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U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Docket No. FDA-2018-N-3522 for Use of the Names of Dairy Foods in the Labeling of Plant-Based Products

The Good Food Institute (GFI), a 501(c)(3) nonprofit organization, appreciates the opportunity to submit these comments to the U.S. Food and Drug Administration (FDA) regarding the labeling of plant-based dairy products.

GFI is comprised of a team of scientists, entrepreneurs, and policy experts with the goal of creating a healthy, sustainable, and just food supply by advocating for and supporting research into plant-based and cultured (cell-based) meat. GFI encourages plant-based innovation and supports the availability of plant-based foods to meet increasing consumer demand.

Through these comments, GFI hopes to clarify the role labels serve on plant-based dairy products and suggest how FDA might approach labeling issues to continue protecting consumers' health and well-being. While FDA must assure that foods sold in the United States are "safe, wholesome, and properly labeled,"¹ it must not overstep its regulatory authority nor violate producers' First Amendment rights. Additionally, we show that clearly labeled plant-based milks, yogurts, cheeses, ice creams, and other similar products are not misleading or confusing to consumers. Instead, they contain names that are widely recognized and understood.

In addition to discussing how consumers use and understand plant-based dairy products, we address the role labels serve overall and how FDA can best seek to protect consumers' health and well-being. FDA should restrict product labeling practices only if labels are misleading or confusing to consumers and, even then, it should regulate in the least restrictive manner possible.

I. FDA Must Comply with Notice-And-Comment Rulemaking If It Decides to Restrict the Use of Qualified Standardized Terms on Product Labels

FDA has requested information on consumers' understanding of plant-based dairy products to help it develop an approach to the labeling of these products. To be clear, as we emphasize throughout this comment, FDA should not restrict plant-based dairy producers from using conventional dairy terms on their labels. However, if the agency were to depart from longstanding practice and create new rules that substantially affect how plant-based dairy

¹ FDA & Ctr. for Food Safety & Applied Nutrition, A Food Labeling Guide: Guidance for Industry, 4 (Jan. 2013), <https://bit.ly/2SsB5Fy>.

producers conduct their business, it must promulgate a new regulation through notice-and-comment rulemaking.

Under the Administrative Procedure Act (APA), agencies must publish notices of proposed rulemaking in the Federal Register that provide the public with “the terms or substance of the proposed rule or a description of the subjects and issues involved” and give the public an opportunity to participate in the rulemaking.² The present request for information is insufficient to satisfy these requirements. While FDA has indicated its intent to restrict labels somehow, the agency has not laid out its proposal in enough specificity that producers and other members of the public can meaningfully comment on its effect. It is not clear, for example, whether the agency will allow the term “milk” to be used on coconut milk or goat’s milk labels, whether any possible prohibition would extend to adjectives like “milky” or “milk-free,” how the agency would enforce any new restrictions, and so on. The agency has simply provided a long list of questions that only invite the public to speculate as to what it may do next.

After several decades of allowing products to be labeled using qualified standardized terms, FDA may not claim that prohibiting this historical practice is a matter of interpretation or a general statement of policy. Instead, new labeling requirements would set explicit standards that producers would have to comply with or risk the consequences of noncompliance and would thus be a legislative rule requiring that the agency give the public notice and an opportunity to comment on the specifics. This was the case in *Appalachian Power Company v. Environmental Protection Agency*. The court held that although the Environmental Protection Agency (EPA) claimed its document outlining periodic monitoring of source point emission was a guidance document, it instead qualified as a new regulation because it “created a new regime,” different from current permit requirements, and had a binding effect.³ The court reasoned that because the issued document outlined the EPA’s settled position on rules that states would be forced to comply with, the rules were legislative rather than merely interpretative.⁴ Similarly, if FDA were to prohibit plant-based dairy producers from using terms such as “milk” on their labels, FDA would be creating new labeling requirements, different from current practices, forcing plant-based dairy producers to comply with new rules.

Furthermore, restricting the historical practice of using qualified standardized terms on product labels could potentially lead to several other labeling changes — rye bread might no longer be permitted to be labeled as rye bread and rice noodles might no longer be permitted to be labeled as rice noodles since the names of these products, and many others, also refer to standardized

² 5 U.S.C. § 553.

³ *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1024 (D.C. Cir. 2000).

⁴ *See id.* at 1021-22 (“If an agency acts as if a document issued ... is controlling in the field, if it treats the document in the same manner as a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties ... to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency’s document is for all practical purposes “binding.””).

terms, but do not conform to their definitions.⁵ FDA would not be justified in only prohibiting plant-based dairy products from referring to standardized foods on their labels, as the agency’s authority to regulate labels stems from its responsibility to protect consumers — not to privilege one set of producers over another.

Instead of requiring plant-based dairy producers to change their product labels (which is the direction FDA has indicated it intends to go), GFI requests that FDA grant our petition for a new regulation that allows the use of compound names on labels.⁶ As we explain in our petition, new foods can reference standardized foods on their labels as long as producers are not representing their products as a standardized product and it is clear to consumers what the food product is — and FDA should explicitly adopt this long-standing practice by regulation.⁷ If, however, the agency decides to impose a new and significant labeling regime on plant-based dairy producers by restricting their ability to use terms like “almond milk” and “soy yogurt,” then it must promulgate a new regulation subject to the notice and public comment requirements of the APA.

II. FDA Should Not Restrict Plant-Based Dairy’s Clear Labels

Congress entrusted FDA with the responsibility of protecting the public health. One of the ways FDA does this is through ensuring the foods Americans purchase and consume are clearly and properly labeled.⁸ Accurate and clear labels serve to protect consumers and allow them to make informed purchasing decisions.

FDA, however, must not abuse its authority. While Congress permits FDA to establish standards of identity for foods through the federal Food, Drug, and Cosmetic Act (FDCA) to prevent food manufacturers from misrepresenting their products, Congress did not give FDA labeling authority to allow it to restrict clear labels or to prevent successful innovation.⁹

⁵ See, e.g., 21 C.F.R. §§ 136.110(a), (c)(1), (c)(3) (defining “bread” as a product primarily consisting of (non-durum) wheat flour and requiring that it be leavened with yeast and baked); 21 C.F.R. § 137.105 (defining “flour” as a product made from “wheat, other than durum wheat and red durum wheat”); 21 C.F.R. §§ 139.150(a), (b) (defining noodles as “ribbon-shaped” products made exclusively from wheat flours (including durum, the variety of wheat typically used in pasta) and requiring that they contain egg products).

⁶ See GFI, *Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food*, Docket No. FDA-2017-P-1298 (Mar. 2, 2017), <https://bit.ly/2sNmOb3>. We incorporate that petition in this submission by including it as Appendix A.

⁷ *Id.*

⁸ See 21 U.S.C. § 341.

⁹ See 21 U.S.C. §§ 393(a), (b) (noting that FDA should protect public health by ensuring foods are properly labeled).

A. FDA Has Historically Allowed Producers to Use Qualified Standardized Terms on Their Labels

The FDCA defines when food is misbranded.¹⁰ Relevant to FDA’s request for information is whether the inclusion of conventional dairy terms on plant-based dairy labels violates the standards of identity for “milk” and other dairy terms and thus are misbranded under the law. They do not.

Under Section 403(g), a food is misbranded if it is represented as a food with a specific standard of identity without meeting that standard.¹¹ If a product does not have an established standard of identity, it is permitted to use a common or usual name as long as it “accurately identifies or describes, in as *simple and direct* terms as possible, the basic nature of the food or its characterizing properties or ingredients.”¹² Common or usual names are often established by widespread usage and are only established by regulation when the common name causes consumer confusion.¹³ A product can also be labeled with an appropriately descriptive term or a “fanciful name” if it does not have a common or usual name.¹⁴

Currently, FDA’s existing standards of identity primarily pertain to traditional American foods, such as conventional dairy products. GFI previously submitted comments to the FDA in response to its Comprehensive, Multi-Year Nutrition Innovation Strategy on this topic, which we attach here and request that you consider in connection with the present request. As we explain in that submission, because of the vast numbers of new foods introduced to the American market each year, it would not be practical for FDA to develop a standard of identity for every one of these products.¹⁵ FDA recently recognized this impracticality by stating that it is reopening the comment period on the rule it proposed with the U.S. Department of Agriculture (USDA) in 2005 to revise the process for setting and updating standards of identity “because of the time that has elapsed since the publication during which time there have been additional technological and other changes in the food industry.”¹⁶ Furthermore, FDA has recognized that several standards of

¹⁰ See 21 U.S.C. § 343(a) (“A food shall be deemed to be misbranded ... [if] its labeling is false or misleading in any particular, or ... its advertising is false or misleading in a material respect or its labeling is in violation of [the ingredients disclosure mandate].”); see also *id.* §§ 343(b)–(y) (requiring non-misleading labels and containers, as well as various disclosures, such as for allergens).

¹¹ See 21 U.S.C. § 343(g).

¹² 21 C.F.R. § 102.5(a) (emphasis added).

¹³ See 21 C.F.R. § 102.5(d).

¹⁴ 21 C.F.R. § 101.3(b)(2).

¹⁵ See generally USDA & Econ. Research Serv., *New Products*, <https://bit.ly/2nGpBC0> (describing upward trend of new food products since the 1990s) (last updated Apr. 5, 2017); see also GFI, *Comment from GFI on FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy*, Docket No. FDA-2018-N-2381 (Oct. 11, 2018), <https://bit.ly/2CKP4zM> (Appendix B).

¹⁶ FDA, *Food Standards: General Principles and Food Standards Modernization (Reopening of Comment Period)*, Abstract, 83 Fed. Reg. 57,803, 57,862 (Nov. 16, 2018), <https://bit.ly/2G2gDYD>.

identity are no longer relevant. FDA recently announced plans to revoke “outdated standards of identity,” such as those for French salad dressing and frozen cherry pie in an effort to remove “old-fashioned barriers to innovation.”¹⁷

Instead of attempting to keep pace with “changes in the food industry,” FDA guidance permits the labels of new products to refer to standardized names to alert consumers to the nature or use of the product.¹⁸ Standards of identity should not prevent new products from referencing standardized terms in their marketing or labeling in conjunction with a qualifier — and historically, such a restrictive approach to labeling has not been FDA’s practice.¹⁹ FDA may only prevent producers from representing such products as the standardized products.²⁰ Thus, a product does not violate the FDCA if it refers to a standardized term and also alerts consumers that the food is distinct from the standardized product.²¹

On several instances, FDA has allowed product labels that pair a standardized term with a qualifier. Bread has a specific standard of identity,²² but FDA has permitted nonconforming products to be labeled as “gluten-free bread,” “flourless bread,” and “rye bread.” The same goes for noodles — noodles have a specific standard of identity,²³ but FDA has permitted products that do not conform to the standard of identity for noodles to use the word “noodles” on their labels, such as rice noodles, ramen noodles, and soba noodles. Finally, although milk has a specific standard of identity, FDA has stated that because chocolate milk does “not purport to be and [is] not represented as milk,” it need not conform to the standard of identity for milk.²⁴ Likewise, as the court in *Gitson v. Trader Joe’s Company* recognized, the existence of a standard

¹⁷ FDA Comm’r Scott Gottlieb, *Fall 2018 Unified Agenda: FDA’s New Regulatory Work to Advance Health and Safety* (Oct. 17, 2018), <https://bit.ly/2ENgwkvy>; see also 21 C.F.R. § 146.120 and FDA History & Law, *Regulatory Nonsense: Frozen Lemonade Concentrate*, FDA Storytime (Nov. 28, 2018), <https://bit.ly/2Ak1UEQ> (noting that the establishment of a standard of identity for frozen lemonade concentrate whereas none exists for fluid lemonade has resulted in more market choices available to consumers for fluid lemonade).

¹⁸ See FDA, *Nonfat Dry Milk, Lowfat Dry Milk, Dry Whole Milk, and Dry Cream; Standards of Identity; Confirmation of Effective Date and a Further Amendment*, 44 Fed. Reg. 3,964, 3,965 (Jan. 19, 1979), <https://bit.ly/2FQ0Mnk> (“the existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in connection with the name of a nonstandardized food ... in some cases, it may be necessary to include a standardized name in the name of a substitute food in order to provide the consumer with accurate, descriptive, and full informative labeling.”).

¹⁹ *Id.*

²⁰ See 21 U.S.C. §§ 343(a–b), (g); see also Appendix B.

²¹ GFI has requested FDA clarify this historical practice by amending 21 C.F.R. § 102.5. See Appendix A.

²² 21 C.F.R. § 136.110.

²³ 21 C.F.R. § 139.150.

²⁴ FDA, *Milk & Cream*, 38 Fed. Reg. 27,924, 27,925 (Oct. 10, 1973), <https://bit.ly/2UjiYIA> (“[s]ince flavored milks, such as chocolate milk, do not purport to be and are not represented as milk, their distribution as nonstandardized foods could be continued after the establishment of an identity standard for milk”).

of identity does not “preclude a company from giving any food product [including plant-based milks] a name that *includes* the word milk.”²⁵

FDA has permitted these products, and many others, to use standardized terms on their labels because these are common terms and reasonable consumers understand that these products are distinct from the standardized products their labels refer to. Any reasonable consumer who sees a qualifying term, such as “flourless,” attached to a standardized term, such as “bread,” is notified that the product does not contain flour but is nonetheless functionally bread.

Similarly, for decades, FDA has allowed plant-based dairy producers to use a qualifier paired with a standardized term on their product labels, and FDA should continue to permit producers to do so. Consumers have long understood that various compound terms such as “soy milk” refer to distinct products that are not made from the lacteal secretions of mammals but rather from plants like soybeans. Terms such as “soy cheese” and “almond milk” have become well-established through continued and wide-ranging use by consumers, producers, and the government, including FDA.²⁶

Moreover, the absurdity of censoring dairy terms is accentuated by the fact that banning dairy terms on plant-based products could result in products like soy milk being labeled “imitation milk.” There is no mechanism for banning a term without allowing the product from which the term has been banned to label itself “imitation.”²⁷ But of course, soy milk is not imitation milk; it is an entirely different product known universally (including by the FDA itself) as soy milk.²⁸ So too with almond milk, and so on. These are different products, not imitation products. Therefore, FDA should continue to allow these products to be labeled using modifiers and conventional terms.

²⁵ *Gitson v. Trader Joe’s Co.*, Case No. 13-cv-01333-VC, 2015 WL 9121232, *1–2 (N.D. Cal. Dec. 1, 2015).

²⁶ See FDA, Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease, 63 Fed. Reg. 62,977, 62,978 (Nov. 10, 1998), <https://bit.ly/2TeVzBV> (referring to “soy milk, soy yogurt, and soy cheese”); USDA, Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP), 81 Fed. Reg. 90,675, 90,693–94 (Dec. 15, 2016), <https://bit.ly/2AZBDfh> (referring to “soy yogurt,” “soy milk,” “soy cheese,” “almond milk,” and “rice milk.”); U.S. Dep’t of Health & Human Servs. (HHS) & USDA, 2015–2020 Dietary Guidelines for Americans, 23 (8th ed., 2015) <https://bit.ly/2RhWQpW> (noting that “soy milk” is a common term and that plant-based milks are marketed as milks) (hereinafter “2015–2020 DGAs”); Nat’l Health & Nutrition Examination Survey, Food Frequency Questionnaire, Question 7 (2004), <https://bit.ly/2RfB4mM>.

²⁷ 21 U.S.C. § 343(c) (requiring that if “a food” is “an imitation of another food,” it must be labeled “imitation _____”).

²⁸ See *Painter v. Blue Diamond Growers*, No. 17-55901 (9th Cir. Dec. 20, 2018) (holding that almond milk is not an imitation of cow’s milk because it is its own “distinct food product”); see also Brief of The Good Food Institute as Amicus Curiae in Support of Defendant-Appellee Seeking Affirmance, *Painter*, No. 17-55901 (9th Cir. Dec. 20, 2018) (No. 22), <https://bit.ly/2B4pl5s> (Appendix C).

B. Plant-Based Milk Producers' Usage of Dairy Terms Is Protected by the First Amendment

FDA would violate the First Amendment if it were to restrict the use of common or usual names (like “soy milk”) and appropriately descriptive terms (like “vegan”) on plant-based dairy products. Product labels are considered commercial speech and are thus protected by the First Amendment.²⁹ According to the seminal Supreme Court case *Central Hudson*, the government may not restrict commercial speech unless it is furthering a substantial government interest.³⁰ Moreover, the government may only restrict commercial speech so long as it is not more extensive than necessary to further its interest.³¹

As explained above, FDA’s labeling authority and interest in clear labels stems from its responsibility to ensure that foods are clearly and accurately labeled and not misleading to consumers. FDA may not ban plant-based dairy producers’ usage of common or usual names or names that clearly describe their products under the guise of ensuring consumer understanding without actually showing that consumers are confused and that it has used the least restrictive means possible of ensuring clarity. In *Ocheesee Creamery LLC v. Putnam*, the Eleventh Circuit held that Florida violated a creamery’s First Amendment rights when it restricted the creamery from labeling its product as “skim milk” simply because its product did not contain vitamin A and thereby did not meet Florida’s definition of skim milk.³² That court held that censoring the product name was more extensive than necessary to inform consumers that the creamery’s fat-free milk did not have exactly the same nutrition as other fat-free milks on the market.

In considering the labels of plant-based dairy products, several courts have held that reasonable consumers are not misled or confused by terms such as “soy milk” and “almond milk” on labels. For example, the court in *Painter v. Blue Diamond Growers* noted that “even the least sophisticated consumer” would not be misled by the term “almond milk.”³³ The Ninth Circuit recently affirmed the lower court’s decision, noting again that “no reasonable consumer could be misled by Blue Diamond’s *unambiguous* labeling” and that no reasonable consumer would be deceived into thinking that almond milk has the same nutritional profile as cow’s milk.³⁴

Indeed, FDA Commissioner Scott Gottlieb has correctly pointed out that there are First Amendment issues involved in restricting the terms plant-based dairy producers can use on their

²⁹ See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 564 (1980).

³⁰ *Id.*

³¹ *Id.*

³² See generally *Ocheesee Creamery L.L.C. v. Putnam*, 851 F.3d 1228 (11th Cir. 2017).

³³ See *Painter v. Blue Diamond Growers*, No. 17-2235 (C.D. Cal. May 24, 2017).

³⁴ *Painter*, No. 17-55901 (9th Cir. Dec. 20, 2018) (emphasis added).

labels and conceded that the word “milk” does not just refer to the lacteal secretions of a cow, but also a product derived from nuts.³⁵

Furthermore, prohibiting words like “milk,” “yogurt,” and “cheese” from appearing on plant-based dairy labels is not the least restrictive method of ensuring consumer understanding and communicating nutritional information to consumers. Many standards of identities, including several pertaining to traditional dairy products, were promulgated in the days before nutrition labels. With few exceptions, now that products are required to have nutrition labels,³⁶ the unlikely consumer that is unsure of what plant-based dairy products are made of can look to those disclosures. Similar to how the *Ocheese* court found that there was a less extensive method of serving “[Florida’s] interest in preventing deception and ensuring adequate nutritional standards” than requiring the creamery to label its skim milk as “imitation milk product,” requiring products to have nutrition labels is a much less restrictive method of serving FDA’s interest in ensuring consumer understanding than if FDA were to require plant-based milks to be labeled as “imitation.”³⁷

Simply put, although FDA is responsible for ensuring foods are properly labeled, restricting plant-based dairy producers’ clear, easy-to-understand labels would violate their First Amendment rights.

III. Consumers Understand the Names of Plant-Based Dairy Products and Are Not Misled By Their Labels

GFI is enthusiastic about the increasing popularity of plant-based meat and dairy. According to Nielsen data, sales of plant-based meat and dairy now exceed \$3.7 billion.³⁸ This data was obtained over the 52-week period ending August 11, 2018 from Nielsen’s Expanded All Outlets Combined (xAOC) channel — which includes grocery stores, drug stores, mass merchandisers, club stores, dollar stores, and military stores — plus Whole Foods Market. In addition to the rising popularity of plant-based meat and dairy, there is also a large amount of new plant-based foods constantly being made available. For example, Atlantic Natural Foods recently released a plant-based seafood,³⁹ Oatly, a leading oat milk producer, has announced plans to open a production facility in the United States this spring,⁴⁰ and Impossible Foods plans to sell its

³⁵ *Pulse Check*, POLITICO, Ep. 128 (Nov. 9, 2018), <https://bit.ly/2TeLIff> (last visited Jan. 26, 2019) (“There’s gonna be constitutional issues in whether or not we can forbid a nut manufacturer from calling almond beverage almond milk because if you look at the dictionary the first term of milk relates to a lactating animal; the second term of milk is something derived from a nut. So there is a speech issue here.”).

³⁶ See 21 U.S.C. § 343(q).

³⁷ *Ocheese*, 851 F.3d 1228 at 1240.

³⁸ GFI, *The Plant-Based Alternatives Market is Skyrocketing* (Aug. 2018), <https://bit.ly/2Nk94RG>.

³⁹ Mary Ellen Shoup, *Plant-based Seafood Brand TUNO Hits Shelves: ‘We recognize that seafood is not an endless resource’*, FoodNavigator-USA (last updated Nov. 6, 2018), <https://bit.ly/2rX13Fj>.

