits, of their food products on their product labels or labeling. However, where the ''healthy'' claim is used in a nutritional context, and therefore suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, FDA's approach ensures that the foods meeting the criteria to bear the claim are those that can be consumed to help consumers in achieving a total diet that conforms to current dietary recommendations. This approach is a ''reasonable fit'' between FDA's ends and the means chosen to accomplish those ends (*Fox,* 492 U.S. at 480).

We carefully considered the requirements of the updated criteria to ensure they align with current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025,* while providing flexibility where possible, based on relevant information such as current market conditions, consumer consumption patterns, consistent evidence of beneficial health effects, and our marketplace review. In certain instances, the rule sets forth exceptions from the updated criteria for certain foods that can contribute to a healthy dietary pattern without meeting the baseline FGE or NTL requirements. For example, after considering comments related to foods with small RACCs and their inability to meet FGE requirements, FDA determined that it is appropriate to apply the ''healthy'' criteria to individual foods with a RACC less than 50 g or less than 3 Tbsp on a per 50 g basis instead of a per RACC basis. This adjustment for small RACC foods is reflective of current nutrition science and Federal dietary guidance because there are many foods recognized by the Dietary Guidelines that are foundational to a healthy dietary pattern but that have RACCs that are smaller than the required FGE. As another example, the rule excludes the inherent saturated fat content in seafood and nuts, seeds, and soybeans, from the saturated fat limit because they have a fatty acid profile that is predominantly unsaturated fats, and scientific evidence demonstrates that there is a beneficial relationship between fatty acids contained in these foods and reduced risk of heart disease.

Moreover, FDA carefully tailored the final rule by making adjustments across FGE and NTL criteria and food categories. Compared to the proposed rule, the final rule establishes more generous limits for FGEs for dairy products and for added sugars limits in a variety of food categories, such as grains, fruits and vegetables, protein foods, and mixed products and main dishes. Where no adjustments have been made, we determined, based on a number of factors, including practical considerations (*e.g.,* current market conditions and the feasibility of food products in certain categories meeting the criteria, ability of consumers to choose from multiple options in such categories), that the foods that are eligible to bear the claim are those that are particularly useful in helping consumers to achieve a diet that conforms to current dietary recommendations.

We disagree with the comments that suggest that informational efforts, such as a consumer education and outreach campaign, would be a sufficiently effective alternative to advancing the government interests. FDA recognizes the utility of consumer education and outreach campaigns and plans to educate consumers on the use of and updated definition for the ''healthy'' claim (see section V.L.4 ''Comments Regarding Consumer Education'' for further discussion of consumer education about the updated ''healthy'' definition). However, we disagree that a consumer education campaign of the type suggested by the comment would be an appropriate alternative to the rule.

Even if a consumer education campaign, or other informational efforts led by FDA, including advertising and other literature, were appropriately designed to inform consumers about foods that are foundational to a healthy eating pattern, these efforts alone are not a practical or legitimate alternative to updating the criteria for the ''healthy'' claim. However helpful such efforts may be in providing general information to consumers about building a healthy eating pattern, they are no substitute for the updated ''healthy'' requirements, which, consistent with Congressional intent, ensure that the ''healthy'' claim on a specific food product serves as a quick signal to consumers, at the point of decision-making, that the food is particularly useful in achieving a diet that is consistent with current dietary recommendations. This situation is thus very far from that considered in *Nat'l Inst. of Family & Life Advocates* v. *Becerra (NIFLA),* where the Court found it crucial that California was seeking to compel private clinics to provide notice that ''in no way relate[d] to the services th[e] licensed clinics provide'' but, instead, ''require[d] these clinics to disclose information about *state*-sponsored services.'' 585 U.S. 755, 769 (2018). The Court's conclusion that a State-sponsored public information campaign is appropriate and effective to inform the public about a State-sponsored service is unremarkable. In the context of a communication about a specific food product's nutritional content, however, informational efforts may not reach the same audience in the same timeframe as a ''healthy'' claim that is compliant with the updated criteria, and the generalized content of the informational campaign efforts would not be directly targeted to communication about a specific product. Here, in contrast to the situation in *NIFLA,* we are regulating claims a private party makes about the very product it is selling.

Furthermore, these comments' suggestions would produce the result of FDA failing to update the original ''healthy'' definition, established in 1994, which is outdated and, in some ways, inconsistent with current nutrition science and Federal dietary guidance, while conducting consumer education and outreach to inform consumers about foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to *current* dietary recommendations. Educational and outreach efforts of this nature are not a viable regulatory alternative because they could contradict the use of the existing ''healthy'' claim due to such claim's reliance on nutrition science and Federal dietary guidance from 1994. Accordingly, these efforts, by themselves, cannot ensure that the use

of the ''healthy'' claim on food packages is consistent with current nutrition science and Federal dietary guidance. Nor do they signal to the consumer, at the point of decision-making, that a specific food is particularly useful in helping them to build a diet that conforms to current dietary recommendations. As such, while we considered a variety of alternative approaches, we determined that they would be insufficiently effective in advancing FDA's interests in providing information to consumers to indicate that a food, because of its nutrient content, may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent nutrient content claims.

We note that FDA's nutrition labeling efforts, including this rule, are broadly intended to provide information to consumers about foods that can help them identify healthier choices and build a healthy eating pattern. Additionally, as explained further in section III. (''Background''), the rule does not represent an endorsement of certain foods by FDA and is not intended to discourage the consumption of certain foods as part of the total diet. To put it plainly, FDA does not have ''preferences'' about foods that consumers eat or do not eat, and therefore, any consumer education campaign pursued by FDA could not be designed to discourage or encourage consumption of foods consistent with such ''preferences.''

(Comment 157) One comment asserts that the proposed definition of ''healthy'' would burden ''far more speech than necessary'' because it prevents ''most objectively healthy foods,'' including those promoted by the Dietary Guidelines, from bearing the ''healthy'' claim. Some comments argue that a large percentage of foods on the official recipe website of the Dietary Guidelines would be unable to bear the ''healthy'' claim. One comment further asserts that many nutrient-dense foods, including many whole grain breads, breakfast bars, yogurts, cereals, canned fruits, canned vegetables, and salad kits could not bear the claim, even though they are included in the current Dietary Guidelines.

