

Questions and Answers About Dietary Guidance Statements in Food Labeling: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1450.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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Dietary Guidance Statements in Food Labeling: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

This guidance provides questions and answers on the use of Dietary Guidance Statements on packaged food labels or in the labeling of conventional foods. It is intended to provide our current thinking on the use of Dietary Guidance Statements (i.e., statements relating a food or food group to a nutritious dietary pattern² defined in greater detail below in Q&A III.1) on packaged food labels and more broadly in the labeling of foods, including any written, printed, or graphic material accompanying a food, such as labeling on websites.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

FDA seeks to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity. We are committed to accomplishing this by promoting healthy starts through improved maternal, infant, and child health, creating a healthier food supply for all, and empowering consumers with more informative and accessible labeling to choose healthier diets. One key component of this work focuses on claims and nutrition-related statements, such as Dietary Guidance Statements, on food

¹ This draft guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² The *Dietary Guidelines for Americans*, 2020-2025 refer to "healthy dietary patterns," however in our discussion of the use of Dietary Guidance Statements in this document we refer to "nutritious dietary patterns" so as not to cause confusion with the "healthy" nutrient content claim, which has specific regulatory criteria for its use (see Q&A III.9).

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labeling. Claims and Dietary Guidance Statements act as quick signals on the front of packages to help consumers, particularly consumers with lower nutrition or healthy literacy, better understand nutrition information. They also can encourage industry to reformulate products to create healthier products that consumers seek.

Typically, labeling claims have focused on specific nutrients and nutrient-disease relationships. However, scientific knowledge and evidence in the field of nutrition has advanced, and dietary recommendations have evolved from those based on specific nutrient-disease relationships to those that take into account the entirety of the diet. Current nutrition recommendations focus on the importance of healthy dietary patterns as a whole, and how foods and beverages act synergistically to affect health (Ref. 1). One way in which we are modernizing our approach to food labeling is by providing guidance and regulations (e.g., the proposed rule titled, *Food Labeling: Nutrient Content Claims; Definition of the Term “Healthy”* (87 FR 59168)) that help facilitate the use of more claims and nutrition-related statements in food labeling that focus on providing more information to consumers about healthy dietary patterns. The use of Dietary Guidance Statements (e.g., fruits and vegetables are part of a nutritious dietary pattern) in food labeling is one such tool to provide consumers with information to further this understanding.

FDA has a broad mandate for nutrition labeling that includes the provision of regulations and policy for the use of voluntary labeling claims. We have regulatory requirements for the use of certain nutrient content claims, such as “healthy,” which are claims that expressly or implicitly characterize the level of a nutrient in a food (21 CFR 101.13(b)). Dietary Guidance Statements are not nutrient content claims, instead they 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 (see Section III.1 below for definition). Dietary Guidance Statements provide manufacturers with a broad range of messages beyond characterizing the nutrient content of the food (compared with nutrient content claims) and communicate to consumers that a food or food group may contribute to or help maintain a nutritious dietary pattern. This guidance provides industry with our current thinking on the appropriate use of Dietary Guidance Statements in food labeling.

On July 26, 2018, we held a public meeting where we sought input on key elements of the agency’s Nutrition Innovation Strategy. Among other things, we sought input on: (1) what types of claims or other nutrition-related labeling statements are most helpful in facilitating product innovation to promote healthful eating patterns; and (2) what types of claims and other labeling statements are most helpful to consumers in selecting foods consistent with recommendations in the Dietary Guidelines for Americans (Dietary Guidelines). The comments we received during the public meeting and to the public meeting docket (docket number FDA-2018-N-2381) from a variety of stakeholders, including industry, consumers, trade associations, and consumer groups demonstrated that there is a clear interest in labeling claims, statements, symbols, and vignettes that will allow consumers to determine how foods and food groups can contribute to nutritious dietary patterns.

This draft guidance provides recommendations on how and when manufacturers should use key or principal recommendations from consensus reports, such as the Dietary Guidelines, as the basis for labeling statements that represent or suggest that an individual food or food group may

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contribute to or help maintain nutritious dietary patterns. We consider these types of labeling statements to be “Dietary Guidance Statements.” In this draft guidance, we define Dietary Guidance Statements and provide information to help industry determine ways to use Dietary Guidance Statements in labeling to make consumers aware of how their product contributes to a nutritious dietary pattern. In addition, we provide recommendations for the source of the Dietary Guidance Statement, recommendations for the amount of the food or food group that is the subject of the statement that a product should contain if it bears a Dietary Guidance Statement (e.g., “food group equivalent”), and recommendations for the amount of sodium, saturated fat, and added sugars that a product should not exceed if it bears a Dietary Guidance Statement. These recommendations are based upon current nutrition science and dietary recommendations, such as the *Dietary Guidelines, 2020-2025* (Ref. 1).

The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) jointly publish the Dietary Guidelines every 5 years. When developing the Dietary Guidelines, HHS and USDA are informed by the science-based recommendations of a panel of experts called the Dietary Guidelines Advisory Committee. The Dietary Guidelines is based on the preponderance of current scientific and medical knowledge, and it provides federal recommendations for healthy dietary patterns for Americans. They serve as the foundation for federal nutrition policy. Although the Dietary Guidelines is issued every 5 years, the objectives of the majority of the recommendations, such as limiting intake of saturated fat, sodium, and sugars, and consuming foods with adequate amounts of fiber, have remained consistent since the first edition was released in 1980 (Ref. 2).

The *Dietary Guidelines, 2020-2025* includes recommended amounts of food from food groups found in three different healthy dietary patterns: the Healthy U.S.-Style Dietary Pattern, the Healthy Mediterranean-Style Dietary Pattern, and the Healthy Vegetarian Dietary Pattern. All three nutritious dietary patterns provide intake recommendations for the following food groups: vegetables, fruits, grains, dairy, protein foods, as well as oils³ (Ref. 1). We used information from the Healthy U.S.- Style Dietary Pattern to develop recommendations for food group equivalents for products bearing a Dietary Guidance Statement because this dietary pattern provides federal recommendations for the amounts of foods that most children and adults in the U.S. population 2 years of age and older should consume in order to meet nutritional needs. While the *Dietary Guidelines, 2020-2025* provides recommendations for infants and children under the age of 2 years, for the purposes of this guidance document, we are providing recommendations for the use of Dietary Guidance Statements for individuals aged 2 and older. We also based our recommendations for the amount of sodium, saturated fat, and added sugars that a product should not exceed if it bears a Dietary Guidance Statement on key recommendations from the *Dietary Guidelines, 2020-2025* for individuals aged 2 and older.

On November 25, 2003, we published an Advance Notice of Proposed Rulemaking (ANPRM) in the *Federal Register* (68 FR 66040) that requested comment on, among other things, the use of Dietary Guidance Statements. We received 18 comments from industry, trade associations, health professional organizations, consumer groups, and a Federal government agency. Nutrition science has evolved as has our thinking on Dietary Guidance Statements since we issued the

³ The *Dietary Guidelines, 2020-2025* do not refer to oils as a “food group,” but they emphasize oils as part of a healthy dietary pattern. For the purposes of this guidance, we refer to oils as a food group.

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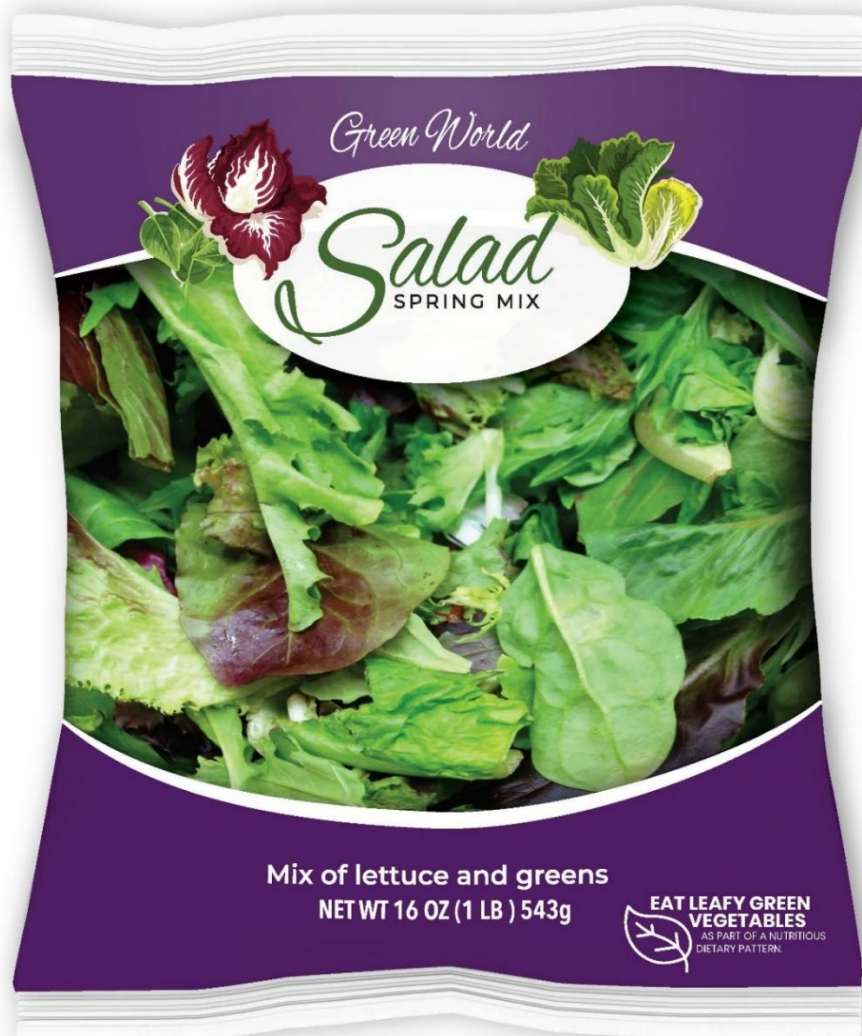
ANPRM, so some comments we received on Dietary Guidance Statements are not relevant to the draft guidance. We have taken relevant comments to the ANPRM, as well as comments we received during and after the public meeting, into consideration when developing this draft guidance.