⁴⁰ Mary Ellen Shoup, *Oatly to Open US Production Facility to Meet Demand for Plant-based Alternatives*, FoodNavigator-USA (Oct. 15, 2018), <https://bit.ly/2ECZXHU>.

Impossible Burger in U.S. grocery stores this year.⁴¹ All of these endeavors and more are in response to the rapidly growing consumer demand for plant-based meat and dairy.

The demand for plant-based dairy products specifically is growing very quickly and plant-based milks now comprise 13 percent of the fluid milk market.⁴² Whereas years ago plant-based dairy products were sought out primarily by individuals with specific dietary preferences (e.g., vegans and vegetarians) or those with lactose allergies, plant-based milks, cheeses, ice creams, and yogurts are now consumed by a wide range of consumers.⁴³ In the last year alone, U.S. retail sales of plant-based milks rose by 9%, 6% for plant-based butters, 40% for plant-based ice creams and frozen novelties, 41% for plant-based cheeses, 54% for plant-based yogurts, and 62% for plant-based creamers.⁴⁴ At the same time, U.S. retail sales for cow's milk declined by 6%.⁴⁵ It is clear that consumers are demanding more and different plant-based dairy products.

FDA has requested information to learn how consumers use and understand plant-based dairy products. While FDA must act to prevent the sale of misbranded foods, FDA may not act to protect the conventional dairy industry from consumers' changing purchasing patterns by requiring plant-based dairy innovators to change their labels or branding. FDA asks several questions involving the manufacturing, naming, and store placement of plant-based dairy products. While possibly indicative of the general plant-based dairy market, the answers to these questions do not relate to FDA's labeling authority nor would they help FDA decide on an approach to the labeling of plant-based dairy products.

For example, FDA asks "How are plant-based products displayed in stores? For example, are they sold in grocery stores next to or mixed with their dairy counterparts or are they sold in areas of the store that are separate or distinct from the areas where their dairy counterparts are sold?" However, whether plant-based dairy products are sold next to or away from conventional dairy products is determined by private contracts, not by labels.⁴⁶ Furthermore, FDA does not exercise authority over product placement in grocery stores. Therefore, even if words like "milk" were prohibited on plant-based dairy product packaging, those products could still be sold in the dairy case, the natural food section, or anywhere else that supermarkets contract to merchandise them.

⁴¹ Elaine Watson, *Plant-based Impossible Burger to Launch in Retail Stores in 2019*, FoodNavigator-USA (Nov. 8, 2018), <https://bit.ly/2ESIcnk>.

⁴² See GFI, *supra* note 38.

⁴³ See NPD Group, *Plant-based Proteins Are Harvesting Year-Over-Year Growth in Foodservice Market and Broader Appeal* (June 6, 2018), <https://bit.ly/2sN3VVg>.

⁴⁴ See GFI, *Plant-based Market Overview*, GFI Blog: Market Research (Aug. 2018), <https://bit.ly/2ErDY5j> (click "Market Overview" subheading) (Appendix D); see also GFI, *supra* note 38.

⁴⁵ Appendix D (click "Market Overview" subheading).

⁴⁶ Gary Rivlin, *Rigged: Supermarket Shelves for Sale*, *Ctr. for Sci. in the Pub. Interest*, 32 (Sept. 2016), <https://bit.ly/2rWwVKc>.

Rather than answering questions outside of FDA’s purview, GFI respectfully requests that FDA base its decisions about plant-based dairy labels on its legal authority and the relevant facts, including consumer understanding.

A. No Reasonable Consumer Is Misled By Labels of Plant-Based Dairy Products

The labels of plant-based dairy products do not explicitly or implicitly suggest that they are equivalent to conventional dairy products. Instead, reasonable consumers see their labels and understand what they are buying.⁴⁷

Consumers are very familiar with seeing plant-based dairy products labeled using the words “milk,” “cheese,” “yogurt,” etc. together with a modifier (e.g., “almond,” “soy,” “cashew”) indicating what the product is primarily made of. Many products also use additional qualifiers, such as “plant-based,” making it even clearer that these products are distinct from conventional milk, cheese, and yogurt products. The labels of plant-based dairy products clearly alert consumers that the products are plant-based and thus do not contain cow’s milk, but are functionally conventional dairy products.⁴⁸ Indeed, as the court in *Ang v. Whitewave Foods* noted, the worry of a reasonable consumer seeing the word “soy milk” and assuming the product is made of cow’s milk “stretches the bounds of credulity.”⁴⁹

Indeed, two in three consumers agree with producers of almond milk, soy milk, and other plant-based milks using the term “milk” on their labels, showing that consumers understand and support producers’ labels.⁵⁰ Additionally, plant-based milks are more often identified in the public media using the term “milk” than “beverage,” showing that consumers relate to and understand, for example, the term “soy milk” better than the term “soy beverage.”⁵¹ From January 1, 2019 to January 21, 2019 there were 1,490 media mentions of “soy milk” but only two of “soy beverage” and 1,880 mentions of “almond milk” but no mentions of “almond beverage.” Furthermore, during this same three week period, there were 942 media mentions of

⁴⁷ See *Painter*, Civ. No. 17-2235 (C.D. Cal. May 24, 2017) (“No reasonable consumer could be misled by Defendant’s unambiguous labeling and factually accurate nutrition statements ... By using the term ‘almond milk.’ even the least sophisticated consumer would know instantly the type of product they are purchasing.”); see also *Ang v. Whitewave Foods Co.*, Civ. No. 13-1953 (N.D. Cal. Dec. 10, 2013) (“[T]hat a reasonable consumer would view the terms ‘soymilk’ and ‘almond milk’ ... and assume that [such] beverages came from cows ... stretches the bounds of credulity.”).

⁴⁸ See GFI, *Producers’ First Amendment Right to Use Clear Labels on Food* (Apr. 6, 2018), <https://bit.ly/2ReTMiw>.

⁴⁹ See *Ang*, Civ. No. 13-1953 (N.D. Cal. Dec. 10, 2013).

⁵⁰ Plant Based Foods Assoc., *Voluntary Standards for the Labeling of Plant-Based Milks in the United States* (2017), <https://bit.ly/2QTz48j>.

⁵¹ These statistics were calculated using a media measurement service that allows search terms to be run over a comprehensive database of media material. Each media mention represents one piece of public media (e.g. news article, blog article) that includes the search term at least one time.

“plant-based milk” but only 248 for “plant-based beverage.”⁵² Indeed, FDA itself, as well as other government agencies, refers to plant-based dairy products using conventional dairy terms.⁵³

It would be counterproductive for plant-based milks and similar products to be labeled as, for example, “almond drink” because this terminology would be foreign to consumers and less indicative of what the product is. Similarly, “beverage” is an overbroad, ambiguous term: the 2015-2020 Dietary Guidelines for Americans (the DGAs) uses the word “beverage” to refer to several different types of products such as soda, sweetened coffee and tea, and flavored waters.⁵⁴ Furthermore, in several instances, the DGAs mention “soy beverages” then clarifies that “soy beverages” are commonly known as “soymilk.”⁵⁵ If FDA is truly concerned about consumer confusion, it must continue to allow plant-based dairy producers to use “milk” and other familiar conventional dairy terminology in their labeling; doing otherwise would only breed confusion where none exists.

B. Consumers Understand the Names of Plant-Based Dairy Products

Innovators make plant-based products to meet consumers’ growing demands. Whether consumers have a specific dietary preference that excludes conventional dairy foods, have an allergy to conventional dairy foods, or simply elect to consume plant-based dairy products along with conventional dairy foods, consumers understand exactly what they are purchasing.⁵⁶

Just as consumers understand that rye bread is made from rye and rice noodles are made from rice, consumers understand that plant-based dairy products are made from specific plants — almond milk is made from almonds, soy yogurt is made from soybeans, and cashew ice cream is made from cashews. Including the words “milk,” “yogurt,” and “ice cream” in the names of plant-based dairy products do not mislead consumers into thinking they contain lacteal secretions from a cow.

A survey by the International Food Information Council (IFIC) Foundation found that when looking at the labels of soy, almond, cashew, coconut, and rice milks, more than 90% of respondents understood that they do not contain lacteal secretions from a cow.⁵⁷ On the other hand, when looking at the labels of branded chocolate milk, organic milk, butter, and lactose-free milk, 16% to 38% of respondents, depending on the product, did not understand that they

⁵² *Id.*

⁵³ See FDA, Health Claims, *supra* note 26.

⁵⁴ 2015–2020 DGAs at 61.

⁵⁵ *Id.* at 23.

⁵⁶ See *Painter*, Civ. No. 17-2235 (C.D. Cal. May 24, 2017) (“even the least sophisticated consumer [knows] instantly the type of product they are purchasing”).

⁵⁷ Int’l Food Info. Council Found., *Consumer Attitudes About Labeling Cow’s Milk, Plant-Based and Non-Dairy Alternatives*, 2 (Oct. 2018), <https://bit.ly/2Rhpk7u>.

actually contain milk from cows.⁵⁸ If there is any confusion among different types of dairy products, it seems to be surrounding conventional dairy products rather than plant-based dairy products.

Further illustrating that consumers understand what plant-based dairy products are made from, when we asked survey respondents to select the primary ingredient used to make a specific type of plant-based milk, consumers identified the correct ingredient more than 92% of the time.⁵⁹ For example, when asked to select the primary ingredient used to make soy milk, 96% of consumers correctly selected soybeans.⁶⁰ When asked to select the primary ingredient used to make skim milk, 89% of respondents correctly selected cow's milk.⁶¹

Requiring plant-based dairy producers to use other words on their labels would only impair and diminish consumer understanding. Using terms that consumers are already familiar with (e.g., milk) with a qualifier that modifies the familiar word and explains the composition of the product (e.g., almond) is the most simple and direct way to label and identify plant-based dairy products. As long as consumers continue to understand producers' clear, truthful labels, FDA has no authority to restrict what terms producers use.

C. Including the Word “Milk” on a Product Label Does Not Lead Consumers to Think the Product is Nutritionally Equivalent to Cow’s Milk

FDA asks several questions surrounding consumers nutritional knowledge of plant-based and conventional dairy products. For example, FDA asks “Do parents and caregivers who purchase these plant-based products for young children or other family members believe that these plant-based products are nutritionally equivalent to their dairy counterparts and can replace them as a food choice?” Commissioner Gottlieb offered a similar concern in his September statement on modernizing standards of identity and the use of dairy names for plant-based substitutes, stating that “the labeling of some plant-based products may lead consumers to believe that those products have the same key nutritional attributes as dairy products, even though these products can vary widely in their nutritional content.”⁶²

FDA’s concern is unfounded and irrelevant. The word “milk” on a product label does not cause consumers to assume the product is nutritionally equivalent to cow’s milk. Plant-based milks and cow’s milks are two distinct product categories. Consumers do not see the word “milk” on a

⁵⁸ *Id.*

⁵⁹ Jessica Almy, *Consumers Not Confused About Ingredients Used to Make Plant-Based Milks*, GFI Blog (July 24, 2018), <https://bit.ly/2RQBy8c>.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² FDA Comm’r Scott Gottlieb, Statement from FDA Commissioner Scott Gottlieb, M.D., on Modernizing Standards of Identity and the Use of Dairy Names for Plant-based Substitutes (Sept. 27, 2018), <https://bit.ly/2AhfwR0>.

label, disregard plant-based qualifiers or modifiers attached to the word, and think the product must be nutritionally the same as cow's milk.⁶³

However, even if consumers were to think plant-based milks were nutritionally equivalent to cow's milk, FDA has already taken care of the problem by requiring nutrition labels, and it has no authority to ban or compel additional speech. As explained above, FDA cannot restrict what terms plant-based dairy producers use on their labels without a showing that consumers are actually confused. And, even then, it may not use more extensive means than necessary to alleviate consumers' confusion, which nutrition labels already do. Nutrition labels provide ingredient disclosures and nutrition facts panels which clearly present all of the information necessary to clear up any potential confusion.⁶⁴

Furthermore, the word "milk" does not convey only one nutritional profile. FDA mentions that the nutritional content of plant-based dairy can vary yet does not mention the variety in nutritional content of cow's milk. For example, the nutritional content of lactose-free skim milk is different from the nutritional content of 2% reduced fat chocolate milk. In comparison to lactose-free skim milk, 2% reduced fat chocolate milk has more fat, more than double the amount of sugar, and nearly four times the amount of cholesterol.⁶⁵ If FDA has no issue with all cow's milk being called "milk" despite possessing a broad range of nutritional attributes, then FDA should not have an issue with the differing nutritional attributes of various plant-based milks.

Nor can FDA's legitimate concern for children's health — including preventing the development of rickets, a disease caused by vitamin D deficiency, and kwashiorkor, a disease caused by a severe lack of protein — justify restricting the use of dairy terms on plant-based labels. Consumers, including parents, already have adequate information to assess the nutritional content of plant-based dairy products as these products are required to bear nutrition labels.⁶⁶ Moreover, neither rickets nor kwashiorkor (which are rare in the United States) are directly tied to an absence of cow's milk in the diet. Americans get most of their vitamin D from sun exposure and a range of fortified foods — beyond fortified cow's milk — including fortified cereals and fortified plant-based milks.⁶⁷ And, on average, Americans, including one- to three-

⁶³ Even Chris Ross, the Vice President of Marketing at HP Hood LLC, a leading provider of conventional dairy products, expressed this same sentiment stating that "consumers don't expect precise organoleptic or nutritional equivalency with dairy milk" when talking about plant-based milks. Elaine Watson, *No Added Sugar: HP Hood Gears Up for National Launch of 'Naturally Sweet' Planet Oat Oatmilk*, FoodNavigator-USA (Dec. 8, 2018), <https://bit.ly/2QpLZCg>.

⁶⁴ See 21 U.S.C. §§ 343(q)(1)(D), (E).

⁶⁵ USDA, Agric. Research Serv., *Full Report (All Nutrients): 45344161, 2% REDUCED FAT CHOCOLATE MILK, UPC: 076850099075*, USDA Branded Food Products Database (July 2018), <https://bit.ly/2CJCPU1> (last accessed Jan. 26, 2019).

⁶⁶ 21 U.S.C. §§ 343(q)(1)(D), (E).

⁶⁷ Nat'l Insts. of Health, Office of Dietary Supplements, *Vitamin D: Fact Sheet for Health Professionals* (Nov. 9, 2018), <https://bit.ly/1M5deq6> (last accessed Jan. 26, 2019).

year-olds, consume adequate amounts of protein.⁶⁸ (In fact, American teenage boys and adult men often consume too much protein.⁶⁹) Because an inadequate amount of protein is almost always tied to an inadequate amount of calories overall, kwashiorkor is generally only seen in regions experiencing famine,⁷⁰ though it could also occur if babies are deprived of breastmilk or high-quality infant formula, which they should be drinking rather than *either* cow’s milk or plant-based milk.⁷¹

In summary, with access to nutrition labels on plant-based dairy products, FDA need not restrict plant-based milk producers’ use of the word “milk” on the basis that consumers believe that any product with the word “milk” on its label has one nutritional profile.

IV. Conclusion

The purpose of food labels is to protect consumers and allow them to make informed purchasing decisions. The labels of plant-based dairy products do just that — the labels are clear, evidenced by the fact that consumers are not confused by them, and they allow consumers to make informed decisions by alerting them that the products are plant-based and providing nutrition information.

When deciding on its approach to the labeling of plant-based dairy products, FDA must keep in mind that restricting the use of common names, like soy milk, would violate producers’ First Amendment rights. The word “milk” is not just reserved for cow’s milk. There are various other mammal milks on the market, like goat’s and sheep’s milk, as well as products containing the word “milk” that do not contain mammalian lacteal secretions, like canned coconut milk or milk of magnesia. Without a showing that consumers are actually confused by the labels of plant-based dairy products, and that there is no less restrictive means possible of ensuring clarity other than prohibiting plant-based dairy producers’ from using conventional dairy terms on their labels, FDA has no authority to act. FDA should not censor labels to protect the conventional dairy industry from consumers’ changing purchasing patterns by requiring plant-based dairy innovators to change their labels or branding.

Again, GFI thanks FDA for the opportunity to submit these comments and would welcome a meeting with you to discuss these issues in greater detail. Please let us know if we can schedule one with you in the near future.

⁶⁸ 2015–2020 DGAs at 50.

⁶⁹ *Id.*

⁷⁰ Healthline Editorial Team, *What is Kwashiorkor?*, Healthline Blog (Natalie Butler, R.D., L.D. ed., July 24, 2017), <https://bit.ly/2pJrT3d>.

⁷¹ Theodore Liu et al., *Kwashiorkor in the United States: Fad Diets, Perceived and True Milk Allergy, and Nutritional Ignorance*, Arch Dermatology (May 2001), <https://bit.ly/2G2EUO1>.

Sincerely,

A handwritten signature in black ink, appearing to read "Nicole Manu". The signature is fluid and cursive, with the first name "Nicole" written in a larger, more prominent script than the last name "Manu".

Nicole Manu
Staff Attorney
The Good Food Institute

A handwritten signature in black ink, appearing to read "Jessica Almy". The signature is cursive and somewhat stylized, with the first name "Jessica" being the most legible part.

Jessica Almy
Director of Policy
The Good Food Institute

Appendix A

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

Petition to Recognize the Use of)
Well-Established Common and Usual)
Compound Nomenclatures for Food)
_____)

Docket No. _____

Submitted by the

Good Food Institute

Bruce Friedrich
Executive Director
The Good Food Institute
1380 Monroe St. NW #229
Washington, DC 20010
(866) 849-4457

Nicole Negowetti
Policy Director
The Good Food Institute

Nigel Barrella
Law Office of Nigel A. Barrella

March 2, 2017



T H E
GOOD FOOD
I N S T I T U T E
1380 MONROE ST. NW #229
WASHINGTON, DC 20010

[by electronic submission]

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

CITIZEN PETITION

The Good Food Institute¹ (“GFI”) submits this petition under sections 403(i), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (“FDCA” or “the Act”)² to request that the Commissioner of Food and Drugs issue regulations clarifying how foods may be named by reference to the names of other foods. Many products named in this fashion are already on the market, with many more likely to be developed in the future. The requested clarification would be consistent with current FDA regulations and policies, would reflect consumer understanding and the current realities of products in the marketplace, and would serve to foster continued innovation. Further, promulgating a general regulation regarding the nomenclature of these products will avert perceived regulatory uncertainty surrounding such product names, and will promote honesty and fair dealing in the interest of consumers.³

¹ The Good Food Institute is a 501(c)(3) nonprofit organization that is working toward a healthy, humane, and sustainable food supply, by publicly advocating for and encouraging research into alternatives to conventional animal foods.

² 21 U.S.C. §§ 343(i), 321(n), 371(a).

³ 21 C.F.R. § 130.5(b). GFI further asserts that it is prepared to substantiate the information in this petition by evidence in a public hearing, if such a hearing becomes necessary. 21 C.F.R. § 130.5(c).

I. Action Requested

GFI requests that FDA issue a regulation clarifying that new foods may be named by reference to other “traditional” foods in a manner that makes clear to consumers their distinct origins or properties. As described herein, the practice of using such names is well-established in the marketplace, and consumers easily understand and accept such common or usual names for a wide variety of products. Specifically, GFI requests that FDA amend 21 C.F.R. § 102.5, to add the following language after part (d):

(e) The common or usual name of a food may be —

- (1) the common or usual name of another food preceded by a qualifying word or phrase that identifies (i) an alternative plant or animal source that replaces the main characterizing ingredient(s) or component(s) of such other food, or (ii) the absence of a primary characterizing plant or animal source, or of a nutrient, allergen, or other well-known characterizing substance, that is ordinarily present in such other food; or
- (2) any other word or phrase comprised of two or more terms, which may be separated by hyphens or spaces; but if such name includes the common or usual name of any other food, it must effectively notify consumers that the product is distinct from such other food.

The use of such a name does not violate section 403 of the act or regulations of this chapter solely because it includes the common or usual name of another food (including a food for which a standard of identity is established) if the entire name serves to notify a reasonable consumer that the product differs from such other food.

GFI further requests that FDA, in the interim while undertaking the proposed rulemaking, publish guidance for industry clarifying that such product names may generally be used, consistent with the proposed regulation and the contents of this petition.

II. Statement of Grounds

A. Statement of Factual Grounds

1. Consumers are increasingly seeking out new variations on familiar foods.

The American food supply today consists of a greater variety of foods than ever before. The diverse array of food products now on the market can cater to the needs and tastes of most any consumer, and the plethora of options available to consumers continues to grow year after year.⁴

The increasingly diverse varieties of food in the marketplace are available because consumers are demanding them, for several reasons. Changing consumer preferences may partly reflect changing demographics and greater awareness (and availability) of the variety of foods from different parts of the world. Additionally, a large and growing share of consumers are becoming more discerning of the food they buy, selecting certain foods over others for reasons of health, environmental and ethical concerns, or personal taste.⁵

⁴ US Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory, USDA National Nutrient Database for Standard Reference Dataset for What We Eat In America, NHANES (Survey-SR), October 2015, available at <https://www.ars.usda.gov/Services/docs.htm?docid=25662> (noting the addition of 265 “new foods” to the latest NHANES survey database); US Department of Agriculture, Economic Research Service, New Products, October 12, 2016, available at <https://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products/> (describing the upward trend of new food product introductions per year since the early 1990s).

