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Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: 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Draft Guidance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 240-402-2371.

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Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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

The purpose of this guidance is to provide FDA's current view on the naming of plant-based foods that are marketed and sold as alternatives for milk (plant-based milk alternatives) in accordance with sections 403(a)(1) and 403(i)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(a)(1) and 343(i)(1)). The guidance also includes our recommendations on the use of voluntary nutrient statements. Industry's use of these voluntary nutrient statements would provide consumers with additional nutrition information to help them understand certain nutritional differences between these products and milk and make informed dietary choices.

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II. Background

A. Overview and Purpose

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

[1] This 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.

informative and accessible labeling to choose healthier diets. Ensuring plant-based milk alternative labels are clear will help enable consumers to quickly ascertain the attributes of products they are purchasing for themselves and their families.

In the *Federal Register* of September 28, 2018, we issued a notice entitled "Use of the Names of Dairy Foods in the Labeling of Plant-Based Products" (notice) requesting comment on the labeling of plant-based alternatives with names that include the names of dairy foods.[2] We invited comment on a variety of issues, including how consumers use plant-based dairy alternatives, how consumers understand terms included in the names of plant-based dairy alternatives, and whether consumers are aware of and understand differences between plant-based dairy alternatives and their dairy counterparts. In addition, we commissioned and conducted focus groups to further inform our understanding of these issues.

In response to the notice, we received over 13,000 comments,[3] most of which focused on plant-based milk alternatives. The comments, other research reviewed, and our analysis of the data (Ref. 1) suggest a potential public health concern related to the substitution of milk with plant-based milk alternatives that contain lower amounts of certain nutrients than found in milk. Given this potential public health concern, this draft guidance focuses only on plant-based alternatives to milk and not plant-based alternatives to other dairy products. Specifically, this draft guidance includes recommendations for the naming and voluntary nutrient statements that, if finalized, would help consumers understand certain nutritional differences between plant-based milk alternatives and milk.[4]

We are issuing this guidance to provide industry with recommendations on voluntary nutrient statements. The use of these statements would support the FDA's goal to improve healthy dietary patterns by providing consumers with additional and more accessible information to enhance their ability to make informed choices about the foods they buy and eat. This draft guidance also provides clarity on the naming of these products.

B. Plant-based Milk Alternatives

There has been an increase in availability in the marketplace and consumption of plant-based milk alternatives. In 2010, one-fifth of U.S. households purchased or consumed plant-based milk alternatives. By 2016, one-third of U.S. households purchased plant-based milk alternatives, totaling $1.5 billion in sales that year (Ref. 2). From 2017 to 2019, sales of plant-based milk alternatives increased nearly 15 percent reaching $2 billion, with refrigerated products accounting for approximately 90 percent and shelf-stable products accounting for around 10 percent (Ref. 3). In 2020, retail sales continued to increase, rising to approximately $2.4 billion (Ref. 4). The variety of plant-based milk alternatives available in the marketplace has also greatly expanded from soy, rice, and almond to include cashew, coconut, flaxseed, hazelnut, hemp seed, macadamia nut, oat, pea, peanut, pecan, quinoa, and walnut-based

[2] See 83 FR 49103.

[3] See www.Regulations.gov Docket FDA-2018-N-3522-0001.

[4] This guidance does not address other types of mammalian milk, such as goat milk, sheep milk, and camel milk, that may be used as substitutes for milk. These types of milk are used far less frequently than plant-based milk alternatives as substitutes for milk and therefore do not pose the same potential public health concern.

beverages. While some plant-based milk alternative products have "beverage" or "drink" in their labeling, the majority of products have the word "milk" in their names (Ref. 3). Consumers purchase plant-based milk alternatives for various reasons, such as allergies, intolerances, religious practices, and lifestyle choices (e.g., vegan diet). Consumers often use plant-based milk alternatives in a similar way as milk, such as in cereal, coffee, and smoothies (Refs. 1 and 3). Additionally, more than a third of respondents to a Consumer Reports survey said that in the past year they have purposely used plant-based milk alternatives as a substitute for milk (Ref. 6).

FDA has not established compositional requirements for plant-based milk alternatives. The composition of these products, including their nutrient profiles, varies depending on the plant source(s), processing methods, and added ingredients. Plant-based milk alternatives are made from liquid-based extracts of plant materials, such as tree nuts (e.g., almond, walnuts, macadamia), legumes (e.g., soybean), seeds (e.g., hemp, flax), or grains (e.g., rice, oat). Water is generally the primary ingredient in these products. In addition to water and the plant extract(s), the products may be fortified with various vitamins and minerals. Other ingredients, such as vegetable oil(s), nutritive and/or non-nutritive sweeteners, salt, and/or other functional or flavoring ingredients, may be added. In addition to direct plant extractions, alternate processing methods are used where individual plant protein solid(s), plant oil(s), water, and other ingredients are combined to formulate a plant-based milk alternative (Ref. 7).

C. Consumer Understanding of Plant-based Milk Alternatives

1. Composition and Naming

In response to FDA's notice mentioned above, several comments included data from consumer studies about consumers' understanding and use of plant-based milk alternatives in comparison to milk. Overall, these studies indicate that consumers understand that plant-based milk alternatives do not contain milk when shopping for various types of products labeled with the term "milk." In particular, one consumer survey suggested that about three-quarters of its respondents understood that plant-based milk alternatives do not contain milk; fewer than 10 percent believed that plant-based milk alternatives do contain milk, and the remainder did not know (Ref. 1).

Focus groups commissioned and conducted by FDA suggested that "milk" is strongly rooted in consumers' vocabulary when describing and talking about plant-based milk alternatives. The focus groups indicated that most participants were not confused about plant-based milk alternatives containing milk and refer to plant-based milk alternatives as "milk." Participants further indicated that they feel familiar and comfortable with the term "milk" when describing plant-based milk alternatives and they preferred to use the term when given a choice of names for plant-based milk alternatives (e.g., "milk," "beverage," "drink," etc.). Participants also said that the term "beverage" and "drink" may suggest lower quality than a product called "milk" (Ref. 1). Other research also appears to show that consumers understand that plant-based milk alternatives are distinct products and choose to purchase plant-based milk alternatives because they are not milk. For example, as noted above, some consumers purchase plant-based milk alternatives because of allergies, intolerances to milk, or lifestyle choices (e.g., vegan diet) (Ref. 1).

