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Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry

Draft Guidance

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For questions regarding this draft document, contact the Human Foods Program at HFP-Policy@fda.hhs.gov.

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**U.S. Department of Health and Human Services
Food and Drug Administration
Human Foods Program**

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Table of Contents

I. Introduction..... 3
II. Background 4
III. Questions and Answers 8
IV. References..... 14

Contains Nonbinding Recommendations

Draft-Not for Implementation

Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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This draft guidance provides FDA's recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods (plant-based alternative foods), especially in the absence of a common or usual name for the product. These recommendations for manufacturers are intended to help ensure that consumers understand the nature or source of individual plant-based alternative foods, including differences among these products, and have the information they need to make informed purchasing decisions.

This draft guidance may also help manufacturers of plant-based alternatives to animal-derived foods ensure that the labeling for, and names of, their products are truthful and non-misleading and accurately describe the food.² FDA's assessment of whether the naming and labeling of these products complies with all relevant provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) will continue to be made on a case-by-case basis, considering the totality of the information.

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

² See 21 U.S.C. 343(a)(1) and 343(i)(1).

Contains Nonbinding Recommendations

Draft-Not for Implementation

The scope of this guidance includes plant-based alternatives to eggs, seafood, poultry, meat, and dairy products (excluding plant-based milk alternatives³) that fall under FDA jurisdiction.⁴ This draft guidance does not address the naming and labeling of plant-based milk alternatives; that topic is being addressed elsewhere.⁵

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our 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 guidance means that something is suggested or recommended, but not required.

II. Background

A. Purpose and Overview

One goal of FDA's nutrition initiatives is to help ensure that food labels provide truthful, non-misleading, and useful information so consumers can make informed purchasing decisions on the products they buy for themselves and their families (Ref. 1). 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. One of the key principles to help people meet the Dietary Guidelines is to encourage them to choose a variety of options from each food group (Ref. 2). The composition of plant-based alternative foods varies, and based on current recommendations, such foods may be considered part of different food groups (i.e., vegetable, protein, or grain) depending on their composition. In this guidance, FDA provides its view on best practices for plant-based alternative food labels that are clear and accurate, to help enable consumers to quickly ascertain the attributes of products they are purchasing. We are committed to accomplishing this by empowering consumers with more informative labeling to make informed dietary choices.⁶ For purposes of this guidance, we refer

³ In the *Federal Register* of February 23, 2023, we published a draft guidance, *Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Draft Guidance for Industry*. When finalized, it will provide FDA's view on the naming of plant-based food products that are marketed and sold as alternatives to milk (plant-based milk alternatives) and our recommendations on the use of voluntary nutrient statements. Available online at <https://public4.pagefreezer.com/browse/FDA/11-12-2023T13:13/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements>.

⁴ This guidance excludes animal proteins produced by microflora.

⁵ *Ibid.*

⁶ FDA recognizes that there are First Amendment considerations when regulating commercial speech such as food labels and labeling. The First Amendment to the United States Constitution prohibits laws that, among other things, abridge the freedom of speech. U.S. Const. amend. I. 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.

Contains Nonbinding Recommendations

Draft-Not for Implementation

to these alternative foods as “plant-based” because they consist of plant-derived ingredients rather than animal-derived ingredients.

This guidance provides information and recommendations around the naming and labeling of plant-based alternative foods in general. The scope of this guidance includes plant-based alternatives to eggs, seafood, poultry, meat, and dairy (excluding plant-based milk alternatives⁷) that fall under FDA jurisdiction.⁸ FDA has regulatory authority over all plant-based alternatives to animal products under the FD&C Act while the United States Department of Agriculture (USDA) has regulatory authority over most animal products, e.g., meat products, poultry products, egg products, and fish of the order Siluriformes (e.g., catfish).

Consumer demand for plant-based alternatives to animal products including eggs, seafood, poultry, meat, and dairy has increased over time. The total U.S. retail plant-based food dollar sales grew from \$5.5 billion in 2019 to \$8.1 billion in 2023 and many new plant-based alternatives to conventional animal products entered the U.S. retail market, including emerging categories (e.g., plant-based eggs) (Ref. 3). According to the Plant-Based Foods Association, their consumer research found 70% of the total U.S. population is consuming plant-based foods (Ref. 4).