(Response 157) We disagree that the updated definition of ''healthy'' is more restrictive than necessary to serve our interests because it excludes ''most objectively healthy foods,'' including those promoted by the Dietary Guidelines or included in the recipes on the Dietary Guidelines website. As discussed at length in different parts of this rule, foods that are eligible to bear the ''healthy'' claim are those that are particularly useful in constructing a diet that conforms to current dietary recommendations. Foods that do not qualify for ''healthy'' are not necessarily ''unhealthy'' and may still be part of a healthy dietary pattern, and their nutritional attributes can be conveyed to consumers through other truthful and not misleading statements on the food label or in food labeling. Furthermore, many of the examples of foods included in the comment may qualify to bear the ''healthy'' claim under the finalized criteria, depending on their specific nutrient profiles. As discussed in section V.D.3 (''Sodium''), our marketplace review found that many canned vegetables, including low-sodium canned vegetables and some reduced-sodium canned vegetables, do not exceed the finalized ≤10% DV sodium limit. As discussed in the same section, many whole grain breads do not exceed the ≤10% DV sodium limit, and we have provided additional flexibility for whole grain products, including whole grain breads, by increasing the added sugars limit from ≤5% DV to ≤10% DV for the grains group. Salad kits, or bagged salads with dressing or toppings, discussed in section V.D.4 (''Added Sugars'') above, could be considered mixed products or main dishes, depending on their formulation, and the final rule increases the added sugars limits for mixed products, meals, and main dishes, to provide more flexibility for these types of nutrient-dense products while still aligning with current nutrition science and Federal dietary guidelines. Similarly, many of the recipes on the Dietary Guidelines' website are mixed products and main dishes rather than individual foods, and therefore, the foods in those recipes may be subject to the criteria for mixed products and main dishes, including the increased added sugars limits. We further note that, as explained in section V.D.6, while all of the MyPlate recipes contain nutrient-dense ingredients, some of the recipes are for foods, such as dessert foods, that are not the foundation of a healthy dietary pattern (*e.g.,* recipes for apple crisps, chocolate squash cake, banana cupcakes, etc.). As such, not all foods for which recipes are included in the MyPlate website are particularly useful in achieving a healthy dietary pattern, and therefore, they may not qualify to bear the ''healthy'' claim.

Additionally, as discussed in Response 155, the rule accounts for specific foods with a nutrient profile that may help consumers maintain healthy dietary practices but that may not meet certain generally applicable NTL or FGE requirements. If no exemption was established, we have determined that it is generally both practicable for foods to meet the updated criteria for the ''healthy'' claim and essential that they do so to ensure that the ''healthy'' claim provides a quick signal to consumers that foods bearing the claim are foundational to a healthy diet. As demonstrated by the examples above, FDA's approach to the updated criteria is narrowly tailored to serve our interests in providing information to consumers to indicate that a food's nutrient content may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent nutrient content claims.

(Comment 158) One comment states a belief that FDA is drawing the line in ''the most restrictive way possible'' and that the ''healthy'' criteria precludes foods from bearing ''healthy'' that align with the Dietary Guidelines. The comment suggests that FDA adopt its alternative approach to updating the ''healthy'' nutrient content claim, which includes a number of suggestions, such as maintaining NTE criteria as an alternative to FGE criteria (see Comment 3), incorporating a small RACC subcategory with modified criteria (see Comment 4), adopting a first ingredient approach (see Comment 7), aggregating food groups (Comment 101), and combining the individual and mixed food categories and increasing sodium, added sugars, and saturated fat limits in a stepwise manner based on RACC size (see Comment 65, Comments 70–72, Comment 102). Another comment says that the proposed limits for added sugars and sodium are ''far more restrictive than necessary'' because less restrictive limitations, such as the 20% DV limitations and alternative RACC Framework proposed by the comment, would allow FDA to better foster the consumption of whole grain products while controlling for added sugar and sodium consumption. The alternative RACC Framework would adopt higher nutrient limits for foods with RACCs above 30 g (*e.g.,* a 20% DV limit for added sugars and sodium) and lower nutrient limits for foods with RACCs at or below 30 g (*e.g.,* a 10% DV limit for added sugars and sodium).

(Response 158) We disagree that the updated ''healthy'' criteria have been developed in the ''most restrictive way possible'' and that they preclude foods from being labeled as ''healthy'' that align with the Dietary Guidelines. Foods

that qualify to bear ''healthy'' based on the updated criteria are those foods that are particularly useful in helping consumers build a diet that conforms to current dietary recommendations. In other sections, we explain why we have or have not adopted the suggestions included in the commenter's proposed alternative approach to updating the ''healthy'' nutrient content claim (see Responses 7, 8, 11, 69, 74–76, 105, and 106). Responses 155 and 156 provide further explanation of why the updated ''healthy'' criteria is narrowly tailored to serve our substantial government interests and information to support that such criteria are consistent with current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025.*

In regard to the alternative RACC framework and higher nutrient limits for sodium and added sugars, as discussed in section V.D.3 (''Sodium''), we agree that there should be a stepwise approach across food categories (*i.e.,* gradual increases in sodium or added sugars for individual foods with smaller RACCs, individual foods with larger RACCs, mixed products, main dishes, and meals), and we have modified the criteria by providing alternative criteria for foods with smaller RACCs. However, we disagree that a ≤20% DV limit for sodium or added sugars for whole grain products is an appropriate less restrictive alternative to the finalized limits. As explained further above, a 20% DV for individual foods would be inconsistent with the *Dietary Guidelines, 2020–2025,* because it could result in the use of the claim on foods that contain more than limited amounts of sodium or added sugars. According to our regulations, products that contain 20% DV of sodium per serving are high in sodium or added sugars (§ 101.54(b)), and therefore, a 20% DV limit for sodium or added sugars would run counter to the Dietary Guidelines recommendations for consumers to limit sodium and added sugars in their diets. However, as discussed in section V.D.4 (''Added Sugars''), we have increased the added sugars limit for whole grain products from ≤5% DV to ≤10% DV such that more nutrient-dense whole grain products, such as whole grain cereals, with limited amounts of added sugars to increase palatability, will qualify for the ''healthy'' claim.

Accordingly, FDA has considered the suggestions included in the alternative approach, including a framework to adopt higher nutrient limits for foods with larger RACCs and lower nutrient limits for foods with smaller RACCs, and nutrient limits at 20% DV for sodium and added sugars for grain products, proposed by these comments, and either determined that the suggestions are appropriate to incorporate in the updated ''healthy'' criteria or that they would not be sufficiently effective in advancing FDA's stated interests in providing information to consumers to indicate that a food's nutrient content may help them maintain healthy dietary practices to promote public health, preventing misleading labeling, and reducing consumer confusion potentially caused by the use of inconsistent nutrient content claims.