2. Nutritional Content

While consumers appear to understand that plant-based milk alternatives are distinct products from milk, several consumer studies submitted in response to the notice indicate that consumers, including consumers who purchase plant-based milk alternatives, do not understand the nutritional differences between milk and plant-based milk alternatives (Ref. 1). In general, research suggests that many consumers lack an accurate understanding about the specific nutrients in plant-based milk alternatives (Ref. 6). The research also suggests that a majority of consumers who purchase plant-based milk alternatives state they do so because they believe the products are healthier than milk (Ref. 6). Additionally, in focus groups conducted by FDA with consumers of plant-based milk alternatives, frequent mentions were made that plant-based milk alternatives may be healthier than milk because they are lower in fat and cholesterol, and do not contain animal ingredients (Ref. 1). Further, a survey reported that 53 percent of its respondents believe that plant-based milk alternatives labeled with the term "milk" in their name have a nutritional content similar to milk. Another survey indicated that the term "milk" paired with "almond" creates a more favorable perception of the nutritional content of the product compared to "almond drink," "almond beverage," or "almond juice." The survey data also indicated that its respondents expect that plant-based milk alternatives are comparable in nutrition to milk and this belief is stronger in those who purchase plant-based milk alternatives (Ref. 1). Some comments submitted to the notice said that consumers do understand the nutritional differences between plant-based milk alternatives and milk; however, the comments did not provide studies or other data to support this assertion.

D. Definition of Milk and Use of the Term "Milk" in the Names of Plant-based Milk Alternatives

1. Statute and Regulations

The FD&C Act gives us the authority to establish definitions and standards of identity for foods.[5] Definitions and standards of identity are established by regulation under the common or usual name of the food. Such foods are said to be "standardized." Under the statute, products that purport to be or are represented as a food for which a definition and standard of identity has been established must conform to the definition and standard and their labels must bear the name specified therein.[6]

Foods that do not have an established definition and standard of identity are "non-standardized foods." The labels of non-standardized foods must bear the common or usual name of the food, if there is such a name.[7] A common or usual name is the name by which an article is known to the American public. Common or usual names are generally established by common usage, although, in some cases, they may be established by regulation.[8] The fact that a standard of identity has been established for a food (under its common or usual name) or that a name is

[5] See 21 U.S.C. 341.
[6] See 21 U.S.C. 343(g).
[7] See 21 U.S.C. 343(i)(1).
[8] See 21 CFR 102.5(d).

specified among the standard of identity regulations for a food does not preclude use of the name in the common or usual name of another food.[9] However, such use must not be misleading.

In the absence of a common or usual name or other name established by federal law or regulation, food sold in packaged form must be labeled with an accurate description of the food or a fanciful name commonly used by the public.[10] Such description or name must not be false or misleading and is referred to as the statement of identity.[11] Words or statements required to appear on the label or labeling must be in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use.[12]

The FD&C Act also provides for labeling of a food product as an "imitation" of another food.[13] We have defined an imitation food as one that substitutes for and resembles another food and is nutritionally inferior to that food.[14] Nutritional inferiority is defined in part as any reduction in the content of an essential nutrient that is present at a level of two percent or more of the Daily Reference Value or Reference Daily Intake, depending on the nutrient, per reference amount customarily consumed.[15]

2. Identity and Naming of Milk and Plant-based Milk Alternatives

In 1973, FDA established a definition and standard of identity for milk.[16] Milk has since been defined as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows." Products that purport to be or are represented as milk are required to conform to the definition and standard, and their labels must bear the name "milk."[17] Products that do not purport to be and are not represented as milk are not subject to these requirements.

Plant-based milk alternatives are not milk; they are made from plant materials rather than the lacteal secretion of cows. Consequently, under the FD&C Act, they may not be offered for sale as "milk."[18] Although many plant-based milk alternatives are labeled with names that bear the term "milk" (e.g., "soy milk"), they do not purport to be nor are they represented as milk. The comments and information we reviewed indicate that consumers understand plant-based milk

[9] See, e.g., the standard of identity for composite units of frozen raw breaded shrimp (21 CFR 161.175(c)(6) and (e)(6)) and the common or usual name regulation for non-standardized breaded composite shrimp units (21 CFR 102.55(a)) (the names of both the standardized food and non-standardized food including "breaded shrimp"); see, e.g., the standard of identity for bread (21 CFR 136.110(a), (c)(1), and (e)(1)) and common usage names of non-standardized bakery products made without wheat flour (e.g., "rice bread") (the names of both the standardized food and the non-standardized food including "bread").

[10] See 21 CFR 101.3(b)(3).

[11] See 21 U.S.C. 343(a)(1); see also 21 CFR 101.3(b).

[12] See 21 U.S.C. 343(f).

[13] See 21 U.S.C. 343(c).

[14] See 21 CFR 101.3(e)(1).

[15] See 21 CFR 101.3(e)(4); Recently, FDA committed to not requiring a producer of non-vitamin-fortified skim milk to label that product as "imitation" (see *South Mt. Creamery, LLC v. United States FDA*, 438 F. Supp. 3d 236 (2020)).

[16] See 21 CFR 131.110.

[17] See 21 U.S.C. 403(g) and 21 CFR 131.110(e).

[18] See 21 U.S.C. 343(b).

alternatives to be different products than milk. While many circumstances attending retail sale of the products are similar to those attending retail sale of milk (e.g., packaging, labeling, location in grocery store), the comments and information we reviewed indicate that consumers, generally, do not mistake plant-based milk alternatives for milk.

Standards of identity have not been established for plant-based milk alternatives. As such, plant-based milk alternatives are non-standardized foods and must be labeled with their common or usual names, or in the absence thereof, a statement of identity that accurately describes the food.[19] The names of some plant-based milk alternatives appear to be established by common usage, such as "soy milk" and "almond milk."

3. First Amendment Considerations

FDA also recognizes that there are First Amendment considerations when regulating commercial speech such as food labels and labeling.[20] For example, FDA is aware of the current lawsuits that challenge state legislative limits to the use of words associated with traditional food products on alternative food product labels, and that some courts have scrutinized such labeling restrictions under the First Amendment. To support a prohibition on such speech, the proponent must demonstrate either that the speech in question is inherently false or misleading or that the regulation is appropriately tailored to directly advance a substantial governmental interest. As of February 2023, some cases remain pending. Some courts have held that, under the First Amendment, the states have failed to justify bans on plant-based alternative products using names associated with meat and/or dairy products.[21] However, some courts have held that a

[19] See 21 U.S.C. 343(i)(1) and 21 CFR 101.3(b).