III. Definitions

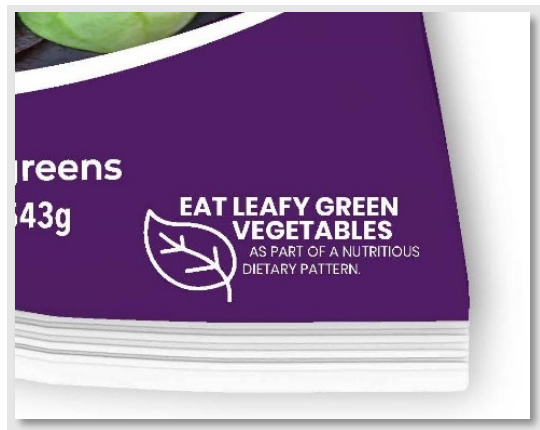
1. What is a “Dietary Guidance Statement”?

For the purposes of this guidance, Dietary Guidance Statements are written or graphic material, based on key or principal recommendations from a consensus report, in food labeling that represent or suggest that a food or a food group may contribute to or help maintain a nutritious dietary pattern (e.g., “make half your grains whole”; “choose fat-free or low-fat dairy products instead of full-fat dairy options”; or “the Dietary Guidelines for Americans recommends eating fruits and vegetables as part of a balanced diet. This food has ½ cup of broccoli per serving.”). A Dietary Guidance Statement is not a nutrient content claim. We include several examples of Dietary Guidance Statements throughout this guidance and in Appendix 1.

Figure 1. Examples of Dietary Guidance Statements in Food Labeling



Close-up of Dietary Guidance Statement:





Close-up of Dietary Guidance Statement:



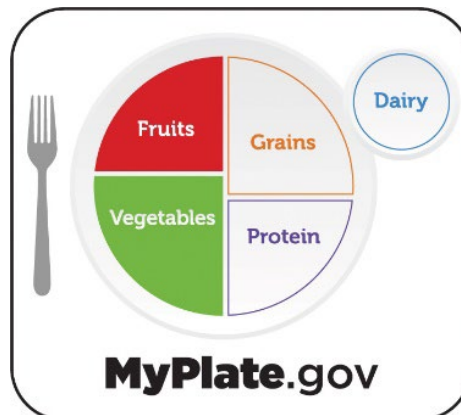
2. May a symbol or vignette be a Dietary Guidance Statement?

Yes. A Dietary Guidance Statement in food labeling may be graphic material, including symbols or vignettes, that convey to consumers that a food or a food group may contribute to or help maintain a nutritious dietary pattern. For example, a symbol showing a 1/2 cup measure with vegetables in it accompanied by a statement that says, “Vegetables are part of a nutritious dietary pattern” may suggest that the food product contains 1/2 cup vegetables, which contribute to or helps maintain a nutritious dietary pattern.

Figure 2: Examples of a Symbols/Vignettes on a Food Label that Would be Considered a Dietary Guidance Statement



Close-up of Dietary Guidance Statement:



3. What is a “Food Group”?

A “food group” is a group of foods recommended for consumption by a consensus report (see section V). For example, the *Dietary Guidelines, 2020-2025* explains that a healthy dietary pattern includes foods from the following food groups (Ref. 1):

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

4. What is an “Individual Food”?

An individual food is a food that is comprised entirely, or almost entirely, of one food group (e.g., milk or a package of frozen mixed vegetables). In cases where the food is comprised of more than one food group and one food group predominates (e.g., oatmeal with a very small amount of raisins added), it is also considered an individual food.

5. What is a “Main Dish Product”?

Main dish products, defined at 21 CFR § 101.13(m),⁴ are larger in size (weighing at least 6 ounces (oz) per labeled serving) than individual foods and are intended to make a major contribution to 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.

⁴ Our regulations at 21 CFR § 101.13(m) define a “main dish product” for the purposes of making a claim as a food that: (1) makes a major contribution to a meal by (i) weighing at least 6 ounces per labeled serving; and (ii) contains not less than 40 grams of food, or combinations of foods, from each of at least two of the following four food groups, except as noted in § 101.13(m)(1)(ii)(E): (A) bread, cereal, rice, and pasta group; (B) fruits and vegetables group; (C) milk, yogurt, and cheese group; (D) meat, poultry, fish, dry beans, eggs, and nuts groups; except that: (E) these foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and (2) is represented as, or is in a form commonly understood to be a main dish (e.g., not a beverage or dessert). Such representations may be made either by statements, photographs, or vignettes.

6. What is a “Meal Product”?

Meal products, defined at 21 CFR § 101.13(l)⁵, are larger in size (weighing at least 10 oz per labeled serving) than main dish products and are intended to provide all of the food for a single eating occasion (i.e., a full meal). An example of a meal product is a frozen dinner.

7. What is the Difference Between Dietary Guidance Statements and Health Claims?

Health claims describe a relationship between a food substance and reduced risk of a disease or health-related condition. Dietary Guidance Statements differ from health claims because they do not contain both basic elements of a health claim: (1) substance; and (2) disease or health-related condition (21 CFR § 101.14(a)(1)). Dietary Guidance Statements also do not describe a relationship between the consumption of a food and a reduced risk of a disease or health-related condition.

Table 1.—Health Claim versus Dietary Guidance Statement Comparison

Health Claim	Dietary Guidance Statement
Basic elements 1. Substance- a specific food or component of food, regardless of whether the food is in conventional food form or dietary supplement that includes vitamins, minerals, herbs, or other similar nutritional substances. 2. Disease or health-related condition	Basic elements 1. A food or food group 2. Contributing to or maintaining a nutritious dietary pattern.
Focus: Disease risk reduction	Focus: Contributing to or maintaining nutritious dietary patterns
Truthful and not misleading	Truthful and not misleading
Generally undergoes review by FDA through a petition process ⁶	Does not undergo review by FDA prior to use in the marketplace
Example: “Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.”	Example: “Eat broccoli as part of a nutritious dietary pattern.”

⁵ Our regulations at 21 CFR § 101.13(l) define meal products for the purposes of making a claim to be food that: (1) makes a major contribution to the total diet by: (i) weighing at least 10 ounces (oz) per labeled serving; and (ii) contains not less than three 40 gram portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section. (A) bread, cereal, rice, and pasta group; (B) fruits and vegetables group; (C) milk, yogurt, and cheese group; (D) meat, poultry fish, dry beans, eggs, and nuts group; except that; (E) these foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and (2) is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, or meal. Such representations may be made either by statements, photographs, or vignettes.

⁶ See 21 U.S.C. 343(r) and 21 CFR § 101.14. For health claims based on an authoritative statement by a U.S. government scientific body, notification is required in accordance with 21 U.S.C. 343(r)(3)(C).

8. What is the Difference Between Dietary Guidance Statements and Nutrient Content Claims?

Dietary Guidance Statements are labeling statements that represent or suggest that an individual food or food group may contribute to or help maintain a nutritious dietary pattern. In contrast, nutrient content claims expressly or implicitly characterize the level of a nutrient in a food (21 CFR § 101.13(b)). For example, a claim that a food is “low” in fat content or “high” in Vitamin D content is considered a nutrient content claim. The term “healthy” is also considered to be an implied nutrient content claim. Therefore, Dietary Guidance Statements provide manufacturers with a broader range of messages to communicate to consumers that a food or food group may contribute to or help maintain a nutritious dietary pattern.

9. What is the Difference Between Dietary Guidance Statements and the Implied Nutrient Content Claim “Healthy”?

“Healthy” is an implied nutrient content claim in certain situations because it characterizes the level of nutrients in that food. “Healthy” suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices. The implied nutrient content claim “healthy” is narrow in scope and only applies to certain uses of the specific term “healthy” and related terms (“health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” and “healthiness”). Therefore, when the word “healthy” or a related term is used in the labeling of a food in connection with an explicit or implicit claim or statement about a nutrient, the product must meet the requirements for the use of the “healthy” nutrient content claim under 21 CFR § 101.65(d).⁷ In contrast, Dietary Guidance Statements do not characterize the nutrient content of a food and, instead, provide manufacturers with a broader range of messages to communicate to consumers how the product contributes to or helps maintain a nutritious dietary pattern.