Consumers purchase plant-based alternative foods for various reasons, such as dietary choices (e.g., vegan/vegetarian diets), allergies, taste preferences, religious practices, and environmental concerns. According to the Plant-Based Foods Association, consumers of plant-based alternative foods span all generations and socioeconomic backgrounds (Ref. 4). Consumers typically use these foods in a similar way to animal-derived foods, as main dishes, side dishes, or snacks. Some plant-based brands seek to appeal to conventional meat eaters, or consumers that try to limit meat consumption and integrate plant-based proteins. The types and varieties of plant-based alternative foods have expanded, and now consumers have product options that are intended to resemble the flavor, form or cut (e.g., burger or fillet), texture, and appearance of foods derived from animals.

The predominant ingredients in these products vary widely. Foods within the category may consist of legumes, tree-nuts, seeds, grains, starches, fungi, fruits, or vegetables alone or in combination with other ingredients (Ref. 5). Given the diversity of predominant ingredients in these foods and the recent market expansion of these foods, this guidance sets forth recommendations for manufacturers. The use of these recommendations will provide consumers with access to information about the primary plant source(s) on the principal display panel to help them when making purchasing decisions that align with their dietary needs, preferences, or desire for nutritional variety. There also may be nutritional differences between a plant-based product and an animal-derived product, and conveying the plant source(s) in the naming of the

However, this guidance provides only recommendations for best practices, and neither compels nor restricts speech. Moreover, this guidance would readily satisfy any applicable First Amendment standard. For example, the recommended disclosures relate to factual and uncontroversial information about product ingredients; will help consumers have ready access to the information they need to make informed purchasing decisions to align with their dietary needs, preferences, or desire for nutritional variety; and leave ample room for speech in other parts of the labeling.

⁷ Ibid.

⁸ This guidance excludes animal proteins produced by microflora.

Contains Nonbinding Recommendations

Draft-Not for Implementation

product may help consumers understand that the composition of the product is different and prompt consumers to review the Nutrition Facts label. Providing information about the primary ingredients in a plant-based food (e.g., “cashew cheese spread”) may also help consumers understand that the composition of the product is different from animal-derived products and prompt consumers with food allergies to review the ingredient declaration and other allergen disclosure statements on the product label. Further, consumers may value or be seeking out certain plant sources as they incorporate foods into their diet, especially as they are looking to build a healthy eating pattern in line with current dietary guidelines, so having this information on the principal display panel is important because it will enable consumers to identify the plant sources more easily.

Many of these alternative foods are labeled with a name that includes the term “plant-based” in combination with the animal food name (e.g., chicken) or form (e.g., burger, sausage). In some cases, the spelling of the animal food name is modified (e.g., “chik’N”). Some products are labeled with names that include the names of foods that have definitions and standards of identity established by FDA or USDA. In addition, the terms “vegetarian” or “vegan” are commonly used. While FDA regulations do not currently define “vegetarian” or “vegan,” the term “vegetarian” is commonly used on food labels to communicate the food does not contain ingredients from meat, fish, or poultry but may contain dairy or eggs, and “vegan” is commonly used to communicate that the food does not contain any animal derived products (e.g., dairy products, eggs, etc.). FDA is using these commonly understood meanings for purposes of this guidance.

B. Overview of Identity and Naming of Plant-Based Alternative Foods

Plant-based alternative foods do not have established definitions and standards of identity and are “non-standardized foods.”⁹ The labels of non-standardized foods must bear the common or usual name of the food, if there is such a name.¹⁰ 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.¹¹ The fact that a standard of identity has been established for a food (under its common or usual name) or that a name is specified among the standard of identity regulations for a food does not

⁹ Section 401 of the FD&C Act (21 U.S.C. 341) gives FDA the authority to establish definitions and standards of identity for foods. 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.” 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 (see 21 U.S.C. 343(g)).

¹⁰ See 21 U.S.C. 343(i)(1).

¹¹ See 21 CFR 102.5(d).

Contains Nonbinding Recommendations

Draft-Not for Implementation

preclude use of the name in the common or usual name of another food.¹² However, such use must not be misleading.¹³

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.¹⁴ Such description or name must not be false or misleading and is referred to as the statement of identity.¹⁵ 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.¹⁶

Because definitions and standards of identity have not been established for plant-based alternatives, these foods 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.¹⁷ Such names or statements of identity are not necessarily precluded from using the names of animal-derived foods, including animal-derived foods for which FDA has established definitions and standards of identity.¹⁸ The use of the names of animal-derived foods in the common or usual name or statement of identity must not cause the labeling to be misleading.¹⁹

Many plant-based alternative foods are novel foods and do not have common or usual names. We have not established common or usual names by regulation for them, and due to their novelty, names do not appear to have been established by common usage. Plant-based alternative foods tend to be sold in packaged form, and therefore, in the absence of a common or usual name, should be labeled with a statement of identity that accurately describes the food. The statement of identity should not mislead consumers as to the source of the food. Its description should inform consumers of the specific plant source(s) and, along with other representations in the labeling, should not suggest to consumers that animal source(s) are present or have been used as ingredients.