[20] The First Amendment to the United States Constitution prohibits laws that, among other things, abridge the freedom of speech. See, e.g., *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2371 (2018). However, the government may, consistent with the First Amendment, require the disclosure of factual information in marketing commercial products where the disclosure is justified by a government interest and does not unduly burden protected speech. See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). The government may also prohibit commercial speech that concerns unlawful activity or is false or inherently misleading. See *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n,* 447 U.S. 557, 563-64 (1980). The government may further regulate commercial speech that is not false or deceptive and does not concern unlawful activities where the regulation directly advances a substantial governmental interest and is no more extensive than necessary to advance that interest. See *id.* at 564.

[21] See *Turtle Island Foods v. Strain*, 594 F. Supp. 3d 692 (M.D. La. 2022) (finding Louisiana may not restrict plant-based meat product to be marketed or sold with terms like "burger" and "sausage" on their labels because there was no evidence that the law was necessary to prevent consumer confusion, and the state failed to address why a less restrictive alternative, such as a disclaimer, would not be sufficient to advance the government interest), *appeal pending*, 22-30236 (5th Cir.); *Miyoko's Kitchen, Inc. v. Ross*, 3:20-cv-00893, 2021 U.S. Dist. LEXIS 193462 (N. D. Cal. Aug. 10, 2021) (finding California may not restrict plaintiff's use of the word "butter" and the phrases "lactose free" and "cruelty free" on the labeling of its "vegan butter"); *Turtle Island Foods v. Soman*, 424 F. Supp. 3d 552 (E.D. Ark. 2019) (preliminarily enjoining Arkansas from enforcing law that prohibited selling an agricultural product under the name of another food), *permanent injunction entered*, 2022 U.S. Dist. LEXIS 179206 (E.D. Ark. Sept. 30, 2022). See also *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228 (11th Cir. 2017) (although "a state can propose a definition for a given term, . . . it does not follow that once a state has done so, any use of the term inconsistent with the state's preferred definition is inherently misleading" particularly where that definition is inconsistent with common usage).

state can require that the labeling on the plant-based alternative product include a prominent disclosure indicating that the product is plant-based.[22]

E. Role of Milk in Healthy Eating Patterns

The U.S. Dietary Guidelines for Americans (Dietary Guidelines) make recommendations for healthy eating patterns that can help reduce chronic disease risk and help individuals meet nutrient needs. Depending on calorie needs and age, the *Dietary Guidelines, 2020-2025* recommends 1⅔-2 cup equivalents (whole-fat) from the Dairy Group per day for toddlers ages 12-23 months and between 2-3 cup equivalents (low-fat or fat-free) from the Dairy Group per day for children (≥2 years of age) and adults to achieve a healthy eating pattern (Ref. 8). However, about 90 percent of the U.S. population does not meet these recommendations (Ref. 8). The Dairy Group includes, but is not limited to, all fluid, dry, or evaporated milk, including lactose-free and lactose-reduced products and fortified soy beverages (soy milk), as well as cheese, yogurt, and soy yogurt alternatives. According to the 2017-2018 National Health and Nutrition Examination Survey (NHANES), the majority of dairy consumed in the U.S. (49 percent) is from milk, primarily as a beverage or on cereal. Overall, dairy intake has not changed over time; however, it has decreased among youth and significantly decreased among children two to five years of age (Ref. 9). Total dairy intake is highest among non-Hispanic White and Hispanic individuals and lowest among non-Hispanic Black individuals for all ages (Ref. 9).

The Dietary Guidelines identify the Dairy Group as a key contributor of calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, vitamin B-12, as well as zinc, choline, and selenium. The *Dietary Guidelines, 2020-2025* (Ref. 8) identifies calcium, vitamin D, and potassium as nutrients of public health concern across all age groups, including ages 12-23 months, and the Scientific Report of the 2020 Dietary Guidelines Advisory Committee (2020 DGAC Report) (Ref. 9) notes vitamin A, magnesium, and choline as nutrients that pose a special public health challenge[23] for individuals one year of age and older. FDA also identified calcium, vitamin D, and potassium as nutrients of public health significance, requiring them to be declared on the updated Nutrition Facts label.[24] The Dairy Group in the *Dietary Guidelines, 2020-2025* includes soy beverages fortified with calcium, vitamin A, and vitamin D because they are similar to milk based on their nutrient composition and use in meals.

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[22] See *Turtle Island Foods v. Richardson*, 425 F. Supp. 3d 1131 (W.D. Mo. 2019) (declining to issue a preliminary injunction against Missouri over a law that prohibited "misrepresenting a product as meat that is not derived from harvested production livestock or poultry" where Missouri issued guidance stating that it would not take enforcement action if the label contained an appropriate qualifier indicating that the product was plant-based or lab-grown), aff'd, 992 F.3d 694 (8th Cir. 2021); *Upton's Nats. Co v. Stitt*, 2020 U.S. Dist. LEXIS 216883 (W.D. Okla. Nov. 19, 2020) (preliminarily upholding mandated disclosure that the product is plant-based in same font size as the product name). In addition, after Mississippi was sued over a law that banned the use of meat product terms to describe plant-based foods, *Upton's Naturals Co. v. Bryant*, 3-19-cv-462 (S.D. Miss.), the state withdrew its proposed implementing regulation and replaced it with a new proposed regulation stating that the state would not consider labeling to be violative if the labeling included an appropriate qualifier indicating the product was plant-based. Plaintiffs then withdrew the lawsuit.

[23] The 2020 DGAC Report explains that "nutrients that pose a special public health challenge" are nutrients that are currently under-consumed, but there is insufficient data to assess adverse clinical and health outcomes.

[24] See 81 FR 33742 at 33884; see also 21 CFR 101.9(c)(8)(ii).

The *Dietary Guidelines, 2020-2025* provides dietary recommendations, including for the Dairy Group and the nutrients it provides, within and across life stages. Diets that do not meet the recommended amounts from the Dairy Group contribute to low intakes of nutrients, particularly calcium and vitamin D. Inadequate consumption of calcium and vitamin D can result in impaired peak bone mass accrual, low bone mass, and osteoporosis (Ref. 9). Although calcium and vitamin D are important across the lifespan, calcium and vitamin D are critically needed during the time period when peak bone mass is still actively accruing (adolescence through 30 years of age), and, for women, in the post-menopausal period when bone remodeling occurs (Ref. 8). Additionally, adequate intake of vitamin D is important because of its role in the regulation of calcium and phosphorus metabolism and bone health. However, as noted above, the percentage of youth with Dairy Group intakes below recommended levels increases dramatically starting at age 9 years, with 79 percent or more between ages 9 and 13 years falling below recommended intakes (Ref. 9). The 2020 DGAC Report cautions that, because foods in the Dairy Group are a significant source of these important nutrients, the downward trend in consumption in youth should be monitored.