There are some foods (e.g., whole fruits and vegetables) that may be eligible to bear both the “healthy” implied nutrient content claim and also include a Dietary Guidance Statement in the product labeling. Manufacturers could choose to use the “healthy” claim because of the foods’ nutrient profile or they may choose to use a Dietary Guidance Statement to convey to consumers that the product fits into a nutritious dietary pattern based on current recommendations. There are other foods (e.g., certain whole grain snacks and flavored yogurt) that may be eligible to include a Dietary Guidance Statement in the product labeling, but not the “healthy” implied nutrient content claim. Both types of labeling can assist consumers with making healthful dietary choices.

⁷ FDA is in the process of updating the definition for the implied nutrient content claim “healthy.” On September 29, 2022, we published a proposed rule titled the “Definition of Term “Healthy” (87 FR 59168).

IV. Recommendations for How to Use Dietary Guidance Statements in Food Labeling

1. What Are Some Ways for Manufacturers to Use Dietary Guidance Statements in Food Labeling to Convey Healthful Attributes of Their Product?

Manufacturers are encouraged to convey healthful attributes of their products to consumers by using Dietary Guidance Statements directly on packaged food labels or in other food labeling. For example, manufacturers may want to use Dietary Guidance Statements in written, printed, or graphic materials that accompany a food (e.g., on a company website or in brochures that accompany the food product).

2. Should Dietary Guidance Statements be Made on Dietary Supplements?

No. Current consensus report recommendations, including the Dietary Guidelines, encourage Americans to meet nutrient requirements through the consumption of whole foods (e.g., whole fruits and vegetables). Therefore, manufacturers should not use Dietary Guidance Statements on products labeled as or purporting to be dietary supplements.

3. Should Dietary Guidance Statements be Made on Foods Represented or Purported to be for Infants and Children Under 2 Years of Age?

While the *Dietary Guidelines, 2020-2025* and other sources provide recommendations for infants and children under the age of 2 years, we are only providing recommendations for the use of Dietary Guidance Statements for individuals aged 2 and older at this time. Infants and children younger than 2 years of age have different nutritional needs that apply to their particular life stages. Furthermore, the recommendations in current consensus reports for amounts of foods to consume and limits on certain nutrients (e.g., added sugars) are very different for children under the age of two than they are for the general U.S. population 2 years and older. We intend to consider the new recommendations for infants and toddlers and whether or how to apply the recommendations to the use of Dietary Guidance Statements on products specifically intended for infants and children under the age of 2 years.

V. Recommendations for the Source of the Dietary Guidance Statement

1. What is a “Consensus Report”?

For purposes of this guidance document, a “consensus report” is a report that represents the consensus produced by a group of qualified experts whose bias and conflicts of interest have been minimized and that are convened to study a specific issue. The consensus report conveys agreed-upon recommendations that reflect widely-accepted, objective views of current scientific evidence. The information presented in a consensus report about nutrition should reflect an objective view of the scientific evidence, should have been thoroughly reviewed for scientific rigor, and should be consistent with sound nutrition science. Some examples of appropriate sources of consensus reports are listed in question V.5 below.

2. Why Should Dietary Guidance Statements be Based on Consensus Reports?

The public health goal of dietary guidance is to improve the health of consumers by providing information through nutrition statements that are based on the best evidence-based scientific research on dietary patterns. To achieve this goal, it is important that Dietary Guidance Statements be based on widely accepted dietary recommendations developed by qualified experts after conducting a comprehensive review of current scientific evidence (e.g., the Dietary Guidelines). Otherwise, Dietary Guidance Statements could be based on recommendations that are not generally accepted as beneficial to good nutrition and public health, and consumers would not be assured that the food or food group recommended in the Dietary Guidance Statement contributes to a nutritious dietary pattern.

3. May Any Statement or Phrase in a Consensus Report be Used as the Basis of a Dietary Guidance Statement?

We recommend using only key or principal recommendations from consensus reports as the basis of a Dietary Guidance Statement. The key or principal recommendations of a consensus report are easily identifiable because they are typically emphasized in some way (e.g., enclosed in a box or highlighted in the executive summary, or in a conclusion at the end of the report). The key or principal recommendations of a report contain the consensus of the group of experts convened to develop the report and the endorsement of the scientific body or health organization that issued the report. Use of key or principal recommendations rather than other individual phrases or statements in a consensus report helps ensure that information is not taken out of context and that the recommendations used as the basis for the Dietary Guidance Statement reflect the views of the organization responsible for issuing the report rather than the views of a minority of contributors or even a single person.

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For example, the *Dietary Guidelines, 2020-2025* includes several key recommendations that are set off in a box within the Executive Summary, such as “the core elements that make up a healthy dietary pattern include fruits, especially whole fruit” and “the core elements that make up a healthy dietary pattern include fat-free or low-fat milk, yogurt, and cheese, and/or lactose-free versions and fortified soy beverages and yogurts as alternatives” (Ref. 1). These key recommendations from the *Dietary Guidelines, 2020-2025* could accurately provide the basis for a Dietary Guidance Statement in food labeling.

Basing Dietary Guidance Statements on a key or principal recommendation from a consensus report is also consistent with the Federal Food, Drug, and Cosmetic Act’s (FD&C Act) requirements for the use of certain health claims and nutrient content claims that are based on an “authoritative statement” from U.S. scientific bodies with public health and nutrition expertise (sections 403(r)(2)(G) and 403(r)(3)(C) of the FD&C Act). The FD&C Act sets forth requirements for the use of certain health and nutrient content claims if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences. The FD&C Act requires that an authoritative statement “shall not include a statement of an employee of the scientific body made in the individual capacity of the employee” (section 403(r)(2)(G) of the FD&C Act). In addition, we have stated that authoritative statements should reflect a consensus within the identified scientific body if published by a subdivision of one of the Federal scientific bodies and be based on a deliberative review by the scientific body of the scientific evidence (Ref. 3). We are recommending a similar approach when determining the types of recommendations upon which Dietary Guidance Statements should be based.

4. Should the Dietary Guidance Statement Use the Same Wording as the Key or Principal Recommendation from the Consensus Report?

We do not expect Dietary Guidance Statements to use the exact language of key or principal recommendations from the consensus report upon which they are based. Dietary Guidance Statements may paraphrase the key or principal recommendations of a report as long as the paraphrase is true to the original recommendation and is not otherwise false or misleading. We understand manufacturers want to use Dietary Guidance Statements that are short, simple, and easily understood, and we encourage the use of simplified statements to help convey important nutrition information and healthful attributes about a product to consumers. For example, if the key or principal recommendation says that “A healthy dietary pattern includes a variety of vegetables from all of the subgroups- dark green, red and orange, legumes (beans and peas), starchy, and other,” a manufacturer may simplify the key or principal recommendation, while keeping in the spirit of the report, by using a Dietary Guidance Statement on a can of vegetables that says, “Eat a variety of vegetables.”

5. What are Appropriate Sources of Consensus Reports for Use as the Basis for Dietary Guidance Statements?

We recommend that consensus reports used as the basis for Dietary Guidance Statements be published, for example, by U.S. Federal government agencies or U.S. scientific bodies or U.S. health organizations outside the Federal government. Consensus reports could be published by the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the Office of the Surgeon General and the Office of Disease Prevention and Health Promotion (ODPHP) within HHS; the Food Safety and Inspection Service (FSIS), Agricultural Research Service (ARS), Food and Nutrition Service (FNS), the Center for Nutrition Policy and Promotion (CNPP), and the National Institute of Food and Agriculture (NIFA) within USDA; and two of the National Academies of Sciences, Engineering, and Medicine (NASEM) (the National Academy of Sciences and the National Academy of Medicine, formerly the Institute of Medicine (IOM)).

In addition to reports from these scientific bodies, appropriate sources could also include a consensus report from a public or private source that: (1) is a U.S. scientific body or health organization that was established with the purpose of protecting and promoting the public health of Americans and whose work directly relates to human nutrition; and (2) is neutral and objective without any conflicts of interest that may bias its review of the scientific evidence. For example, if a consensus group of nutrition experts convened by the U.S. Preventive Service Task Force develops a report with nutrition recommendations for the general healthy U.S. population that reflects the totality of the publicly available evidence, such a group could be an appropriate source for a consensus report. A key or principal recommendation from such a report could be used as the basis for a Dietary Guidance Statement.