⁵ The “new foods” added to the 2013–2014 NHANES database “include mainly commercially processed foods such as several gluten-free products, milk substitutes, sauces and condiments such as sriracha, pesto and wasabi, Greek yogurt, breakfast cereals, low-sodium meat products, whole grain pastas and baked products, and several beverages including bottled tea and coffee,

As part of this trend, consumers have become accustomed to seeing various qualifiers and claims in food labeling and advertising: organic, low-fat, reduced fat, fat-free, reduced calorie, low-carb, gluten-free, wheat-free, dairy-free, soy-free, no artificial colors, non-GMO, grown without pesticides, raised without antibiotics, no added sugars — the list goes on. Some of these qualifiers are subject to definitions under the law and regulations administered by FDA and USDA; others are constrained only by the general requirement that they not be false or misleading.

FDA and Congress have responded to these changes in the marketplace and in consumer demand by providing frameworks for new labeling claims (whether mandatory or voluntary), while also giving producers flexibility in formulating new products to suit these changes in consumer demand. One significant example of this trend is FDA’s regulation relating to nutrient content claims, promulgated after the passage of the Nutrition Labeling and Education Act of 1990 (NLEA).⁶ In that regulation, 21 C.F.R. § 130.10, FDA permitted modified versions of foods to be labeled with a “nutrient content claim and a standardized term,” even if they did not comport with the standard of identity for the standardized term. This allowed new products with reduced levels of nutrients of concern to consumers (e.g. fat, sodium, calories) to be labeled in a clear manner that references standardized food terms (e.g. ice cream), leading to products with names like “low-fat ice cream” or “reduced calorie salad dressing.”

coconut water, malt beverages, hard cider, fruit-flavored drinks, fortified fruit juices and fruit and/or vegetable smoothies.” USDA NHANES survey, note 4, above.

⁶ Public Law 101-535.

Since the early 1990s, the list of nutrients or ingredients of interest to consumers has grown significantly. For example, the prevalence of common food allergies has apparently increased for unknown reasons,⁷ and more consumers now seek foods free of specific allergens. Congress has responded by amending the FDCA to require labeling disclosures of common allergens,⁸ and food producers have responded by making available varieties of (and alternatives to) traditional foods that do not contain common allergens such as wheat, milk, peanuts, egg, or soy. Similarly, the prevalence and identification of celiac disease appears to be increasing;⁹ consumers with celiac disease are advised to avoid gluten, and many other consumers avoid gluten due to non-celiac gluten sensitivity or for other reasons. FDA has responded by defining the term “gluten-free,”¹⁰ and food producers have responded by creating new varieties of traditional foods that do not contain gluten and are labeled “gluten-free.”

Yet another significant (and growing) group of consumers has sought to reduce or eliminate certain animal products — especially dairy products — from their diet. Some of these consumers are avoiding allergens as described above (as milk is among the most

⁷ K.D. Jackson et al. *Trends in Allergic Conditions among Children: United States, 1997–2011*. National Center for Health Statistics Data Brief (CDC), May 2013, available at <https://www.cdc.gov/nchs/data/databriefs/db121.pdf>.

⁸ See Food Allergen Labeling and Consumer Protection Act of 2004, Pub. Law 108-282; 21 U.S.C. §§ 343(w), 321(qq).

⁹ See, e.g. J.F. Ludvigsson et al. *Increasing Incidence of Celiac Disease in a North American Population*, 108 AM. J. GASTROENTEROL. 818 (2013), available at <http://www.nature.com/ajg/journal/v108/n5/full/ajg201360a.html>.

¹⁰ FDA, “Final Rule: Gluten-Free Labeling of Foods” 78 Fed. Reg. 47154 (Aug. 5, 2013).

common food allergies). Additionally, many consumers avoid dairy products due to lactose intolerance.¹¹ Still other consumers have reduced or eliminated their consumption of dairy for reasons of health, due to environmental or ethical concerns, or for mere personal taste. This trend has been most visible in recent years with a sharp increase in the consumption of alternatives to traditional fluid dairy milk. From 2011–2015, sales of almond milk grew 250%, surpassing the next most popular alternative (soy milk) and reaching nearly \$900 million in annual sales in 2015.¹² Other plant-based alternatives to traditional dairy products (such as yogurt, cheese, and ice cream) are becoming more common as well, as just one part of a larger thriving plant-based food industry that has been growing so rapidly in response to consumer demand.

In sum, the growth in “new foods” described above, as well as many others has been ongoing since at least the 1990s and shows no signs of slowing.¹³ Whether due to changes in demographics, or due to health, environmental, or ethical concerns of consumers, or merely due to changes in taste, the American food supply will continue to grow more diverse with a greater variety of products. GFI therefore submits this petition, requesting FDA to clarify that food producers may label and name their new products in

¹¹ Demographic shifts in the American population may contribute to an increasing incidence of lactose intolerance; FDA, citing NIH estimates, has noted that “up to 75% of all adult African Americans and Native Americans and 90% of Asian Americans are lactose intolerant.” FDA, *Problems Digesting Dairy Products?*, October 2009, available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143705.pdf>.

¹² Nielsen Insights, *Americans Are Nuts for Almond Milk* (Mar. 31, 2016), available at <http://www.nielsen.com/us/en/insights/news/2016/americans-are-nuts-for-almond-milk.html>.

¹³ See note 4 above.

a clear, commonsense manner consistent with consumer expectations, with the law applied fairly and equally to each.

2. Many products on the market are already named in a manner consistent with the standard GFI proposes.

The new food products described above — whether brought from other parts of the world or newly invented — often resemble familiar products that are considered traditional in the American diet. Consumers often name them by reference to such familiar and “traditional” products by adding a qualifying term in front of the name of the traditional product (as GFI proposes). Example of this practice are too many to list comprehensively, but in this section, GFI discusses numerous examples, some of which pre-date the FDCA itself. And more specifically, this section focuses on well-known food products that incorporate the most closely regulated food names — those with established standards of identity.

To start, consider bread, a food as old as civilization. Historically, bread has been made from the ground meal or flour of a variety of plant species, usually (but not always) leavened with yeast. Virtually every culture around the world has its own versions of this dietary staple — countless variations with different ingredients and methods of preparation that have been developing for centuries.

But in the United States, FDA has specifically defined “bread” as a product primarily consisting of (non-durum) wheat flour, and requires that it be leavened with

yeast and baked.¹⁴ “Nonwheat flours, nonwheat meals, nonwheat grits, . . . and nonwheat starches” may be used, but only “if the total quantity is not more than 3 parts for each 100 parts by weight of [wheat] flour used.”¹⁵ Additionally, “bread” must weigh half a pound or more.¹⁶ Does this regulation mean that other types of bread (e.g. unleavened or nonwheat varieties from around the world, cooked by different methods, in different shapes and sizes) cannot be called bread?

The answer, of course, is no. Almost any American consumer is aware of the existence of rye bread, cornbread, and potato bread — just a few examples of breads commonly eaten in the United States (especially in certain regions or communities). Consumers know that bread can take different forms, such as flatbreads like pita bread or matzo. Some consumers seek out “multigrain” breads precisely because they contain a variety of nonwheat grains.¹⁷ Still other consumers with celiac disease or gluten sensitivity seek out gluten-free breads, a variety of which are now on the market, along with gluten-free rolls and buns.¹⁸ No consumers purchasing these diverse offerings are deceived or confused by the fact that they are labeled “_____ bread” even if the products do not conform to the standard of identity for “bread.” The qualifying term immediately

¹⁴ 21 C.F.R. § 136.110(a), (c)(1), (c)(3); 21 C.F.R. § 137.105 (defining “flour” as a product made from “wheat, other than durum wheat and red durum wheat.”).

¹⁵ 21 C.F.R. § 136.110(c)(11).

¹⁶ 21 C.F.R. § 136.3(a).

¹⁷ A purchaser of “12-grain bread” might be unpleasantly surprised if the product *did* conform to the general standard of identity for “bread” (because in that case, the 11 nonwheat grains would, in total, constitute less than 3% of the total flour used).

¹⁸ Rolls and buns must follow the same standard as “bread” except as to weight.

preceding “bread,” denoting alternative grain sources or other origins or properties, provides enough clarity that the product is different from (unqualified) “bread.”

Consider also another staple in many cultures — noodles. As with bread, FDA has defined noodles as “ribbon-shaped” products made exclusively from wheat flours (including durum, the variety of wheat typically used in pasta), and requires that they contain egg products.¹⁹ (Per FDA’s identity standards, ordinary pasta and similar products that do not contain eggs are “macaroni products.”)²⁰ But many cultures, in East Asia and Southeast Asia for example, eat noodles made from rice, sometimes broad and flat rather than ribbon-shaped, and such noodles hardly ever contain egg. Other noodles of the world are made from different grains (e.g. Japanese *soba* noodles, made from buckwheat) or are made from wheat but without egg (e.g. ramen noodles). Are these products wrong to call themselves “noodles” in light of FDA’s standard of identity? Of course not: they are rice noodles, ramen noodles, bean thread noodles, and so on. Again, the qualifying term — the “_____” in “_____ noodles” — notifies any reasonable consumer

¹⁹ 21 C.F.R. § 139.150(a), (b).

²⁰ This antiquated term (established in 1944 under the heading “alimentary pastes”, 9 Fed. Reg. 14881) demonstrates how far some standards of identity have fallen behind the evolution of the English language and consumer expectations: Americans today simply call it “pasta” and understand “macaroni” to refer exclusively to small tubular pasta varieties (meanings that reflect the Italian *pasta* and *maccheroni*). The standardized term is frankly confusing to the modern consumer, and the regulatory meaning cannot even be found in many modern dictionaries. Thus, some pasta producers have chosen to identify their products with the universally-understood term “pasta” rather than “macaroni products.” This may technically violate FDA regulations, but justifiably so: pasta is simply the true common or usual name of these products, notwithstanding the outdated standard of identity.

that the product is distinct from what FDA may define as “noodles” (to the extent the reasonable consumer knows about FDA’s definition of “noodles” from 1944).²¹

To give another example of similar compound names in action, “butter” has a standard of identity defined by statute — a product of more than 80% milkfat.²² In spite of this, FDA defined standards for “peanut butter” and “fruit butters” (such as apple butter), products that do not contain butter.²³ And outside of FDA’s identity standards, other “nut butters,” such as almond butter or cashew butter, are now common in the market (for those allergic to peanuts, or who just prefer the taste), and consumers readily understand that these products are not (dairy) butter or other “_____ butters.”

It is in a similar vein that another global food — soy milk or soymilk — came to the United States in the mid-20th Century from areas of the world where cow’s milk was often not traditionally consumed. And although the (unqualified) term “milk” has a standard of identity that refers exclusively to cow’s milk,²⁴ consumers have long understood that various compound terms of the form “_____ milk” or “milk of _____” refer to distinct products unrelated to cow’s milk. (Goat milk, buffalo milk, coconut milk, almond milk, or milk of magnesia, to name a few.) These compound constructions are so thoroughly lexicalized that they often appear in dictionaries as part of the first or

²¹ Similarly, many wheat-free pasta products are now on the market (e.g. “gluten-free pasta,” “brown rice pasta”), and these products often incorporate the names of standardized “macaroni products” (e.g. “gluten-free spaghetti”). 21 C.F.R. § 139.110(b)–(d).

²² 21 U.S.C. § 321a.

²³ 21 C.F.R. § 150.110; 21 C.F.R. § 164.150.

²⁴ 21 C.F.R. § 131.110.

second definition of the word “milk,”²⁵ and the overwhelming majority of consumers refer to these products by these names.²⁶ The government itself (including FDA) has played its role in this linguistic trend, using the common names of products like soy milk and other dairy alternatives in public statements and documents.²⁷

These linguistic patterns are hardly limited to the English language or the U.S. market — various languages from around the world use the same semantic constructions to describe the same products.²⁸ And almond milk is similarly well-established —

²⁵ See, e.g. Merriam-Webster Online, Definition of MILK, available at <https://www.merriam-webster.com/dictionary/milk> (accessed January 26, 2017): “1 b . . . (2): a food product produced from seeds or fruit that resembles and is used similarly to cow’s milk <coconut *milk*> <soy *milk*>. 2: a liquid resembling milk in appearance[.]”

²⁶ Google statistics show that since 2004, consumer searches in the United States for the terms “soy milk” and “almond milk” have outnumbered searches for alternative names (“soy drink,” “soy beverage,” etc.) by more than 30-to-1. <https://goo.gl/DLhGz0>.

²⁷ See, e.g. FDA, *Health Claims; Soy Protein and Coronary Heart Disease* 63 Fed. Reg. 62977, 62978 (Nov. 10, 1998) (referring to “soy milk, soy yogurt, and soy cheese.”); USDA, *Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP)* 81 Fed. Reg. 90675, 90693–94 (Dec. 15, 2016) (referring to “soy yogurt,” “soy milk,” “soy cheese,” “almond milk,” and “rice milk.”); DHHS & USDA, *2015–2020 Dietary Guidelines for Americans* at p. 23 (describing dairy alternatives from soy and other plants, marketed as plant “milks”).

²⁸ In China, the country of soy milk’s origin, 豆奶 (Mandarin *dòu nǎi*, literally “bean milk”) is used as one possible name of the product, although the name 豆浆 (*dòu jiāng*, loosely translated as “bean slurry”) is more common in most places. The former name (literally “bean milk”) is especially common in Taiwan. The Japanese 豆乳 (*tonyu*) has the same literal meaning of “bean milk,” and the Korean 두유 (*duyu*) has a similar linguistic origin. This construction has extended to Western countries where the product appeared later in history — the French and Spanish *lait de soja* and *leche de soja* (literally “milk of soy”) and the German *Sojamilch* (“soymilk”) are a few examples. Often these alternative meanings of “milk” are thoroughly lexicalized and refer to other milky liquids, including other cow’s milk alternatives. See, e.g. “leche” in *DICCIONARIO DE LENGUA ESPAÑOLA*, available at <http://dle.rae.es/?id=N2tsDWF>, accessed January 26, 2017 (definition 3, translating as “white juice obtained from some plants, fruits, or seeds. *Milk of coconut, of almonds.*”) The European Union has generally disapproved of the use of such terms in food labeling since 2007 (later adding exceptions for almond and coconut milks), but Google

though it has had the recent astronomical rise in popularity described above, it was common (and named similarly) in Western and Middle Eastern kitchens *centuries* ago.²⁹ Clearly, names of this form have deep historical and linguistic roots.

Further, these age-old foods with names of the form “_____ milk” are now as familiar and clear to consumers as rye bread, rice noodles, or cashew butter. Consumers choose these products precisely because they are not cow’s milk, whether due to allergies, other ingredient sensitivities or health concerns, ethical concerns, environmental concerns, or simple taste preference. And although some have claimed that including the word “milk” may confuse consumers (leading them to think the product contains cow’s milk), consumer research has demonstrated that practically all consumers who have heard of these products (including those who do not consume them) are aware of their basic nature as cow’s milk alternatives that do not contain cow’s milk.³⁰

Non-wheat breads, non-wheat noodles, non-dairy butters, and non-dairy milks are merely a few of the instances in which established products on the market incorporate the

statistics reveal that the EU has failed in its effort to regulate natural language: use of these names persists and predominates over alternative names. See <https://goo.gl/9CLoKg>.

²⁹ For example, the 14th-Century French recipe book *Le Viandier de Taillevent* contains numerous references to *lait d’almendes* (or in Modern French, *lait d’amande* — milk of almond). 23 LE VIANDIER DE TAILLEVENT (1892 transcription of the oldest surviving manuscript, circa 1326–1395), available at https://books.google.com/books?id=D_EYAAAAYAAJ&pg=PA23.

³⁰ Soyfoods Association of North America, *Summary of Research on Consumer Awareness of Soy milk and Dairy Milk*, appended to this petition as Attachment A. In this 814-consumer survey conducted in 2006, the share of consumers who answered that they believe “cow’s milk” is an ingredient in “soymilk” was less than 0.5%, with approximately 3% reporting “milk” as an ingredient.

common or usual name of another food to clearly and directly describe what the product is, despite being a very different product.³¹ This structure, the addition of one word to another to form an entirely different word with a new meaning, is not just a matter of how marketing works — it is simply a matter of how language works. GFI submits this petition asking that FDA acknowledge and accept this fact and practice, not only for the products described above, but for others that may become part of the American diet in the future. As described in detail below, doing so would be consistent with the FDCA and with FDA policy and past practice. It would also be consistent with FDA’s responsibilities under the Constitution: to regulate the market neutrally and with due respect to the First Amendment rights of food producers to label their products in a clear manner that consumers understand and accept.

B. Statement of Legal Grounds

1. GFI’s proposed regulation is consistent with the FDCA and with FDA policy and practices.

GFI is asking FDA to establish a framework that formally recognizes the reality of the marketplace regarding the compound naming of foods that incorporate the common names of other foods in a way consumers clearly understand. In a way, what GFI requests is a regulation that clarifies existing law and practice; not only has FDA allowed

³¹ And for good measure, here are a few more: herbal teas (like peppermint, chamomile, or ginger teas) that contain no tea; coconut water, which is not water; turkey bacon, which is not bacon; coconut cream and non-dairy creamer, neither of which contain cream; root beer, which contains no beer; English muffins, which are not muffins; shellfish, which are not fish; jellyfish, which are neither jelly nor fish; and rice cakes, which seem particularly unworthy of being called “cake.”

products with such names to remain on the market, but the standard proposed by GFI is also consistent with FDA's longstanding interpretation of the FDCA and its regulations.

Even though the proposed regulation would do nothing more than clarify existing law and practice, such clarification would be helpful to industry and the public. The full meaning of the law and regulations is not always apparent to those who simply read the general language found in the United States Code or the Code of Federal Regulations, because the meaning of these provisions develops over time through interpretation by FDA and the courts, as well as through the agency's practices and policies. To put it bluntly, this is an area of law that is sometimes misunderstood or misapplied by some. For example, the Act's standard-of-identity provision is sometimes misread to completely preclude the use of standardized terms in non-standardized food names, and the Act's prohibition on unlabeled "imitation" foods is misread to cover any similar-looking food that can be used in place of another. Such misapprehensions of the law are clearly incorrect, but the fact that they persist can still do real harm to competitive industry and the public.

Such harm is not merely speculative, but concrete and apparent. For example, misguided statements of the law are often put forth by some members of industry in an anticompetitive effort to increase regulatory burdens on other members of industry. The most visible example of this today is a campaign by dairy producers against plant-based dairy alternatives — particularly soy milk and almond milk, which (as described above)

have become particularly popular and mainstream in recent years.³² These dairy industry campaigns against regulatory flexibility for new products have spanned decades,³³ and have only intensified as demand for soy milk, almond milk, and other dairy alternatives has grown.³⁴ Recently, members of Congress from dairy-producing states were enlisted to argue on behalf of the dairy industry’s distortions of the law,³⁵ and one Senator has even proposed to amend the FDCA in service of the dairy industry’s anticompetitive goals.³⁶ These efforts spawn confusion and uncertainty for producers — many of which are startups and small businesses particularly sensitive to perceived regulatory risk.

³² Due to the attention these products have received, this petition will frequently use them as examples to illustrate how the proposed general language would apply.

³³ See, e.g. *Nat’l Milk Producers Fed. v. Harris*, 653 F.2d 339, 343 (8th Cir. 1981) (unsuccessful challenge to FDA’s interpretation of the Act’s “imitation” provisions); Letter from National Milk Producers Federation to CFSAN, February 14, 2000, available at <http://www.fda.gov/ohrms/dockets/dailys/04/may04/050404/97p-0078-c00166-vol2.pdf>; Comments of National Milk Producers Federation, July 28, 2010, available at <https://www.regulations.gov/document?D=FDA-2010-N-0210-0092>; Comments of National Milk Producers Federation, May 5, 2014, available at <https://www.regulations.gov/document?D=FDA-2009-D-0430-0074>.

³⁴ However, the dairy industry does not speak with one voice on this issue. For example, Dean Foods, the largest processor and distributor of fluid milk in the country, wrote to FDA in 2000 that “the term ‘soymilk’ has been widely recognized in our industry as the commonly used name for natural beverages made out of soybeans, water and other vegetable based ingredients for a number of years. We recognize this term to be accurately descriptive, meaningful and widely understood We have not found this term to be misleading to ourselves or our customers, [and w]e have not received any complaints from customers or consumers regarding this issue.” Comment from Dean Foods Company, March 8, 2000, available at <https://www.regulations.gov/document?D=FDA-1997-P-0016-0024>. This comment, and many others like it, regards a 1997 citizen petition requesting that FDA establish a standard for “soymilk.” GFI believes that this step is currently unnecessary because the name has already been clearly established by common usage, per 21 C.F.R. § 102.5(d).

³⁵ See Letter to Commissioner Califf from Congressman Peter Welch (D-Vt.) et al., Dec. 16, 2016, available at <http://www.nmpf.org/files/Welch-Simpson%20Letter.pdf>.

³⁶ DAIRY PRIDE Act, S. 130, 115th Cong. (2017), proposed by Senator Baldwin (D-Wisc.)

These misapprehensions of the law also manifest themselves in the courts. Some lawsuits have been filed alleging that soy milk and almond milk products are improperly named, and though such frivolous contentions have (so far) generally been dismissed at the pleading stage,³⁷ more such lawsuits have recently been filed.³⁸ Defending against these lawsuits creates costs for the producers of these products, and these costs may ultimately be passed on to the consumer. And these meritless lawsuits, just like perceived regulatory risk, can have a chilling effect that may dissuade businesses (especially small ones) from labeling their products in a clear, accurate manner that consumers understand. FDA's clarification of the law would pre-empt meritless lawsuits like these, to the benefit of producers and consumers alike.