While all foods recommended in the Dairy Group in the Dietary Guidelines provide calcium and the other important nutrients of interest, dairy is generally consumed in forms with higher amounts of sodium (e.g., cheeses) and saturated fat (e.g., higher fat milks and yogurts). The Dietary Guidelines advise that consuming more dairy in low-fat or fat-free forms than current amounts would provide more vitamin A, vitamin D, potassium, and choline and decrease amounts of sodium, cholesterol, and saturated fats.

F. Nutritional Differences between Plant-based Milk Alternatives and Milk

While the nutritional value of milk and its role in healthy eating patterns is well documented, the nutritional content of plant-based milk alternatives varies considerably across types (e.g., "almond milk" vs. "oat milk") and within the same type depending on the raw materials used, processing, fortification with vitamins and minerals, and addition of other ingredients, such as sugar and oil (Refs. 5, 11, and 12). As noted above, the *Dietary Guidelines, 2020-2025* includes soy beverages and soy yogurt alternatives that are fortified with calcium, vitamin A, and vitamin D in the Dairy Group because they have similar nutrient compositions and use in meals. However, the *Dietary Guidelines, 2020-2025* states that "other products sold as "milks" but made from plants (e.g., almond, rice, coconut, and hemp "milks") may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages."

The Scientific Report of the 2015 Dietary Guidelines Advisory Committee (2015 DGAC Report) included a modeling analysis "to examine the nutritional consequences of not consuming milk and milk products, to explore possible food alternatives to fill the nutrient gaps left in the diet if milk and milk products are not consumed" (Ref. 10). The analysis demonstrated that, while individuals can consume these nutrients from sources other than milk, the number of potential alternatives to provide sufficient calcium would provide too many calories and/or be a large amount to consume daily. Therefore, the Dietary Guidelines recommend three cup equivalents from the Dairy Group for individuals nine and older to support an increased requirement for calcium that is needed during these life stages. The question of bioavailability of calcium in

non-dairy products was not addressed in the modeling analysis. (Ref. 10). Calcium- and vitamin D-fortified plant-based milk alternatives are alternatives to milk to consider, but they may vary in other potentially important nutrients (e.g., protein, magnesium, phosphorus, and potassium).

The 2020 DGAC Report built on this analysis by evaluating beverages' contribution to healthy eating patterns, and the inclusion of only fortified soy beverages in the Dairy Group remained. Further, the 2020 DGAC Report notes that inadequate intakes from the Dairy Group may contribute to low intakes of calcium, protein, vitamins A and D, magnesium, and phosphorous. Some of these essential nutrients can be difficult to replace in a healthy dietary pattern. Americans already consume less from the Dairy Group than what is recommended by the Dietary Guidelines and the nutritional composition of plant-based milk alternatives varies greatly and often is not similar to milk. Therefore, consistently consuming plant-based milk alternatives that do not have a similar nutritional composition to milk in place of milk, without the addition of other foods to supply the missing nutrients, could lead to further inadequate intakes of nutrients of public health concern and other nutrients that pose a special public health challenge. This, in turn, could lead to adverse health effects such as impaired peak bone mass accrual, low bone mass, and osteoporosis (see Section II.E. of this Guidance).

Recognizing the important role of milk in healthy dietary patterns, the Department of Agriculture's (USDA) National School Lunch Program (NSLP), School Breakfast Program (SBP), and Child and Adult Care Food Program (CACFP) require milk to be served as part of a reimbursable meal. However, recognizing that some children and adults cannot consume milk due to non-disability medical or other special dietary needs (e.g., lactose intolerance), the Richard B. Russell National School Lunch Act (School Lunch Act) requires that fluid milk substitute served as an alternative to milk in the NSLP, SBP, and CACFP must be nutritionally equivalent to milk and meet nutritional standards set by the U.S. Department of Agriculture (USDA).[25] Specifically, the School Lunch Act requires that the nutritional standards for fluid milk substitute must, at a minimum, be fortified with calcium, protein, vitamin A, and vitamin D to levels found in milk.[26] Citing that milk is the primary food source for riboflavin, vitamin B-12, magnesium, phosphorus, and potassium for children, USDA's Food and Nutrition Service (FNS) extended the nutrition standards for fluid milk substitute to include these additional vitamins and minerals.[27] Therefore, a fluid milk substitute must contain a minimum amount of calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B-12 (Appendix 1) to be part of a reimbursable meal in the NSLP, SBP, and CACFP.[28] These are the same nutrients that the Dietary Guidelines identify as key contributions from the Dairy Group except for zinc, choline, and selenium (see Section II.E. above). Choline and selenium were not discussed in the *2005 Dietary Guidelines* which was the current version at the time USDA's FNS developed the fluid milk substitute nutrient criteria. Certain soy-based beverages are also allowed as substitutes for milk in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC Program). To maintain consistency, the WIC Program

[25] See sections 9(a)(2)(B)(i) and 17(g)(4)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1758(a)(2)(B)(i) and 1766((g)(4)(B)).
[26] Ibid.
[27] See 7 CFR 210.10 (d)(3), 220.8(d), and 226.20(g)(3).
[28] Ibid.

uses the same nutrition standards as the NSLP, SBP, and CACFP for defining allowable soy-based beverages as alternatives to milk.[29]

As discussed above (Section II.C.b.), consumer studies indicate that, in general, while consumers do not understand the nutritional differences between plant-based milk alternatives and milk, they believe plant-based milk alternatives are healthier than milk and expect that products labeled with the term "milk" in the name are comparable in nutrition to milk (Ref. 1). Considering that consumers may not understand the nutritional differences between plant-based milk alternatives and milk and the potential public health concerns associated with replacing milk with plant-based milk alternatives that do not have a similar nutritional composition to milk,[30] FDA is providing recommendations for voluntary nutrient statements for plant-based milk alternatives that include "milk" in their names (e.g., "soy milk," "almond milk," "oat milk," etc.) and have a nutrient composition that is different than milk to help consumers understand the nutritional differences between such products and milk.[31]

III. Questions and Answers

The following section provides information and recommendations in a question and answer format about: (1) naming principles for plant-based milk alternatives; and (2) recommendations for voluntary nutrient statements.

1. Identity and Names

1.1. Is there an established standard of identity for plant-based milk alternatives?

No, plant-based milk alternatives are non-standardized foods as no definition or standard of identity has been prescribed for them by regulation.

