



PennState Law

Center for Agricultural
and Shale Law

PENNSYLVANIA DEPARTMENT OF AGRICULTURE  AGRICULTURAL BUSINESS DEVELOPMENT CENTER

Understanding Agricultural Law Webinar Series

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Webinar Series

Understanding the Basics of

Food Labeling

January 26, 2024

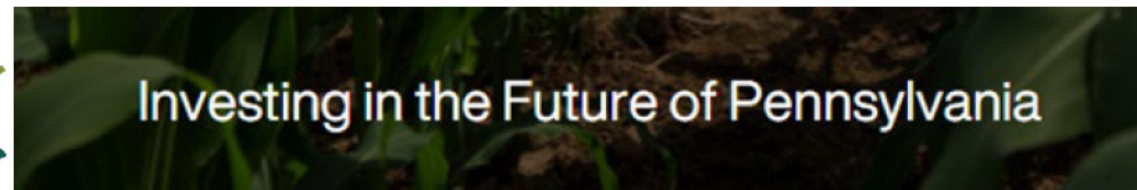
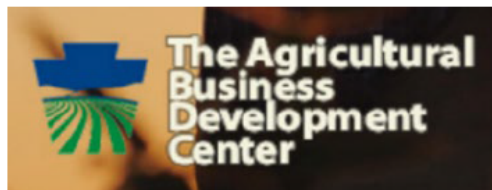




Understanding Agricultural Law

**A Legal Educational Series for General Practice Attorneys and
Business Advisors Representing Agricultural and Rural Clients**

This webinar series is specifically tailored to create subject matter literacy and competence on fundamental issues of agricultural law for attorneys, advisors, and service providers to agricultural producers and agri-businesses.





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- Agricultural Labor Laws
- Leasing Farmland for Energy Development
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- Statutory Protections for Ag Operations
- Agricultural Cooperatives
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- Crop Insurance
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- Licensing & Regulation of Direct Agricultural Product Sales
- Agricultural Finance
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- Animal Confinement Laws
- Conservation Easements
- Landowner Immunity Statutes
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- Pesticides
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- Perishable Agricultural Commodities Act (PACA)

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Mar. 22, 2024 *Understanding the Basics of Organic Production*

Mar. 22, 2024 *Understanding the Basics of Producer Protections for Buyer Default*

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Feb. 13, 2024 *Quarterly Dairy Legal Webinar—Overview of PA Milk Marketing Law (Beyond OOP)*

Mar. 6, 2024 *ACRE Law 101: Agriculture, Local Regulations, and Nutrient Management*

Apr. 16, 2024 *Quarterly Dairy Legal Webinar—Overview of U.S. State Milk Pricing Systems*

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Understanding the Basics of Food Labeling

Overview of today's presentation

- **FDA and USDA's Role in Food Labeling**
- **Geographic Origin Labeling for Food Products**
- **Labeling requirements and label claims for conventional foods and dietary supplements**
 - Nutrient content, health, and structure/function claims
- **Other labeling statement claims**
 - Organic and animal welfare certifications
 - "Natural" and gluten-free claims
 - Bioengineered food disclosure
- **Labeling standards for plant-based food alternatives**
- **Deceptive food labeling and claims**



Regulating Food Labeling in the United States

- **USDA Responsibilities**

- The USDA Food Safety Inspection Service (FSIS) has the authority to regulate meat, poultry and egg product labeling under the **Federal Meat Inspection Act (FMIA)**, **Poultry Products Inspection Act (PPIA)**, and **Egg Products Inspection Act (EPIA)**.
- The National Organic Program (NOP) is responsible for regulating the use of the USDA seal on food products.

- **FDA Responsibilities**

- The **Food, Drug, and Cosmetic Act (FDCA)** grants the FDA authority to regulate food labeling; prohibits false or misleading claims on food labels.