6. What are Some Important Factors in Determining Whether a Dietary Guidance Statement is Based on a Consensus Report?

We consider the following factors to be important when determining whether a Dietary Guidance Statement is based on a consensus report and recommend these be considered in evaluating the statements:

- a. Individuals developing a report that is used as a source of a Dietary Guidance Statement should be knowledgeable of the subject matter.
- b. The report should be developed by a group of experts who, by their knowledge and expertise, are qualified to evaluate the evidence on the subject of the Dietary Guidance Statement and who have minimal bias and conflicts of interest.
- c. The report should be developed by a group of experts who were convened to address a specific scientific issue or topic related to the Dietary Guidance Statement.
- d. The report should be based on sound nutrition science that is the result of a comprehensive review of available scientific evidence on the topic that is the subject of the Dietary Guidance Statement.

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- e. The report recommendations used to develop a Dietary Guidance Statement should be based on data that have been replicated and fully examined in well-designed, peer-reviewed research studies.
- f. Evidence to support a relationship between consumption of a food or food groups and its benefit to health should be well-established and widely accepted in the scientific community.
- g. The report should make its sources of scientific information publicly available (e.g., through citations or a bibliography).
- h. The report recommendations used to develop a Dietary Guidance Statement should reflect the current thinking and consensus of the scientific community on the topic.

7. May a Dietary Guidance Statement be Based upon Information in a Consensus Report Published Many Years Ago?

The key or principal recommendations from a consensus report used to develop a Dietary Guidance Statement should reflect the current thinking of the scientific community on the topic. Therefore, we recommend using only consensus reports that are currently in effect (i.e., have not been superseded by more recent reports or recommendations that address similar subjects) and are based on current science to develop the Dietary Guidance Statement.

VI. Recommendations for Meaningful Amounts of Recommended Foods or Food Groups a Product Should Contain When Making a Dietary Guidance Statement

1. Why Should a Product Bearing a Dietary Guidance Statement Contain a Meaningful Amount of the Food That is the Subject of the Statement?

It is important that foods bearing Dietary Guidance Statements contain a meaningful amount of the food or food groups that are the subject of the Dietary Guidance Statement so that consumers can be assured that the product bearing the Dietary Guidance Statement contributes to a nutritious dietary pattern when consumed. If a product bearing a Dietary Guidance Statement about a food group (e.g., fruit) contains little or no amount of that food group (e.g., only 1 teaspoon fruit per serving), we would consider this information when evaluating if a Dietary Guidance Statement may be misleading or imply something false in product labeling. We are concerned that if a product bears such a Dietary Guidance Statement in those circumstances, consumers could be persuaded to purchase and consume the food believing that the product makes a meaningful contribution to a nutritious dietary pattern, when in fact, it does not. To ensure that products bearing a Dietary Guidance Statement contain a meaningful amount of the food that is the subject of the claim, we are providing “food group equivalents” recommendations.

2. What are “Food Group Equivalents”?

“Food group equivalents” represent a way of calculating a meaningful amount of the food or food group that is the subject of the Dietary Guidance Statement. As the Dietary Guidelines serves as the cornerstone of Federal nutrition policy, our concept for food group equivalents is based on the amount of food from different food groups recommended for consumption at the 2,000 calorie level in the Healthy U.S.-Style Dietary Pattern in the *Dietary Guidelines, 2020-2025* (Ref. 4). We are developing our food group equivalent recommendations based on amounts recommended at the 2,000 calorie level because 2,000 calories is often used for general nutrition advice, and it also is used for other purposes in nutrition labeling (e.g., when determining the Daily Values for some nutrients declared on the Nutrition Facts label).

The Healthy U.S.-Style Dietary Pattern establishes specific daily food group and subgroup amounts in cup-equivalents, ounce-equivalents, or grams, depending on the type of food. Cup- and ounce-equivalents identify the amounts of foods from each food group with similar nutritional content. For example, while the forms of whole-wheat bread and brown rice are very different, the *Dietary Guidelines, 2020-2025* considers one slice of whole wheat bread to be nutritionally similar to one half cup of cooked brown rice, and both represent an ounce-equivalent of grains.

The *Dietary Guidelines, 2020-2025* says (Ref. 4):

- Vegetables and fruits, 1 cup-equivalent is: 1 cup raw or cooked vegetable or fruit, 1 cup 100% fruit juice or vegetable juice, 2 cups leafy salad greens, ½ cup dried fruit or vegetable.
- Grains, 1 ounce-equivalent is: ½ cup cooked rice, pasta, or cereal; 1 ounce dry pasta or rice; 1 medium (1 ounce) slice bread, tortilla, or flatbread; 1 ounce of ready-to-eat cereal (about 1 cup of flaked cereal).
- Dairy, 1 cup-equivalent is: 1 cup milk, yogurt, or fortified soymilk; 1½ ounces natural cheese such as cheddar cheese or 2 ounces of processed cheese.
- Protein Foods, 1 ounce-equivalent is: 1 ounce lean meats, poultry, or seafood; 1 egg; ¼ cup cooked beans or tofu; 1 tablespoon (Tbsp) nut or seed butter; ½ ounce nuts or seeds.

3. What are the Food Group Equivalent Recommendations When an Individual Food or Food Group is the Subject of the Dietary Guidance Statement?

We recommend that when the subject of the Dietary Guidance Statement is an individual food or food group (e.g., apples or fruit), the product should provide ¼ of the daily recommended amount of the food or food group at the 2,000 calorie level in the Healthy U.S.-Style Dietary Pattern found in the *Dietary Guidelines, 2020-2025* per Reference Amount Customarily Consumed (RACC).

In the past, we have assumed that the typical American eating pattern is three meals and one snack per day, i.e., four eating occasions (see final rules on general requirements for health claims and nutrient content claims in food labeling, 58 FR 2478 at 2495, January 6, 1993, and 58

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FR 2302 at 2379 to 2380, January 6, 1993). In other words, we assume that individuals generally have four opportunities in a day to meet the recommended daily food group amounts in the Healthy U.S.-Style Dietary Pattern. Consistent with this assumption and our past approach, our current thinking on food group equivalents is based on four eating occasions per day.

To calculate the recommended food group equivalents, we divided the recommended daily food group amounts in the 2,000-calorie dietary pattern by four eating occasions and rounded to the nearest half cup, ounce, or gram. For example, because the recommended daily amount of fruit in the 2,000-calorie level pattern is 2 cup equivalents, we determined that the food group equivalent for fruit would be ½ cup equivalent (i.e., 2 cup equivalents divided by four). This would mean that when the subject of the Dietary Guidance Statement is fruit, the product (e.g., frozen berries) should contain ½ cup equivalent of fruit per RACC for packaged foods. The default food group equivalent was adjusted for certain protein subgroups to reflect different subgroup recommendations. We provide our thinking on the adjustment of the default amounts for the protein subgroups further in Question VI.4.

The recommended amounts of a food or food group that should be present in a food product per RACC when it is the subject of a Dietary Guidance Statement (food group equivalents) are provided in the following table:

Table 2.--Food Group Equivalents

Food Group and/or Subgroup	Food Group Equivalent
Vegetables	½ cup equivalent vegetable
Fruits	½ cup equivalent fruit
Whole Grain	12 grams whole grains
Dairy	¾ cup equivalent dairy
Protein Foods	
Game Meats	1.5 ounce (oz) equivalent
Seafood	1 oz equivalent
Egg	1 oz equivalent
Beans, peas, and soy products	1 oz equivalent
Nuts and seeds	1 oz equivalent
Oils	7 grams

Appendix 2 provides recommendations for the amount of food that should be present in a food per RACC for the different forms that foods take within each food group (e.g., cooked vs. raw) when the product bears a Dietary Guidance Statement.

4. How Were the Food Group Equivalent Recommendations for Protein Foods Adjusted?

Because specific recommendations for foods within the protein foods group vary, the protein foods group is divided into subgroups. We are providing food group equivalent calculations only for subgroups of protein foods that are regulated by FDA under the FD&C Act. The subgroups that we include in this draft guidance include beans, peas, and soy products, nuts and seeds, and the animal sources of protein that we regulate (i.e., game meats, shell eggs, and

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seafood (excluding catfish), but not all meats and poultry). After applying the calculations used for the food group equivalents for other food groups (i.e. recommended daily food group amounts in the 2,000-calorie dietary pattern divided by four eating occasions), we rounded the resulting values. To make it easier for manufacturers to follow, the food group equivalents are stated in half and whole ounces rather than fractions of ounces. To determine if the food group equivalent value should be rounded up or down, we took into consideration information about foods that are encouraged by the *Dietary Guidelines, 2020-2025*.

The recommendation for protein foods in the Healthy U.S.-Style Dietary Pattern at the 2,000-calorie level is 5 ½ ounce-equivalents per day. As one fourth of 5 ½ is 1 ¼ (assuming 4 eating occasions per day), based on standard rounding rules, we have calculated the food group equivalent for game meat to be 1 ½ ounce-equivalent. We are rounding down to 1 ounce-equivalent for beans, peas, and soy products, nuts and seeds, and seafood to increase the number of products containing these subgroups that would be eligible to bear a Dietary Guidance Statement, and therefore encourage consumption of these foods. This approach is consistent with the *Dietary Guidelines, 2020-2025* strategy to increase the variety of choices made by replacing some meats, poultry, and egg intake with seafood, legumes, nuts, and seeds. We are rounding down to 1 ounce-equivalent for eggs because one egg is typically 1 ounce, and one egg is a common serving size.