1.2. What are the common or usual names of plant-based milk alternatives?

Common or usual names have been established by common usage for some plant-based milk alternatives. Among these names are "soy milk" and "almond milk" and others that qualify the term "milk" with the plant source of the food. Names that qualify the terms "beverage" or "drink" with the plant source of the food are used less frequently, but also appear to be in common usage. These names include "soy beverage" and "almond beverage."

1.3. Do plant-based milk alternatives need to include the term "milk" in their names (e.g., "soy milk," "almond milk," etc.)?

[29] See 7 CFR 246.10(e)(10-12).

[30] Plant-based milk alternatives that contain the minimum amount identified in Appendix 1 (USDA's FNS Fluid Milk Substitutes Nutrient Criteria) are considered nutritionally similar to milk.

[31] At this time, FDA is not aware of a potential public health concern associated with substituting other mammalian milks for milk. The percent of U.S. households that purchase plant-based milk is much higher than those that consume other mammalian milks (e.g., goat, camel). Therefore, the recommendations for a voluntary nutrient statement in this guidance focus on plant-based milk alternatives and not other mammalian milks.

No. Non-standardized foods are required to be labeled with their common or usual name if such a name exists.[32] As explained in 1.2, many plant-based milk alternatives appear to have multiple common or usual names. Under section 403(i)(1) of the FD&C Act (21 U.S.C. 343(i)(1)), plant-based milk alternatives must be labeled with a common or usual name, but there is no requirement that they be labeled with more than one common or usual name. Consequently, a plant-based milk alternative may be labeled with the term "beverage," "drink," or "milk."

1.4. How should the term identifying the plant source appear in reference to the term "milk," "beverage," or "drink"?

In the names of plant-based milk alternatives, the term "milk" (or "beverage" or "drink") should be qualified by the plant source of the food. The name may be a single word (i.e., "soymilk"), multiple words (e.g., "soy milk"), or hyphenated (e.g., "soy-milk").

1.5. Is "plant-based milk" an appropriate name for plant-based milk alternatives?

No, while "plant-based" or "plant" may be used to describe a plant-based milk alternative, we do not recommend using only these terms in the name of the food. "Plant-based milk" is not the common or usual name of plant-based milk alternatives. Moreover, omitting a descriptor of the particular legume, nut, grain, seed, or other plant-source in the name of the food may be confusing to consumers, as the product would not be readily distinguishable from other types of plant-based milk alternatives. The nature or source of the characterizing or predominant ingredients is important information for consumers and should be included in the name or statement of identity to identify and describe the food and distinguish it from similar foods. Consumers should be able to easily determine the particular plant source when looking at the name of the food on the label (e.g., almond or oat).

1.6. How should plant-based milk alternatives that are blends of different plant sources be labeled?

If a plant-based milk alternative is derived from different plant sources, we recommend that the different plant sources be included in the name so that consumers can easily identify the nature of the food and distinguish it from similar foods. We recommend that the predominant plant source be stated first in the name or statement of identity. For example, a plant-based milk alternative that is a blend of walnuts and cashews, with walnuts predominating, should be labeled with "walnut" first, followed by "cashew"; possible names include: "Walnut & Cashew Milk," "Walnutmilk with Cashewmilk," or "Walnut-Cashew Milk."

For plant-based milk alternatives that are blends of two or more plant-sources, the name should accurately convey to the consumer that multiple plant sources are present. For example:

[32] See 21 U.S.C. 343(i)(1).

- "Soy and Nut Milk Blend" (for a product that contains a blend of soy, almonds, and cashews)
- "7 Grain Plant-Milk Blend" (for a product that contains a blend of only grains (e.g., oats, wheat, barley, rice))

All plant sources must be declared in the ingredient statement as required by 21 CFR 101.4.

1.7. Should plant-based milk alternatives be labeled "imitation milk"?

As previously discussed, we have defined an imitation food under the FD&C Act as one that substitutes for and resembles another food and is nutritionally inferior to that food. Not all plant-based milk alternatives meet this definition, but to the extent they do, based on our current understanding, we intend to exercise enforcement discretion with respect to section 403(c) of the FD&C Act (21 U.S.C. 343(c)).

When section 403(c) of the FD&C Act (21 U.S.C. 343(c)) was enacted in 1938, Congress was seeking to protect the consumer from uninformed purchase of an inferior substitute product which could be mistaken for a traditional food product (e.g., jams).[33] The information we reviewed demonstrates that consumers generally do not mistake plant-based milk alternatives as milk, understand that they are distinct products, and often purchase plant-based milk alternatives because they are not milk (e.g., lactose-intolerance, vegan diet).

1.8. Should plant-based milk alternatives be labeled as "dairy-free" or "non-dairy"?

The use of truthful and not misleading label statements (e.g., "dairy-free," "non-dairy") that help inform consumers that the products are derived from plants, and are not milk and do not contain milk, is encouraged. However, the term "dairy-free milk" is not an adequate name for any plant-based milk alternative because it does not describe the nature of the plant-source and therefore does not distinguish the product from other types of plant-based milk alternatives. The nature or source of the characterizing or predominant ingredients is important information for consumers and should be included in the name or statement of identity to identify and describe the food and distinguish it from similar foods. Thus, such terms are not appropriate names for plant-based milk alternatives but may be used as additional information on product labels to help inform consumers that the products are not made with dairy or milk.

[33] See 38 FR 2138 (Jan. 19, 1973).

2. Recommendations for Voluntary Nutrient Statements

FDA recommends that plant-based milk alternatives that use the term "milk" in their name (e.g., "soy milk," "almond milk," "oat milk," "almond-macadamia milk blend," etc.) and have a nutrient composition that is different than milk (e.g., calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, or vitamin B12 (see Appendix 1)) bear an additional nutrient statement on the product label describing how it is nutritionally different. The use of these statements is voluntary.

2.1. What is the purpose of voluntary nutrient statements for plant-based milk alternatives?

FDA recommends the use of these statements to help consumers understand certain nutritional differences between milk and plant-based milk alternatives that use the term "milk" in their name (e.g., "soy milk," "almond milk," "oat milk," "almond-macadamia milk blend," etc.) and have a nutrient composition that is different than milk. As discussed above, milk plays an important role in healthy diets, and the Dietary Guidelines encourage increased consumption of milk to help alleviate specific nutrient shortfalls. Additionally, consumer research indicates that, while the majority of consumers understand that milk and plant-based milk alternatives are different products, consumers may not understand the nutritional differences between them. Consumer research also indicates that consumers perceive plant-based milk alternatives labeled with the term "milk" to have a more favorable nutritional profile than similar products labeled with terms like "drink" or "beverage" (Ref. 1).

2.2. How should manufacturers determine if their plant-based milk alternatives have different nutrient compositions to milk?