Key Elements of a Food Label

Principal Display Panel (PDP)—most prominent part of packaging

- Statement of identity
- Net quantity of contents statement

Information Panel (Optional)—serves as a supplement to the PDP and may include

- Ingredient list
- Manufacturer or distributor information
- Nutrition Facts panel
- Allergen information
- Nutrient, Health, and/or Structure/Function claims
- Other relevant labeling claims

Must be located directly to the right of the PDP



Key Elements of a Food Label

Meat and poultry labeling

- USDA inspection mark with establishment number
 - Must be prominently displayed on the PDP
- Handling statement
 - Informs consumers about safe storage and handling
 - Must be prominently displayed on the PDP
 - E.g., “keep refrigerated,” “keep frozen,” “perishable—keep refrigerated or frozen”
- Safe handling instructions
- For raw or partially cooked meat and poultry products.

For further information: [A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products, USDA FSIS](#)



Geographic Origin Labeling for Food Products

- **Mandatory Country of Origin Labeling (COOL) requirements**
 - **Retail food stores:** must notify consumers about the country of origin for certain foods: lamb, chicken, goat meat, wild and farm-raised fish and shellfish, perishable agricultural commodities (fresh and frozen fruits and vegetables), macadamia nuts, pecans, peanuts, and ginseng.
 - **Imported meat and poultry products:** must clearly indicate the country of origin on the label.
- **Voluntary “Product of USA” claims**
 - **Meat, Poultry, and Egg Products:** FSIS Food Standards and Labeling Policy Book allows “Product of USA” labeling for animal products that have undergone minimal processing in the United States
 - **[Proposed Rule; Voluntary Labeling of FSIS-regulated products with U.S.-Origin Claims](#)** (88 FR 15290; published March 2023): would allow “Product of USA” and “Made in USA” claims for: (1) products derived from animals born , raised, slaughtered, and processed in the U.S; (2) multi-ingredient products when all FSIS-regulated products are derived from animals born , raised, slaughtered, and processed in the U.S and all additional ingredients, other than spices and flavorings, are of domestic origin.
- **“Made in USA” labeling rule (16 CFR 323)**
 - “For a product to be called *Made in USA* ... the product must be ‘all or virtually all’ made in the U.S.”



Statement of Identity

- Statement of identity = ***name of the product***
- Some product names are subject to **standards of identity**
- Standards of identity ensure that products meet consumer expectations and product integrity
- More than 250 standards of identity for food products, such as milk, cheese, yogurt, peanut butter, ice cream, ketchup, frozen desserts, margarine, fruit pies, cacao products, etc.
- Example: **peanut butter** (21 CFR 164.150)
 - (1) at least 90% of the product must be peanuts
 - (2) up to 10% of safe and suitable seasoning and stabilizing ingredients, such as salt, sugar, or emulsifiers, can be added
 - (3) the fat content must not exceed 55%
 - (4) prohibited ingredients: artificial flavorings and sweeteners, chemical preservatives, and color additives.



Net Quantity of Contents Statement

- **Precise amount of product contained in a package or container**
- Must be displayed in the lower third of the Principal Display Panel (PDP)
- For solids, the NQC is expressed in **weight**, using units like ounces (oz) or grams (g)
- For liquids, the NQC is expressed in **volume**, using units like fluid ounces (fl oz) or liters (L)
- Must include the metric weight quantity



Ingredient List

- Ingredient list = ***roadmap to the contents of a food product***
- Ingredients are listed by their common or usual name, in descending order of weight, from the most predominant to the least
- **Multi-component ingredients**
 - When a product contains multi-component ingredients, the ingredient list must break down their composition within parenthesis.
- **Ingredient grouping**
 - Some ingredients, like spices, natural flavors, or artificial flavors, may be grouped together.
 - This grouping applies when these ingredients make up a minor portion of the product.
- Water added to a food during processing must be listed in the ingredient list, unless it is completely removed from the food during baking or other processing methods.



Name & address of manufacturer/distributor

- **Identifying the responsible party**
- Every food label must clearly display the name and physical address of the company responsible for manufacturing, packing, or distributing the product.
- When the listed name is not the actual manufacturer, a qualifying statement must be included to indicate the company's role in the production process.
 - E.g., “manufactured for [company name]” or “distributed by [company name]”



Nutrition Facts Panel

- **Nutrition Facts panel = *a roadmap to nutritional information***
- It is a standardized label found on packaged foods and dietary supplements, providing valuable information about the nutritional content of a product.
- The 2016 Nutrition Facts Panel Update: [Final Rule; Food Labeling: Revision of the Nutrition and Supplement Facts Label](#) (81 FR 33742; effective July 26, 2016)
 - Emphasis on calories and serving size
 - Daily Value (DV) for nutrient comparison
 - Breakdown of the total fat, cholesterol, total carbohydrate, and protein content in a serving of the food
 - Total sugars and added sugars declarations
 - Vitamins D, calcium, iron, and potassium; the FDA no longer requires vitamins A and C to be listed on the nutrition facts panel.