5. How Was the Food Group Equivalent for Whole Grains Derived?

According to the *Dietary Guidelines, 2020-2025*, 1 ounce-equivalent of 100 percent whole grains has 16 grams of whole grains (Ref. 1). Therefore, we used 16 grams of whole grains in calculating the food group equivalent for whole grain foods. The food group equivalent recommendation for whole grains is provided in grams rather than in ounce equivalents because, when whole grains are added as an ingredient to a product, it may be easier for manufacturers to determine the number of grams added rather than the number of ounce equivalents added to the product in formulation. The recommended intake of whole grains per day for a 2,000 calorie diet in the Healthy US-Style Dietary Pattern is 3 ounce-equivalents per day. Assuming 4 eating occasions, the food group equivalent for whole grains is calculated as follows:

3 ounce-equivalents x 16 grams per ounce-equivalent = 48 grams whole grains recommended per day

48 grams/4 eating occasions = 12 grams whole grains

6. What are the Food Group Equivalent Recommendations For a Mixed Product or When More than One Food or Food Group is the Subject of the Dietary Guidance Statement?

Mixed products are products that are similar in size to an individual food, but they contain significant amounts of food from more than one food group. Within the mixture of foods, no one food group predominates. For example, a mixed product could include granola that contains whole grains and nuts. Another example is a trail mix that contains dried fruit and nuts.

If the subject of the Dietary Guidance Statement is the entire mixed product (e.g., trail mix), we recommend that the product contain at least half of one food group equivalent from two different food groups. For example, a bag of trail mix with fruit and nuts bearing a Dietary Guidance Statement about the entire product (e.g., “Trail mix can be part of a well-balanced diet.”) should contain $\frac{1}{4}$ cup-equivalent of fruit and $\frac{1}{2}$ ounce-equivalent of nuts.

If the subject of the Dietary Guidance Statement, however, is about more than one food or food group (e.g., fruits and vegetables) that are ingredients of the overall food product, we recommend that the product contain at least one food group equivalent from each of the different foods or food groups that are the subject of the Dietary Guidance Statement. For example, if a frozen dinner bears a Dietary Guidance Statement about whole grains and seafood, we recommend the product contain 12 grams of whole grains and 1 ounce-equivalent of seafood.

7. What are the Food Group Equivalent Recommendations For Main Dishes and Meals?

Due to the larger size and purpose in the diet of main dishes and meals, we recommend that, if the subject of a Dietary Guidance Statement is about a main dish product (e.g., baked chicken), the product contain at least one food group equivalent each from at least two different food groups. If the subject of the Dietary Guidance Statement is the entire meal product (e.g., a frozen dinner), the product should contain at least one food group equivalent each from at least three different food groups.

8. What if a Product Bearing a Dietary Guidance Statement Does Not Meet the Food Group Equivalents Recommendations?

We recommend that foods bearing a Dietary Guidance Statement meet the food group equivalent recommendations set forth in this draft guidance. However, we recognize that some foods or food groups that are the subject of a key or principal recommendation from a consensus report may not meet the recommendations for food group equivalents, but nonetheless food manufacturers should not be discouraged from using Dietary Guidance Statements on these types of products. For example, current dietary recommendations encourage Americans to increase their consumption of all whole fruits and vegetables (Ref. 1). Despite the long-standing recommendation to consume fruits and vegetables, more than three-fourths of the population has a dietary pattern low in vegetables and fruits (Ref. 1). Manufacturers may use Dietary Guidance Statements to encourage consumption of whole fruits and vegetables. Therefore, while we are

providing food group equivalent recommendations for most foods, raw, whole fruits and raw, whole vegetables⁸ may not meet any food group equivalent recommendations but may still bear Dietary Guidance Statements. For example, an apple should be able to bear a Dietary Guidance Statement even though it may not always contain ½ cup equivalent of fruit.

9. What about Plant-Based Milk Alternatives and Plant-based Yogurt Alternatives?

According to the *Dietary Guidelines, 2020-2025*, “soy beverages (commonly known as “soy milk”) and soy yogurt – which are fortified with calcium, vitamin A, and vitamin D – are included as part of the dairy group because they are similar to milk and yogurt based on nutrient composition and in their use in meals.” The nutritional profiles of fortified soy beverages and fortified soy yogurt alternatives are similar to the nutritional profile of the dairy food group. The *Dietary Guidelines, 2020-2025* does not include other products and beverages made from plants (e.g., almond, rice, coconut, oat, and hemp products) as part of the dairy group nor do they contribute to meeting the dairy group recommendation because their overall nutritional content is not similar to dairy foods. However, it is possible that in the future, these types of products may be formulated or fortified to have nutritional profiles that are more similar to the profile of the dairy food group. To support the availability of non-dairy choices for individuals who are lactose intolerant or allergic to dairy or choose not to consume dairy, it is appropriate for products labeled as plant-based alternatives to milk and yogurt to bear Dietary Guidance Statements when these products are fortified to have an overall nutritional content similar to products in the dairy group. If the subject of the Dietary Guidance Statement is dairy, we believe that consumers could reasonably expect that a plant-based alternative to milk or yogurt makes meaningful contributions of the nutrient(s) found in milk or yogurt. According to the *Dietary Guidelines, 2020-2025*, “soy beverages (commonly known as “soy milk”) and soy yogurt – which are fortified with calcium, vitamin A, and vitamin D – are included as part of the dairy group because they are similar to milk and yogurt based on nutrient composition and their use in meals.” However, to support the availability of non-dairy choices, we support the use of Dietary Guidance Statements on all plant-based milk and yogurt alternatives – not just soy based alternatives – that have an overall nutritional content that provides similar amounts of nutrients as found in the dairy group.⁹ For example, a fortified almond beverage could bear a Dietary Guidance Statement saying, “Drink fortified almond beverages as part of a nutritious dietary pattern.” These products should adhere to the recommended nutrient levels not to exceed when bearing Dietary Guidance Statements (see Section VII.).

⁸ The Dietary Guidelines describe whole fruit as fruit in their complete form, in contrast to fruit in the form of fruit juice. They describe that whole fruits include fresh, canned, frozen, and dried fruits and can be eaten in a variety of forms, such as cut, sliced, diced, or cubed. For the purpose of Dietary Guidance Statements, we are similarly using the phrase “whole fruits and vegetables” to include fresh, canned, frozen, and dried forms and to exclude fruit juice, to be consistent with the Dietary Guidelines.

⁹ To determine whether a plant-based milk or yogurt alternative has an overall nutritional content that provides similar amounts of nutrients as found in the dairy group, FDA recommends using USDA’s FNS fluid milk substitutes nutrient criteria (e.g., calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, and vitamin B12). These are the same nutrients that the Dietary Guidelines identify in the Dairy Group as key contributors of nutrients, except for zinc, choline, and selenium (Ref. 1).

10.If a Food Product Bears a Dietary Guidance Statement on the Label, May the Label Also Include a Statement About How Much of the Food or Food Group the Product Contains in Addition to the Dietary Guidance Statement?

As an option, the product may include a statement on its label near or adjacent to the Dietary Guidance Statement that tells consumers the amount of the food or food group that is the subject of the Dietary Guidance Statement present in one serving of the product (e.g., “This food has ½ cup vegetables per serving”). Many nutrition-related consensus reports provide information about the amounts of food from each food group one should strive to consume per day for a healthy dietary pattern (e.g., USDA Food Patterns). Statements about how much of the food or food group the product contains provide additional quantitative information about the amount of a recommended food or food group in a product. This information can help consumers determine how the food contributes to recommended amounts of foods in nutritious dietary patterns and how the food fits into their overall dietary patterns.

11.What Information Should a Statement About How Much of the Food or Food Group the Product Contains Include?

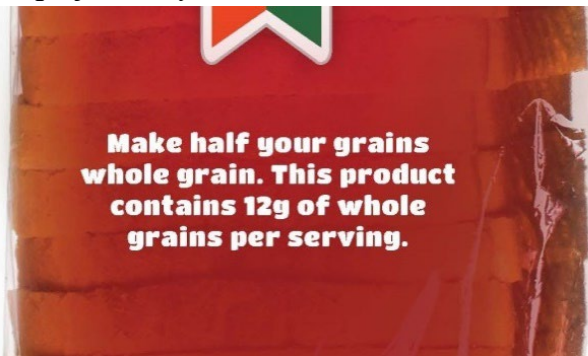
When a statement about the amount of a recommended food or food group in a serving of a product is made alongside a Dietary Guidance Statements on a food label, we recommend that the statement include the amount of the food or food group that is the subject of the Dietary Guidance Statement in one labeled serving of the product. For example, if a statement is made on the label of a product that contains a meaningful amount of whole grains, the statement could say, “This food has 12 grams of whole grains per serving.” A statement about the amount of broccoli might say, “This food has ½ cup of broccoli per serving.” If the subject of the Dietary Guidance Statement is a food group, the statement may be about the amount of the broader food group in a serving of the product (e.g., “This food has ½ cup fruit per serving”).