Although we are not establishing common or usual names by regulation for plant-based alternative foods, we note the principles under 21 CFR 102.5(a) that we consider when doing so.²⁰ FDA considers whether the name accurately identifies or describes the basic nature of the food or its characterizing properties or ingredients. FDA also examines whether the name is

¹² 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”).

¹³ See 21 U.S.C. 343(a)(1).

¹⁴ See 21 CFR 101.3(b)(3).

¹⁵ See 21 U.S.C. 343(a)(1); see also 21 CFR 101.3(b).

¹⁶ See 21 U.S.C. 343(f).

¹⁷ See 21 U.S.C. 343(i)(1) and 21 CFR 101.3(b).

¹⁸ Among the animal-derived foods for which FDA has established definitions and standards of identity are dairy products (e.g., yogurt, certain cheeses), egg products, and seafood products (e.g., canned tuna).

¹⁹ See 21 U.S.C. 343(a)(1).

²⁰ See 21 CFR 102.5(a).

Contains Nonbinding Recommendations

Draft-Not for Implementation

uniform among identical or similar products and whether the name is confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Under these criteria, the names of classes or subclasses of foods should distinguish one class or subclass from another. For example, plant-based alternatives to yogurt that are soy-based should bear names that distinguish these alternatives from those that are almond-based. Qualifying the names with “soy” or “almond” would inform consumers of the nature or source of the food while also distinguishing one subclass of alternatives from another.

We recommend that manufacturers take these principles into consideration in the naming of plant-based alternative foods to help ensure consumers have the information they need to make informed purchasing decisions. Currently, products available in the marketplace are identified in multiple ways, sometimes inconsistently across a class or subclass. Statements of identity that contain a limited amount of information may not sufficiently describe the basic nature of the food or its characterizing properties or ingredients. For example, names such as “Plant-Based Burger,” “Meatless Meatballs,” or “Vegetarian ChickN Sausage” may signal to consumers that the food is a meat alternative, but they do not identify the plant source comprising the food.

We reiterate that, per existing regulation, the statement of identity must be presented in bold type on the principal display panel in a size reasonably related to the most prominent printed matter.²¹ The labels of many products prominently display brand names and statements that the food is plant-based but do not conspicuously disclose the nature or source of the food. Consumers should be able to readily observe this information when reading the label.

III. Questions and Answers

The following section provides information and recommendations for best practices for the naming and labeling of plant-based alternative foods in a question-and-answer format.

1. Are there established standards of identity for plant-based alternative foods?

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

2. What should be included in the statement of identity for a plant-based alternative food that also includes the name of a food that has an established definition and standard of identity (e.g., “cheddar cheese”)?

If the labeling of a plant-based alternative food includes the name of a standardized food as part of the statement of identity, the name of the standardized food should be qualified by the type of plant source. The nature of the plant-based 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 see and determine the particular plant source when looking at the name of the food on the label. The graphic below illustrates how a food could identify the plant source in the statement of identity.

²¹ 21 CFR 101.3(d).

Contains Nonbinding Recommendations

Draft-Not for Implementation



3. What are important considerations when using “plant-based [animal derived food]” (e.g., “plant-based fish nuggets,” “plant-based sausage,” etc.) as part of the name for plant-based alternative foods?

While “plant-based” or “plant” are terms that convey to the consumer that the food is derived from plants rather than animals, we recommend identifying the source of the plant-based ingredient(s) as part of the name when these terms are included in the name of the food. “Plant-based [animal derived food]” by itself does not help ensure that consumers have the information they need to make informed purchasing decisions. Omitting a descriptor of the 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 similar plant-based alternatives. The nature or source of the characterizing or predominant ingredients may be 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. When looking at the name of the food on the label, consumers should be able to easily determine not just that the product is plant-based but also the plant source (e.g., soy, lentil, walnut, etc.). The graphic below illustrates one example for both using the general term, “plant-based,” and describing the plant source on a label.