Allergen Information

- The Food Allergen Labeling and Consumer Protection Act (FALCPA) amended food labeling regulations by requiring the clear identification of **major food allergens** on packaged food labels.
- Major food allergens covered by FALCPA:
 - **Milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and ...**
 - **Sesame**—“...effective January 1, 2023, foods containing sesame will be subject to a specific food allergen regulatory requirement, including labeling and manufacturing requirements. Sesame is joining the list of major food allergens defined in the law as the result of the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, which was signed into law April 23, 2021.” *Source: [FDA Reminds Manufacturers of Effective Date for Sesame as a Major Food Allergen](#).*



Nutrient Content Claims on Food Labels

- Nutrient content claims are statements on food labels that make a **direct or indirect claim about the amount of nutrient in the food.**
- The FDA has established strict guidelines for nutrient content claims; to use a nutrient content claim, a food must meet certain criteria related to the nutrient level and the reference food.
- Examples of nutrient content claims:
 - “Calorie free”—the food contains less than 5 calories per serving. (21 CFR 101.60(b))
 - “Sugar free”—the food contains less than 0.5 grams of sugar per serving and does not contain any ingredients that are sugars and that are generally understood by consumers to contain sugars. (21 CFR 101.60(c))
 - “Reduced fat”—the food contains 25% less fat per serving than a similar product. (21 CFR 101.62(b)(3))
- The label must clearly state the nutrient content and the basis for the claim.



Health Claims on Food Labels

- Health claims are statements on food labels that make **a direct or implied link between a food or substance in food and a disease or health-related condition.**
 - E.g., “diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors”
- These claims are carefully regulated by the FDA to ensure they are based on scientific evidence and do not mislead consumers
- The FDA recognizes two types of health claims:
 - **Authorized health claims:** these claims must be based on “significant scientific agreement” (SSA) among experts, indicating that a substantial body of research supports the link between a food or food component and a specific health outcome.
 - E.g., “adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.”
 - **Qualified health claims:** these claims must be supported by *some* scientific evidence.
 - E.g., “scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, may reduce the risk of diabetes mellitus type 2.”



“Healthy” Claims on Food Labels

- Health claims and *healthy* claims are both terms that can appear on food labels, but they have **different meanings and regulatory requirements**.
- *Healthy* claims are voluntary statements that **indicate a food meets certain nutritional criteria based on the Dietary Guidelines for Americans, 2020-2025**. These claims are designed to promote nutrient-rich foods.
- Under the current FDA definition, a food can be labeled as *healthy* if it meets the following requirements:
 - It has a limited amount of total fat, saturated fat, cholesterol, and sodium.
 - It provides at least 10% of the recommended daily intake (RDI) for one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, and fiber.
- **FDA proposed updates to the *healthy* claim definition** (87 FR 59168; published in September 2022)—the proposed changes would include:
 - Requiring foods to contain a certain amount of ingredients from at least one of the five food groups or subgroups that the Dietary Guidelines for Americans recommend as part of a healthy diet.
 - Limiting the amount of saturated fat, sodium, and added sugars in foods.



Structure/Function Claim on Food Labels

- Structure/Function claims are statements that **describe the role of a nutrient or ingredient in the body's structure or function.**
 - E.g., “fiber maintains bowel regularity;” “calcium builds strong bones,” “antioxidants maintain cell integrity”
- Health claims v. Structure/Functions claims: a structure/function claim focuses on the physiological aspects of a food or substance in food on the body and does not make a reference to a disease.
- Structure/Functions claims **do not require prior FDA approval**; however, manufacturers are responsible for substantiating the claims they make, demonstrating that there is a reasonable basis to support the claim.
- If a dietary supplement label includes such a claim, it must state in a disclaimer that FDA has not evaluated the claim.
 - E.g., “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”