Consumers in the United States generally measure oils using teaspoons or tablespoons rather than in grams. Serving size amounts on the Nutrition Facts label are given in tablespoons. Consumers may understand a statement about oils better if the amount of oil provided in a labeled serving of a food is given in teaspoons or tablespoons as well as in grams. Therefore, we recommend that when a statement is made about oils, both the gram amount and the number of teaspoons or tablespoons of oil per serving be stated (e.g., This food has ___tablespoon(s) or ___gram(s) of oil per serving). The first blank would contain the number of teaspoons or tablespoons of oil in the food and the second blank would contain the number of grams of oil in the food.

Figure 3: Examples of Dietary Guidance Statements with a Statement About the Amount of the Recommended Food or Food Group in a Serving of the Product



Close-up of Dietary Guidance Statement with a Food or Food Group Statement:



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Close-up of Dietary Guidance Statement with a Food or Food Group Statement:



VII. Recommendations for Nutrient Levels When A Product Bears a Dietary Guidance Statement

1. Why Should Products Not Exceed Certain Nutrient Levels When Bearing a Dietary Guidance Statement?

Along with containing a meaningful amount of a recommended food or food group, it is important that food products bearing Dietary Guidance Statements not exceed certain nutrient levels that are inconsistent with healthy dietary patterns. If they do, the Dietary Guidance Statement may cause consumers to believe that the product will contribute to a diet that promotes better health, when, in fact, the product contains levels of certain nutrients that are inconsistent with nutritious dietary patterns.

Recommending foods adhere to certain nutrient limits when a product bears a Dietary Guidance Statement is consistent with FDA’s existing claims requirements. For example, our health claim regulations establish disqualifying nutrient limits at 20 percent of the Daily Value (DV) (21 CFR § 101.14(a)(4)). This means foods that exceed one of those nutrient limits are disqualified from bearing a health claim. Similarly, our nutrient content claim regulations require products bearing a nutrient content claim to also bear a disclosure statement when the product exceeds 20 percent of the DV for certain nutrients (21 CFR § 101.13(h)). Additionally, foods must adhere to certain nutrient requirements to bear the nutrient content claim “healthy” (21 CFR § 101.65(d)).

We considered these nutrient requirements as well as the *Dietary Guidelines, 2020-2025* recommendations for nutrients to limit while determining the recommended nutrient levels for Dietary Guidance Statements. We also wanted to ensure that a wide variety of products containing foods or food groups consistent with dietary recommendations fall below the recommended nutrient levels for Dietary Guidance Statements. We note that the recommended nutrient levels for Dietary Guidance Statements provide greater flexibility than the “healthy” claim nutrient requirements. We would consider whether a product falls below the recommended nutrient levels in this guidance when evaluating if a Dietary Guidance Statement is truthful and not misleading.

2. What Nutrients Should be Limited in Products that Bear a Dietary Guidance Statement?

Products bearing a Dietary Guidance Statement should not exceed certain nutrient levels for saturated fat, sodium, and added sugars. Most Americans exceed the *Dietary Guidelines, 2020-2025* recommended intake of saturated fat, sodium, and added sugars. Excess consumption of these nutrients can increase caloric intake and/or the risk of chronic disease and, therefore, diminish the potential public health impact of Dietary Guidance Statements. There is a well-established relationship between the consumption of saturated fat and its effect on blood cholesterol levels (Ref. 5). Evidence shows that diets lower in saturated fat are associated with a decreased risk of cardiovascular disease (CVD) (Ref. 6). Dietary recommendations have also

long emphasized lowering sodium intake because there is a relationship between sodium consumption and blood pressure, and sodium consumption and CVD risk (Ref. 7). Additionally, scientific evidence shows that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a decreased risk of CVD (Ref. 6). Further, the *Dietary Guidelines, 2020-2025* recommends limiting consumption of saturated fats, sodium, and added sugars as part of its key or principal recommendations for a healthy dietary pattern.

3. What is the Recommended Level of Saturated Fat an Individual Food Should Not Exceed When the Product Label Bears a Dietary Guidance Statement?

To ensure a variety of products containing foods or food groups as well as help Americans identify foods lower in saturated fat to achieve a healthy dietary pattern, we recommend that individual foods (including mixed products as described in Section VI, Question 6) bearing Dietary Guidance Statements not contain more than 10 percent of the DV for saturated fat (2 grams) per RACC. Foods with inherently higher levels of saturated fat which are recommended by, for example, the Dietary Guidelines, such as low-fat dairy products, eggs, seafood, and oils, fall below this recommended level. Additionally, we recommend this saturated fat level for products bearing a Dietary Guidance Statement because this level is consistent with other consensus report recommendations (Ref. 5 and 8) and the *Dietary Guidelines, 2020-2025* saturated fat recommendation (less than 10 percent of calories per day).

We are not recommending maximum nutrient levels for *trans* fat and cholesterol because the *trans* fat and cholesterol contents of food products are already sufficiently limited by the recommended saturated fat level. Further, in 2015, we issued a final determination that partially hydrogenated oils (PHOs), the primary dietary source of industrially produced *trans* fat, are no longer recognized as safe for use in food (80 FR 34650, June 17, 2015), resulting in the elimination of the majority of uses of PHOs. The compliance date for this determination was June 18, 2018, for most foods, with extended compliance dates to 2019, 2020, and 2021 for certain uses of PHOs (83 FR 23358, May 21, 2018). As a result, the primary dietary source of *trans* fat has been largely removed from the food supply.

4. Should Nut or Seed Products that Exceed the Recommended Saturated Fat Level Bear Dietary Guidance Statements?

We do not want to discourage the use of Dietary Guidance Statements on nut and seed products that are recommended as part of a nutritious dietary pattern but that may exceed the recommended saturated fat level for products bearing a Dietary Guidance Statement. Unsalted nuts and seeds are considered nutrient dense protein foods due to their nutrient profiles (e.g., they provide important nutrients such as unsaturated fatty acids and vitamin E). While nuts and seeds contain saturated fat, they have a fat profile of predominately monounsaturated and polyunsaturated fats and are recommended by the Dietary Guidelines as part of a healthy dietary pattern. Numerous studies have demonstrated that replacing other sources of saturated fat in the

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diet with nuts has beneficial effects on cardiovascular disease risk, including nuts with higher saturated fat content (Ref. 9 and Ref. 10). Some nuts are higher in saturated fat than other nuts. However, the *Dietary Guidelines, 2020-2025* recommends consuming nuts without differentiating between types. Specifically, the *Dietary Guidelines, 2020-2025* recommends reducing saturated fat by substituting certain ingredients with sources of unsaturated fats, including using nuts and seeds in a dish instead of cheese.

Recommending that the saturated fats contributed from nuts and seeds count towards the recommended saturated fat limits for the use of Dietary Guidance Statements would be inconsistent with the scientific evidence demonstrating a beneficial effect of nut consumption on health outcomes, which is the basis for current dietary recommendations that nuts and seeds are part of a healthy dietary pattern. Therefore, when considering whether a product exceeds the recommended saturated level for Dietary Guidance Statements, the saturated fat content of the nuts and seeds should not contribute towards the overall recommended saturated fat level. For example, a peanut butter product containing peanuts, sugar, vegetable oil, and salt should not contain more than 10 percent of the DV for saturated fat per RACC when it bears a Dietary Guidance Statement, but the saturated fat from the peanuts would not contribute to the recommended level. Additionally, if a product only contains nuts, such as a jar of raw, unsalted peanuts, the product may exceed the recommended saturated fat level of 10 percent DV per RACC and bear a Dietary Guidance Statement. Although, we are not recommending that nut and seed products meet the recommended saturated fat level for all other products bearing a Dietary Guidance Statement, we do recommend that nut and seed products as well as products containing nuts and seeds not exceed the recommended levels of sodium and added sugars discussed below.

5. What is the Recommended Level of Sodium an Individual Food Should Not Exceed When the Product Label Bears a Dietary Guidance Statement?

Americans consume, on average, 3,400 milligrams (mg) of sodium per day – nearly 50 percent more than the 2,300 mg intake level per day, and even less for children younger than age 14, the *Dietary Guidelines, 2020-2025* and NASEM recommend not to exceed as part of a nutritious dietary pattern. Therefore, it is important to help consumers identify foods lower in sodium. To ensure a variety of products containing foods or food groups recommended by the Dietary Guidelines may bear Dietary Guidance Statements and that those foods fit within a nutritious dietary pattern that is consistent with recommended sodium intake levels, individual foods (including mixed products as described in Section VI, Question 6) bearing Dietary Guidance Statements should not contain more than 15 percent of the DV for sodium (345 milligrams) per RACC. This sodium level for products bearing Dietary Guidance Statements is recommended because a lower level would restrict the number of products that could bear a Dietary Guidance Statement, and a higher level could perpetuate sodium intakes above the *Dietary Guidelines, 2020-2025* and NASEM's recommendations.