To determine if a plant-based milk alternative is nutritionally different than milk, 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; see Appendix 1). These are the same nutrients that the Dietary Guidelines identify the Dairy Group as a key contributor of except for zinc, choline, and selenium (see Section II.E.).

2.3. What information does FDA recommend be included in the voluntary nutrient statement?

Due to the potential public health concern of underconsumption of certain nutrients otherwise provided by milk, we recommend that plant-based milk alternatives that use the term "milk" in their name (e.g., "soy milk," "almond milk," "oat milk," "almond-macadamia milk blend," etc.) and have a nutrient composition that is different than milk

(Appendix 1) bear a voluntary nutrient statement on the product label about the nutrient levels compared to milk, such as:

- "Contains lower amounts of [nutrient name(s)] than milk."

This type of voluntary nutrient statement will clearly communicate to consumers when a plant-based milk alternative is lower in nutrients in comparison to milk (see also question 2.8).

2.4. How does FDA recommend the voluntary nutrient statement be presented on the label?

We recommend placing the voluntary nutrient statement on the principal display panel (PDP) near and visually connected to the name of the product if space allows. A symbol (e.g., "†") may be placed next to the name of the product that directs consumers to the voluntary nutrient statement on the PDP. We also recommend that the voluntary nutrient statement be prominent on the food label so that it is easily identifiable for consumers.

Figure 1: Example of Voluntary Nutrient Statement on Product Label next to Product Name

Figure 2: Example of Voluntary Nutrient Statement on Product Label next to Product Name - *Close-up of Voluntary Nutrient Statement*

Figure 3: Example of Voluntary Nutrient Statement on Product Label Using a Symbol

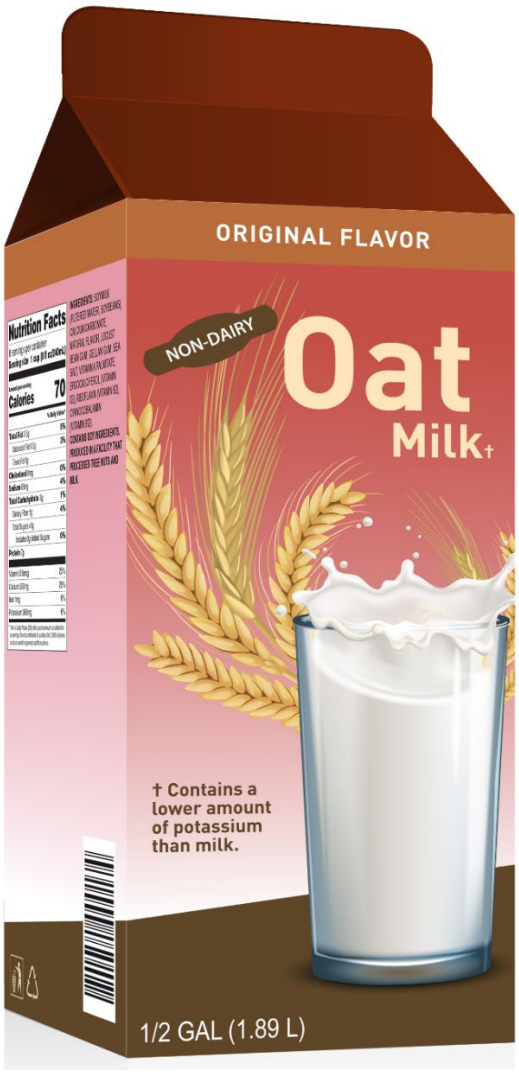
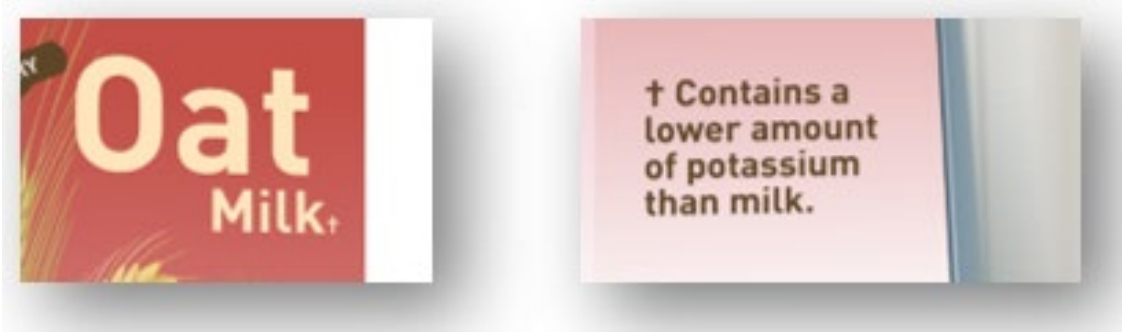


Figure 4: Example of Voluntary Nutrient Statement on Product Label Using a Symbol - *Close-up of Symbol and Voluntary Nutrient Statement*



2.5. Why does FDA recommend certain plant-based milk alternatives bear additional information on their label when nutrition information is already provided in the Nutrition Facts label?

We recommend plant-based milk alternatives that use the term "milk" in their name and have a nutrient composition that is different than milk (Appendix 1) bear additional information because consumer research indicates that consumers may not understand the nutritional differences between plant-based milk alternatives and milk (Ref. 1). The term "milk" may create a more favorable perception of plant-based milk alternatives' nutritional content compared to the use of terms like "drink" or "beverage" (Ref. 1). Further, product labels for half of the top 10 brands of plant-based milk alternatives include direct nutrient comparisons to milk, primarily for calcium (e.g., "50% more calcium than milk"), yet some of these products may contain lower amounts of other important nutrients found in milk including under-consumed nutrients discussed in section II.E. (Refs. 3, 11, and 12).

Because milk plays an important role in healthy eating patterns, it is important to provide consumers with additional information about how a plant-based milk alternative may be nutritionally different than milk by providing that information on the PDP. Additionally, not all the important nutrients found in milk, as identified by the Dietary Guidelines (e.g., vitamin A, magnesium, magnesium, phosphorus, riboflavin, and vitamin B12), are required to be listed on the Nutrition Facts label. Therefore, a voluntary nutrient statement on the PDP that describes how the plant-based milk alternative is nutritionally different than milk, based on USDA's FNS nondairy beverages nutrient criteria (Appendix 1), will provide additional information to consumers to help them make informed decisions about the products they purchase and consume.

2.6. If my plant-based milk alternative contains the same amount of nutrients of public health concern as milk, but has lower levels of magnesium, which is not under-consumed, does FDA recommend that my product still bear a voluntary nutrient statement?