(Comment 159) One comment states that the rule is not narrowly tailored to its objective because it would exclude many foods that are nutrient-dense from qualifying to bear the ''healthy'' claim due to small differences between the criteria and the foods' food group amounts, added sugars content, and sodium content. It also states that in many instances, the rule would exclude products that might have otherwise met the ''healthy'' criteria, but that due to an added component, such as a sauce, may exceed the proposed nutrient limits, even though the sauce is the component that is likely to encourage consumers to eat the food. Another comment asks FDA to consider whether the nutrient limits in the rule are no more extensive than needed, particularly where a healthy dietary pattern could accommodate more flexibility in added sugars, sodium, and food groups than proposed, and where the rule would exclude foods encouraged as healthful by dietary guidance.

(Response 159) We carefully considered comments that suggest lower FGE requirements and higher nutrient limits as part of the ''healthy'' criteria, and in some cases, have adopted more generous FGE requirements and nutrient limits where this will result in more nutrient-dense foods recommended by the *Dietary Guidelines, 2020–2025* being able to qualify for the ''healthy'' claim. In particular, to address concerns about the potential inability for nutrient-dense foods with limited amounts of added sugars to qualify for ''healthy,'' we increased the added sugars limit for individual fruits, vegetables, and protein foods, as well as mixed products, meals, and main dishes, to accommodate the purpose of added sugars in the formulation of these products, including texture, flavor standardization, and use of seasonings, sauces, and other ingredients in the formulation of recipes, while still aligning with current nutrition science and Federal dietary guidance. See section V.D.4 (''Added Sugars'') for further discussion of the added sugars limits for fruits, vegetables, and protein foods.

Additional flexibility has been incorporated into other FGE requirements and nutrient limits, where aligned with the Dietary Guidelines recommendations and feasible and practical as demonstrated by our marketplace review. For example, we are finalizing a lower FGE requirement for dairy products at ⅔ c-eq per RACC, as opposed to the proposed ¾ c-eq per RACC. We are increasing the added sugars limit for whole grain products from ≤5% DV to ≤10% DV and are excluding the inherent saturated fat in seafood and nuts, seeds, and soybeans from the saturated fat limits. We are further providing for automatic qualification, regardless of FGE or NTL criteria, for the following single-ingredient, nutrient-dense foods, with no other added ingredients except for water: vegetables, fruits, whole grains, fat-free and low-fat dairy, lean game meat, seafood, eggs, beans, peas, lentils, nuts, and seeds, and for waters (carbonated or noncarbonated), coffee, and tea containing certain non-caloric ingredients such as flavors, low- or no-calorie sweeteners, vitamins, and minerals that contain less than 5 calories per RACC and per labeled serving. Consequently, the adjustments and exceptions from the FGE and NTL requirements are intended to strike a balance between alignment with the Dietary Guidelines recommendations to consume nutrient-dense foods with little or no added sugars, sodium, or saturated fat, and providing for practical flexibility for consumers and industry.

We reiterate that all foods can be part of a healthy dietary pattern, but foods that qualify for the ''healthy'' claim are those foods that, based on current nutrition science and Federal dietary guidance, are particularly useful in constructing a diet that conforms to current dietary recommendations. Foods that do not qualify for the ''healthy'' claim are not necessarily unhealthy and may have beneficial nutritional attributes that can be promoted through other truthful and not misleading statements on the food label or in food labeling.

(Comment 160) Some comments assert that FDA failed to consider less restrictive alternatives for the added sugars requirements. One comment states that disclosure of the amount of added sugars in a food is already required on the Nutrition Facts label and FDA cannot explain why consumer cannot make decisions based on this data. The comment suggests that FDA could require foods with added sugars and bearing the ''healthy'' claim to

include the added sugars in larger type or in a separate box. Other comments suggest that FDA could require foods containing certain amounts of added sugars and bearing the ''healthy'' claim to bear an additional disclosure contextualizing the use of the word ''healthy,'' such as ''see nutrition information for added sugars content.''

(Response 160) We disagree that the added sugars declaration on the Nutrition Facts label or an alternative disclosure regarding added sugar content in addition to the ''healthy'' claim is a reasonable alternative to the added sugar limits in the definition of the ''healthy'' claim. First, the added sugars declaration and the ''healthy'' nutrient content claim convey distinct information on food labels and labeling. The added sugars declaration discloses the amount of added sugars in a food, while the ''healthy'' claim, when voluntarily used in a nutritional context, makes an implicit claim that the levels of nutrients in a food are such that the food is particularly useful in constructing a diet that conforms to current dietary recommendations. As explained in the proposed rule, current nutrition science, as reflected in the *Dietary Guidelines, 2020–2025,* recommends limiting consumption of foods higher in added sugars, which provide excess calories to the diet without contributing significant amounts of essential nutrients. The original ''healthy'' criteria do not include limits for added sugars, which makes the criteria inconsistent with current nutrition science and Federal dietary guidance (87 FR 59168 at 59173). The updated ''healthy'' definition is intended to better represent the overall nutrient profile of foods and to identify foods that are nutrient dense—described in the *Dietary Guidelines for Americans, 2020–2025,* in part, as having little or no added sugars—and can be the foundation of a healthy dietary pattern. Therefore, updating the ''healthy'' criteria without imposing the added sugars limit, as suggested by these comments, would result in foods with added sugars over the recommended levels qualifying to bear the ''healthy'' claim, which could thus provide inaccurate or misleading information to consumers about whether the food contains nutrient levels that may help them maintain healthy dietary practices. Such an approach would not be sufficiently effective in advancing FDA's asserted government interests.

Second, requiring an additional disclosure of added sugar content on the label of products bearing the ''healthy'' claim or a statement to ''see nutrition information for added sugars content'' would be problematic under the same reasoning. Although such disclosures may provide or highlight information about a food's added sugars content, foods with excess added sugars could still qualify to bear the ''healthy'' claim, and therefore, the claim would not help consumers identify foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current nutrition science and Federal dietary guidance. This result would undermine the purpose of the ''healthy'' claim.