6. What Is the Recommended Level of Added Sugars an Individual Food Should Not Exceed When the Product Label Bears a Dietary Guidance Statement?

Healthy dietary patterns can accommodate nutrient-dense foods with small amounts of added sugars. However, as the amount of added sugars increases in the diet, it becomes more difficult to stay within calorie limits. To help Americans identify foods lower in added sugars while also ensuring that a variety of products fall below the recommended added sugars level for products bearing Dietary Guidance Statements, we recommend that individual foods (including mixed products as described in Section VI, Question 6) bearing Dietary Guidance Statements not contain more than 10 percent of the DV for added sugars (5 grams) per RACC. This level is recommended because a lower level would prevent foods that may contribute to a nutritious dietary pattern and are recommended by the Dietary Guidelines from bearing Dietary Guidance Statements.

7. What Are the Recommended Levels of Nutrients for Main Dish and Meal Products Bearing Dietary Guidance Statements?

Because of their larger size and because the products represent a whole meal or substantial proportion of a meal, the recommended levels of nutrients for main dish and meal products bearing Dietary Guidance Statements are more flexible. Consistent with the disqualifying nutrient limits for health claims and nutrient content claim nutrient levels for disclosure statements, main dishes bearing a Dietary Guidance Statement ideally should not exceed 30 percent of the saturated fat and sodium DVs per RACC. Main dishes bearing a Dietary Guidance statement should also not exceed 20 percent of the DV per RACC for added sugars. Similarly, consistent with the disqualifying nutrient limits for health claims and the nutrient content claim nutrient limits for disclosure statements, we recommend that meals bearing a Dietary Guidance Statement not exceed 40 percent of the saturated fat and sodium DVs per RACC. Meal products bearing Dietary Guidance Statements should also not exceed 30 percent of the DV per RACC for added sugars. These nutrient levels balance the goal of promoting consumption of products that contain foods or food groups that contribute to or help maintain a nutritious dietary pattern while helping consumers limit their intake of nutrients that can increase their risk of chronic disease.

8. What If a Product Exceeds the Recommended Nutrient Levels for Dietary Guidance Statements, but is Recommended as Part of a Nutritious Dietary Pattern in a Consensus Report?

We recognize that some foods recommended by a consensus report as part of a nutritious dietary pattern may exceed the recommended nutrient levels for Dietary Guidance Statements. Ingredients added to some food products may help increase the consumption of foods recommended as part of nutritious dietary pattern. For example, sugar is often added to fat-free and low-fat yogurt products, and these products are among the dairy foods encouraged by the Dietary Guidelines.

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In situations when a food is recommended by a consensus report as part of a nutritious dietary pattern and the food has a nutrient profile that exceeds the recommended nutrient levels in this guidance, we continue to find it appropriate for such a product to bear a Dietary Guidance Statement. However, when products exceed a recommended nutrient level set forth in this guidance, we recommend that these products bear a disclosure statement about the recommended nutrient level(s) it exceeds. For example, a yogurt product bearing a Dietary Guidance Statement that contains 20 percent of the DV of added sugars should also bear a disclosure statement, such as:

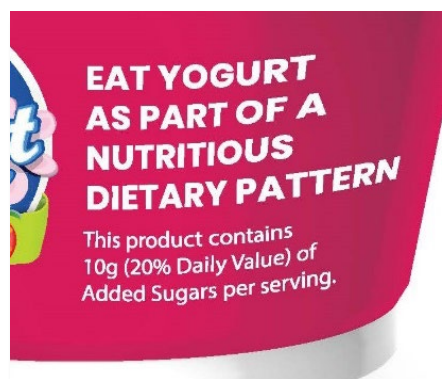
“This product contains 10g (20% Daily Value) of Added Sugars per serving.” Alternatively, manufacturers may choose to direct consumers to the Nutrition Facts label by using a disclosure statement such as: “See nutrition information for _____ content.”

We recommend placing the disclosure statement on the label near and visually connected to the Dietary Guidance Statement. The statement will help ensure consumers have the information necessary to maintain nutritious dietary patterns.

Figure 4: Example of Product Bearing a Dietary Guidance Statement with a Disclosure Statement



Close-up of Dietary Guidance Statement with a Disclosure Statement:



9. If a Nut or Seed Product Exceeds the Recommended Saturated Fat Level and Bears a Dietary Guidance Statement, Should it also Bear a Disclosure Statement?

We do not want to discourage manufacturers from providing a disclosure statement about the saturated fat content of a nut or seed product when it exceeds the recommended saturated fat level because it would provide additional nutrition information to consumers. However, we recommend manufacturers not include such a disclosure statement when a nut or seed product exceeds the recommended saturated fat level due to the saturated fat content of the nut or seed itself. As described in Question 4 of this Section, while nuts and seeds contain saturated fats, they have a fat profile of predominately monounsaturated and polyunsaturated fat and are recommended by the Dietary Guidelines without distinguishing between different types. When considering whether a product exceeds the recommended saturated fat level for Dietary Guidance Statements, the saturated fat content of the nuts and seeds should not contribute towards the overall recommended saturated fat level. Therefore, we do not think a nut or seed product that bears a Dietary Guidance Statement and exceeds the recommended saturated fat level due to the saturated fat of the nut or seeds in the product should bear a disclosure statement about the saturated fat level of the product. However, if a nut or seed product bearing a Dietary Guidance Statement exceeds the saturated fat level due to the saturated fat content of other ingredients (e.g., vegetable oil in peanut butter), or exceeds the recommended sodium level or added sugar level outlined in this guidance, we recommend that the product bear a disclosure statement as described in Question 8 of this Section.

VIII. References

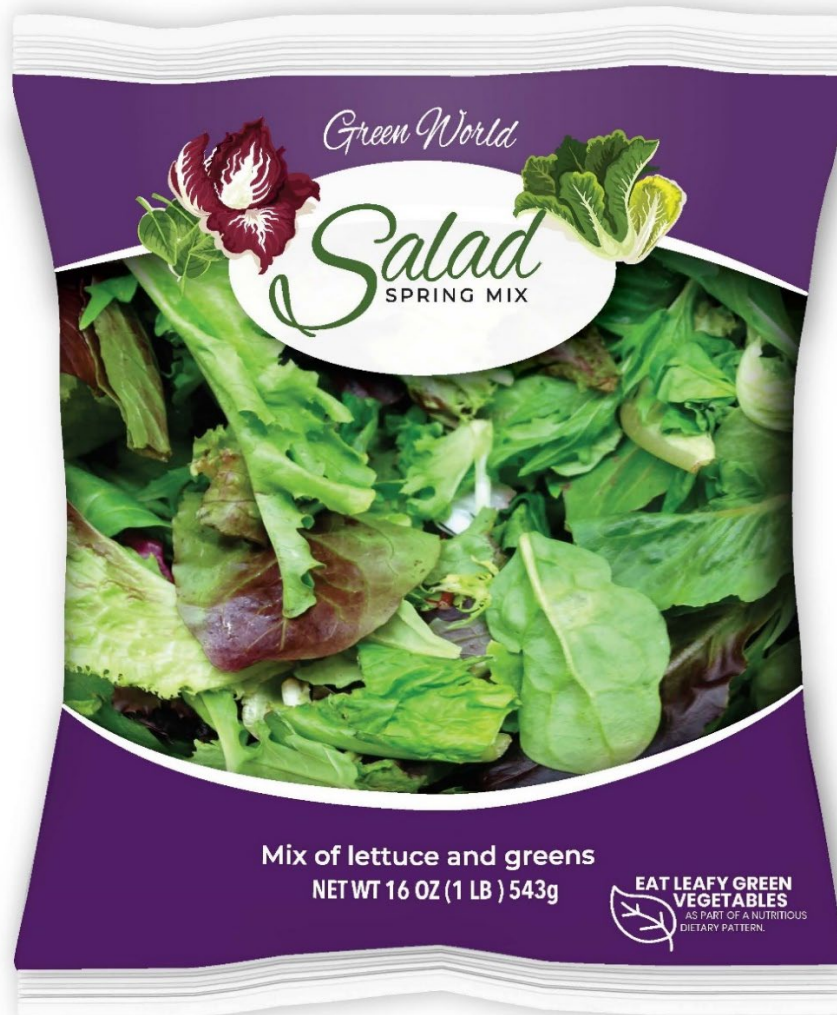
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Appendix 1. Examples of Dietary Guidance Statements

- Make half your grains whole grain.
- Make half your plate fruits and vegetables.
- Focus on whole fruit.
- Vary your veggies.
- Choose fat-free or low-fat dairy products instead of full-fat dairy options.
- Eat a variety of protein foods, including nuts and seeds.
- Vary your protein routine.
- Eat leafy green vegetables as part of a nutritious dietary pattern.
- The Dietary Guidelines for Americans recommends eating fruits and vegetables as part of a nutritious dietary pattern. This food has ½ cup of broccoli per serving.
- Use vegetable oils instead of solid fats, when cooking.
- Seafood, including shrimp, is part of a nutritious dietary pattern.