To see how GFI's proposed language is consistent with the FDCA, and how it embodies FDA's policies and practices, this petition now reviews the (arguably) relevant provisions of the Act, and how they have been interpreted by FDA, and their applicability to names of the form GFI has proposed. This includes an analysis of (1) the Act's protection of standards of identity for certain foods; (2) the Act's requirement that products bear their common or usual name; and (3) the Act's provision regarding "imitation" foods.

³⁷ See Order, *Gitson v. Trader Joe's Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013). These opinions are appended to this petition as Attachment B.

³⁸ *Kelley v. WWF Operating Co.*, 17-cv-117 (E.D. Cal., filed Jan. 24, 2017); *Painter v. Blue Diamond Growers*, BC 647816 (Los Angeles Super. Ct., filed Jan. 23, 2017).

Standards of Identity

When considering food names that incorporate the names of standardized food, section 403(g) of the Act³⁹ is sometimes seen to serve as the starting point of the analysis. That section states that a food is misbranded if it “purports to be or is represented as a food for which a definition and standard of identity has been prescribed . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard[.]” For the various nonconforming articles described in detail above, the question, then, is whether a food name that merely includes the name of a standardized food necessarily “purports to be or is represented as” the standardized food.

The clear answer, as FDA and courts⁴⁰ have long recognized, is no. By their own terms, standards of identity only govern *unqualified* food names. Thus, this provision creates no barrier to qualified uses of standardized terms, because the use of a qualifier will generally indicate that the food does not purport to be the standardized food. So peanut butter does not purport to be “butter,” rice noodles do not purport to be “noodles,” and potato bread does not purport to be “bread,” at least insofar as these terms are defined by regulation (as opposed to ordinary language).

Once again, take “milk” as an example. Despite the recent objections to qualified uses of the word “milk” described above, FDA has already recognized that its identity

³⁹ 21 U.S.C. § 343(g).

⁴⁰ See e.g. *62 Cases of Jam v. United States*, 340 U.S. 593, 600 (1951) (“Congress used the words ‘purport’ and ‘represent’—terms suggesting the idea of counterfeit.”)

standard applies only to the unqualified term — indeed, FDA has recognized this fact for as long as the term has been standardized. In the very same regulation establishing the standard of identity for “milk,” FDA addressed its applicability to “flavored milk products” (e.g. chocolate milk).⁴¹ On that topic, FDA stated, “[s]ince flavored milks, such as chocolate milk, *do not purport to be and are not represented as milk*, their distribution as nonstandardized foods could be continued after the establishment of an identity standard for milk.”⁴² Similarly, FDA formerly prescribed a standard for a food known as “ice milk”⁴³ (what is today called “low-fat ice cream”) without any question that this product purported to be milk. And of course, buttermilk and milks from other animals (e.g. goat milk) have long existed on the market as nonstandardized foods, without any reasonable suggestion that they purport to be or are represented as “milk,” as defined by regulation. By the same token, section 403(g) of the Act presents no problem for names like “soy milk” or “almond milk,” as such products simply do not purport to be “milk.”⁴⁴

More generally, FDA noted long ago that the “existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in

⁴¹ 38 Fed. Reg. 27924, 27925 (Oct. 10, 1973).

⁴² *Id.* (emphasis added.) The Commissioner nonetheless found it “reasonable” to include provisions for such products in the standard of identity itself.

⁴³ 25 Fed. Reg. 7125 (Jul. 27, 1960).

⁴⁴ See *Gitson*, at 3–4 (“the standardization of milk simply means that a company cannot *pass off* a product as ‘milk’ if it does not meet the regulatory definition of milk. . . . Soymilk, in short, does not ‘purport[] to be’ from a cow within the meaning of section 343(g).”)

connection with the name of a nonstandardized food, as ‘in some cases it may be necessary to include a standardized name in the name of the substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling.’”⁴⁵

Regarding “substitute foods” specifically, FDA explained more fully in 1983:

in some cases, it may be reasonable and appropriate to include the name of a standardize[d] food or other traditional food in the name of a substitute food in order to provide the consumer with an accurate description. When this is done, the name of the food must be modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute. The modification of the traditional or standardized food’s name must be descriptive of all differences that are not apparent to the consumer. Thus, the procedure for naming these foods will depend on the nature of the substitute food and the manner and extent to which it differs from the food it simulates.⁴⁶

General principles like these were reflective of FDA’s shift away from prescribing standards of identity for new foods, and towards regulating most foods under general principles governing common or usual names.⁴⁷ These principles chiefly govern the food naming patterns that are the subject of this petition, and we examine them next.

Common or Usual Names

Under section 403(i) of the Act, if a food does not represent itself as a standardized food, it must bear “the common or usual name of the food, if any there

⁴⁵ 44 Fed. Reg. 3964, 3965 (Jan. 19, 1979), quoting 38 Fed. Reg. 20702, 20703 (Aug. 2, 1973).

⁴⁶ 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

⁴⁷ See e.g. *id.* (withdrawing a proposal to establish standards of identity for milk, cheese, and cream substitutes). The fact that FDA has not established a standard of identity for any new food since 2002 (“white chocolate,” 67 Fed. Reg. 62177) is reflective of FDA’s change in approach.

be[.]”⁴⁸ The most natural reading of this provision is that food producers must simply label their products in accordance with what consumers commonly or usually call them.⁴⁹

In clarifying this requirement, FDA has issued a regulation establishing general principles governing common or usual names.⁵⁰ (It is this regulation, 21 C.F.R. § 102.5, that GFI proposes amending.) The regulation, consistent with the ordinary meaning of section 403(i) described above, notes that the “common or usual name of a food may be established by common usage[.]”⁵¹ In the more general case (e.g. when there is no such established common usage), the regulation states that the common or usual name of a food “shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients.”⁵² The regulation also states that the common or usual name “may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.”⁵³

For the purposes of naming variations on other foods, this last provision is unfortunately somewhat vague and open to subjective interpretation. What names are

⁴⁸ 21 U.S.C. § 343(i).

⁴⁹ Additionally, the language “if any there be” implies that some foods may *not* have a common or usual name, and that in such a case, there is no such obligation to identify the food under any particular name.

⁵⁰ Broadly speaking, this regulation is entitled to judicial deference under the *Chevron* doctrine, but only to the extent that it is a reasonable interpretation of the legal requirement of the Act. If, for example, FDA’s regulation could be interpreted to prohibit the use of a name that consumers commonly use to identify a product, such an interpretation may not be entitled to judicial deference, particularly in light of the First Amendment concerns described later in this petition.

⁵¹ 21 C.F.R. § 102.5(d).

⁵² 21 C.F.R. § 102.5(a).

⁵³ *Id.*

“confusingly similar”? What names are “not reasonably encompassed within” another name? Without clarification of FDA’s practices and policies, the vagueness of this provision leads to reasonable concerns about the risk of arbitrary (or even discriminatory) enforcement against some food products but not others.

Fortunately, FDA’s stated policies and actual practices have added some clarity to these provisions. As we saw above, since the 1970s FDA has taken the position that it is sometimes “necessary” to include one name within another “in order to provide the consumer with accurate, descriptive, and fully informative labeling.”⁵⁴ In the case of “substitute” foods, it is “reasonable and appropriate” to do so, as long as “the name of the food [is] modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute.”⁵⁵

This policy faced opposition from some in industry — most notably the dairy industry, which was opposed to any use of dairy terms in the names of modified dairy products (most commonly, products with decreased milkfat content). But to the extent there was debate over naming such products,⁵⁶ it was largely settled with the passage of the NLEA in 1990 and FDA’s subsequent promulgation of regulations under that law.⁵⁷ As a result of this change, food producers have been allowed to label food products with

⁵⁴ 44 Fed. Reg. 3964, 3965 (Jan. 19, 1979), quoting 38 Fed. Reg. 20702, 20703 (Aug. 2, 1973).

⁵⁵ 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

⁵⁶ FDA established standards for some such products, but was not always consistent in its positions on other unstandardized products.

⁵⁷ 21 C.F.R. § 130.10.

nutrient-content qualifiers modifying the names of traditional foods. These names can be surprising at first, like “fat-free cheddar” (cheese without milkfat) or “fat-free ice cream” (ice cream without cream), often outright contradicting what consumers would ordinarily expect from these products. And the contradictions are not limited to the qualifying terms: FDA also allowed such food products to deviate from the standards of identity for the standardized foods in ways besides the clearly-identified changes in nutrient content. FDA permitted deviations from “non-ingredient provisions” such as “moisture content, food solids content requirements, or processing conditions.”⁵⁸ Additionally, FDA permitted the addition of any “safe and suitable ingredients” “used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness,” even if the addition of such ingredients to the standardized food would ordinarily violate the standard of identity.⁵⁹

As FDA explained at the time of this change, the qualifying nutrient-content language, together with “accompanying label statements[] and nutrition labeling, will enable consumers to distinguish traditional foods from modified versions of these foods”⁶⁰ This language demonstrates FDA’s position that if qualifying language in

⁵⁸ 21 C.F.R. § 130.10(c).

⁵⁹ 21 C.F.R. § 130.10(d)(1). However, ingredients “specifically prohibited by the standard” are not permitted in the modified foods. 21 C.F.R. § 130.10(d)(3).

⁶⁰ 58 Fed. Reg. 2431, 2439 (Jan. 6, 1993). The introduction of nutrition labeling by the NLEA was especially important — if a consumer is confused by what exactly “fat-free ice cream” is (because the ingredients of this product can vary drastically from brand to brand), the consumer has access not just to a list of all the ingredients, but also to detailed nutritional information about the product. The “Nutrition Facts” panel has become familiar to consumers over the past two decades, and consumer consciousness of this information has significantly decreased consumer reliance on expectations that food products conform to recipes specified in identity standards.

the product name, together with other information on the label, effectively enables consumers to distinguish the modified food from the traditional food, consumers will not be confused or otherwise deceived by the product, notwithstanding the inclusion of the name of a traditional food that it resembles. The language that GFI proposes in this petition follows this standard.

This general principle applies just as well to cashew butter, rice noodles, and soymilk, as it does to “fat-free [cream-free] ice cream.” Indeed, the first three terms are (if anything) *clearer* than the last, as they provide much more information as to what *is* in the product, as opposed to what is not. More analogous still would be products like gluten-free bread — as above, if a consumer is confused by what exactly “bread” is without gluten (or wheat), the ingredients list and Nutrition Facts are no more than a panel away.

Imitation

Finally, it is necessary to discuss how GFI’s proposed regulation is consistent with the law and FDA policies governing “imitation” labeling, as some food products (like soymilk) are sometimes argued to be “imitations.”⁶¹ Section 403(c) of the Act deems any product misbranded if it is “an imitation of another food, unless its label bears . . . the word ‘imitation’ and, immediately thereafter, the name of the food imitated.”⁶² By

⁶¹ See, e.g. Comments of National Milk Producers Federation, May 5, 2014, available at <https://www.regulations.gov/document?D=FDA-2009-D-0430-0074>.

⁶² 21 U.S.C § 343(c).

regulation, FDA has clarified that a food “shall be deemed to be an imitation . . . if it is a substitute for and resembles another food but is nutritionally inferior to that food.”⁶³

FDA described this regulation as “fully consistent” with early court cases interpreting section 403(c), which “discussed factors of resemblance, substitution, and inferiority in concluding that the products involved were imitations.”⁶⁴ These early cases discussed “substitution and resemblance” in terms of taste, smell, appearance, color, texture and body, as well as its intended uses and method of manufacture, packaging, sale.⁶⁵ (Elsewhere in its regulations, FDA uses the catchall term “organoleptically” — pertaining to all senses, including sight, taste, touch, and smell — to determine whether a food is a “substitute for” another food in deeming it an “imitation.”)⁶⁶ Further, in establishing its regulation regarding imitation foods, FDA made clear that new food products (clearly identified as such) would not be deemed imitations, favorably citing cases “holding that a vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace cream, is not an ‘imitation cream’ but rather a separate and distinct product that should bear its own common or usual name.”⁶⁷

In light of these narrow criteria for what makes a food an “imitation” of another food, specified in FDA’s regulatory decisions and early court cases, only convincing

⁶³ 21 C.F.R. § 101.3(e)(1).

⁶⁴ 38 Fed. Reg. 20702, 20702 (Aug. 2, 1973).

⁶⁵ *United States v. 651 Cases . . . Chil-Zert*, 114 F. Supp. 430, 432 (N.D.N.Y. 1953).

⁶⁶ 21 C.F.R. § 101.13(d).

⁶⁷ 38 Fed. Reg. at 20702, citing *Coffee-Rich, Inc. v. Kan. State Bd. of Health*, 388 P.2d 582 (Kan. 1964), *Coffee Rich, Inc. v. Mich. Dept. of Agriculture*, 135 N.W.2d 594 (Mich. 1965).

counterfeit products (which are also nutritionally inferior) fall into the category of “imitation” foods. Partly due to this exacting standard, and partly due to the more recent trends in “common or usual” nomenclature described in this petition, the “imitation” label is practically never seen on any products today.

Arguments that products like soymilk or almond milk are “imitations” of cow’s milk rely too much on FDA’s language “substitute[s] for and resembles another food,” without evaluating this language in terms of the court decisions this language codifies (or even FDA’s own use of the term “organoleptically”). A basic flaw in such arguments is that they appear to construe “resembles” too narrowly in a visual sense — essentially, they argue that because soymilk *looks* like cow’s milk and is used in similar ways, it is an imitation. For one thing, this completely ignores other “organoleptic” factors (like taste, smell, and texture) that are manifestly different to anyone who has compared such products. Another obvious flaw in this argument is that, if taken at face value, it would prove too much: rye bread would be “imitation bread” and gluten-free spaghetti would be “imitation spaghetti,” because both products look very much like their wheat counterparts and are used in the same way. Even goat milk would not escape this fate — it has significantly less Vitamin B₁₂ than milk from cows — and would therefore need to bear the name “imitation milk.” This would be nonsense. The Act’s “imitation” provision has, since at least the 1960s, been understood to target nutritionally-inferior, cheap

counterfeit products — and not distinct food products that clearly identify themselves as such.⁶⁸

For the reasons stated above, the standard described by GFI is consistent with FDA’s recent policy and practices regarding the naming of new food products.⁶⁹ The language GFI proposes would allow labels to state clearly, as qualifiers to other common names, “alternative plant or animal source[s] that replace[] the main characterizing ingredient(s) or component(s) of” these other foods — be it goat milk or almond milk, rye bread or cornbread, rice noodles or buckwheat noodles. In the modern marketplace, consumers are very familiar with products like these that advertise alternative plant and animal sources. Products may also state, as clear qualifiers to other common names, the “absence of a primary characterizing plant or animal source, or of a nutrient, allergen, or other well-known characterizing substance” — like gluten-free bread, dairy-free ice

⁶⁸ On this point, some are apparently attempting to relitigate bygone unsuccessful challenges to FDA’s narrow definition of “imitation.” *Nat’l Milk Producers Fed. v. Harris*, 653 F.2d 339, 343 (8th Cir. 1981) (citing *Fed. of Homemakers v. Schmidt*, 539 F.2d 740 (D.C. Cir. 1976)).

⁶⁹ GFI recognizes that, in 2008 and 2012, FDA issued warning letters expressing an opinion that “soy milk” is not an appropriate name simply because “milk” is a standardized term. *See* Warning Letter to Fong Kee Tofu Co., March 7, 2012, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm295239.htm>; Warning Letter to Lifesoy, Inc., August 8, 2008, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048184.htm>. But FDA has maintained (and courts have agreed) that such letters are “informal and advisory.” *Holistic Candles and Consumers Assn. v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012). As such, courts have not deferred to interpretations in such letters. *See, e.g. Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) (declining to recognize these warning letters as FDA’s considered, reasoned policy); *cf. Nat’l Mining Assn v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) (noting lack of deference to interpretive rules and statements of policy) (citing *United States v. Mead Corp.*, 533 U.S. 218 (2001)). For the reasons stated in this petition, GFI does not believe that FDA would, after careful consideration, formally adopt the line of reasoning stated briefly and informally in these warning letters.

cream, or wheat-free soy sauce.⁷⁰ As FDA has stated for qualifiers like “fat-free,” these qualifiers effectively serve to notify consumers that these products differ from their traditional counterparts, and other information on the label enables consumers to inform themselves exactly how such products differ, including nutritionally. For the same reasons, the regulation also generally allows for any other compound name, provided it clearly notifies consumers that the product differs from the standardized or traditional food.

Finally, although the principles described in this petition are firmly rooted in established FDA policy and the practice of the agency, GFI is motivated to file this petition because others vocally disagree and, as noted earlier, have recently urged FDA to take a different course, specifically regarding plant-based dairy alternatives. As described below, this is constitutionally perilous territory: if FDA (or Congress) were to heed such calls and target new (and old) non-dairy alternative products for selective enforcement, it would violate the First Amendment rights of the producers of these

⁷⁰ GFI is also aware of 21 C.F.R. § 105.62, governing “food [that] purports to be or is represented for special dietary use by reason of the decrease or absence of any allergenic property or by reason of being offered as food suitable as a substitute for another food having an allergenic property[.]” At first blush, this regulation seems to provide some support for GFI’s more general language, as it requires (and deems sufficient) “qualification of the name of the food . . . to reveal clearly the specific plant or animal [sources].” But it also contains onerous provisions, like requiring such products to label the “*proportion* of each ingredient” and the “specific plant or animal” source of *each* ingredient. A broad reading would imply that all foods that bear claims like “soy-free,” “wheat-free,” or “dairy-free,” as well as many substitute foods, would be subject to these burdensome and heightened labeling requirements. Because it is unclear what (if any) relevance this provision has today in view of developments since its initial promulgation in 1941 (6 Fed. Reg. 5921) — such as mandatory allergen labeling and the NLEA — GFI has chosen not to discuss this provision extensively in this petition. GFI instead simply notes that this language, similar to GFI’s proposal, has previously been used by FDA.

products to label and describe their products in a truthful and clear manner consistent with consumer expectations.⁷¹

2. Restrictions on commercial speech are subject to judicial scrutiny under *Central Hudson*, and proposed restrictions against dairy alternatives do not withstand such scrutiny.

Forbidding producers and sellers of products like soymilk or almond milk⁷² from using such names would be a restriction on protected commercial speech, and would be subject to judicial scrutiny under the First Amendment. The constitutionality of such restrictions is determined under the Supreme Court’s four-prong *Central Hudson* test:⁷³ if commercial speech (1) concerns lawful activity and is not misleading; and (2) the government asserts a substantial interest in restricting such speech; then (3) the government regulation must directly advance that interest and (4) not be more extensive than necessary to serve that interest. As described below, attempts to restrict food producers from using names of traditional products to describe new products would fail to satisfy this standard and would therefore violate the First Amendment.

Those who propose banning names like “soymilk” and “almond milk” frequently refer to such names as “misleading,” simply because the products do not contain cow’s

⁷¹ Further, in light of the First Amendment concerns described in this petition, courts would likely construe the Act and FDA’s regulations as narrowly as possible to avoid these serious constitutional questions. See, e.g. *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng’rs*, 531 U.S. 159, 172–73 (2001). This consideration would strongly favor the interpretation of the Act and regulations described above.

⁷² GFI uses these products throughout this section for illustrative purposes because these products have been most visibly targeted by the dairy industry. However, the analysis is much the same for any other product conforming to the standard proposed by GFI.

⁷³ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980).

milk. Under the first prong of *Central Hudson*, regulations of false or misleading speech do not require extensive constitutional analysis, but the meaning of “misleading” in this context is narrowly delineated. Only when speech is *inherently* misleading will it fall outside of the protection of the First Amendment.⁷⁴ Otherwise, if speech is only *potentially* misleading, *Central Hudson* scrutiny applies in full, and the government may restrict such speech only in a manner that directly and narrowly serves its interest in preventing deception (or any other demonstrated substantial interest).⁷⁵ Further, the *government* carries the burden of demonstrating that such an interest in preventing deception is “substantial” and directly and narrowly served by the speech restriction.⁷⁶

The government would not meet the very high bar of demonstrating that common names such as soymilk or almond milk are inherently misleading.⁷⁷ These products have long carried these names, and as described extensively in this petition, names such as these (constructed by adding a qualifying term in front of the name of another food) are used extensively in the marketplace for many products (as well as in natural language) without any apparent confusion. And courts that have considered the issue have concluded, as a matter of law, that no reasonable consumer would be misled by these

⁷⁴ See *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (citing, *inter alia*, *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

⁷⁵ *Id.* at 655–56.

⁷⁶ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1217 (D.C. Cir. 2012) (citing *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993)).

⁷⁷ See *Pearson*, 164 F.3d at 655 (describing “inherently misleading” standard in terms of “awesome impact” leaving consumers “bound to be misled.”)

product names.⁷⁸ Furthermore, consumer research on the understanding of the name “soymilk” has demonstrated that the proportion of consumers confused by the name is nearly zero.⁷⁹ It is unclear whether the government would be able to demonstrate that the term even has substantial *potential* to mislead, given the results of such research and how courts have addressed the issue. However, because this petition concerns the prospective nomenclature of a variety of products, we may assume for the sake of argument that the naming of at least *some* such products may have the conceivable potential to be misleading.