Organic Claim on Food Labels

- Organic claims indicate that **a product has been grown or produced using sustainable farming practices**, following strict production standards established by the USDA National Organic Program (NOP).
- The USDA NOP is responsible for establishing and enforcing the standards for organic production, handling, and labeling.
- To be certified as organic, a product must follow a rigorous certification process by a USDA-approved certifying agent.
- Organic claims are categorized into four levels based on the percentage of organic ingredients:
 - **100% organic:** the product is entirely composed of organic ingredients
 - **Organic:** the product contains at least 95% organic ingredients
 - **Made with organic ingredients:** the product contains at least 70% organic ingredients
 - **Some organic ingredients:** some organic ingredients are present in the product, but the percentage does not meet the 70% requirement.

For further information, please check out the [Labeling Packaged Products under the National Organic Standards guidelines](#).



Animal Welfare Claim on Food Labels

- Animal welfare claims **inform consumers about the treatment of animals used in the production of food products.**
- Animal welfare claims are voluntary statements for most products, except for meat, poultry, and egg products, which require approval from the USDA Food Safety and Inspection Service (FSIS)
 - E.g., “humanely raised,” “cage free,” “hormone free,” “raised without antibiotics”
- Animal welfare claims can be classified into two main categories based on verification requirements:
 - **Third-party verified claims:** must be supported by a third-party audit or certification process to reflect the animal welfare practices of the producer or manufacturer
 - **Unverified claims:** based on the manufacturer’s own assessment of their animal welfare practices



“Natural” Claim on Food Labels

- A “natural” claim on a food label suggests that **“nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food”** —*FDA interpretation of “natural”*
- There is currently no regulatory definition for the term “natural”
- Factors not addressed by FDA:
 - Food production methods
 - Food processing or manufacturing methods
 - Nutritional or health benefits



Gluten-Free Claim on Food Labels

- Gluten-free refers to foods that do not contain gluten, a protein found in wheat, rye, barley, and crossbreeds of these grains.
- The FDA has set a **strict limit of 20 parts per million (ppm) of gluten for foods** that can be labeled as “gluten-free;” see [Final Rule; Food Labeling; Gluten-Free Labeling of Foods](#) (78 FR 47154; effective September 4, 2013; compliance August 5, 2014)
- Ingredient restrictions for gluten-free foods—foods labeled as “gluten-free” cannot contain:
 - Ingredients that are any type of wheat, rye, barley, or crossbreeds of these grains
 - Ingredients derived from these grains that have not been processed to remove gluten
 - Ingredients derived from these grains that have been processed to remove gluten but still contain 20 or more ppm of gluten.
- FDA gluten-free compliance requirements for fermented and hydrolyzed foods; see [Final Rule; Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods](#) (85 FR 49240; effective October 13, 2020)



Bioengineered Food Disclosure

- The [National Bioengineered Food Disclosure Standard \(NBFDS\)](#), established in 2018, governs the labeling of bioengineered (BE) foods in the United States.
 - Mandatory uniform national standard for disclosure of BE foods.
 - Bioengineered food refers to food "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature."
 - Mandatory compliance: January 1, 2022—instead of terms such as "Genetically Modified Organism," "GMO," and "genetic engineering," manufacturers must now use the terms "bioengineered food" or "contains bioengineered food ingredient(s)" to comply with the NBFDS.
- Disclosure methods:
 - Text, such as "bioengineered food" or "contains bioengineered food ingredient(s)"
 - Symbol
 - Electronic or digital link and phone number
 - Text message



Bioengineered Food Disclosure

- Exemptions from disclosure:
 - **Small food manufacturers**
 - Manufacturers with annual receipts below \$2,500,000
 - **Animal-derived products**
 - Foods derived from animals fed bioengineered feed
 - **National Organic Program-certified food products**
 - Food and ingredients certified as organic
 - Meat, poultry, and egg products, with two exceptions (1) if the most prevalent ingredient in the product, as listed on the ingredient statement, is an ingredient subject to FDA labeling requirements, disclosure is required and (2) if the most prevalent ingredient is broth, stock, water, or any similar ingredient, and the second ingredient is an ingredient subject to FDA labeling requirements.