Yes, if a manufacturer chooses to use the term "milk" in the name of a plant-based milk alternative that has a lower amount of magnesium than milk, we recommend the product bear a voluntary nutrient statement on the PDP, such as:

- "Contains a lower amount of magnesium than milk."

To provide information to consumers about the nutritional differences between milk and plant-based milk alternatives that use the term "milk" in their name, we recommend such plant-based milk alternatives that are lower in any nutrient listed in USDA's FNS non-dairy beverages nutrient criteria (Appendix 1) bear a voluntary nutrient statement. Magnesium is a nutrient listed in USDA's criteria.

2.7. The name "Almond Milk" appears in multiple places on the label of my plant-based milk alternative that does not have a similar nutrient composition as milk. Does FDA recommend that there be a voluntary nutrient statement or a symbol leading to a voluntary nutrient statement next to all the uses of "Almond Milk" on the label?

Our goal in recommending that plant-based milk alternatives that have a nutrient composition that is different than milk (Appendix 1) and use the term "milk" in their name bear a voluntary nutrient statement is to make the information readily available to consumers to help them make more informed purchasing choices. However, we recognize that space is limited on food labels. Therefore, we recommend a voluntary nutrient statement or a symbol (e.g., "†") leading consumers to the voluntary nutrient statement on the PDP be placed next to the product name when it appears on the PDP, but not necessarily when it appears in other places on the label.

Figure 5: Example of Voluntary Nutrient Statement on Product Label When Name Appears on Label Multiple Times

Figure 6: Example of Voluntary Nutrient Statement on Product Label When Name Appears on Label Multiple Times - *Close-up of Symbols and Voluntary Nutrient Statement*

2.8. May plant-based milk alternatives that have a nutrient composition that is different than milk bear a relative claim comparing the product to milk?

Yes. Currently, some plant-based milk alternatives make relative claims comparing the products' nutrition profile to milk on the PDP (e.g., "50% more calcium than milk," "contains similar amounts of calcium as milk"[34]). However, some products may contain lower amounts of other important nutrients found in milk that are identified in USDA's FNS nondairy beverages nutrient criteria (Appendix 1). In these scenarios, we recommend that a voluntary nutrient statement or a symbol (e.g., "†") leading consumers to the voluntary nutrient statement on the PDP be placed next to such relative claims. We also recommend that the voluntary nutrient statement be as prominent on the food label as the relative claim so that it is easily identifiable for consumers. This will help ensure consumers have information about the plant-based milk alternative's nutrient profile in comparison to milk.

[34] For more guidance on food labeling, see FDA's Guidance for Industry, *Food Labeling Guide* (January 2013) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide.

Figure 7: Example of Voluntary Nutrient Statement next to a Relative Claim Comparing the Product to Milk

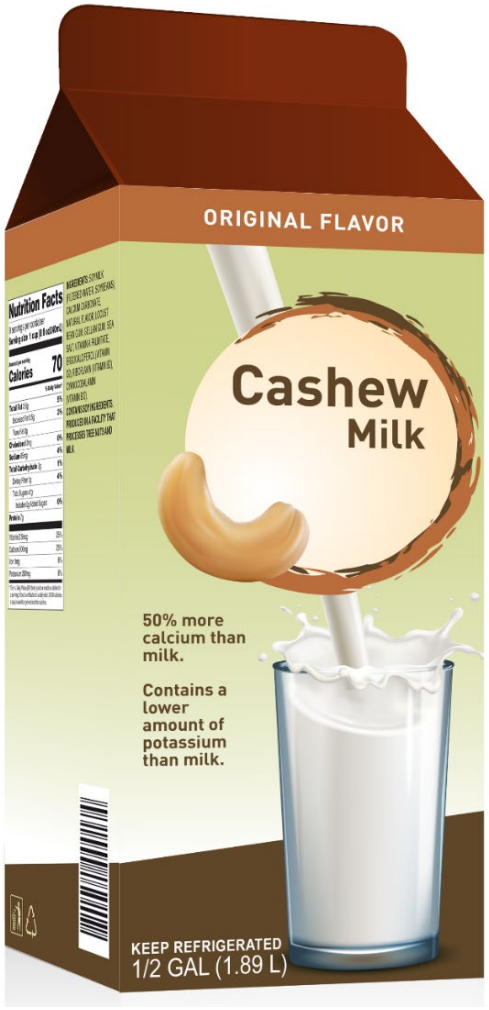


Figure 8: Example of Voluntary Nutrient Statement next to a Relative Claim Comparing the Product to Milk - *Close-up of Relative Claim and Voluntary Nutrient Statement*

Figure 9: Example of Voluntary Nutrient Statement Using a Symbol next to a Relative Claim Comparing the Product to Milk

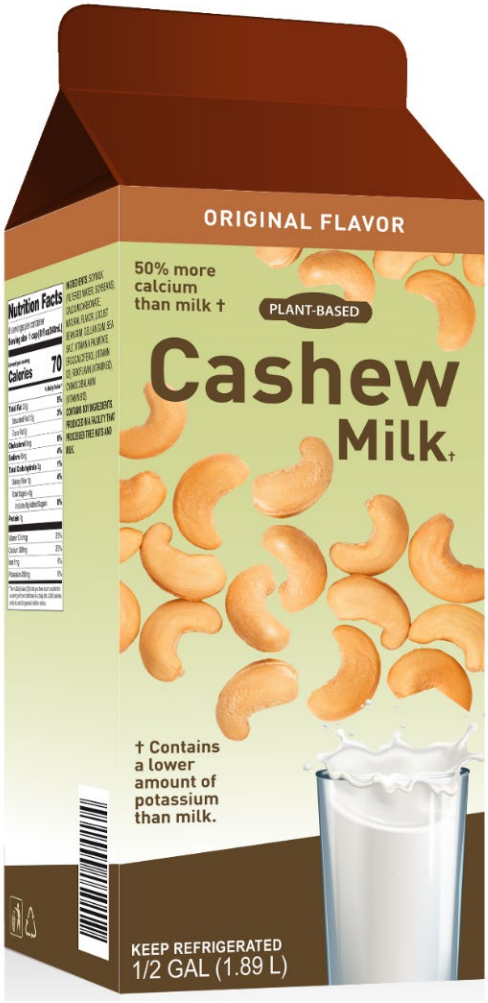
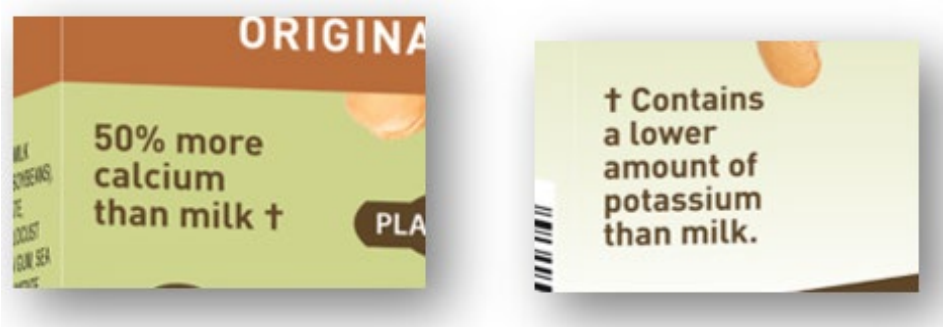