But even if the government could demonstrate that such names have substantial potential to mislead consumers, an outright ban on such names would still need to satisfy the final two prongs of *Central Hudson*. To do so, the restriction of such names must “directly advance” the interest in preventing consumer deception or confusion to a “material degree,”⁸⁰ and must be no more extensive than necessary to serve that interest. In the case of soymilk and almond milk, forbidding such names, which an overwhelming majority consumers already understand and use to refer to such products, could not

⁷⁸ See Order, *Gitson v. Trader Joe’s Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) (“The first words in these products’ names should be obvious to even the least discerning of consumers. . . . [Claiming that] a reasonable consumer might confuse plant-based beverages such as soymilk or almond milk for dairy milk . . . stretches the bounds of credulity. Under Plaintiff’s logic, a reasonable consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper.”) These opinions are appended to this petition as Attachment B.

⁷⁹ Soyfoods Association of North America, *Summary of Research on Consumer Awareness of Soymilk and Dairy Milk*, appended to this petition as Attachment A.

⁸⁰ *R.J. Reynolds*, 696 F.3d at 1218 (citations omitted).

possibly “directly and materially” serve an interest in preventing deception or confusion. (Labeling with an alternative name, like “soy beverage,” might *itself* be confusing to consumers who are used to calling it “soymilk.”) Although in general, banning a potentially confusing name outright may directly avoid potential confusion, banning the use of an already well-established name would result in *more* consumer confusion, and so would hardly serve the government’s interest in *preventing* confusion.

Yet even in cases where the government could show that banning a potentially confusing name would “directly and materially” avoid deception, the government would still need to satisfy the last part of the *Central Hudson* test. It is here that restrictions on GFI’s proposed naming pattern would *always* fail to withstand scrutiny: such restrictions are emphatically *not* necessary to serve any interest in preventing confusion or deception, and are not narrowly tailored to that end. The government has many alternative tools at its disposal for combating whatever potential deception it might claim; in fact, many of these tools are already in place. The FDCA requires food labels to bear a full list of ingredients that can instantly dispel most any question a confused consumer may have, such as whether there is any wheat in gluten-free bread, or whether there is any egg in rice noodles, or whether there is any cow’s milk in soymilk. Similarly, nutritional labeling is already required, which allows consumers to compare these foods to their traditional counterparts in yet another way.⁸¹

⁸¹ This was the very same logic FDA used in addressing objections to nutrient-content qualified names like “fat-free ice cream.” 58 Fed. Reg. 2431, 2439 (Jan. 6, 1993).

In the case of soymilk and almond milk, these measures are more than sufficient to fully inform consumers, as courts have recognized.⁸² And even if they were not, the government has no shortage of other, more narrowly-tailored options available. For example, the government could potentially require products to label themselves with additional statements that describe significant differences that are alleged to be a source of potential confusion (e.g. requiring soymilk and almond milk products to bear “dairy-free” declarations — as most already do.)⁸³ In sum, there are many alternative narrowly-drawn ways to dispel potential deception, and “[i]f the First Amendment means anything, it means that regulating speech must be a last — not first — resort.”⁸⁴ The government would bear a heavy burden in demonstrating that these alternative approaches (especially those already in effect) are insufficient to advance its interests before courts would permit an outright speech ban⁸⁵ — and this, GFI submits, the government would be unable to do for any of the names under GFI’s proposed standard.

Proponents of a ban on the names “soymilk” and “almond milk” also argue alternatively that consumers may suffer some sort of nutritional injury if they purchase

⁸² See *Gitson and Ang* (Attachment B).

⁸³ However, GFI notes that even less-restrictive measures like this would be difficult to justify constitutionally, in light of the negligible risk of consumer confusion and the mandatory ingredient and nutritional labeling already required by the FDCA.

⁸⁴ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

⁸⁵ See *Pearson*, 164 F.3d at 659–60 (describing First Amendment preference for disclaimers and disclosures over suppression.)

and consume these products believing them to be nutritionally equivalent to cow's milk.⁸⁶ But no reasonable consumer would assume that two distinct products have identical nutritional content,⁸⁷ so this speculative risk cannot possibly justify a ban on such names.⁸⁸ Under *Central Hudson*, the government would first face the (likely impossible) task of showing that a significant number of consumers hold a belief that these distinct products are totally nutritionally equivalent. And even assuming the government could demonstrate that this presents a real, substantial, and material risk, the government has available other tools for addressing it, all of which are more narrowly drawn than an outright speech ban. In fact, mandatory nutritional labeling already suffices to inform consumers not just *that* the products are distinct, but exactly *how* they are distinct nutritionally — and this comprehensive disclosure is more than enough to protect against any supposed risk of deception.⁸⁹ Just as above, this argument in favor of an outright ban on such names would fail to stand up to *Central Hudson* scrutiny.⁹⁰

⁸⁶ See Comment from National Milk Producers Federation, July 28, 2010, available at <https://www.regulations.gov/document?D=FDA-2010-N-0210-0092>.

⁸⁷ “[A] reasonable consumer (indeed, even an unsophisticated consumer) would not assume that two distinct products have the same nutritional content; if the consumer cared about the nutritional content, she would consult the label.” *Gitson*, at 3.

⁸⁸ Further, a logical extension of this argument would require a ban on labeling goat or sheep or buffalo milk with the word “milk,” as all of these products have different nutritional profiles from cow's milk. And the same is true for rye bread vis-à-vis wheat bread, rice noodles vis-à-vis wheat noodles, and so on.

⁸⁹ See *Gitson*, at 3 (quoted above, note 87). And as above, in addition to already-mandatory comprehensive nutritional labeling, courts would also consider whether any other possible measures for disclosure would be more narrowly-drawn and therefore preferable to an outright speech ban. See *Pearson*, 164 F.3d at 659–60.

⁹⁰ Note also that, before the passage of NLEA and FDA's subsequent regulations, federal courts used similar reasoning in analyzing state bans on the use of dairy names by other products,

For these reasons, proposals to ban common names for dairy alternatives would run afoul of the First Amendment, failing to withstand scrutiny under *Central Hudson*. Additionally, such proposals infringe the First Amendment for other reasons, discussed next.

3. Attempts to restrict or ban common names for dairy alternatives would be subject to heightened scrutiny.

Although restrictions on commercial speech are generally subject to *Central Hudson* “intermediate” scrutiny, recent developments in the law indicate that, in some cases, such restrictions will require an even greater level of judicial scrutiny. Proposals that particularly target dairy alternatives with a ban on their commonly-used names would fall into this category, and would not withstand heightened judicial scrutiny.

The Supreme Court has recently made clear that “content-based” burdens or restrictions are subject to “heightened” judicial scrutiny, even in the commercial context.⁹¹ The Court has not clarified exactly what form this “heightened” scrutiny takes, though it has noted that ordinarily, it is “all but dispositive to conclude that a law is content-based.”⁹² Further, even some restrictions that *appear* on their face to be content-neutral “will be considered content-based regulations of speech: laws that cannot be

striking down such restrictions under the First Amendment. See, e.g. *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 651–52 (S.D. Ohio 1989); *Anderson, Clayton & Co. v. Washington St. Dept. of Agriculture*, 402 F. Supp. 1253, 1257–58 (W.D. Wash 1975).

⁹¹ *Sorrell v. IMS Health*, 31 S. Ct. 2653, 2664–65 (2011).

⁹² *United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012), quoting *Sorrell*, 31 S. Ct. at 2667.

‘justified without reference to the content of the regulated speech’ or that were adopted by the government ‘because of disagreement with the message [the speech] conveys.’”⁹³

Restricting the common names of dairy alternatives, such as soymilk, would be a content-based restriction on speech, because such restrictions cannot be justified without reference to the content of such speech — to wit, the fact that such names reference dairy products specifically. Such content-based restrictions are “presumptively invalid,”⁹⁴ and the government would need to put forth compelling evidence-based justifications to overcome this heavy presumption.

To avoid this heightened level of scrutiny, the government would need to develop and apply any proposed restriction in a content-neutral manner.⁹⁵ In order for a restriction of this sort to be truly content-neutral, it would need to apply with equal force to *any* product name that encompasses another, and not merely non-dairy alternatives to dairy products. The government, for example, could potentially ban *any* product from bearing the name of another unless it satisfies the definition of such other product. But the government could not do so without contradicting established FDA policies regarding the naming of foods with nutrient-content claims (e.g. “fat-free cheddar cheese”), or established commonsense practice regarding other product names that incorporate standardized terms (such as rye bread or rice noodles).

⁹³ *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015) (citation omitted).

⁹⁴ *Sorrell*, 131 S. Ct. at 2667 (quoting *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992)).

⁹⁵ The current legislative proposal for such restrictions is not content-neutral; it exclusively singles out dairy terms for protection. DAIRY PRIDE Act, S.130, 115th Cong. § 3 (2017).

Nor could the government, in this context, rely on the content-neutral justification that it is merely targeting “potentially misleading” names of any sort, because many other products with similar names have *greater* potential to mislead or confuse consumers than products like soymilk or almond milk (which declare their basic nature — “soy” and “almond” — clearly and up-front). Take multigrain bread, for instance. There is no standard for such product, and a “5-grain bread” could conceivably be 98% white flour, with the other four grains constituting the remaining 2% — not the significant share consumers might expect.⁹⁶ Or rice noodles, the name of which does not declare up-front whether it contains egg or wheat, as required of “noodles” under FDA’s standard of identity.⁹⁷ And so on. The government could offer no content-neutral justification for banning outright the names of “soymilk” or “almond milk,” while allowing other products named in similar fashion to keep their names.

This highlights yet another reason a ban on such non-dairy names would be subject to heightened judicial scrutiny: courts would likely determine that such a restriction is a content-based *and* speaker-based restriction, targeting producers of plant-based alternative products specifically. For one thing, it would be a speaker-based restriction because it would forbid only producers of such products (though not consumers, academics, or even the government itself) from using such names to describe

⁹⁶ Ironically, as noted earlier, such a product would satisfy the standard of identity for “bread” — and would be all the more misleading for it!

⁹⁷ Also, unenriched rice flour contains lesser amounts of some nutrients (like protein and iron) than wheat flour does. This mirrors the situation of unfortified soymilk *vis-à-vis* cow’s milk.

these products.⁹⁸ But it would also not escape judicial notice that these restrictions have been publicly and loudly demanded by the dairy industry for many years in an effort to protect its market share. This historical fact would infect any subsequent government action with the stench of favoritism — using the power of the state to benefit one politically powerful group at the expense of its competitors — and could lead a reviewing court to conclude that such government action is an attempt to burden “disfavored speech by disfavored speakers.”⁹⁹ As the cases cited herein demonstrate, courts are particularly likely to strike down speech restrictions in such circumstances.

Simply put, proposed restrictions on the names of dairy alternatives cannot be justified in a content-neutral way, and even if they could be, such restrictions would fail to withstand *Central Hudson* scrutiny. FDA should resist the dairy industry’s calls for anticompetitive regulation, and instead adopt GFI’s neutral regulation that allows not just dairy alternatives, but *any* alternative products, to use clear and concise compound names noting alternative sources, properties, or origins, which consumers readily understand. This framework is not merely a good idea — under our Constitution, the freedom to use such names must generally be maintained.

⁹⁸ See *Caronia*, 703 F.3d at 165; *Sorrell*, 131 S. Ct. at 2663.

⁹⁹ *Sorrell*, 131 S. Ct. at 2663.

III. Conclusion and request for action

For the reasons described above, and consistent with FDA policy and practice as well as the First Amendment, GFI respectfully asks that FDA adopt the proposed regulation to clarify that FDA will generally allow the use of compound food names whenever a reasonable consumer would understand that such a modified food name denotes a distinct product.

IV. Environmental Impact

Preparation of an environmental assessment (EA) or an environmental impact statement (EIS) is not ordinarily required for the “issuance, amendment, or repeal of a food standard,” 21 C.F.R. § 25.32(a).

V. Economic Impact

Pursuant to 21 C.F.R. § 10.30, information on economic impact will be submitted only if requested by the Commissioner following review of this petition.

* * *

VI. Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes (1) all information and views on which the petition relies and (2) any representative data and information known to the petitioner that are unfavorable to the petition.

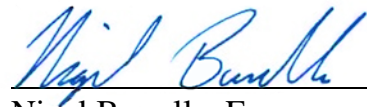
Sincerely,

Bruce Friedrich
Executive Director
The Good Food Institute

Nicole Negowetti
Policy Director
The Good Food Institute

Nigel Barrella
Law Office of Nigel A. Barrella

By:



Nigel Barrella, Esq.

Attachments:

- A. Soyfoods Association of North America, Summary of Consumer Research
- B. Orders from Federal Court Cases: *Gitson* and *Ang*

Appendix B



1380 MONROE ST. NW #229
WASHINGTON, DC 20010

October 11, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**RE: Docket No. FDA-2018-N-2381
FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy**

The Good Food Institute (GFI) appreciates the opportunity to submit these comments regarding FDA's Nutrition Innovation Strategy. GFI commends FDA for its interest in improving nutritional choices and public health by reducing barriers to innovation. While FDA regulations often serve a vital role in protecting human health and welfare, some regulations may impede innovation or protect established players in the market from competition. GFI welcomes FDA's review of its regulatory approach to nutrition, including improvements to standards of identity, labeling claims, and ingredient information.

As FDA reviews its regulations, we hope FDA will also pay particular attention to how these regulations are interpreted and enforced. FDA should always seek to ensure that its regulations are enforced fairly and neutrally without favor to any party or industry, with protecting consumer health and safety as FDA's primary objective.

GFI is a nonprofit organization working toward a healthy, humane, and sustainable food supply by publicly advocating for and encouraging research into new ways of meeting global demand for meat and dairy, including with plant-based options such as plant-based burgers and plant-based milks. This mission aligns with public health, as significant scientific research has observed that diets lower in animal-based foods and higher in plant-based foods result in lower mortality from some causes, including America's top killer, heart disease.¹ One possible mechanism for decreased mortality is the positive effect of plant-based diets on blood lipid profiles.² As more Americans show an interest

¹ Tao Huang et al., *Cardiovascular Disease Mortality and Cancer Incidence in Vegetarians: A Meta-Analysis and Systematic Review*, 60 ANNALS OF NUTRITION & METABOLISM 233 (2012).

² Fenglei Wang et al., *Effects of Vegetarian Diets on Blood Lipids: A Systematic Review and Meta-Analysis of Randomized Controlled Trials*, 4 J. AM. HEART ASS'N (2015) (4:e002408. doi: 10.1161/JAHA.115.002408).

in consuming plant-based foods, it is important that the channels of innovation remain clear for new plant-based products.

A varied diet is also a well-recognized ideal for optimal health.³ And the American diet is expanding to include more variety by the year, with new foods and foods adopted from across the globe proliferating in the marketplace.⁴ Yet FDA’s existing standards of identity largely deal with “traditional” American foods, often made from a limited set of “traditional” dietary ingredients like wheat, dairy, and eggs. It would likely be undesirable — and is in any event impractical — for FDA to develop standard-of-identity-style recipes for the plethora of products now on the American market. A more worthy and attainable goal would be the clarification that existing standards of identity are not to be interpreted in a way that impedes the introduction or sale of innovative foods, even if the new foods are used as alternatives to existing standardized foods.

For these reasons, GFI focuses this comment on FDA’s suggestion of “modernizing” standards of identity. GFI believes it especially important for FDA to clarify the role that standards of identity play in its overall regulatory regime — and the role they do *not* play. Historically, standards of identity have never been understood to prevent new products from referring to standardized terms in their marketing or labeling.⁵ It is only when a new product is purported to be and represented as the *genuine* standardized product that the new product is misbranded under section 403(g) of the Act.⁶ After all, identity standards were mainly intended to address fraud and economic adulteration, by preventing one product from falsely representing itself as another.⁷ A new product with its own clear and distinct identity does not present such a risk.

³ See generally U.S. Dep’t of Health & Human Serv. & U.S. Dep’t of Agric., *2015–2020 Dietary Guidelines for Americans* 14 (2015).

⁴ See generally U.S. Dep’t of Agric., Econ. Research Serv., *New Products*, <https://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products/> (last updated Apr. 5, 2017) (describing the upward trend of new food product introductions per year since the early 1990s).

⁵ Indeed, “in some cases it may be *necessary* to include a standardized name in the name of a substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling.” 44 Fed. Reg. 3,964, 3,965 (Jan. 19, 1979) (quoting 38 Fed. Reg. 20,702, 20,703 (Aug. 2, 1973)) (emphasis added).

⁶ See *62 Cases of Jam v. United States*, 340 U.S. 593, 600 (1951); 38 Fed. Reg. 27,924, 27,925 (Oct. 10, 1973) (noting that “flavored fluid milk products” like “chocolate milk” “do not purport to be and are not represented as milk” within the meaning of section 403(g)).

⁷ U.S. Cong. Research Serv., *Standards of Identity for Foods and Plant-Based Food Products* 2 (Jan. 18, 2018); see also Richard A. Merrill & Earl M. Collier, Jr., “*Like Mother Used to Make*”: *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 561 (1974).

Yet some voices in industry have advocated for FDA to weaponize identity standards against innovative products, contrary to this historical understanding. Doing so would work against public health, would be out-of-step with the trends and realities of the marketplace, would raise grave First Amendment concerns, and would contravene FDA's mission to regulate the marketplace fairly and neutrally in the interest of consumers.

Modernizing Standards of Identity

GFI generally supports FDA's goals in proposing "modernization" of standards of identity. Producers should always have the freedom to innovate, adapt, and create new products to offer consumers more and better choices. But standardized foods are far from the only game in town – they are a dwindling minority of foods available in today's diverse marketplace. While specific standards could be updated on a case-by-case basis, it is more important to clarify whether and when existing standards cast a regulatory shadow over other, nonstandardized foods. GFI urges FDA to clarify that any such shadow is much narrower than some appear to believe.

An example may illustrate the issue. Multiple commenters have noted the strict definition of "canned tuna," which does not permit flavoring ingredients other than lemon oil. As a result, some have suggested updating the standard to allow the addition of any "safe and suitable" flavoring ingredient, or to allow the addition of vegetables like peppers or celery. It seems patently absurd that in today's market tuna processors feel the need to seek a regulatory amendment so that consumers may buy canned tuna with vegetables or spices.

There is a better way. GFI has submitted a rulemaking petition (FDA-2017-P-1298, attached) to codify common nomenclature patterns for nonstandardized foods. In the petition, GFI asks FDA to clarify that a new food's name may refer to a standardized term so long as a reasonable consumer would understand that the new food's name connotes a distinct product. A consumer purchasing "seasoned tuna and red peppers" would hardly be surprised to find red peppers mixed in with her tuna, nor would she be surprised to discover that "spicy Sriracha tuna" has flavoring other than lemon oil. Whatever the definition of "canned tuna" may be, products *not* conforming to that definition should be permitted in commerce, and no regulatory cloud should hang over their very existence merely because they contain tuna and come in cans. Such products should only need an appropriate name that notifies consumers of the product's distinct nature. GFI's proposed approach goes beyond canned tuna, creating space for numerous nonstandardized alternatives to standardized foods, such as cheddar-style buffalo milk cheese or cheddar-style soy cheese, goat milk yogurt or cashew milk yogurt, brown rice noodles or zucchini noodles, and more.

FDA has made significant steps towards allowing flexibility and innovation like this before. As noted above, FDA has repeatedly and explicitly noted that “substitute” food names may sometimes *necessarily* include the names of the standardized foods they replace.⁸ Another significant advancement came in 1993 with FDA’s treatment of foods named with nutrient content claims.⁹ In a food named with a nutrient content claim and a standardized term, FDA permits the addition of new ingredients not permitted in the standardized food, including “safe and suitable ingredients” “used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness.”¹⁰

Rather than going case-by-case through existing standards or developing new standards, FDA should simply continue this historical trend toward greater flexibility. For over 25 years now, FDA has allowed modified versions of standardized foods to deviate from identity standards when the foods’ names are qualified by a narrow set of claims like “reduced fat” or “low calorie.” But there is a whole universe of other potential qualifying terms that would adequately inform consumers that a new product is fundamentally distinct, allowing endless possibilities for innovation in nonstandardized foods. The regulation proposed in GFI’s petition would codify some of these possibilities, many of which are already commonly used without confusion.

Changes in the market and consumer understanding since 1993 also counsel in favor of a more flexible approach. Twenty-five years ago, comprehensive nutritional labeling was a new addition to food labels, and before that time, standards of identity played a critical role in not just preventing consumer deception or fraud but also ensuring nutritional adequacy in products that did not provide consumers with any nutritional information. Today, consumers are very familiar with alternatives to “traditional” foods, including those using nutrient content claims, as well as the variety of entirely new products on the market. Further, consumers can now easily inform themselves about nutritional differences between different products, empowered by the now-familiar Nutrition Facts panel. Indeed, FDA noted in 1993 that the addition of nutritional information, together with nutrient content claims and other information on the label, would “enable consumers to distinguish traditional foods from modified versions of these foods.”¹¹

Historical practice also establishes the viability of GFI’s proposed approach. As noted in GFI’s petition, many foods already have names that reference or qualify standardized terms, and such foods have existed on the market for decades without any reasonable question about possible “violations” of standards of identity. It is patently obvious to any consumer that goat milk is milk from a goat, notwithstanding FDA’s prescription that

⁸ 44 Fed. Reg. 3,964, 3,965 (Jan. 19, 1979).