Moreover, even if a product bearing a ''healthy'' claim included an additional disclosure or disclaimer to ''contextualize the use of the word, 'healthy,''' as suggested by the comment, or to explain that a food product bearing the ''healthy'' claim includes added sugars above the levels recommended by current nutrition science and Federal dietary guidance, such a statement would be contradictory to the ''healthy'' claim. Adding a disclaimer that does not serve to help consumer understanding, but merely contradicts the claim, is not a viable regulatory alternative. See, *e.g., Resort Car Rental System, Inc.* v. *FTC,* 518 F.2d 962, 964 (9th Cir. 1975) (per curiam) (upholding FTC order to excise ''Dollar a Day'' trade name as deceptive because ''by its nature [it] has a decisive connotation for which any qualifying language would result in contradiction in terms.''), *cert denied,* 423 U.S. 827 (1975); *Continental Wax Corp.* v. *FTC,* 330 F.2d 475, 480 (2d Cir. 1964) (same); *Pasadena Research Labs* v. *United States,* 169 F.2d 375 (9th Cir. 1948) (discussing ''self-contradictory labels''). In the FDA context, courts have repeatedly found such disclaimers ineffective see, *e.g., United States* v. *Millpax, Inc.,* 313 F.2d 152, 154 & n.1 (7th Cir. 1963) (disclaimer stating that ''no claim is made that the product cures anything, either by the writer or the manufacturer'' was ineffective where testimonials in a magazine article promoted the product as a cancer cure); *United States* v. *Kasz Enters., Inc.,* 855 F. Supp. 534, 543 (D.R.I. 1994) (''The intent and effect of the FDCA in protecting consumers from . . . claims that have not been supported by competent scientific proof cannot be circumvented by linguistic game-playing.''), *judgment amended on other grounds,* 862 F. Supp. 717 (1994). Here, because an added sugars-related disclaimer would be similarly ineffective, FDA reasonably chose to incorporate an added sugars limit into the updated criteria for the ''healthy'' claim.

4. Other Legal Issues

(Comment 161) One comment suggests that FDA ensure that express preemption protection apply during the ''transition period'' between the publication of the final rule and the compliance date for the rule to prevent an influx of State lawsuits alleging that a failure to comply immediately with the new Federal requirements (before the Federal compliance date of such requirements) is actionable under State law. The comment noted that implied preemption was found by many courts during the designated Federal regulatory compliance period for other rules and specifically requested that FDA confirm that: (1) State law claims are preempted if they arise from labeling (on products manufactured, sold or distributed during the transition period) that complies with either the current version or the new version of the rule; and (2) failure to comply with the new rule is not a basis for determining that a product is not eligible for a ''healthy'' implied nutrient content claim until the final rule's compliance date. Other comments request that, should FDA give companies the choice of whether to comply with either the current version of the rule or the new version of the rule during the period between the publication of the final rule and the compliance date, FDA confirm that both versions of the rule would establish preemptive Federal ''requirements'' for the ''healthy'' nutrient content claim within the meaning of section 343–1 of the FD&C Act—such that section 343–1(a) of the FD&C Act expressly preempts State law requirements that differ from either version of the rule.

(Response 161) As discussed in Section V.J (''Effective and Compliance Dates''), manufacturers would not be required to comply with requirements of the final rule until the compliance date. Thus, once any new requirements for the definition of the nutrient content claim ''healthy'' are in effect, manufacturers could either comply with the new requirements or continue to use the original definition of ''healthy'' until the compliance date.

The express preemption provision in section 403A (21 U.S.C. 343–1) of the FD&C Act preempts State and local requirements specifically regarding food labeling claims. In FDA's view, the rule's compliance period does not create any exemption from the normal operation of preemption under section 403A of the FD&C Act or other applicable preemption principles. To the extent the theories raised in State

lawsuits regarding a failure to comply immediately with the new Federal requirements for the ''healthy'' claim depend on the contours of FD&C Act requirements, FDA does not intend to enforce against products that are in compliance with the original definition of ''healthy'' before the compliance date. We also highlight that section 745(a) of the Consolidated Appropriations Act, 2024 (Pub. L. 118–42), signed into law on March 9, 2024, states that manufacturers may continue to comply with requirements of the original definition of ''healthy'' until the compliance date of this final rule. Section 745(b) of the Consolidated Appropriations Act, 2024 states that any food manufactured and labeled as ''healthy'' before the compliance date of this final rule shall not be subject to state requirements for bearing the claim that 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 this final rule.

(Comment 162) One comment asserts that the rule would result in a significant number of labeling and product formulation changes and that it would take longer to comply than the compliance period allows. The comment suggests that, instead of finalizing the rule, FDA should ''try out the new requirements on a small scale'' such as with only one food group initially, which would take ''into account the principles of avoidance of unnecessary barriers to trade and harmonization in the Agreement on Technical Barriers to Trade.'' Another comment raises the issue of U.S. products sold in other countries and suggests that companies, consumers, and investors are helped by alignment and transparency regarding the criteria and thresholds for front-of-pack labels and claims on food products.

(Response 162) FDA has gone through an extensive and transparent rulemaking process to update the definition of the ''healthy'' claim and has established a 3-year compliance period. The comment failed to assert why additional time was needed beyond the 3 years provided in the proposed compliance date and made general, vague assertions about the difficulty of complying with the new definition. We address similar comments in section V.J (''Effective and Compliance Dates''). We do not agree that dividing the rule and only promulgating the new definition for one food group will serve the purpose of the definition of the claim and the comment did not provide any information about which food group it was proposing to begin the gradual change with, thus we have no basis on which to make such a decision to change the rule in this way. Further, we do not see how any unnecessary barriers to trade have been created with the updated rule, as the rule applies equally to foods manufactured in all parts of the world and sold in the United States and all food manufacturers have been provided 3 years to make any adjustments to their products. This is a voluntary claim, not a mandatory claim that would apply to all products. We note that our estimates (Ref. 39) indicate that only a small number of products will need to be relabeled or reformulated to comply with the new definition. Also, for products manufactured in the United States but sold abroad, we agree that alignment on labeling issues is helpful to the extent possible, but different countries have different legal structures and authorities under which to promulgate their labeling regulations, and that is no different for the area of claims than it is for any of our other labeling efforts. Whether there is a need for transparency regarding thresholds for various NTL as part of the healthy claim criteria is discussed in section V.K.2 (''Administrative Procedure Act'').

L. Miscellaneous Comments

1. Comments Regarding Infants and Children Under 2 Years of Age

(Comment 163) Comments supporting our proposal state that it would not be appropriate to allow the ''healthy'' claim on products intended for infants and children under 2 years of age because they have very specific nutritional needs in this life stage. Some comments express concern that the ''healthy'' claim could be used to market products not recommended by nutrition experts for this age group (*e.g.,* ''toddler milks'' that often contain added sugars). Another requests we limit use of the claim on products marketed to children in an age range that includes 2 years, such as 12–36 months.