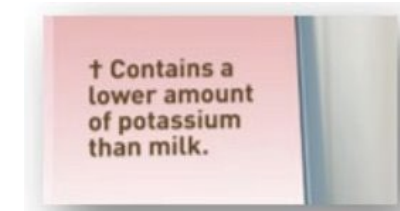
Labeling Standards for Plant-Based Food Alternatives

- *“Global retail sales of plant-based food alternatives may reach \$162 billion by 2030, or 7.7% of the expected \$2.1 trillion global protein market,”* Source: [Plant-Based Foods Poised for Explosive Growth, Bloomberg Intelligence \(August 2021\)](#)
- *“U.S. per capita fluid cow’s milk consumption has been trending downward since about the mid-1940s, and it fell at a **faster rate during the 2010s** than it did during each of the previous six decades. Milk consumption per person fell at an average annual rate of 1.0 percent during the 2000s. It then fell at an average rate of 2.6 percent during the 2010s.”*
- *“Products known to compete with fluid cow’s milk include plant-based milk alternatives, such as ‘almond milk’ and ‘soy milk.’ Using retail scanner data, Steward et al. (2020) confirmed that **sales of these beverages negatively affect purchases of fluid cow’s milk**. However, given that the increase in their sales is much smaller than the decrease in sales of fluid cow’s milk, plant-based milk alternatives can only explain a **small share of overall trends**. Sales of plant-based milk alternatives **may be contributing to, but are not likely to be, a primary driver of sales trends for fluid cow’s milk.**”* Source: [Examining the Decline in U.S. Per Capita Consumption of Fluid Cow’s Milk, 2003-18, USDA Economic Research Service \(October 2021\)](#)



Labeling Standards for Plant-Based Food Alternatives

- [FDA Draft Guidance for Industry: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements](#) (issued February 2023)
- *“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. In general, research suggests that many consumers lack an accurate understanding about the specific nutrients in plant-based milk alternatives.”*
- The FDA recommendations take the form of Q&As (pp. 12 to 26):
- The FDA recommends that the term “milk” should be qualified by the plant source of the food and terms such as “plant-based milk” or “dairy free milk” should not be used.
- The FDA also recommends that plant-based milk alternatives with different nutrient compositions from dairy milk should have an additional nutrient statement on the product label.





Deceptive Food Labeling and Claims

- The Food, Drug, and Cosmetic Act (FDCA) (21 U.S. Code § 331) prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.”
- Similar provisions under the Federal Meat Inspection Act (FMIA) (21 U.S. Code § 607(d)); the Poultry Products Inspection Act (PMIA) (21 U.S. Code § 457(c)); the Egg Products Inspection Act (EPIA) (21 U.S. Code 1032).
- Misbranding occurs when food labeling fails to meet certain standards, including providing false or misleading information, using deceptive names or containers, and non-compliance with ingredient disclosures, quantity statements, quality standards, and dietary use claims.



Mislabeling v. Misbranding

- **Mislabeling** includes errors or omissions in the product's label information.
 - E.g., incomplete ingredient lists, incorrect nutrition facts, inaccurate product descriptions, use of illegible fonts, omission of a major food allergen.
- **Misbranding** involves misleading or false claims about the product.
 - E.g., advertising a product as organic without proper certification, labeling a product "Made in USA" while containing significant foreign ingredients.
- Both mislabeling and misbranding can result in legal action against the responsible parties.
- The law provides that **a food is misbranded if it contains false or misleading information about the product.**



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **It is marketed with a name that is misleading to consumers**
 - *Stark Management, Inc. v. Koon Chun Hing Kee Soy & Sauce*, USDC E.D. New York, No. 1:07-cv-3208 (filed August 3, 2007)
 - Plaintiff sued a company for using the term “hoisin” to label its sauce products, claiming the term was misleading because it literally translates to fish or seafood even though there were no such ingredients present in the sauce.
 - The court ruled in favor of the company, stating that “sauces are not named after their ingredients, but are named after the foods they accompany” and citing the example of steak sauce.