⁹ 21 C.F.R. § 130.10(c)–(d).

¹⁰ 21 C.F.R. § 130.10(d)(1).

¹¹ 58 Fed. Reg. 2,431, 2,439 (Jan. 6, 1993).

standardized “milk” comes from cows alone.¹² It is equally obvious that soymilk is a milky-white liquid made from soybeans.¹³ Just as obviously, rice noodles are noodles made from rice rather than wheat, though the standard of identity for “noodles” requires wheat. And gluten-free spaghetti and rye bread are pasta and bread products made from non-wheat grains, despite the standards of identity dictating that “bread” and “macaroni products” be made from wheat. Similarly, any reasonable consumer knows that coconut cream or non-dairy creamer are entirely distinct products from cow’s cream, and the list goes on.¹⁴

Thus, rather than proceeding piecemeal through existing identity standards to create specific updated product recipes, FDA should simply explain how foods not meeting existing standards may be named by reference to the standardized foods, so long as the full name ensures that consumers are not confused or deceived. To this end, FDA should grant GFI’s rulemaking petition. This approach would allow greater flexibility for continued innovation and consumer choice while minimizing the risk of consumer confusion. Such an approach would also minimize FDA’s future need to repeatedly evaluate proposed changes to standards of identity to account for new consumer preferences or for changes in food technology and nutrition science.

Labeling Claims

FDA has invited comments on the possibilities for “new or enhanced labeling statements or claims.” GFI recognizes that a large number of labeling statements and claims have proliferated in the marketplace, and few are defined or regulated by FDA. Some are regulated by third-party certification. e.g. kosher and halal certifications, vegan certifications, or non-GMO certifications. Many more are only constrained by the Act’s general requirement that label statements not be “false or misleading in any particular.”

GFI views the variety of labeling claims on the market as a necessary and often desirable consequence of commercial free speech. However, FDA should take action against

¹² 21 C.F.R. § 131.110.

¹³ Certain interest groups have long targeted common names of plant-based dairy alternatives by promoting a different interpretation of the law, and many comments at the public hearing focused on this issue. As noted in GFI’s petition, these repeated demands for bovine-dairy favoritism illustrate the First Amendment perils of an inflexible approach to food standards. But FDA has opened a Request for Information on the matter of plant-based dairy alternatives, and GFI will reserve its full comments on that specific issue for the corresponding docket, FDA-2018-N-3522.

¹⁴ Beyond the FDA-standardized-name context, other examples abound: reasonable consumers know that veggie burgers or turkey burgers do not contain beef, veggie bacon or turkey bacon do not contain pork, peppermint tea contains no tea, and so on.

labeling claims in circumstances presenting a particular risk of consumer deception and injury.

GFI echoes the concerns expressed by Food Allergy Research & Education (FARE) during FDA's public meeting, specifically regarding "non-dairy" labeling claims. To a reasonable consumer, "non-dairy" means no dairy ingredients, yet several products on the market are prominently labeled "non-dairy" but *do* contain dairy ingredients. Such labeling creates serious health risks for some individuals with dairy allergies, and in any event is misleading to consumers who may not wish to purchase dairy products.

More broadly, FDA should examine the use of "non-" or "-free" claims, particularly when common allergens are disclaimed, to ensure the use of such modifiers is truthful and not misleading. Consumers should have confidence that foods claiming to be "non-" or "-free" are free of any ingredients derived from the disclaimed source.

Improvements to Ingredient Information

GFI supports FDA's goal of improving the usefulness of ingredient information and generally supports improvements to readability of ingredient lists.

The content of ingredient lists presents important issues as well. FDA's regulation of the common or usual names of food ingredients has caused some confusion and inconsistent practices in industry, to the detriment of consumers. FDA has occasionally interpreted its regulation regarding "intervening material"¹⁵ to forbid producers from including additional information about food ingredients, even where that information is likely to be of interest to consumers. For example, FDA has occasionally objected in warning letters to ingredients like "fresh ginger root" or "fresh basil," stating that "fresh" is not part of the common or usual name of these ingredients and therefore is "intervening material." But it is apparent here that using the modifier "fresh" helps consumers distinguish these ingredients from the common, dried forms of these herbs and spices.

FDA has also occasionally stated that its "intervening material" regulation does not permit the use of modifiers to ingredient names generally, including for example "filtered" (e.g. filtered water) or "non-GMO." But a restrictive approach such as this could have negative impacts on potential innovation and labeling that is fully informative to consumers.

For example, chymosin is an enzyme (commonly called rennet) used in making most hard cheeses. This enzyme was traditionally derived from the stomachs of young ruminant animals. Today, due to advances in biotechnology, most of the rennet used in cheeses produced in the United States is produced through microbial fermentation. Some

¹⁵ 21 C.F.R. § 101.2(e).

consumers prefer to consume only this newer form of rennet, and therefore some cheese producers may describe the microbial-produced enzyme as “non-animal rennet” or “vegetarian rennet.” But a strict interpretation of FDA’s “intervening material” or common-or-usual name regulations may preclude the use of such modifiers, however clear they may be to consumers.

In a similar vein, gelatin is a generic name for collagen proteins derived from any number of animals. But some individuals with religious dietary restrictions are forbidden to consume gelatin derived from pigs or horses. To better serve these consumers, many products are labeled with ingredient names like “kosher gelatin” or “fish gelatin,” although such modifiers could perhaps be considered intervening material.

With ever more ingredients being produced using biotechnology, the possibility for ambiguity in the origins of certain ingredients will only grow. Companies are now working on producing at industrial scale microbially-derived whey protein, gelatin, casein, and much more. Because these new ingredients will be functionally and chemically indistinguishable from their animal-originating counterparts, it may be considered “intervening material” to alert consumers to the origin of such ingredients. Yet consumers may be interested in those origins, and producers should not be prevented¹⁶ from giving consumers that information in the most natural place possible: the ingredients list.

FDA should not object to “intervening material” in ingredients lists when it serves the important interest of informing consumers about ingredient origins or forms. FDA should also consider whether a generic descriptive modifier such as “non-animal” is permissible and clear enough to describe ingredients like rennet, gelatin, whey protein, or vitamin D that may have either animal or non-animal origins. In general, producers should not be prevented from communicating to consumers features about their products and ingredients about which consumers may be interested.

* * *

¹⁶ However, any such disclosures should be strictly optional, not mandatory, unless FDA determines that the ingredient is fundamentally different in its relevant characteristics.

Again, GFI appreciates the opportunity to comment on the issues raised by FDA and interested parties at the public meeting and thanks the agency for its careful review of these comments. We look forward to working with the agency to ensure that the path to innovation remains clear for the sake of public health, better nutrition, and consumer choice.

Sincerely,



Bruce Friedrich
Executive Director
The Good Food Institute



Jessica Almy, Esq.
Policy Director
The Good Food Institute

Of Counsel:



Nigel Barrella, Esq.
Law Office of Nigel A. Barrella

Appendix C

No. 17-55901

**IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

CYNTHIA CARDARELLI PAINTER, individually and on behalf of other
members of the general public similarly situated,
Plaintiff-Appellant,

v.

BLUE DIAMOND GROWERS,
Defendant-Appellee.

On Appeal from the United States District Court
for the Central District of California
No. 2:17-cv-02235-SVW-AJW
Hon. Steven V. Wilson

**BRIEF OF THE GOOD FOOD INSTITUTE
AS AMICUS CURIAE IN SUPPORT OF
DEFENDANT-APPELLEE SEEKING AFFIRMANCE**

NIGEL A. BARRELLA
LAW OFFICE OF NIGEL A. BARRELLA
1001 Pennsylvania Ave. NW
Suite 1300N
Washington, DC 20004
(202) 768-7510
nigel@barrellalaw.com

Attorney for Amicus Curiae the Good Food Institute

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, the Good Food Institute states that it is a non-profit corporation and, as such, no entity has any ownership interest in it.

Date: March 9, 2018

s/ Nigel Barrella
Nigel A. Barrella

*Attorney for Amicus Curiae
Good Food Institute*

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INTEREST OF AMICUS CURIAE

The Good Food Institute (GFI) is an independent, non-profit organization devoted to creating a healthy, humane, and sustainable food supply. Through research, education, and advocacy, GFI promotes the development and adoption of new, innovative foods, including plant-based foods. See www.gfi.org.¹ GFI regularly engages with FDA, USDA, Congress, and industry stakeholders about regulatory issues governing innovative foods, including the need for clear labeling.

If the Court adopted an overbroad interpretation of the “imitation” provision, it would cast a regulatory cloud over many innovative new foods as well as many well-established foods, to the detriment of consumer choice and free market competition. GFI requests that the Court recognize a clear, specific, and narrow definition of “imitation” that has historically allowed innovative and distinct products to be labeled with simple language that consumers understand.

¹ This brief is submitted with a Motion for Leave to File under Fed. R. App. P. 29(a)(3); Painter withheld consent to its filing. No counsel for a party has authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than amicus curiae has made a monetary contribution to its preparation or submission.

SUMMARY OF ARGUMENT

This case about almond milk² carries broader implications. The sweeping, expansive definition of “imitation” offered by Painter would also extend to a diverse array of products including coconut milk, soy milk, and goat milk, and would compel each of these distinct products to bear the same, uninformative name: “imitation milk.” And the mischief of such a definition does not end with various milks — that is only the beginning. Rye bread and cornbread would be “imitation bread,” just as rice noodles and cellophane noodles would be “imitation noodles,” and turkey bacon and veggie bacon would be “imitation bacon” — the list goes on. The absurdity of this interpretation speaks for itself.

While this theory of imitation may be bold, it is not entirely novel. It may better be described as anachronistic. Similar arguments were sometimes advanced in the early- to mid-20th century, an era when notorious bans on modified dairy products were implemented and

² Although Blue Diamond brands its product “almondmilk,” various dictionaries show that in modern and historic English usage (dating to the 14th century as “almande mylk” or “almaunde milke”), this generic term is ordinarily styled as two words. See “almond milk,” OXFORD ENGLISH DICTIONARY ONLINE, Jan. 2018, *available at* www.oed.com/view/Entry/5595. GFI adopts the ordinary usage in this brief.

enforced for the economic protection of the dairy industry — a practice tolerated by the judiciary, at least for a time.³ The requirement that “imitation” foods be labeled “imitations” is itself a product of that bygone era. Yet even in that period, courts had the wisdom not to interpret the “imitation” provision (and analogous state provisions) as broadly as urged by Painter and those who came before her. The decisions of those courts control the outcome in this case.

This case, like those prior cases, involves a question of interpretation: what is the meaning of “imitation” in section 403(c) [21 U.S.C. § 343(c)] of the 1938 Federal Food, Drug, and Cosmetic Act (“FDCA” or “the Act”)? If almond milk is not within the reach of this provision, then Painter’s claim must fail, premised entirely as it is on the supposed violation of this provision. In 1973 FDA promulgated a rule interpreting the “imitation” provision, now codified at 21 C.F.R. § 101.3(e). In promulgating this regulation, FDA stated that it synthesized and incorporated the elements of “imitation” that had been established by courts in the mid-20th century. But Painter focuses

³ See, e.g. *United States v. Carolene Products*, 304 U.S. 144 (1938) (upholding the constitutionality of the Filled Milk Act, 21 U.S.C. §§ 61–63).

exclusively on one specific technical element defined by FDA — “nutritional inferiority” — while completely ignoring every other element of imitation (substitution and resemblance) derived from judicial decisions. These other elements, defined by case law and adopted by FDA, foreclose a broad reading of the Act that would deem almond milk an “imitation.”

Traditional canons of construction also dictate an interpretation of the Act’s imitation provision (and FDA’s corresponding regulation) that excludes almond milk and similar distinct products from its scope. For one, the absurd results noted above (among others) amply demonstrate that FDA and Congress would never intend to give the law such broad sweep. Further, an expansive reading that reaches distinct products like almond milk leads not merely to absurd results, but also to *unconstitutional* results, and the Court should therefore read the law as narrowly as possible to avoid serious questions of its constitutionality. For each of these reasons, the imitation provision should be narrowly interpreted to exclude distinct products like almond milk.

ARGUMENT

I. SECTION 101.3(e) INTERPRETS THE FDCA’S “IMITATION” PROVISION.

GFI begins by noting the primary source of federal law that governs this case: section 403(c) of the FDCA [21 U.S.C. § 343(c)]. Painter and Blue Diamond frame this case in terms of an FDA regulation, 21 C.F.R. § 101.3(e), but this regulation simply interprets the operative section of the Act. And although the regulation’s text references section 403(c) twice, neither party cites or discusses this original governing provision of federal law.

This is noteworthy because Painter incorrectly argues that her claim arises under the Act’s general “false or misleading” provision, section 403(a) [21 U.S.C. § 343(a)], rather than the “imitation” provision, section 403(c). Painter Brief at 15–19, 22–23. This distinction is important because of the preemptive effect of 21 U.S.C. § 343-1(a)(2), which expressly preempts any state “imitation” requirement that goes beyond section 403(c). Blue Diamond is therefore correct that Painter’s claim is expressly preempted to the extent it exceeds the federal “imitation” labeling requirement, including the

regulation interpreting section 403(c).⁴ Blue Diamond (“BD”) Brief at 42–45. For this reason, this case turns entirely on the question of whether the “imitation” provision applies to distinct products like almond milk.

Further, the regulation repeats verbatim the clear requirement of the Act: if “a food” is “an imitation of another food,” it *must* be labeled “imitation ____.” 21 U.S.C. § 343(c); 21 C.F.R. § 101.3(e). The use of any other name would render the product misbranded, making its sale in interstate commerce a crime. 21 U.S.C. §§ 331(a), 333(a).

The statutory “imitation” provision is strong medicine indeed. It does not allow producers of imitation foods to “opt out” of its application by using a distinct product name. Painter tries to cushion the blunt force of the statutory mandate by suggesting that almond milks could simply be renamed “Almond Beverages” (II ER 164:14–15; Painter Brief at 20), but the Act does not permit such flexibility. If almond milk were truly an “imitation” of cow’s milk under the Act, it could bear no other

⁴ Although Blue Diamond and the district court cite 21 U.S.C. § 343-1(a)(3) rather than (a)(2), Blue Diamond accurately describes the latter’s preemptive effect.

name besides “imitation milk.” This is the inescapable plain meaning of the statutory text, and its consequences must not be minimized.

Finally, the regulation’s statutory origin sheds light on its meaning. Ultimately, the parties’ focus on the regulation makes some sense: the statute itself does not define “imitation.” Meanwhile, the regulation (somewhat more precisely) defines “imitation” in terms of three essential elements: substitution, resemblance, and inferiority.

But these elements were not invented by FDA from whole cloth.

Rather, they were all derived from cases interpreting section 403(c), and can only be understood in that light. Resorting to this history and case law is also necessary because the regulation’s language “substitute[s] for and resembles” is not precisely defined. As demonstrated below, a full accounting of the history, case law, and principles of construction all point to one conclusion: distinct products like almond milk are not (and have never been) “imitations” under the Act.

II. THE FDCA’S “IMITATION” PROVISION DOES NOT APPLY TO DISTINCT PRODUCTS LIKE ALMOND MILK.

A. The history of the regulation supports a narrow reading of “imitation” that excludes distinct products like almond milk.

Section 101.3(e)(1) defines a food as an “imitation” if it “is a substitute for and resembles another food but is nutritionally inferior to that food.” This definition has three elements, all of which must be present for a food to be an imitation: substitution, resemblance, and inferiority. The regulation precisely defines only the last element, leaving the first two undefined.

In ordinary language, the first two elements are susceptible to varying interpretations; they may be read broadly or narrowly. For instance, does Coca-Cola “substitute for” Guinness Irish Stout? While both may quench one’s thirst, few would consider these beverages substitutes for each other. Similarly, does Coca-Cola “resemble” Guinness? Though both are bubbly brown liquids, if resemblance also includes taste and smell, they could hardly be more different. In each instance, a narrow reading is more natural.

Though Painter never expressly interprets “substitute[s] for and resembles,” she apparently believes this language should be read

broadly. Perhaps, in her view, almond milk “substitutes for and resembles” cow’s milk because both are white liquids that can be poured over breakfast cereal. But a narrow reading is also possible: most people would be displeased if they ordered one in a restaurant and received the other, and anyone would instantly notice the difference by taking a sip. In this narrower sense, almond milk and cow’s milk do not “substitute for” or “resemble” one another at all. In any case, Painter makes no effort to show that a broad reading is the *only* possible reading of the regulation.

Because the plain language of the regulation fails to define “substitution” and “resemblance,” other indicators of the agency’s intent must be considered. *See City of Las Vegas v. FAA*, 570 F.3d 1109, 1117 (9th Cir. 2009) (when “a regulation is ambiguous, we consult the preamble of the final rule as evidence of context or intent of the agency”); *see also Lal v. INS*, 255 F.3d 998, 1005 (9th Cir. 2001) (considering “clear intent of the agency in creating the rule,” even when plain language is clear).

The Federal Register notice for this regulation instantly clarifies FDA’s intent: the codification of the legal elements of “imitation” from

court opinions interpreting section 403(c). FDA concluded that its definition of imitation was “fully consistent” with court opinions “which discussed factors of resemblance, substitution, and inferiority...” See *Imitation Foods*, 38 Fed. Reg. 20702, 20702 (Aug. 2, 1973).

Here, FDA cited two cases of “imitation,” which are broadly instructive of how FDA understood the term.⁵ “Imitation” in the first case meant taking an existing product, stripping out some of its components, and replacing them with different (cheaper) components. *United States v. 651 Cases ... Chil-Zert*, 114 F. Supp. 430, 432 (N.D.N.Y. 1953). The second case involved “watering down” an existing product, using less of the key ingredients and adding cheap filler ingredients instead. *62 Cases of Jam v. United States*, 340 U.S. 593, 594–95 (1951). These cases not only present useful archetypes of imitation foods (modification and dilution), but they also confirm that resemblance is about more than just appearances: smell, taste, and texture are also elements. *Chil-Zert*, 114 F. Supp. at 432.

Notably, section 101.3(e) is not FDA’s only regulation addressing imitation foods. In a regulation governing nutrient content claims for

⁵ *Cf. Lal*, 255 F.3d at 1005 (analyzing court decision codified in regulation).

modified foods,⁶ FDA defined foods as “substitutes” when they “may be used interchangeably with another food,” and defined “resemblance” as “organoleptically, physically, and functionally ... similar.” 21 C.F.R. § 101.13(d). “Organoleptically” means relating to all senses, including taste, smell, and touch, further confirming that the regulatory meaning of “resemblance” goes beyond appearance. This regulatory context also reinforces the purpose behind “imitation” labeling — ensuring that *modified* versions of familiar foods are not nutritionally inferior.⁷ See Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. 2431, 2432–33 (Jan. 6, 1993) (describing how “modified foods” can be “imitations” if nutritionally inferior under § 101.3(e)).

Further, in promulgating section 101.3(e) FDA did not rely solely on the elements of imitation described in older cases like *Chil-Zert*.

Rather, FDA approvingly noted then-recent developments:

⁶ These are common qualifiers on many products, such as “low-fat,” “light,” and in the case of milk, “skim.”

⁷ One common example of how modification can affect nutrition: when milkfat is removed from dairy products, fat-soluble vitamins go with it. This is why generally speaking, low-fat and non-fat dairy products must be fortified with vitamin A, or else be deemed “nutritionally inferior” imitations.

[S]everal State court cases in the past 10 years [held] that a vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace cream, is not an “imitation cream” but rather is *a separate and distinct product* that should bear its own common or usual name.... These cases represent the most current and definitive judicial interpretation of the term “imitation.”

38 Fed. Reg. at 20702 (emphasis added).

Here FDA made a broader point: “imitation” labeling does not apply to “separate and distinct products,” even in cases of very close resemblance and actual substitution. As Blue Diamond argues, this may be viewed as a “reasonable consumer” standard — whether a reasonable consumer could be deceived into believing it is the same product. BD Brief at 24–31. Other indicators of intent support this: according to FDA, the imitation provision was intended “to protect the consumer from *uninformed* purchase of an inferior substitute product, *which could be mistaken* for a traditional food product.” Application of Term “Imitation,” 38 Fed. Reg. 2138, 2138 (Jan. 19, 1973) (emphasis added).

Ultimately, FDA made clear that “separate and distinct products” are not within the scope of “imitation.” In doing so, FDA referred to existing judicial interpretations, including those of state courts. These precedents are properly considered as further indicators of FDA’s

intent. As demonstrated next, such cases reinforce the fact that products like almond milk are separate and distinct products with their own identities, not imitations.

B. Cases interpreting the Act’s “imitation” provision require a very close resemblance to the food imitated, which excludes distinct products like almond milk.

In GFI’s view, the simplest answer to this case is that almond milk does not “resemble” cow’s milk. This accords with precedent. The most detailed FDA-cited decision analyzing resemblance is *Chil-Zert*, 114 F. Supp. 430 (N.D.N.Y. 1953). In that case, the product “Chil-Zert” was an imitation of ice cream, because

Chil-Zert is identical with ice cream in its method of manufacture, packaging and sale. It is similar in *taste, appearance, color, texture, body and melting qualities*. It has identical uses; its composition differs *only* from ice cream in the substitution of a cheaper ingredient; namely, vegetable oil in place of milk products.