Contains Nonbinding Recommendations

Draft-Not for Implementation

4. How should plant-based alternative foods that are blends of different plant sources be labeled?

If a plant-based alternative food is derived from several plant sources, we recommend that the primary types of plant sources be included in the name so that consumers can easily identify the particular plant source and distinguish the food from similar foods. We recommend that the predominant plant source by weight be stated first in the name or statement of identity. The graphics and examples below illustrate some ways that multiple plant sources could be identified in the statements of identity.

For plant-based alternative foods that are blends of two or more plant sources, we recommend that the name accurately convey to the consumer the primary plant sources present. For example:

- “Black Bean Mushroom Veggie Patties” (for a product that contains a blend of black beans, mushrooms, and multiple vegetables, with black beans as the predominate ingredient)
- “Chia and Flax Seed Egg-less Scramble” (for a product that contains a blend of chia and flax seeds, with chia seeds predominating)

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



Contains Nonbinding Recommendations

Draft-Not for Implementation



5. What are important considerations when using “[animal or meat]-free” or “non-[animal or meat]” in the labeling of plant-based alternative foods?

If these terms accompany the name of the food, FDA recommends that the specific plant source(s) be included in the name of the food along with these terms. “Non-[name of animal or meat type]” or other similar names (e.g., “Cluck-less Egg,” “Beef-less Ground Meat”) do not describe the nature of the plant source and therefore do not distinguish the product from other similar plant-based alternative foods. The graphics below illustrate ways that the plant source can be conveyed to help consumers distinguish the product from other types of plant-based alternative foods.



Contains Nonbinding Recommendations

Draft-Not for Implementation



6. What are important considerations when using a modified spelling, such as Chik’N, Be’f, Cheeze, as a name for plant-based alternative foods?

We recognize many plant-based products are novel products with names that include the use of modified spelling. We recommend, if using this type of modified spelling, that the label also make clear what the product is and that the name describes the nature of the plant source. We recommend that the statement of identity clearly distinguishes the product from other types of plant-based alternative foods.

7. How should the statement of identity appear on the label?

Under our regulations, the statement of identity must be in bold type on the principal display panel.²² The type size must be reasonably related to the most prominent printed matter on the principal display panel.²³ We recommend using prominent print or type for the statement of identity to help consumers easily identify the product. Generally, we consider a prominent print or type for the statement of identity to be at least 1/2 the size of the largest print on the label. The graphic below illustrates a way that the statement of identity could be presented prominently.



²² See 21 CFR 101.3(d).

²³ Ibid.

Contains Nonbinding Recommendations

Draft-Not for Implementation

8. What are important considerations when labeling plant-based alternative foods as “vegan” or “meat-free”?

The use of truthful and non-misleading label statements (e.g., “vegan,” “meat-free,” “animal-free,” etc.) that help inform consumers that the products are derived from plants, and are not derived from animals, is appropriate. However, we recommend not using only “vegan,” “meat-free,” or “animal-free” terms as the name or statement of identity of the food, as it does not describe the nature of the plant source and therefore does not distinguish the product from other types of plant-based alternative foods.

9. Can vignettes or other statements be used to convey characterizing flavors?

Yes. If the label or labeling of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, we would consider such flavor to be the characterizing flavor, and the flavor, under our regulations, must be declared and labeled consistent with 21 CFR 101.22(i). FDA recognizes vignettes can be a way to portray a characterizing flavor(s) of a product, and manufacturers should ensure they do not convey or communicate that animal-based ingredients are the source of the product when in fact it is plant-based. This can create consumer confusion and could imply that the ingredients in the product are animal-derived rather than plant-based, and in considering the labeling in the context of the entire label, could be misleading. The graphic below illustrates one example for using a vignette to convey a characterizing flavor but not imply the plant-based product is derived from an animal source.



Contains Nonbinding Recommendations

Draft-Not for Implementation

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. FDA. “FDA’s Nutrition Initiatives.” Available online: <https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives>. Accessed January 31, 2023. *
2. U.S. Department of Health and Human Services and U.S. Department of Agriculture. “Dietary Guidelines for Americans (2020-2025).” Available online: https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf. Accessed June 3, 2024. *
3. The Good Food Institute. “2023 State of the Industry Report Plant-based meat, seafood, eggs, and dairy.” Available online: https://gfi.org/wp-content/uploads/2024/05/2023-State-of-the-industry-report_Plant-based.pdf. Accessed June 3, 2024.
4. Plant Based Foods Association. “Plant-Based Foods State of the Marketplace Summary Report 2022.” *
5. The Good Food Institute. 2021. “Plant Protein Primer.” Available online: <https://gfi.org/resource/plant-protein-primer/>. Accessed June 8, 2023.