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **It imitates another product unless stated as such on the label**
 - *Jam v. United States*, 340 U.S. 593 (1951)
 - The U.S. government sued a manufacturer, alleging that its product labeled as “Delicious Brand Imitation Jam” was mislabeled as jam, because it did not meet the federal definition of jam, which required a minimum of 45% fruit content.
 - The federal district court ruled in favor of the manufacturer, stating the product was accurately labeled as “imitation” and that consumers were not likely to be misled.
 - The federal appellate court reversed the district court’s decision, finding that the product was misbranded despite the “imitation” declaration.
 - The U.S. Supreme Court ultimately sided with the manufacturer, concluding that the product was not misbranded—*“the name ‘imitation jam’ at once connotes precisely what the product is: a different, an inferior preserve, not meeting the defined specifications.”*



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **The packaging misleads consumers about the contents of the product**

- *Buso v. ACH Food Companies*, USDC S.D. California, No. 3:17-cv-1872 (filed September 14, 2017)
 - Plaintiff, a consumer who purchased a box of Fleischmann's Simply Homemade® Baking Mix Cornbread, alleged that the container "had more than 50% empty space," referring to this deceptive practice as "slack-fill."
 - The case eventually settled out of court.
- *Iglesia v. Tootsie Roll Industries, LLC*, USDC New Jersey, No. 3:20-cv-18751 (filed December 10, 2020)
 - Plaintiff claimed that the opaque packaging of the candy products concealed the true amount of candy inside; argued that this "slack-fill" practice was deceptive and unfair as it was intended to maximize profits at the expense of consumers.
 - The court ruled in favor of Tootsie Roll Industries, finding that the net weight of the candy, clearly displayed on the packaging, was sufficient to inform consumers about the actual amount of candy they were purchasing.
- *Jackson v. General Mills, Inc. et al.*, USDC S.D. California, No. 3:18-cv-2634 (filed November 16, 2018)
 - Plaintiff alleged that the cereal boxes contained approximately 30-50% empty space, misleading consumers into believing they were purchasing a larger quantity of cereal than was actually the case.
 - The court dismissed the case ruling in favor of General Mills, citing the fact that the cereal was sold by weight and the number of servings was clearly labeled on the packaging.



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **The label does not include essential information, such as a complete ingredient list or a clear quantity statement**
- **The product's ingredients and composition do not meet the legal requirements for its standard of identity**
 - *Libby McNeil & Libby v. United States*, 148 F.2d 71 (1945)—products that claim to be standardized but contain ingredients that are not recognized by the applicable standard of identity, should be considered misbranded regardless of whether the label accurately describes the ingredients.



Plant-Based Labeling Litigation

And the milk terminology ...

- ***Gitson, et al. v. Trader Joe's Company***, USDC N.D. California, No. 3:13-cv-1333
 - Plaintiffs were purchasers of Organic Chocolate Soy Milk and Organic Soymilk products manufactured, marketed, distributed and sold by Trader Joe's Company.
 - *"Adding the name of a plant material in front of the word 'milk' does not result in an appropriate name for non-dairy products, as these products do not contain milk or milk ingredients ... There can be no doubt that these products have been formulated and positioned to mimic the positive quality attributes of milk from lactating cows and, because of this, are nothing more than imitation milks that should be labeled as such."* Complaint (March 25, 2013)
- ***Ang, et al. v. Whitewave Foods Co.***, USDC N.D. California, No. 3:13-cv-1953
 - Plaintiffs were purchasers of Silk and Horizon Plant-Based milk and dairy products manufactured, marketed, distributed, and sold by Whitewave Foods Co. Dean Foods Co., WWF Operating Co., and Horizon Organic Dairy, LLC.
 - *"Defendants' actions illegally mislead the public by inappropriately employing names and terms reserved by law for standardized dairy products, thereby creating false impressions that these products provide comparable quality, taste, or nutritional benefits when they do not."* Complaint (April 29, 2013)
- ***Painter v. Blue Diamond Growers, et al.***, USDC C.D. California, No. 2:17-cv-2235
 - Plaintiffs were purchasers of Almond Breeze Almond Milk Beverage manufactured, marketed, distributed, and sold by Blue Diamond Growers.
 - *"By calling its Almond Beverages 'milk,' a term historically used to define cow's milk, Defendant has capitalized on reasonable consumers' understanding of the well-known health benefits and essential nutrients that dairy milk provides without actually providing those health benefits and essential nutrients."* Complaint (March 22, 2017)



Plant-Based Labeling Litigation

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Plant-Based Labeling Litigation