Id. at 432 (emphases added) (adding that “[s]mell is included”).

Painter makes no claim that these elements of resemblance are met — i.e. that almond milk has the taste, smell, texture, body, or any other qualities of whole cow’s milk.⁸ And GFI submits that nobody who

⁸ Although Painter compares Blue Diamond’s product to “2% reduced-fat milk, vitamins A & D added,” only one food may bear the

has tried almond milk would describe it as having these qualities.⁹ Nor would any reasonable person expect that a product made of water and almonds would somehow have the taste, smell, and texture of cow's milk. *See* I ER 4 (citing cases holding that no reasonable consumer would confuse two distinct products or their properties).

Further, even if almond milk theoretically *could* be engineered to have the taste, smell, mouthfeel etc. of cow's milk (perhaps through the miracles of modern food science), FDA implies even this would not suffice to render it an imitation if the product retains a separate and distinct identity. Recall FDA's citation of cases holding that a "vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace cream" was not an "imitation cream" but rather a

unqualified name "milk" — whole cow's milk without added vitamins. *See* 21 C.F.R. § 131.110(a)–(b), (e)(1)(i) (vitamin addition optional; added vitamins must be separately noted). If almond milk were to be an imitation of "milk," it would need to resemble whole, unfortified milk.

⁹ Because almond milk is a well-known product in southern California, the basic characteristics of almond milk are judicially noticeable under Fed. R. Evid. 201(b)(1). *See Castillo-Villagra v. INS*, 972 F.2d 1017, 1026 (9th Cir. 1992) (judges need not "check their knowledge and experience of life at the courthouse door," citing e.g., no need for formal proof that gin is an intoxicating liquor).

“separate and distinct product.” 38 Fed. Reg. at 20702. These cases most clearly foreclose Painter’s interpretation.

The cases cited by FDA involved “Coffee-Rich,” a product generically known today as non-dairy creamer. In *Coffee-Rich v. Kansas State Board of Health*, 388 P.2d 582 (Kan. 1964), the Kansas Supreme Court decided that this “new and distinct food product having characteristics unique unto itself” could not be deemed an imitation. *Id.* at 587. While the lower court distinguished finer features of the products (e.g. noting the creamer’s sweeter taste compared to dairy’s “cowy” flavor, *id.* at 586), the basis of the appellate court’s ruling was that the creamer was unique and novel, or “*sui generis*.” *Id.* at 587. It could therefore be “no more an imitation of cows’ cream ... than nylon is an imitation of silk, saccharine an imitation of sugar, or Crisco an imitation of lard.” *See also Coffee-Rich v. Dep’t of Agric.*, 135 N.W.2d 594, 595 (Mich. 1965).

Earlier courts had reached similar conclusions about other non-dairy products. In *Midget Products v. Jacobsen*, 295 P.2d 542 (1956), the California Court of Appeals addressed “Mel-O-Dee Whip Topping,” a product generically known today as whipped topping (think Cool

Whip®). The product, which was used in place of whipped cream on pies and sundaes, “contain[ed] no milk or milk fat” and was argued to be “imitation whipped cream.” The court rejected this argument, noting the distinctive character of the product which was clear to the public. *Id.* at 545. And *Aeration Processes v. Jacobsen*, 184 Cal. App. 2d 836 (1960), yielded the same result regarding a non-dairy whipped topping in a (now-familiar) pressurized can.

As one further example, margarine was long ago argued to be an imitation of butter from cows, especially when colored yellow. But courts found that margarine’s clear labeling as a vegetable product rendered it “distinctive” and “not an imitation of creamery butter.” *Baltimore Butterine Co. v. Talmadge*, 32 F.2d 904, 909 (S.D.Ga. 1929).

To be sure, many of the above cases noted an imperfect “resemblance” when comparing new products with “traditional” products. *See Coffee-Rich*, 388 P.2d at 586 (more uniform color and less “cowy” flavor); *Midget Products*, 295 P.2d at 544 (pinker color, better heat tolerance); *Aeration Processes*, 184 Cal. App. 2d at 840 (stiffer consistency, “snow-white” vs. “generally yellow” cream, sweeter flavor); *Baltimore Butterine*, 32 F.2d at 909 (lower melting point, difference in

taste). But (consistent with Blue Diamond’s position) each case also emphasizes that consumers would understand that they are purchasing and consuming a distinct product. *Coffee-Rich*, 388 P.2d at 587 (noting the purpose of the law to “protect consumers from deception or injury” “not to protect other industries”) (quoting *Baltimore Butterine*); *Midget Products*, 295 P.2d at 544. And consistent with FDA’s approach, these cases repeatedly refer to the products as “distinct” or “distinctive” in deciding they are not imitations.

FDA therefore reasonably concluded that even in instances of very close resemblance, a food may be so clearly “separate and distinct” that the imitation provision would not apply. 38 Fed. Reg. at 20702. Almond milk (even *if* it resembled cow’s milk) would be such a product. It is made from water and almonds, not bovine “lacteal secretions,” 21 C.F.R. § 131.110. *See also Chil-Zert*, 114 F. Supp. at 432 (comparing “method of manufacture”). The district court in this case concluded that Painter’s claim was implausible because no reasonable consumer would expect almond milk to have the same properties as cow’s milk (I ER 4). This finding of implausibility applies just as well to Painter’s (unstated) allegation that almond milk resembles cow’s milk — anyone would

understand that these are “separate and distinct” products, and no one would expect them to have the same taste, smell, texture, etc. As in the cases above, the “imitation” provision simply has no application to such a distinct product.

C. A narrow reading of the “imitation” provision avoids absurd results.

Until now, GFI has only discussed the primary two elements of imitation: substitution and resemblance. The primacy of these elements over the third (“nutritional inferiority”) is confirmed by the regulatory history:

Nutritional inferiority is *not* the only criterion involved in defining “imitation” status. An evaluation of the overall impression conveyed by the food must *first* establish that the food is a substitute for and resembles another food.

38 Fed. Reg. at 20702 (emphasis added). Painter’s emphasis of this last element is therefore misplaced. Moreover, without a narrow limitation provided by the first two elements, “nutritional inferiority” under the regulation becomes utterly senseless and leads to absurd results.

This is easily seen by considering milks from other animals — goat milk, sheep milk, buffalo milk, etc. If almond milk can ever be said to resemble cow’s milk, then other animal milks must also bear

resemblance to cow's milk — and a much closer resemblance at that. After all, these other milks are all mammalian “lacteal secretions” (like cow's milk), while almond milk is made of almonds and water. And while there are likely differences in flavor to a trained palate (maybe goat milk tastes “goaty” rather than “cowy,” *Coffee-Rich*, 388 P.2d at 586), basic biology and common sense tell us that goat milk and cow's milk must be more similar (and similar in more ways) than cow's milk and almond milk could ever be. But goat milk is not an imitation of cow's milk (nor vice versa) because, like almond milk, it is plainly a separate and distinct product, any similarities or similar uses notwithstanding.

Under a broad reading that reaches almond milk, these other animal milks are also “imitations.” And indeed, in an administrative filing, Painter has admitted that she interprets “imitation” this broadly. See Comment from Capstone Law.¹⁰ In addressing the broad category of what Painter termed “milk-substitutes” including “soymilk, goat

¹⁰ Available at www.regulations.gov/document?D=FDA-2017-P-1298-0120. See *id.* 1 n.1 (noting representative capacity of filing for Painter). See also Fed. R. Evid. 201(b); *Interstate Natural Gas Co. v. S. Cal. Gas Co.*, 209 F.2d 380, 385 (9th Cir. 1953) (courts “may take judicial notice of records and reports of administrative bodies.”)

milk, buffalo milk, coconut milk, [and] almond milk,” Painter wrote that producers of these products “must fortify their milk-substitutes to avoid nutritional inferiority ... or else label their products with the words ‘imitation milk’” *Id.* at 2. Thus, like other “milk-substitutes,” goat milk (if nutritionally inferior) would in Painter’s view be “imitation milk.” As in this appeal, Painter focused only on nutrition, neglecting any consideration of whether other milks are separate and distinct products, or even whether they resemble cow’s milk at all.

For the sake of argument, assume (as Painter does) that all these products “substitute for and resemble” cow’s milk. Are milks from other animals also “nutritionally inferior” to cow’s milk, as defined by the regulation? Indeed, *all* of them are, but this is due to the regulation’s idiosyncratic definition of the term. The regulation defines nutritional inferiority as “[a]ny reduction in the content of an essential nutrient that is present in a measurable amount.” 21 C.F.R. § 101.3(e)(4)(i). In short, this means if the original food contains at least 2% of the daily recommendation of a nutrient per serving (as listed on the familiar Nutrition Facts panel), and the alleged “imitation” contains any less of that nutrient, it is “nutritionally inferior.” Importantly, this definition

takes no account of the alleged imitation's *overall* nutritional profile. So even if the alleged imitation is ever-so-slightly lower in only a single nutrient, yet much *higher* in *every other* nutrient, it would still be “nutritionally inferior,” per the regulation.

Consider how this applies to the profiles of various milks. As Painter would have it, unfortified goat milk would be “imitation milk” because it is “nutritionally inferior” to cow’s milk, being lower in folate, zinc, riboflavin, and vitamin B₁₂. (This despite goat milk having *higher* values for protein and nine essential vitamins and minerals.)¹¹ Similarly, buffalo milk must be “imitation milk” because it is lower in zinc, riboflavin, and vitamins B₆ and B₁₂ (though higher in protein and ten essential vitamins and minerals).¹² Going further still, *human* milk (breast milk) would be a mere “imitation” of cow’s milk: it has less protein, calcium, magnesium, phosphorus, potassium, folate, zinc,

¹¹ See USDA, National Nutrient Database for Standard Reference Release 28 (“NDB”), available at <https://ndb.nal.usda.gov/ndb/search/>. For ease of reference, GFI refers to foods by their database numbers (“NDB No.”), and the data can be accessed by typing this number into the “Search” box on the above-linked website and clicking “Go.” Here, compare “milk, goat, fluid, with added vitamin D” NDB No. 01106, with “milk, whole, 3.25% milkfat,” NDB No. 01211.

¹² See “milk, indian buffalo,” NDB No. 01108; NDB No. 01211.

thiamin, riboflavin, and vitamins B₆ and B₁₂ (though on the plus side, it has more niacin and vitamins A, C, and E).¹³

Painter correctly notes where Blue Diamond's almond milk is lower than cow's milk in nine nutrients, though she fails to note its *higher* values in seven others (calcium, iron, copper, manganese, and vitamins A, D, and E).¹⁴ Painter Brief at 5–6. (By the regulation's terms, cow's milk is just as “nutritionally inferior” to almond milk as vice versa.)¹⁵ Blue Diamond's almond milk is also higher in fiber and unsaturated fat, while lower in total fat, saturated fat, cholesterol, and calories — all beneficial differences in the context of the standard American diet.

¹³ See “milk, human, mature,” NDB No. 01107; NDB No. 01211.

¹⁴ See “Almond Breeze, ... Original,” NDB No. 45222754; NDB No. 01211. Painter claims that cow's milk has more vitamin D, but this is because she references a fortified milk product rather than plain “milk.” See *supra* note 8.

¹⁵ Blue Diamond uses this fact to present a slightly different absurdity argument: under a broad reading, cow's milk could be considered “imitation almondmilk.” BD Brief at 41. This turning-of-the-tables would not quite work because “milk” has an FDA-prescribed standard; cow's milk would always be “milk” regardless of whether buffalo, goat, or plant milks are nutritionally superior. This “most-favored-product” status may be somewhat arbitrary but presents no problem if the regulation is properly understood to avoid the comparison of distinct products. If misapplied, however, it raises a problem of constitutional dimension; see section II.D below.

Ultimately, though, these fine-grained nutritional analyses only demonstrate that the regulation is a blunt instrument, entirely unsuited for dealing with complex nutritional comparisons between totally distinct products. The absurdity of applying the regulation to distinct foods can be stated broadly: two distinct foods will *inevitably* have different nutritional profiles. Any reasonable consumer understands this, *see* I ER 4 (quoting *Gitson II*).¹⁶ And if two foods have different nutritional profiles, one will almost always be lower in some nutrients, though higher in others. In that case, the regulation would deem *both* products “nutritionally inferior” *to each other*, because each is lower than the other in at least one nutrient. Indeed, this paradox of “mutual inferiority” is true for *any two* of the above-described milks.¹⁷

But FDA was not engaged in a farce when it crafted this definition. Rather, it was dealing with an actual problem involving *true* imitation foods — the archetypes discussed earlier, modified foods (*Chil-Zert*) and diluted foods (*62 Cases of Jam*). In the context of these

¹⁶ “A reasonable consumer (indeed, even an unsophisticated consumer) would not assume that two distinct products have the same nutritional content” *Gitson v. Trader Joe’s Co.*, 13-cv-1333-VC, 2015 WL 9121232 at *1 (N.D. Cal. Dec 1, 2015).

¹⁷ Cow’s milk bests all other milks in zinc; the same is true for goat (potassium), buffalo (protein), human (vitamin C), and almond (iron).

archetypes, the regulation’s definition of “nutritional inferiority” makes good sense — when *modifying* an existing food, one should take steps to maintain that food’s nutritional value. And the regulation itself refers to “any *reduction*” in essential nutrients — language that by its very terms suggests a modification *reducing* a food’s nutrient content, not a nutrient comparison between two independent foods. 21 C.F.R. § 101.3(e)(4)(i). A definition of “nutritional inferiority” intended to apply to unrelated, distinct foods would not use the word “reduction,” and would account for nutritional strengths as well as weaknesses. Thus, while the regulation is sensible in the modified-food context in which it was drafted, when one attempts to conscript it into the comparison of distinct products, absurdity ensues.

And looking beyond milks, the absurdity only grows. For instance, FDA makes wheat flour the default ingredient in many standardized products, including breads, rolls, and noodles.¹⁸ But many familiar variations on these foods use different grains, e.g. rye bread, cornbread, rice noodles, and potato rolls. Under Painter’s broad reading, if these alternative look-alikes were lower in any nutrient than

¹⁸ See 21 C.F.R. §§ 136.110 (bread, rolls, and buns), 139.110 (pasta), 139.150 (noodles).

standardized “bread” or “noodles,” they would be “imitation bread” or “imitation noodles.” And of course, different grains *do* have different nutritional profiles, including lower levels of certain nutrients — rye has less iron than wheat, while rice, corn, and potatoes have less protein (among other nutrients).¹⁹ Thus rye bread, cornbread, and potato bread (despite being distinct, established foods) would all be “imitation bread,” unless fortified with protein and every vitamin and mineral that is lower than in wheat bread. Similarly, unless extensively fortified, simple rice noodles (a staple in many cultures) would be but “imitation noodles.”

The imitation provision also has application beyond FDA-standardized foods like milk and bread; it covers any food that “is an imitation of another food,” including the great majority of foods that are not standardized. Thus, a broad reading of “substitution and resemblance” would be almost without limit on the foods affected.

Turkey bacon and veggie bacon would be “imitation bacon,”²⁰ bison

¹⁹ Compare NDB Nos. 20064 (rye), 20090 (rice), 11413 (potato), 20649 (wheat).

²⁰ Compare NDB No. 10123 (pork bacon) *with* NDB Nos. 07254 (turkey bacon, less thiamin), 45118630 (veggie bacon, less iron).

burgers and veggie burgers “imitation burgers,”²¹ turkey chili and bean chili “imitation chili,”²² and so on. New food products for people with dietary restrictions — such as gluten-free foods for those with celiac disease or gluten sensitivity — would often likewise be “imitations.”²³

Finally, it bears repeating that none of these consequences can be resolved by renaming these foods to omit the name of the supposedly-imitated food. By the clear language of the statute and regulation, if turkey bacon is truly an “imitation” of bacon, it *must* be labeled “imitation bacon,” just as almond milk, soy milk, coconut milk, and goat milk would all need to bear the same, uninformative name: “imitation milk.” To require the rebranding of *all* these foods (and perhaps hundreds more) with the uninformative (and derogatory) name “imitation _____” would be patently absurd.

It is also a result the Court can avoid. Here the Court is presented with two different interpretations of the law. On the one hand, Blue Diamond and GFI present a narrow interpretation that

²¹ NDB Nos. 17331 (bison), 16147 (veggie); less protein, zinc and other nutrients than NDB No. 23568 (beef).

²² NDB Nos. 45133816 (turkey chili), 45133815 (vegetarian chili); less protein than NDB No. 45134268 (chili con carne).

²³ NDB Nos. 45223796 (spaghetti), 45223787 (gluten-free spaghetti, less protein).

excludes distinct foods, consistent with the regulation’s text, history, and case law. On the other, Painter presents a broad definition focused entirely on nutritional differences, but which sweeps up countless distinct foods simply because they look somewhat similar and have similar uses. Her definition also (paradoxically) allows distinct foods to be compared on terms that deem them *mutually* “nutritionally inferior” to one another. Even *if* Painter presented a plausible interpretation of “imitation,” the Court “cannot adopt a construction that leads to absurd results.” *Ma v. Ashcroft*, 361 F.3d 553, 561 (9th Cir. 2004). The Court should therefore adopt the former, narrow interpretation which avoids the limitless absurd results described above.

D. A narrow reading of the “imitation” provision avoids serious constitutional questions.

In addition to causing endless absurdity, construing the regulation to reach distinct products would raise serious questions of the law’s constitutionality, particularly under the First Amendment. If possible, the Court should construe the regulation to avoid such constitutional problems. *Overstreet v. United Brotherhood of Carpenters*, 409 F.3d 1199, 1208–09 (9th Cir. 2005).

Notably, early imitation cases sometimes addressed constitutional issues. However, because these cases pre-dated the widespread recognition of commercial free speech, they usually addressed due process or equal protection, concluding that compulsory imitation labeling would have no rational basis as applied to distinct products. *See Midget Products*, 295 P.2d at 523 (forcing whipped topping to label itself “imitation” would be “an unconstitutional application” of the law); *Coffee-Rich*, 388 P.2d at 584 (noting district court found “unconstitutional application” of imitation labeling to non-dairy creamer). *Cf. Coffee-Rich v. Commissioner*, 204 N.E.2d 281, 289 (Mass. 1965) (striking down, for lack of rational basis, state “imitation” statute that effectively outlawed sale of non-dairy creamer).

But more obviously under modern jurisprudence, the “imitation” provision raises serious concerns under the First Amendment as a regulation of commercial speech. This is especially true for a product with an established name like “almond milk,” a name used in English since the 14th century.²⁴ Rather than allowing Blue Diamond to label its product with the established name consumers know, Painter seeks

²⁴ *Supra* note 2.

to force Blue Diamond to label its product with the uninformative derogatory name “imitation milk.” This is both a restriction on commercial speech (forbidding the use of the established name) and a compelled speech regulation (requiring the use of the “imitation” name).

A recent case in the 11th Circuit, *Ocheese Creamery v. Putnam*, is particularly on point. 851 F.3d 1228 (2017). In that case, Florida enforced its state “imitation” law to forbid a natural skim milk (without added vitamin A) from using the words “skim milk,” instead requiring “imitation milk product.” *Id.* at 1232. (This is largely consistent with federal law: removing milkfat without replacing the associated vitamin A creates a skim milk that is “nutritionally inferior” to whole milk.) Analyzing this as a speech restriction under *Central Hudson*, the court found it unconstitutional as applied, noting that the state had “less restrictive and more precise means” available, such as requiring disclosure of the missing vitamin A. *Id.* at 1240.

A similar analysis shows that any application of “imitation” labeling to distinct products like almond milk would not withstand scrutiny under *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n*, 447 U.S. 557, 564 (1980). First, there is nothing false or

inherently misleading about common names like almond milk (or goat milk, rice noodles, or turkey bacon). Indeed, when courts in this Circuit have addressed the names “soy milk” and “almond milk,” they have held that *no* reasonable consumer would be misled by such product names — far short indeed of finding them “inherently misleading.” *See* I ER 3–4 (citing cases); *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106–07 (9th Cir. 2004) (describing distinction between “inherently” and “potentially” misleading). It might be argued that such names are *potentially* misleading, perhaps because they (arguably) carry nutritional implications. However, the district court (and others) have noted that no reasonable consumer would believe that two distinct products have the same nutritional qualities. *See* I ER 4 (citing *Gitson II*).

But even if Painter could demonstrate a real risk that consumers would be misled by such names, any restriction would still need to “directly advance” the asserted governmental interest (preventing deception) and be no “more extensive than necessary” to serve that interest. *Am. Acad.*, 353 F.3d at 1109, 1111. It is hard to see how forbidding soy milk, almond milk, coconut milk, and goat milk from

bearing the names consumers know and understand would serve any interest in preventing deception or informing consumers; indeed, forcing each of these products to be called “imitation milk” does quite the opposite, obscuring from consumers each product’s basic nature. Such a requirement is also far more extensive than necessary, and hardly a reasonable fit to the interest asserted. *Id.* As in *Ocheesee Creamery*, disclosure of any serious nutritional differences would be a much more narrowly-tailored (and effective) approach.²⁵ *See also Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999) (noting First Amendment preference for disclosures over suppression).