Other comments disagree with our proposal to exclude use of the claim on products intended for infants and children younger than 2 years of age. Some comments suggest we use recommendations in the *Dietary Guidelines, 2020–2025* or data from the Feeding Infants and Toddler Study to develop specific requirements or a framework for the use of the claim on foods intended for infants and children under the age of two. This could include modifying the ''healthy criteria'' to reflect the amount of food and number of eating occasions in this age group, adjusting FGEs to account for the dietary patterns of children 1 to 2 and 2 to 3 years of age, and considering other age-appropriate nutritional considerations. Without doing so, a comment asserts that products intended for 2 to 3 year olds, such as pureed fruit and vegetable pouches, cannot meet the definition and other products recommended by the Dietary Guidelines, such as iron and zinc fortified infant cereal products, cannot bear the claim. The comment asserts that this could confuse parents if other fruit and vegetable products, such as canned or frozen varieties that may include added salt and sugar, are labeled ''healthy'' while baby food versions are not simply because they are marketed for infants. Additionally, some comments raise concern about unintended consequences given infants and children under two eat many of the same foods as older children and adults. For example, only skim milk bearing the ''healthy'' label when very young children require whole, full-fat milk for development or 100% fruit juice being labeled ''healthy,'' when it is not recommended for consumption in children under the age of 2. A comment also recommends that any ''healthy'' symbol clearly indicates age ranges.

(Response 163) Infants and children under the age of 2 years have specific nutrient needs, consume small amounts more frequently than do older children and adults, and the types and amounts of foods that they can consume change rapidly, particularly in the first year of life. Proper nutrition is critically important for growth and brain development in this age group. As discussed in the proposed rule (87 FR 59168 at 59181), we relied primarily on the science articulated in the *Dietary Guidelines, 2020–2025* in developing the specific criteria on which to base the definition of the ''healthy'' claim. Historically, the Dietary Guidelines have been directed to adults and children 2 years of age and older. However, the *Dietary Guidelines, 2020–2025* highlights the importance of encouraging healthy dietary patterns at every life stage and includes new recommendations for healthy dietary patterns for infants and children younger than 2 years of age in this lifespan approach. The Dietary Guidelines, *2020–2025* also notes that this is a key time for establishing healthy dietary patterns that may influence the trajectory of eating behaviors and health throughout the course of life (Ref. 1).

Infants and children younger than 2 years of age have specific nutritional

needs that apply to their particular life stages and their dietary recommendations are different from the recommendations for other age groups. In our last update to the Nutrition Facts label (81 FR 33742), we established DVs specifically for infants 7 through 12 months and children 1 through 3 years of age. The science underlying the recommended intake levels of individual nutrients demonstrates the specific nutritional needs of infants and children in this life stage. Evaluating the specific nutritional needs of this population can help us in determining whether it is appropriate to extend use of the claim ''healthy'' to foods directed at infants and children younger than 2 years of age in the future. While the comments provided helpful data and information for consideration, at this time, given our limited resources and considering the importance of ensuring that any labeling provided for this vulnerable age group is sound, we are not extending use of the ''healthy'' claim to foods marketed for consumption by infants and children younger than 2 years of age. We need additional time to consider current nutrition recommendations for children under 2 years of age as well as unique considerations for products intended for this age group as they relate to the ''healthy'' claim.

With respect to the comments expressing concerns that parents may unknowingly feed a product with a ''healthy'' claim to an infant or child under the age of two where the product is not recommended for that age group, the ''healthy'' claim is but one piece of information on the label that can be used by consumers to identify foods that contribute to a healthy dietary pattern. It does not take the place of advice from a pediatrician, or other healthcare provider, nor should it signal that the product should be consumed by all individuals, regardless of their unique health considerations.

As for the comments that express concern that products intended for children 2 through 3 years of age would not be eligible to bear the claim because the RACCs for those foods are smaller than the proposed FGEs, as discussed in Response 9, individual foods and mixed products comprised of one or more foods encouraged by the Dietary Guidelines with no added ingredients, except for water, automatically qualify to bear the claim. Therefore, products intended for children 2 to 3 years of age, such as fruit and vegetable puree pouches, with no other ingredients added other than water, would be eligible to bear the claim.

2. Comments Regarding Coordination With Other Nutrition Initiatives

(Comment 164) Some comments recommend that the ''healthy'' definition and healthy symbol align and work together and that FDA share consumer research data they have collected so that companies can make the best use of the ''healthy'' claim and symbol. The comments encourage FDA to complete research and consumer testing on ''healthy'' symbols and state that the release of this final rule should include the symbol. Some comments request clarity regarding the regulatory relationship between the ''healthy'' definition and the development of front-of-package (FOP) labeling and request that research related to this endeavor be shared.

(Response 164) The healthy symbol is intended to represent the nutrient content claim ''healthy.'' While these initiatives related to ''healthy'' are related, they are on separate tracks, and therefore, we disagree the ''healthy'' claim final rule should include the symbol. FDA is continuing research into and consideration of the ''healthy'' symbol, and this work should not hold up the implementation of the ''healthy'' final rule and its associated benefits given that the current definition is not consistent with current nutrition science and Federal dietary guidelines.

FDA's work on front-of-package (FOP) nutrition labeling is a separate initiative and is intended to complement the Nutrition Facts label that is required on food packages by displaying simplified, at-a-glance nutrition information that gives consumers additional context to help them quickly and easily make more informed food selections. We have announced our intent to publish a proposed rule on this topic. Additional information about our FOP research may be found on FDA's website (*https://www.fda.gov/food/food-labeling-nutrition/front-package-nutrition-labeling*) and will be shared as part of that rulemaking.

3. Comments Regarding Coordination With USDA

(Comment 165) The comments express concerns that given that meat and poultry were not included as protein foods under FDA's proposed ''healthy'' definition, and FSIS has not yet proposed a similar definition that looks at food groups such as meat and poultry, it is unclear how to assess FSIS-regulated products under FDA's proposed framework. The comments state that this makes it challenging for companies to assess the impact of the proposed rule across their entire product portfolios, particularly where the term ''healthy'' is used in a brand name across a portfolio, and to provide comments on how this framework would impact all foods. The comments explain that there is considerable uncertainty as to whether FSIS will update its ''healthy'' rule, whether there will be a significant delay in any such update, and whether FSIS will take a similar approach to that of FDA, for example, because FDA has not addressed meat and poultry products, it is not clear if a chicken noodle soup that contains ½ FGE protein (*i.e.,* chicken) and ½ FGE vegetables (*i.e.,* the food group requirements for a mixed product), and otherwise satisfies the NTL criteria, would qualify for the claim. The comments assert that this example underscores that close coordination between the Agencies responsible for the regulation of food labeling in the United States is needed for cohesive and consistent implementation of the rule and request that, before finalizing the rule, FDA seek input from FSIS on when FSIS plans to update its ''healthy'' definition and what approach will be used, to ensure that the approach specifically would work equally for FDA-regulated and FSIS-regulated products.