- **Gitson, et al. v. Trader Joe's Company**, USDC N.D. California, No. 3:13-cv-1333
 - *"... Plaintiffs' cannot save their claims by pointing to the FDA's standard of identity for 'milk' and FDA warning letters to two soy milk manufacturers. These warning letters are not binding. Nor does either the standard of identity or the warning letters address reasonable-consumer standard under state law or the critical context and express disclosures plainly set forth on the soy milk products at issue ... such claims are preempted on the grounds that they cannot be premised on the FDA's purported interpretations of the FDCA."* Defendant's motion to dismiss (July 12, 2013)
- **Ang, et al., v. Whitewave Foods Co., et al.**, USDC N.D. California, No. 3:13-cv-1953
 - *"Plaintiffs cannot allege in good faith that a reasonable consumer would view 'soymilk,' 'almondmilk' or 'coconutmilk,' sold under the long-established Silk brand for plant-based beverages, and believe that she were purchasing a product made from cow's milk. Such logic also necessarily would lead to the conclusion that the majority of consumers would pick up a package of feta cheese that stated it was made from sheep's milk and believe that the presence of the word 'milk' on the label meant that the product actually came from a cow. The absurdity of these allegations stems from the erroneous notion that the reasonable consumer has adopted the FDA's narrow definition of the word "milk" and applies that definition to every product in the marketplace indiscriminately. This defies common sense."* Defendants' motion to dismiss (August 1, 2013)
- **Painter v. Blue Diamond Growers, et al.**, USDC C.D. California, No. 2:17-cv-2235
 - *"Plaintiffs' claims are expressly preempted under the Federal Food, Drug & Cosmetic Act ("FDCA") because her complaint seeks to impose new and more stringent labeling requirements on almondmilk manufacturers than are required by the U.S. Food and Drug Administration ("FDA") and under the FDCA. Alternatively, Plaintiffs' claims should be dismissed or stayed under the primary jurisdiction doctrine because if the appropriate product name for almondmilk is going to be changed, it should be determined in the first instance by the expert agency, the FDA."* Defendants' motion to dismiss (April 17, 2017)



Plant-Based Labeling Litigation

- **Gitson, et al. v. Trader Joe’s Company**, USDC N.D. California, No. 3:13-cv-1333
 - *“If a food label does not violate the federal statute, any state law claim arising from that label is automatically preempted, because when it comes to food labels, state law may only impose liability for what the federal statute proscribes ... The threshold question in this case, then, is whether the use of the word ‘soymilk’ in the Trader Joe’s products could conceivably violate the federal Food, Drug and Cosmetic Act. The answer to that question is no.”* Court order (December 1, 2015)
- **Ang, et al., v. Whitewave Foods Co., et al.**, USDC N.D. California, No. 3:13-cv-1953
 - *“An agency’s reasonable interpretation of its own regulation is entitled to wide deference. However, the brief statements in the two warning letters cited by Plaintiffs are far from controlling ... Moreover, it is simply implausible that a reasonable consumer would mistake a product like soymilk or almond milk with dairy milk from a cow. The first words in the products’ names should be obvious enough to even the least discerning of consumers. And adopting Plaintiffs’ position might lead to more confusion, not less, especially with respect to other non-dairy alternatives such as goat milk or sheep milk.”* Court order (December 10, 2013)
- **Painter v. Blue Diamond Growers, et al.**, USDC C.D. California, No. 2:17-cv-2235
 - *“Any further labeling requirements, achieved through a lawsuit pursuant to California’s Sherman Law, would directly or indirectly establish labeling requirements not identical to the FDCA – and thus are preempted.”*
 - *“By using the term ‘almondmilk,’ even the least sophisticated consumer would know instantly the type of product they are purchasing. If the consumer is concerned about the nutritious qualities of the product, they can read the nutrition label – which Plaintiff does not allege is false or misleading.”* Court order (May 24, 2017)



Plant-Based Labeling Litigation

In *Miyoko's Kitchen v. Ross, et al.*, USDC N.D. Cal., No. 3:20-cv-893, a federal district court in California ruled that **plant-based food producer can use dairy terms to describe vegan butter**.