*Contains Nonbinding Recommendations
Draft-Not for Implementation*

Example Graphics of Products Bearing Dietary Guidance Statements



Close-up of Dietary Guidance Statement:



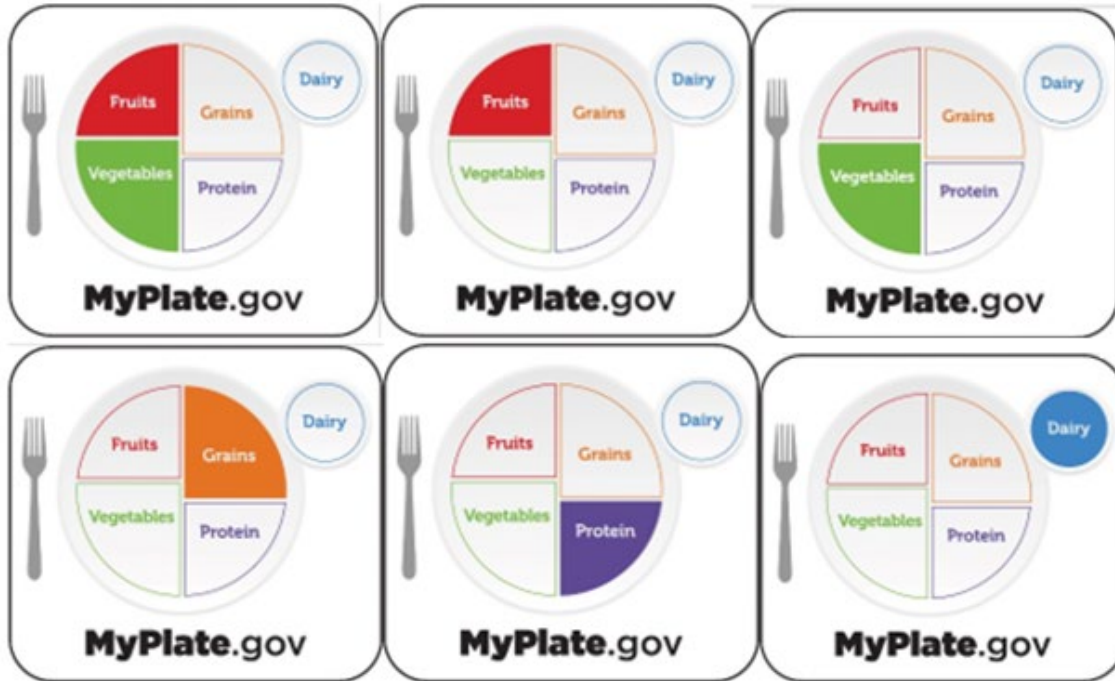
Contains Nonbinding Recommendations
Draft-Not for Implementation



Close-up of Dietary Guidance Statement:



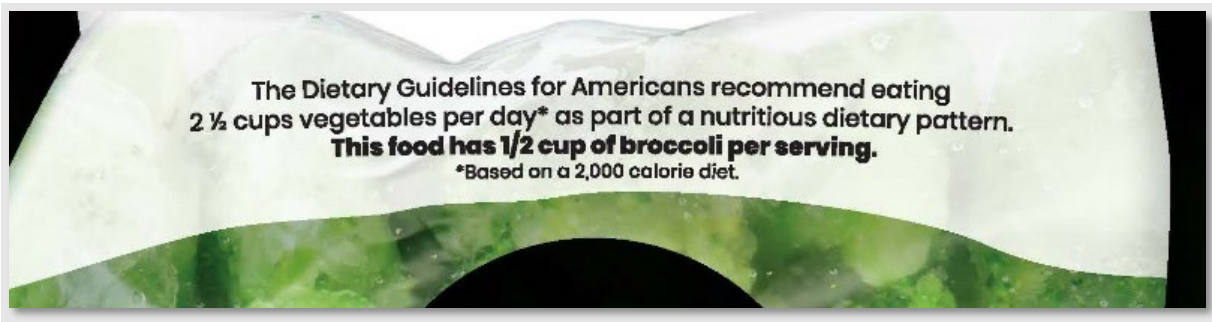
MyPlate visuals:



*Contains Nonbinding Recommendations
Draft-Not for Implementation*



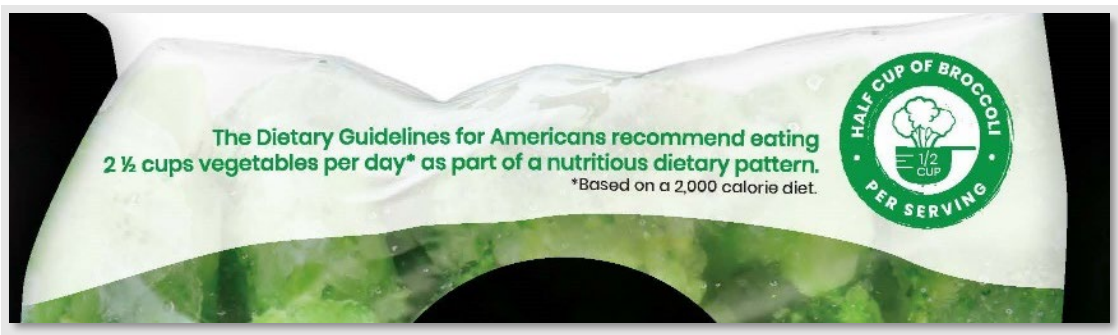
Close-up of Dietary Guidance Statement with a Food Group Equivalent Statement:



*Contains Nonbinding Recommendations
Draft-Not for Implementation*



Close-up of Dietary Guidance Statement with a Food Group Equivalent Statement:



*Contains Nonbinding Recommendations
Draft-Not for Implementation*

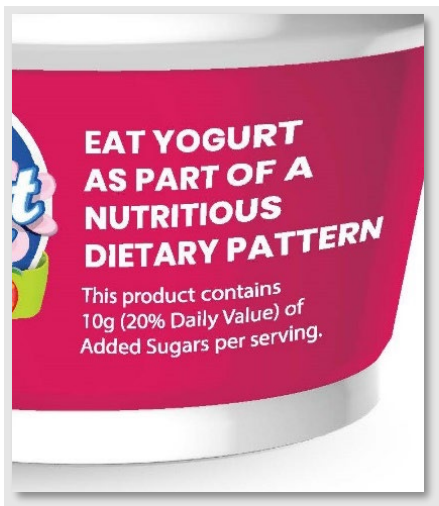


Close-up of Dietary Guidance Statement:





Close-up of Dietary Guidance Statement with a Disclosure Statement:



Appendix 2. Recommendations for the Amount of Food that Should be Present per RACC by the Form of Food and Food Group If a Product Bears a Dietary Guidance Statement

Food Group	Recommended Amount per RACC
Vegetables and Fruits	
Raw or cooked	½ cup
Vegetable or fruit juice	½ cup
Leafy salad greens	1 cup
Dried fruit or vegetable	¼ cup
Whole Grains	12 grams
Dairy	
Milk, yogurt or fortified plant-based beverage	¾ cup
Natural cheese such as cheddar cheese	1 ounce
Processed cheese	1.5 ounces
Protein foods	
Seafood	1 ounce
Game Meats	1.5 ounces
Egg	1 egg
Cooked beans or tofu	¼ cup
Nut butter	1 Tbsp
Nuts or seeds	½ ounce
Oils	7 grams

Appendix 3. Recommendations for Products Bearing Dietary Guidance Statements

Product	The subject of the DGS is...	Then the food group equivalent (FGE) recommendation is...	And the recommended saturated fat level per RACC is...	The recommended sodium level per RACC is...	The recommended added sugar level per RACC is...
Individual food	A food, food group, or the entire food product	At least 1 FGE per RACC from 1 food group	10% DV (2 g)	15% DV (345 mg)	10% DV (5 g)
Mixed product	Entire product	At least 1/2 FGE per RACC each from 2 different food groups	10% DV (2 g)	15% DV (345 mg)	10% DV (5 g)
Main dish	A food or food group	At least 1 FGE per RACC from 1 food group	30% DV (6 g)	30% DV (690 mg)	20% DV (10 g)
Main dish	Two or more food groups	At least 1 FGE per RACC from each of the food or food groups in the DGS	30% DV (6 g)	30% DV (690 mg)	20% DV (10 g)
Main dish	Entire product	At least 1 FGE per RACC each from 2 different food groups	30% DV (6 g)	30% DV (690 mg)	20% DV (10 g)
Meal	A food or food group	At least 1 FGE per RACC from 1 food group	40% DV (8 g)	40% DV (920 mg)	30% DV (15 g)
Meal	Two or more food groups	At least 1 FGE per RACC from each of the food or food groups mentioned in the DGS	40% DV (8 g)	40% DV (920 mg)	30% DV (15 g)
Meal	Entire product	At least 1 FGE per RACC each from 3 different food groups	40% DV (8 g)	40% DV (920 mg)	30% DV (15 g)