One comment encourages FDA to engage with FSIS to ensure that the FDA healthy criteria can be voluntarily applied to products under FSIS's authority if a food company wants to use the claim. The comments also ask FDA to encourage USDA to provide enforcement discretion for products that would qualify for the FDA's updated definition to bear a ''healthy'' claim, assuming that meat or poultry would be considered part of the protein foods group, as is the case under the Dietary Guidelines. One comment notes the ambiguity in determination/calculation of FGE of certain dairy foods such as yogurt and suggests that to remediate this problem, FDA should maintain and publish a compendium or database for manufacturers to use in calculating the amount of FGEs delivered by each food. The comment suggests this should be done in coordination with USDA—who maintains such information for the purpose of dietary monitoring programs via the FPED. One comment asserts that the changes in the rule would likely lead to change to the USDA meal patterns in the National School Lunch and School Breakfast Programs and stated that transition time for implementation to address such changes would be helpful.

(Response 165) FDA consulted with USDA and other Federal Agencies to ensure we appropriately considered the

policies established by those Agencies when updating the ''healthy'' nutrient content claim. While we have different regulatory frameworks and authorities, FDA and USDA routinely collaborate on issues, including those related to food labeling and the healthy claim.

4. Comments Regarding Consumer Education

(Comment 166) Some comments recommend, given that ''healthy'' is a voluntary nutrient content claim, that the use of the claim be accompanied by efforts that help consumers make informed food choices. The comments recommend that the ''healthy'' rule provide additional opportunities for meaningful nutrition education and improved consumer understanding of healthy dietary patterns, asserting that as proposed, the rule does not afford consumers any additional context on how the ''healthfulness'' of a food is determined. One comment says FDA should allow for or require additional labeling to facilitate consumer education on the meaning of ''healthy'' when it is used as a nutrient content claim and state one such example could be the labeling scheme identified by USDA MyPlate, which requires the additional quantitative declaration of the amount of FGEs afforded by a food for consumer education (*e.g.,* ''this product provides ¾ cup dairy equivalent. According to the DGA, 3 cup equivalents are recommended per day'') in order to use the MyPlate logo on foods. The comments claim that a greater public understanding of the criteria on which a ''healthy'' food is determined would further contribute to a reduction in chronic disease and support health equity, more specifically, consumers would have a basis for structuring all decisions in the context of their daily food group requirements. Some comments recommend that culturally appropriate resources on the food labeling update be disseminated to Native Americans, Alaskan Natives, and Native Hawaiian communities upon issuing the rule.

(Response 166) We agree that consumer education about nutrition and healthy dietary practices would likely benefit a number of consumers in the United States and that consumer education will be an important tool for implementing the updated ''healthy'' claim and for maximizing the effectiveness of the ''healthy'' claim to help consumers identify foods that can be the foundation for a healthy dietary pattern. We are committed to helping increase understanding and use of the updated ''healthy'' claim to improve healthy dietary patterns through consumer education, in collaboration with key Federal partners, as well as with industry partners. Broadly, aspects of those education and outreach activities may include how the presence of the claim is important to consider when constructing a healthy dietary pattern making clear that foods labeled as ''healthy'' are foundational foods in a healthy dietary pattern and that the claim does not imply that all other foods are considered unhealthy and the importance of choosing a variety of nutrient-dense foods and beverages across all food groups, in recommended amounts, while staying within calorie limits, to build a healthy dietary pattern consistent with the Dietary Guidelines.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866, section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is a significant regulatory action under Executive Order 12866, section 3(f)(1).

Because this rule is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule falls within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that the economic impact of this final rule will not exceed 3 percent of annual revenue, we certify that this rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule will result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

Some consumers use nutrient content claims such as ''healthy'' to inform their food purchases. Based on a 2019 meta-analysis on the effects of food labeling, we estimate that a small number of these consumers (0 to 0.4% of people that try to follow current dietary guidelines) would use the ''healthy'' implied nutrient content claim to make meaningful, long-lasting food purchasing decisions (Ref. 45). If the foods bearing the ''healthy'' claim more closely align with Federal dietary guidance, the claim can help consumers who are selecting those products in choosing a more healthful diet, which may result in lower chronic, diet-related diseases, including cardiovascular disease and type 2 diabetes. Quantifiable benefits of the final rule are the estimated reduction over time in all-cause mortality stemming from consumers selecting and consuming more healthful foods. This is calculated through the negative association between a Healthy Eating Index score and all-cause mortality. The estimated benefits account for expected uncertainty and variability in consumer use of the ''healthy'' nutrient content claim and its long-term health impact. Discounted at 3 percent over 20 years, the mean present value of benefits accrued to consumers using the ''healthy'' nutrient content claim is $686 million, with a lower bound estimate of $21 million and an upper bound estimate of $1.9 billion. Discounted at 7 percent over 20 years, the mean present value of benefits of the final rule is $438 million, with a lower bound estimate of

$14 million and an upper bound estimate of $1.2 billion.

Quantified costs to manufacturers associated with updating the ''healthy'' claim are labeling, reformulating, and recordkeeping. Overall, about 27,000 UPCs, or 10 percent of total UPCs, qualify for the original ''healthy'' implied nutrient content claim but only 5 percent (12,500 UPCs) choose to label. The use of the ''healthy'' nutrient content claim is voluntary, but if the final rule results in some products needing to remove the claim to avoid being misbranded, manufacturers would incur costs due to the rule. Manufacturers with food products currently using the ''healthy'' claim would need to confirm whether the products meet the proposed criteria and decide whether a label change is needed.

Manufacturers with products that currently do not meet the ''healthy'' criteria but do meet the final rule's criteria have the option of labeling these products. In some cases, manufacturers may choose to reformulate a product so that it meets the final rule's criteria. Some recordkeeping is required for certain products using the ''healthy'' claim and the required food components equivalents are likely to increase time spent on recordkeeping. It is possible that manufacturers of products that include the term ''healthy'' within the brand name may choose to rebrand products instead of reformulating. We lack the data to quantify this effect but discuss it qualitatively. The estimated costs account for expected uncertainty and variability in industry use of the ''healthy'' nutrient content claim and industry response to the final rule, including potential reformulation. Discounted at 3 percent over 20 years, the mean present value of costs accrued to manufacturers using the ''healthy'' nutrient content claim, assuming the current 5 percent adoption rate, is $403 million, with a lower bound of $188 million and an upper bound of $737 million. Discounted at 7 percent over 20 years, the mean present value of costs of the proposed rule is $346 million, with a lower bound of $161 million and an upper bound of $633 million.