December 2019 – the California Department of Food & Agriculture (CDFA) [requested](#) Miyoko's Kitchen, Inc. to review the label for their vegan butter bearing the terms “butter,” “lactose free,” “hormone free,” “cruelty free,” and “revolutionizing dairy with plants” as well as website pictures of animal agriculture.

“The product cannot bear the name ‘Butter’ because the product is not butter” as defined in 21 U.S.C. 321a as a product “made exclusively from milk or cream, or both, with or without common salt ... and containing no less than 80 per centum by weight of milk fat.”

February 2020 – Miyoko's Kitchen, Inc. [filed](#) a lawsuit against CDFA, challenging the regulatory authority of the state and arguing speech suppression.

August 2021 – the Federal district court [found](#) that:

“... there is no denying that § 312a's dairy and fat-content requirements exclude Miyoko's 'vegan butter' ... this alone cannot doom commercial speech ...” “Quite simply, language evolves.”

And determined that the state of California may not regulate Miyoko's use of the terms “butter,” “lactose free,” “cruelty free,” and “revolutionizing dairy with plants” whereas the term “hormone free” is not constitutionally protected commercial speech.



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **A food product's advertised claims about quality or quantity are not supported by accurate information on the label**
 - *Hunt v. General Mills Sales Inc.*, USDC E.D. Illinois, No. 1:22-cv-2835 (filed May 29, 2022)
 - Plaintiff, who purchased Nature Valley Crunchy Granola Bars, noticed that the front label prominently featured the words "Oats 'n Honey" and a dripping honey dipper and argued that this imagery/phrasing created a misleading impression that honey was one of the primary ingredients in the granola bars. However, the plaintiff discovered that sugar was listed as the second ingredient after whole grain oats.
 - The case was voluntarily dismissed.
- **Pasteurized food products do not clearly indicate that they have been pasteurized**



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **Food products marketed for specific dietary needs make misleading health claims without providing clear nutrition information**
 - *Ackerman v. Coca-Cola Company*, USDC E.D. New York, No. 1:09-cv-395
 - Plaintiff alleged that Coca-Cola’s marketing of its Glaceau Vitamin Water products misled consumers into believing they were nutritious and healthy beverages. Coca-Cola’s marketing campaigns emphasized the presence of vitamins and nutrients, while downplaying the high sugar content.
 - The parties reached an agreement, with Coca-Cola agreeing to make significant changes to its Vitamin Water labeling and marketing guidelines:
 - Prominently displaying the phrase “with sweeteners” on the label
 - Listing the calorie count per bottle
 - Including the statement “see nutrition facts for more detail” when making claims about the nutrient content
 - Refraining from using specific statements that promote Vitamin Water’s alleged health benefits, such as “vitamins + water = all you need.”



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **Food products fail to disclose the presence of artificial flavoring, artificial coloring, or chemical preservatives**
 - *Santiful et al. v. Wegmans Food Markets, Inc.*, USDC S.D. New York, No. 7:20-cv-2933
 - Plaintiffs alleged that Wegmans' "vanilla cake mix" was mislabeled as naturally flavored despite containing ethyl vanilla, an ingredient considered artificial.
 - The court dismissed the lawsuit, finding that the plaintiffs had failed to provide any credible evidence to support their claim that ethyl vanilla is not derived from natural sources.
 - *Hoffman v. Kraft Heinz Food Co.*, USDC S.D. New York, No. 7:22-cv-397
 - Plaintiffs alleged that the "all natural" labeling of Kraft Heinz's Mango Peach MiO beverage was deceptive, because the product contained DL-malic acid, a form of malic acid synthetically produced.
 - The court dismissed the lawsuit, finding that the plaintiffs' allegations about the presence of DL-malic acid were based on speculation and lacked concrete evidence from product testing.



Understanding Misbranding in Food Labeling

Under the FDCA (21 U.S. Code § 331), a food product is considered misbranded when:

- **Food products fail to disclose the use of any pesticide chemicals after harvest**
- **Food products' packaging and labeling fail to meet regulatory requirements for color additives and pharmaceutical labeling standards.**

For a more comprehensive understanding of food labeling disputes, please check out the [National Agricultural Law Center's Case Law Index Food Labeling](#), documenting relevant food labeling cases from 1995 to 2023.



Thank you for joining us!

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