Figure 10: Example of Voluntary Nutrient Statement Using a Symbol next to a Relative Claim Comparing the Product to Milk - *Close-up of Relative Claim and Voluntary Nutrient Statement*



2.9. May a manufacturer make a statement about other nutrients not in USDA's FNS nondairy beverages nutrient criteria or about higher amounts on the label?

Yes, manufacturers may make truthful and not misleading statements about nutrients that are not listed in USDA's FNS nondairy beverages nutrient criteria (Appendix 1). As stated in Q&A 2.8, comparison statements also may be included in the nutrient statements.

- "Contains 20% more of the Daily Value for iron than milk."
- "Contains 50% more calcium than milk."

2.10. If a plant-based milk alternative is named "Soy Beverage" and it bears a relative claim comparing the product to milk, does FDA recommend that it bear a voluntary nutrient statement?

Yes, FDA also recommends that plant-based milk alternatives that use "beverage" or "drink" in their name (e.g., "almond beverage," "oat drink," etc.) and bear a relative claim comparing the product to milk (e.g., "50% more calcium than milk") use a symbol next to the claim; the symbol would lead to a voluntary nutrient statement about other nutrients found in milk (Appendix 1) that are present in lower amounts in the plant-based milk alternative. Similar to plant-based milk alternatives that use the term "milk" in their name, this will help ensure consumers have information about a plant-based milk alternative's nutrient profile when comparisons to milk's nutrient content are made.

2.11. Some plant-based milk alternatives come in sweetened varieties with added sugars. Does FDA recommend that the added sugars content of such products be communicated to consumers in the voluntary nutrient statement?

No, FDA's recommendations for voluntary nutrient statements are limited to the nutrients listed in Appendix 1. We note that plant-based alternatives come in unsweetened and sweetened versions, and the amount of added sugars in the sweetened versions varies. The Dietary Guidelines recommend limiting consumption of added sugars as part of its key recommendations for a healthy eating pattern. Data show that the added sugars content of sweetened plant-based milk alternatives appears to be similar to or lower than sweetened, flavored milks' (e.g., chocolate milk, strawberry milk) added sugars content (Ref. 13). Additionally, the gram amount and percent Daily Value of Added Sugars must be declared on the updated Nutrition Facts label,[35] making the information readily available to consumers.

[35] See 21 CFR 101.9(c)(6)(iii).

2.12. Do the voluntary nutrient statement recommendations outlined in this guidance apply to other plant-based dairy alternatives such as plant-based cheese, yogurt, or kefir alternatives?

No, the voluntary nutrient statement recommendations outlined in this guidance are limited to plant-based milk alternatives and are not intended apply to any other foods.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, 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. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, CFSAN Consumer Studies Memorandum (February 2023). *
2. A Consumer's Guide to Identifying the Best Non-Milk Alternatives, Cornucopia Institute (June 2019).
3. Allis Information Management, Dairy & Plant-Based Dairy Alternatives (PBDA) in the U.S.: Market & Industry Practices (August 2020). *
4. Watson, Elaine, Oatmilk edges past soymilk for #2 slot in US plant-based milk retail market, Food Navigator-USA.com (September 25, 2020).
5. Thorning, TK, Raben, A, Thorning, T, Soedamah-Muthu, SS, Givens, I, Astrup, A., Milk and Dairy Products: Good or Bad for Human Health? An Assessment of the Totality of Scientific Evidence. *Food & Nutrition Research*, 60: 32527 (2016).
6. CR Consumer Reports Survey, Survey Research Report, Plant-Based Milk Survey, Nationally Representative Phone Survey (October 31, 2018).
7. McClements, D.J., Newman, E.N., and McClements, I.F., Plant-based Milks: A Review of the Science Underpinning Their Design, Fabrication, and Performance. *Comprehensive Reviews in Food Science*, Vol. 18: 2047-2067 (2019).
8. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Dietary Guidelines for Americans (2020-2025). Available by visiting https://www.dietaryguidelines.gov/, (last accessed 11/29/2021). *
9. U.S. Department of Agriculture, Agricultural Research Service, Dietary Guidelines Advisory Committee, Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. Washington, DC (2020). Available by visiting https://www.dietaryguidelines.gov/2020-advisory-committee-report, (last accessed 11/29/2021). *
10. U.S. Department of Agriculture, Agricultural Research Service, Dietary Guidelines Advisory Committee, Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Appendix E-3.6: Dairy Group and Alternatives, Washington, DC (2015). Available by visiting https://health.gov/sites/default/files/2019-09/15-Appendix-E-3.pdf, (last accessed 11/29/2021). *

11. Scholz-Ahrens, K.E., Ahrens, F, Barth, C.A., Nutritional and Health Attributes of Milk and Milk Imitations. *European Journal of Nutrition*, 59: 19–34 (2020).
12. Singhal, S, Baker, RD, Baker, SS, A Comparison of the Nutritional Value of Cow's Milk and Nondairy Beverages. *Journal of Pediatric Gastroenterology and Nutrition*, 64(5): 799-805 (2017).
13. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling Memorandum (February 2023). *

Appendix 1

USDA's FNS Fluid Milk Substitutes Nutrient Criteria (7 CFR 210.10 (d)(3), 220.8(d), 226.20(g)(3), and 246.10(e)(10-12))

Nutrient	Per cup (8 fluid ounces) (minimums)
Calcium	276 milligrams (mg)
Protein	8 grams
Vitamin A	500 International Units (IU)*
Vitamin D	100 IU*
Magnesium	24 mg
Phosphorus	222 mg
Potassium	349 mg
Riboflavin	0.44 mg
Vitamin B12	1.1 micrograms

*FDA is aware that USDA has issued a proposed rule (85 FR 4094) to update the units of measure for vitamin A and vitamin D to align with how they are declared on the updated Nutrition Facts label, which is in micrograms.