Table 2.--Summary of Benefits, Costs, and Distributional Effects of the Final Rule, millions of 2023$

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$41.3	$1.29	$114.5	2023	7%	20	Monetized benefits account for consumer's lost pleasure from eating less healthy foods they may nevertheless prefer.
		$46.1	$1.44	$127.6	2023	3%	20	
	Annualized Quantified					7%		
						3%		
	Qualitative	To the extent consumers use the "healthy" nutrient content claim to maintain healthy dietary practices, following a healthy diet could reduce the risk of morbidity and prolong life.						
Costs	Annualized Monetized ($m/year)	$32.6	$15.2	$59.7	2023	7%	20	
		$27.1	$12.6	$49.6	2023	3%	20	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
	Other Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
Effects	State, Local or Tribal Government: None Distributional: American Indian, Alaskan Native, Hispanic, and Non-Hispanic Black adults and children, as well as the lower-income or publicly insured may accrue a larger proportion of the estimated health benefits. However, this distributional shift may be reduced if these populations do not use, or do not have access to, products that bear the "healthy" nutrient content claim to meaningfully change their diet. Finally, any distributional shift may be dampened if costs are passed onto consumers in the form of increased prices of foods labeled as "healthy." Small Business: Potential impacts on small manufacturers of packaged food and beverages due to removing the "healthy" claim or reformulating some products. Wages: None							

We have developed an Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 39) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

The final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual recordkeeping and third-party disclosure burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Labeling Regulations, OMB Control Number 0910–0381—Revision.

Description of Respondents: The respondents to this information collection are manufacturers of food products using the ''healthy'' implied nutrient content claim marketed in the United States. Respondents are from the private sector (for-profit businesses).

Description: The final rule amends § 101.65(d) to require manufacturers using the ''healthy'' implied nutrient content claim on their products to make and keep written records to verify that the products comply with this requirement. Examples of these records include analyses of databases, recipes, formulations, information from recipes

or formulations, or batch records. Manufacturers must provide these records upon request from FDA during an inspection for official review and photocopying or other means of reproduction.

The final rule also requires some manufacturers to relabel products to comply with the criteria for the ''healthy'' implied nutrient content claim. A product that does not meet the criteria will need to remove the claim from its label, and a product that becomes eligible will be permitted to use the claim on its label.

We estimate the recordkeeping burden of this collection of information as follows:

Table 3.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
101.65; recordkeeping to verify "healthy" nutrient content claim	1,900	1	1,900	0.5 (30 minutes)	950

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The final rule requires that each manufacturer of a food that bears the implied nutrient content claim ''healthy'' must create and maintain written records to verify that the food meets the FGE requirements when it is not apparent from the label of the food. Examples of records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. However, the product label (including the Nutrition Facts label, the ingredient list, the statement of identity, and any other information) may be used to verify compliance with the food group requirements for certain foods. For example, it would be apparent from the ingredient list of an oil product whether the product contains 100% oil. Similarly, it would likely be ascertainable from the ingredient list of a frozen spinach product that contains only spinach and salt whether the product contains enough spinach (vegetables) to bear the ''healthy'' claim. Thus, this recordkeeping estimate does not include food groups where the equivalent requirements are apparent from the label of the food. These estimates are based on the analysis in Table 12 of the Final Regulatory Impact Analysis (FRIA) (Ref. 39). Table 12 of the FRIA estimates that 5,702 products will need recordkeeping, which equals about 1,900 products annually over a 3-year period (5,702 ÷ 3). We estimate that each year approximately 1,900 manufacturers will each create and maintain 1 written record for a total of 1,900 records. We estimate that each record will require 15 to 30 minutes of recordkeeping for an annual recordkeeping burden of 950 hours (1,900 records × 0.5 hour).

Table 4.--Estimated One-Time Relabeling Burden[1]

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs[2]
Relabel for "healthy" claim	7,109	1	7,109	1	7,109	$19,750,964

[1] One-time labeling burden.

[2] There are no operating and maintenance costs associated with this collection of information.

We assume there are two categories of UPCs that could require re-labeling. First, if a UPC currently labeled ''healthy'' does not meet the required criteria, the manufacturer could choose to remove the ''healthy'' claim or reformulate. In either case, the label would need to change, either to remove the ''healthy'' claim or to change the NFL after reformulation. Given the current UPCs labeled ''healthy'' that do not meet the required criteria, we estimate the number of UPCs that would remove the ''healthy'' claim or reformulate. Second, if a UPC not labeled ''healthy'' now meets the required criteria, the manufacturer could choose to add the ''healthy'' claim. Table 8 of the FRIA estimates the need for 21,328 total label changes, which would be about 7,109 label changes annually over a 3-year period. Because this claim is voluntary, we do not know how many establishments will make labeling changes. For the purpose of this analysis, we assume that the number of respondents is the same as the number of disclosures. Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 7,109 hours.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides, with minor exceptions,

that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce with respect to any requirement for nutrition labeling of food that is not identical to requirements established under section 403(r) of the FD&C Act.

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Public Law 101–535 (1990)); however, it is possible that such a requirement could be preempted on another basis, such as under principles of implied preemption. This final rule creates requirements that fall within the scope of section 403A(a) of the FD&C Act.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 101.13, revise paragraph (b)(2)(ii) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) * * *

(2) * * *

(ii) Suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, where there is also implied or explicit information about the nutrition content of the food (*e.g.,* ''healthy'').

* * * * *

■ 3. In § 101.65, revise paragraphs (a)(2) and (d) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

(a) * * *

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13, with the exception of § 101.13(h) when the nutrient content claim is made in accordance with paragraph (d) of this section; and

* * * * *

(d) *General nutritional claims.* (1) This paragraph covers labeling claims that are implied nutrient content claims because they suggest that a food may help consumers maintain healthy dietary practices due to its nutrient content, where there is also implied or explicit information about the nutrition content of the food.

(2) For purposes of this section, a ''food group equivalent'' identifies qualifying amounts of foods from each food group based on nutritional content. A food group equivalent is equal to the following:

TABLE 1 TO PARAGRAPH (d)(2)

Food group	Food group equivalent	Examples
(i) Vegetable	1/2 cup equivalent vegetable	1/2 cup cooked green beans; 1 cup raw spinach
(ii) Fruit	1/2 cup equivalent fruit	1/2 cup strawberries; ½ cup 100% orange juice; ¼ cup raisins
(iii) Grains	3/4 oz equivalent whole grain	1 slice of bread; ½ cup cooked brown rice
(iv) Dairy	2/3 cup equivalent dairy	2/3 cup fat free milk; 1 oz nonfat cheese
(v) Protein foods	1½ oz equivalent game meat	1½ oz venison
	1 oz equivalent seafood	1 oz tuna
	1 oz equivalent egg	1 large egg
	1 oz equivalent beans, peas, or lentils	1/4 cup black beans
	1 oz equivalent nuts, seeds, or soy products	1/2 oz walnuts

(3) You may use the term ''healthy'' or derivative terms ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'' as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if the food meets the criteria of one or more of the following paragraphs (d)(3)(i) through (vi) of this section as follows:

(i) 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:

(A) Vegetable;

(B) Fruit;

(C) Whole grains;

(D) Fat-free or low-fat dairy;

(E) Lean meat, seafood, eggs, beans, peas, lentils, nuts, or seeds.

(ii) Individual foods.

(A) An individual food that has a reference amount customarily consumed (RACC) greater than 50 g or greater than 3 tablespoons and meets the conditions per RACC in table 2 of this section; or

TABLE 2 TO PARAGRAPH (d)(3)(ii)(A)

If the food is . . .		It must contain at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	The saturated fat content must be no greater than . . .
Main category	Sub-category (if applicable)				
(*1*) A vegetable product.	.....	1/2 cup equivalent vegetable.	2% DV	10% DV	5% DV.
(*2*) A fruit product	.....	1/2 cup equivalent fruit.	2% DV	10% DV	5% DV.
(*3*) A grain product	.....	3/4 oz equivalent whole grain.	10% DV	10% DV	5% DV.
(*4*) A dairy product	.....	2/3 cup equivalent dairy.	5% DV	10% DV	10% DV.
(*5*) Protein Foods	*(i)* Game meats	1½ oz equivalent	2% DV	10% DV	10% DV.
	(ii) Seafood	1 oz equivalent	2% DV	10% DV	5% DV, excluding saturated fat inherent in seafood.
	(iii) Egg	1 oz equivalent	2% DV	10% DV	10% DV.
	(iv) Beans, peas, and lentils.	1 oz equivalent	2% DV	10% DV	5% DV.
	(v) Nuts, seeds, and soy products.	1 oz equivalent	2% DV	10% DV	5% DV, excluding saturated fat inherent in nuts, seeds, and soybeans.
(*6*) Oils	*(i)* 100% Oil	.....	0% DV	0% DV	20% of total fat.
	(ii) Oil-based spreads whose fats come solely from oil.	.....	0% DV	10% DV	20% of total fat.
	(iii) Oil-based dressing containing at least 30% oil and oils meet the requirements in paragraph (d)(3)(ii)(A) or (B)(6)(*i*) of this section.	.....	2% DV	10% DV	20% of total fat.

(B) An individual food that has a RACC of 50 g or less or 3 tablespoons or less and meets the conditions per 50 g of food in table 3 of this section:

TABLE 3 TO PARAGRAPH (d)(3)(ii)(B)

If the food is . . .		It must contain at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	The saturated fat content must be no greater than . . .
Main category	Sub-category (if applicable)				
(*1*) A vegetable product.	.....	1/2 cup equivalent vegetable.	2% DV	10% DV	5% DV.
(*2*) A fruit product	.....	1/2 cup equivalent fruit.	2% DV	10% DV	5% DV.
(*3*) A grain product	.....	3/4 oz equivalent whole grain.	10% DV	10% DV	5% DV.
(*4*) A dairy product	.....	2/3 cup equivalent dairy.	5% DV	10% DV	10% DV.
(*5*) Protein Foods	*(i)* Game meats	1½ oz equivalent	2% DV	10% DV	10% DV.
	(ii) Seafood	1 oz equivalent	2% DV	10% DV	5% DV, excluding saturated fat inherent in seafood.
	(iii) Egg	1 oz equivalent	2% DV	10% DV	10% DV.
	(iv) Beans, peas, and lentils.	1 oz equivalent	2% DV	10% DV	5% DV.
	(v) Nuts, seeds, and soy products.	1 oz equivalent	2% DV	10% DV	5% DV, excluding saturated fat inherent in nuts, seeds, and soybeans.
(*6*) Oils	*(i)* 100% Oil	.....	0% DV	0% DV	20% of total fat.
	(ii) Oil-based spreads whose fats come solely from oil.	.....	0% DV	10% DV	20% of total fat.
	(iii) Oil-based dressing containing at least 30% oil and oils meet the requirements in paragraph (d)(3)(ii)(A) or (B)(6)(*i*) of this section.	.....	2% DV	10% DV	20% of total fat.

(iii) A mixed product that meets the following conditions per RACC:

TABLE 4 TO PARAGRAPHS (d)(3)(iii)

If the mixed product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than . . .
One total food group equivalent with no less than ¼ food group equivalent from at least two food groups, as specified in paragraph (d)(2) of this section.	10% DV	15% DV	10% DV.

(iv) A main dish product as defined in § 101.13(m) that meets the following conditions per labeled serving:

TABLE 5 TO PARAGRAPH (d)(3)(iv)

If the main dish product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than . . .
Two total food group equivalents with no less than ½ food group equivalent from at least two food groups, as specified in paragraph (d)(2) of this section.	15% DV	20% DV	15% DV.

(v) A meal product as defined in § 101.13(l) that meets the following conditions per labeled serving:

TABLE 6 TO PARAGRAPH (d)(3)(v)

If the meal product contains at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	Excluding the saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable), the saturated fat content must be no greater than . . .
Three total food group equivalents with no less than ½ food group equivalent from at least three food groups, as specified in paragraph (d)(2) of this section.	20% DV	30% DV	20% DV.

(vi) All water, tea, and coffee with less than 5 calories per RACC and per labeled serving.

(4) Each manufacturer of a food (other than foods where the standard information required on the food label, such as the list of ingredients, provides sufficient information to verify that the food meets the food group equivalent requirements to bear the claim, and foods described in paragraphs (d)(3)(i) and (vi) of this section) 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, or batch records) to verify that the food meets the food group equivalent requirements of paragraph (d)(2) of this section. These records must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction. Records may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records that must be kept in accordance with part 11 of this chapter. These records must be accurate, indelible, and legible.

Dated: December 12, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

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