And “imitation” labeling goes further than mere suppression. It also compels producers to use the word “imitation,” which courts (and dictionaries) recognize as a disparaging term carrying an implication of inferiority. *See Coffee-Rich*, 388 P.2d at 587. As noted above, distinct products like almond milk, soy milk, and goat milk also have nutritional *strengths* compared to cow’s milk. But labeling each “imitation milk” would imply they are all inferior, regardless of their

²⁵ Indeed, the government took this approach in 1990 by mandating the Nutrition Facts panel on every label, 21 U.S.C. § 343(q). This source of consumer-facing information obviates the need for imprecise monikers like “imitation” that may have been more useful in 1938.

benefits. It cannot reasonably be said that this would merely arm consumers with “factual and uncontroversial” information, *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). Rather, it seems intended to denigrate all products that compete with the State’s favored selection (cow’s milk), conveying “embarrassment” on alternative products and “browbeat[ing] consumers into” choosing dairy. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216–17 (D.C. Cir. 2012).²⁶

Considering these implications, one may fairly question whether the application of this law to distinct products like almond milk would have *any* rational basis (as early imitation cases questioned), or whether such an application would be an unconstitutional exercise of economic protectionism. *Cf. Merrifield v. Lockyer*, 547 F.3d 978, 991–92 & n.15 (9th Cir. 2008); *Milnot Co. v. Richardson*, 350 F. Supp. 221, 224–25 (S.D. Ill. 1972) (invalidating Filled Milk Act as “devoid of rationality”). Further, to the extent that Painter seeks to force almond

²⁶ Notably, a case addressing the proper scope of “factual and uncontroversial” disclosures under *Zauderer* is pending before this Court en banc. *See Am. Beverage Ass’n v. City & Cnty. of San Francisco*, 871 F.3d 884, 896 (9th Cir. 2017), *vacated for reh’g en banc*, 880 F.3d 1019.

milk to drop the word “milk” from its name (however inconsistent this is with the law’s clear requirement for “imitations”), courts have recognized that restricting non-dairy or modified-dairy labels and advertisements from using dairy terms likewise violates the First Amendment. *See Lever Bros. v. Maurer*, 712 F. Supp. 645, 651–52 (S.D. Ohio 1989); *Anderson, Clayton & Co. v. Wash. State Dep’t of Agric.*, 402 F. Supp. 1253, 1257–58 (W.D. Wash. 1975). And preserving the word “milk” for the State’s preferred dairy products — despite the historic existence of almond milk, soy milk, coconut milk, and milks from other animals — would be a restriction targeting “disfavored speech by disfavored speakers,” calling for heightened scrutiny. *Sorrell v. IMS Health*, 564 U.S. 552, 564 (2011).

Ultimately, though, the Court need not decide any of these weighty constitutional questions to resolve this case. The Court need merely recognize that the constitutional questions presented would be “serious.” *See Meinhold v. Dep’t of Def.*, 34 F.3d 1469, 1476 (9th Cir. 1994). Even if Painter presented an “otherwise acceptable construction of the statute,” if such construction “would raise serious constitutional problems,” the Court “*must*” construe the provision (if possible) to avoid

such problems. *Id.* (citations omitted). And this principle applies where the Court is interpreting a regulation as well as a statute, *see e.g.* *Flores-Chavez v. Ashcroft*, 362 F.3d 1150, 1162–63 (9th Cir. 2004).

It cannot reasonably be maintained that the constitutional problems presented above are not at least “serious” — indeed, many of the above-cited courts *in fact* invalidated similar restrictions as applied to distinct foods (sometimes invalidating the laws entirely). And with recent developments in commercial free speech doctrine — including *Ocheesee Creamery* and this Court’s pending en banc review of a controversial compelled-commercial-speech regulation — the First Amendment questions are particularly serious indeed. GFI and Blue Diamond present the Court with a “possible” construction of the law (consistent with its text, history, and case law), one that avoids these constitutional problems by preventing the law’s application to separate and distinct foods. The principle of constitutional avoidance only reinforces this construction.

CONCLUSION

The relevant text, history, and case law all confirm that the scope of “imitation” under the Act has been interpreted narrowly by FDA and the courts. The two avoidance canons of construction — of absurd results and serious constitutional problems — reinforce this narrow reading. Any broader reading of the law would needlessly call into question the regulatory status of countless foods currently on the market, while raising regulatory barriers for innovative new foods. For these reasons, GFI respectfully requests that the Court affirm the narrow scope of imitation labeling, and accordingly affirm the judgment below.

Respectfully submitted,

Dated: March 9, 2018

s/ Nigel Barrella

NIGEL A. BARRELLA
LAW OFFICE OF NIGEL A. BARRELLA
1001 Pennsylvania Ave. NW
Suite 1300N
Washington, DC 20004
(202) 768-7510
nigel@barrellalaw.com

*Attorney for Amicus Curiae
Good Food Institute*

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Signature of Attorney or Unrepresented Litigant

s/ Nigel Barrella

Date

March 9, 2018

("s/" plus typed name is acceptable for electronically-filed documents)

CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2018, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system.

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s/ Nigel Barrella

Appendix D

The contents of this appendix can be accessed in a more convenient viewing format by visiting the website address below:

<https://www.gfi.org/marketresearch>

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Plant-Based Market

[WHY GOOD FOOD?](#)[WHAT WE DO](#)[OUR TEAM](#)[RESOURCES](#)[BLOG](#)[WE'RE HIRING!](#)

Overview

[Intro](#)

Introduction


Plant-based alternatives to conventional animal products are a booming business. Recently commissioned data from leading market research firm Nielsen shows U.S. retail sales of plant-based foods that directly replace animal products (as defined by GFI) have grown 17% in the past year to over \$3.7 billion. With the addition of SPINS U.S. retail sales data on plant-based alternatives in the natural channel, the total U.S. plant-based retail market is worth over \$4.1 billion. As more households across the country purchase plant-based options, the market for these products is rapidly expanding well beyond vegetarian and vegan consumers. We've summarized highlights of the data along with key insights here, both for the market as a whole and for the top plant-based alternative categories.

About the Data



The custom data summarized here represent retail sales of plant-based foods that directly replace animal products as defined by GFI, including meat, seafood, eggs, and dairy, as well as meals that contain direct animal ingredient replacements. This data was obtained over the 52-

week period ending August 11, 2018 from Nielsen's Expanded All Outlets Combined (xAOC) channel – which includes grocery stores, drug stores, mass merchandisers, club stores, dollar stores, and military stores – plus Whole Foods Market.

 **SPINS** In a few instances, SPINS natural channel sales data of plant-based alternatives has been added to provide a comprehensive view of the retail market. This data was obtained over the 52 week period ending August 12, 2018 using the SPINS attribute “plant-based positioned”.

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Overview

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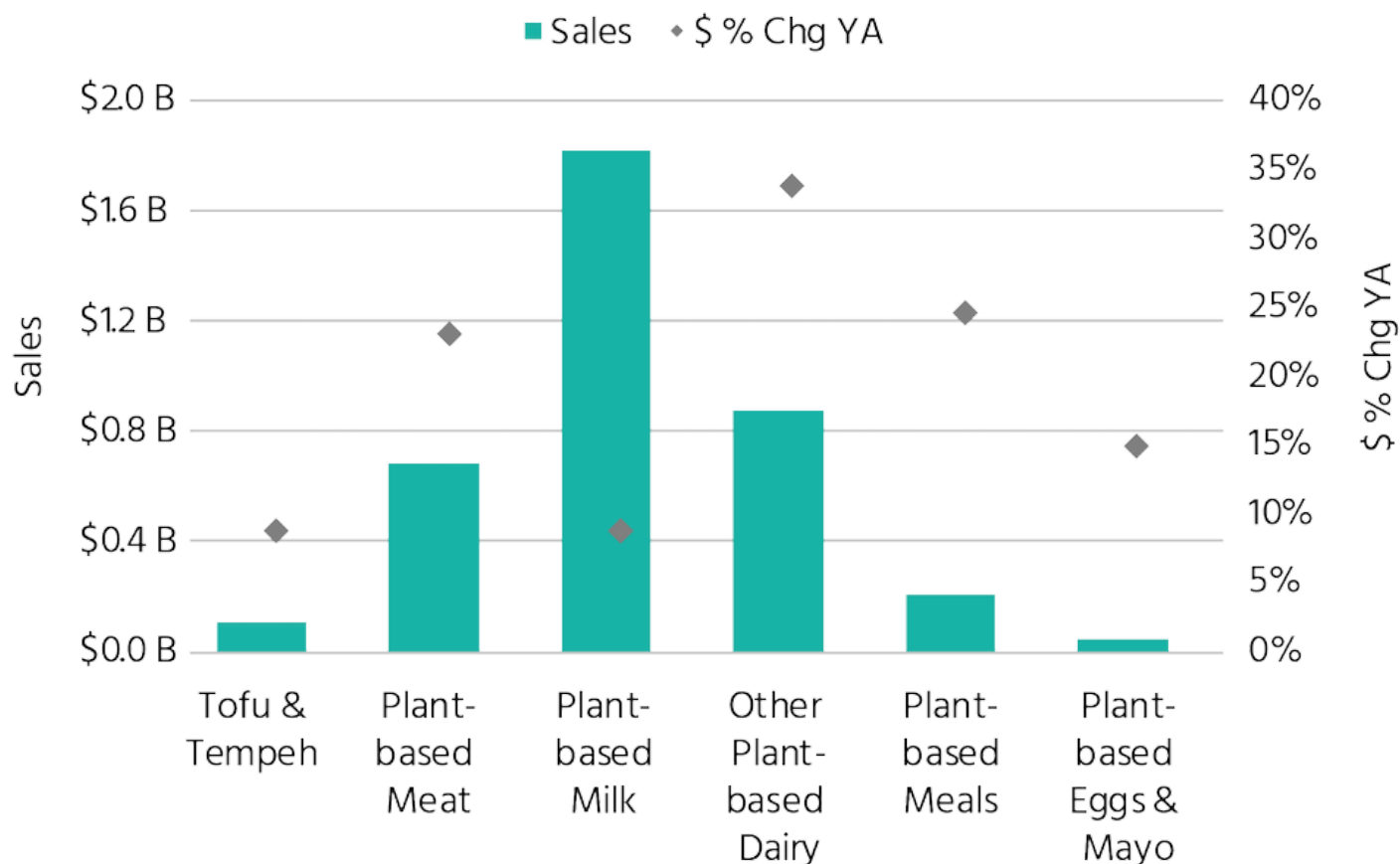
Plant-Based Market Overview

The plant-based alternatives (to conventional animal foods) retail market is worth over \$3.7B.

- With the additional of natural channel sales data, the total plant-based alternative retail market is worth over \$4.1B.

 **SPINS** In the natural channel, the plant-based alternative market is worth \$409MM.¹

Plant-based alternative dollar sales and dollar sales growth by category



Source: Nielsen xAOC + WFM, 52 weeks ending 8/11/18.

Dollar sales of plant-based alternatives grew 17% in the past year.

- Comparatively, total U.S. retail food dollar sales grew just 2%.
- Plant-based dollar sales growth has accelerated in the past year compared to the prior year. [Previous data](#) from August 2017 showed plant-based dollar sales had grown 8% in the preceding year.

Plant-based category dollar sales

Category	Sales	\$ Sales Chg vs. YA
Plant-based Milk	\$1,821,994,474	9%
Plant-based Meat	\$683,745,719	23%
Plant-based Ice Cream and Frozen Novelty	\$232,051,340	40%
Plant-based Meals	\$209,720,127	25%
Plant-based Yogurt	\$174,195,525	55%
Plant-based Butter	\$168,877,629	6%
Plant-based Cheese	\$133,283,346	41%
Plant-based Creamer	\$124,553,130	62%
Tofu and Tempeh	\$107,214,670	9%
Plant-based Eggs and Mayo	\$42,467,047	15%
Plant-based RTD Coffee	\$34,154,295	-12%
Plant-based Dressings, Sour Cream, Dips	\$12,483,131	29%
Total Plant-based	\$3,744,740,433	17%

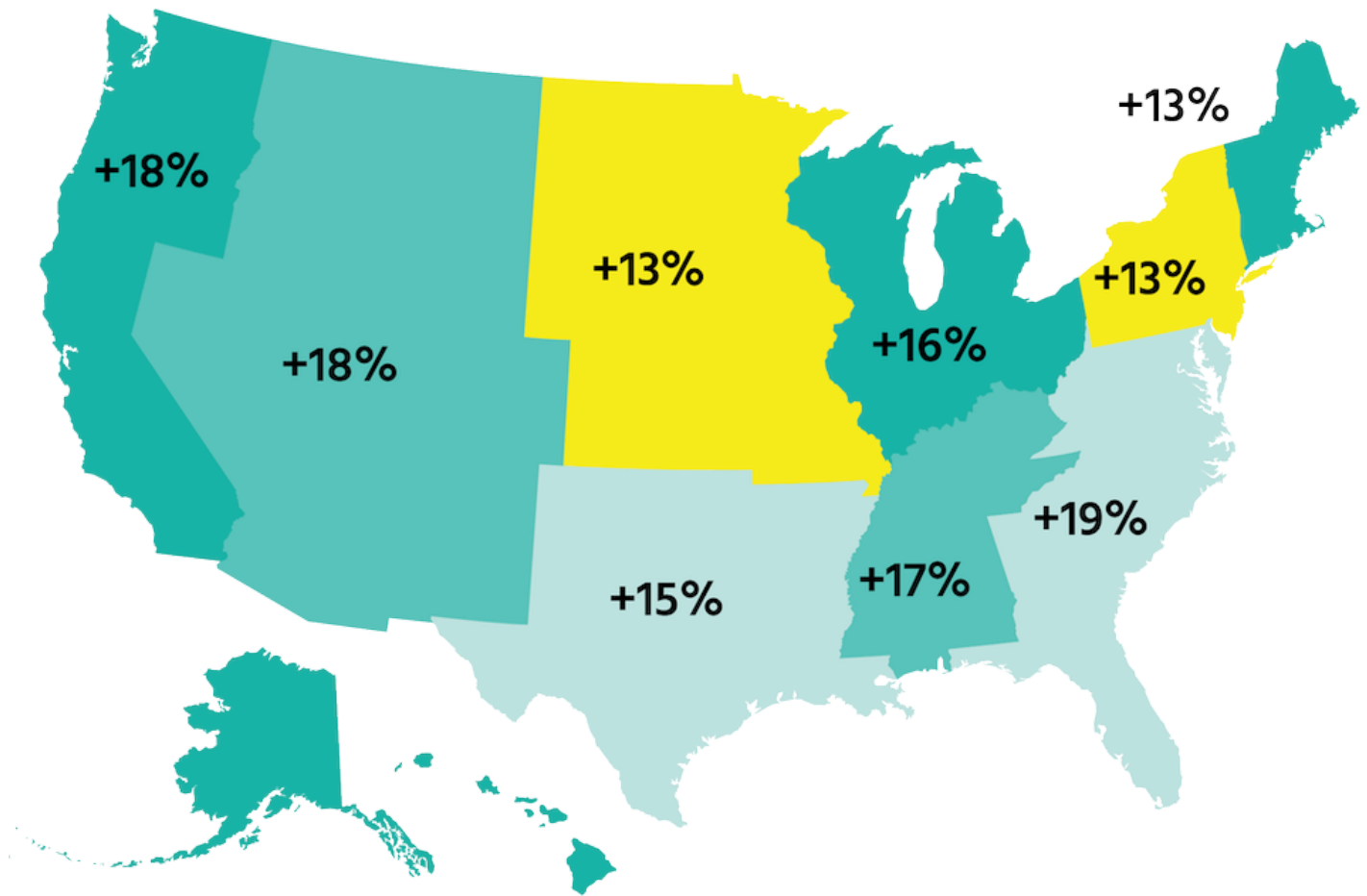
Source: Nielsen xAOC + WFM, 52 weeks ending 8/11/18.

("\$ Sales Chg vs. YAG" = \$ Sales Change versus Year Ago)

Plant-based dollar sales are increasing double-digits in every region of the country.

- This indicates that the shift towards plant-based is not confined to the coasts or urban areas, but instead is occurring across the country.

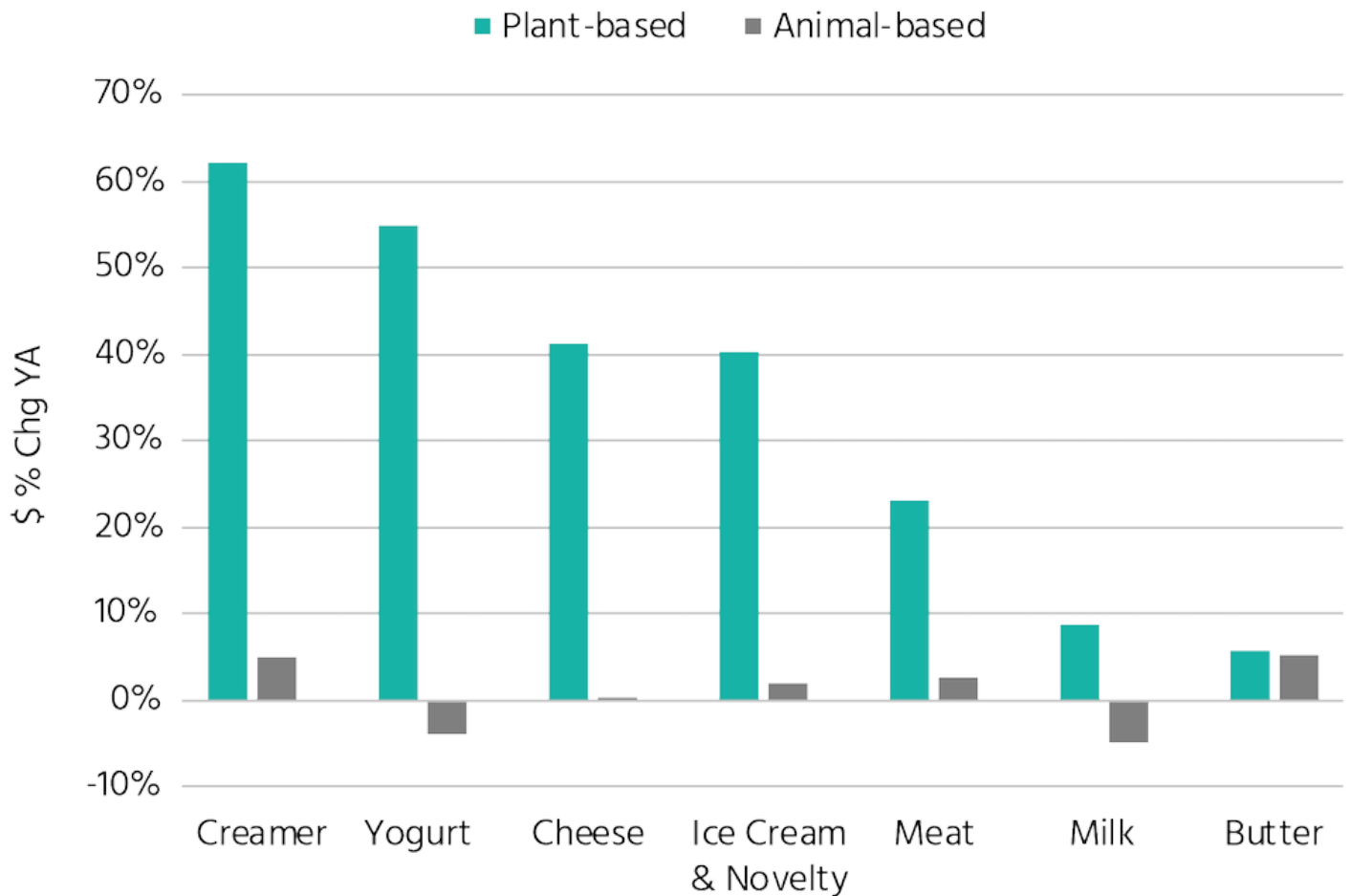
Plant-based alternative dollar sales growth by region



Source: Nielsen xAOC + WFM, 52 weeks ending 8/11/18.

In key categories, plant-based dollar sales are growing significantly, while animal-based dollar sales are declining or growing only modestly.

Plant-based and animal-based product dollar sales change by category



Source: Nielsen xAOC + WFM, 52 weeks ending 8/11/18.

Plant-based distribution is increasing across categories, as measured by ACV and TDP.

The average unit price of plant-based alternatives is below \$5 across all categories.

- The average unit price of plant-based alternatives is still greater than that of animal-based foods across most categories, including meat, milk, cheese, yogurt, and ice cream & novelty.

Footnotes:

¹ SPINS: Total US - Natural Channel, Plant Based Positioned, 52 weeks ending 8/12/18.

² Nielsen: Total US Household Panel, 52 weeks ending 10/6/18.

Additional details on Nielsen custom dataset:

To ensure we were able to capture all direct replacements for animal products, we did not require that all products be vegan. Rather, we required that all products be vegetarian and that each product be significantly more plant-based than the animal-based product it replaces.

Milk is defined as ready-to-drink liquid milk products and excludes condensed, evaporated, and canned milk products.

Butter is defined as vegan products marketed using the terms "butter," "buttery spread," or "vegan spread." Margarines that are not specifically marketed to function as butter replacements were not included.

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Plant-Based Meat

Plant-Based Meat Category Sales

The plant-based meat category is worth \$684MM.

- With the additional of natural channel sales data, the total plant-based meat category is worth over \$767MM.

 **SPINS** In the natural channel, the plant-based meat category is worth \$83MM.¹

Dollar sales of plant-based meat grew 23% in the past year.

Over 157MM units of plant-based meat were sold in the past year.

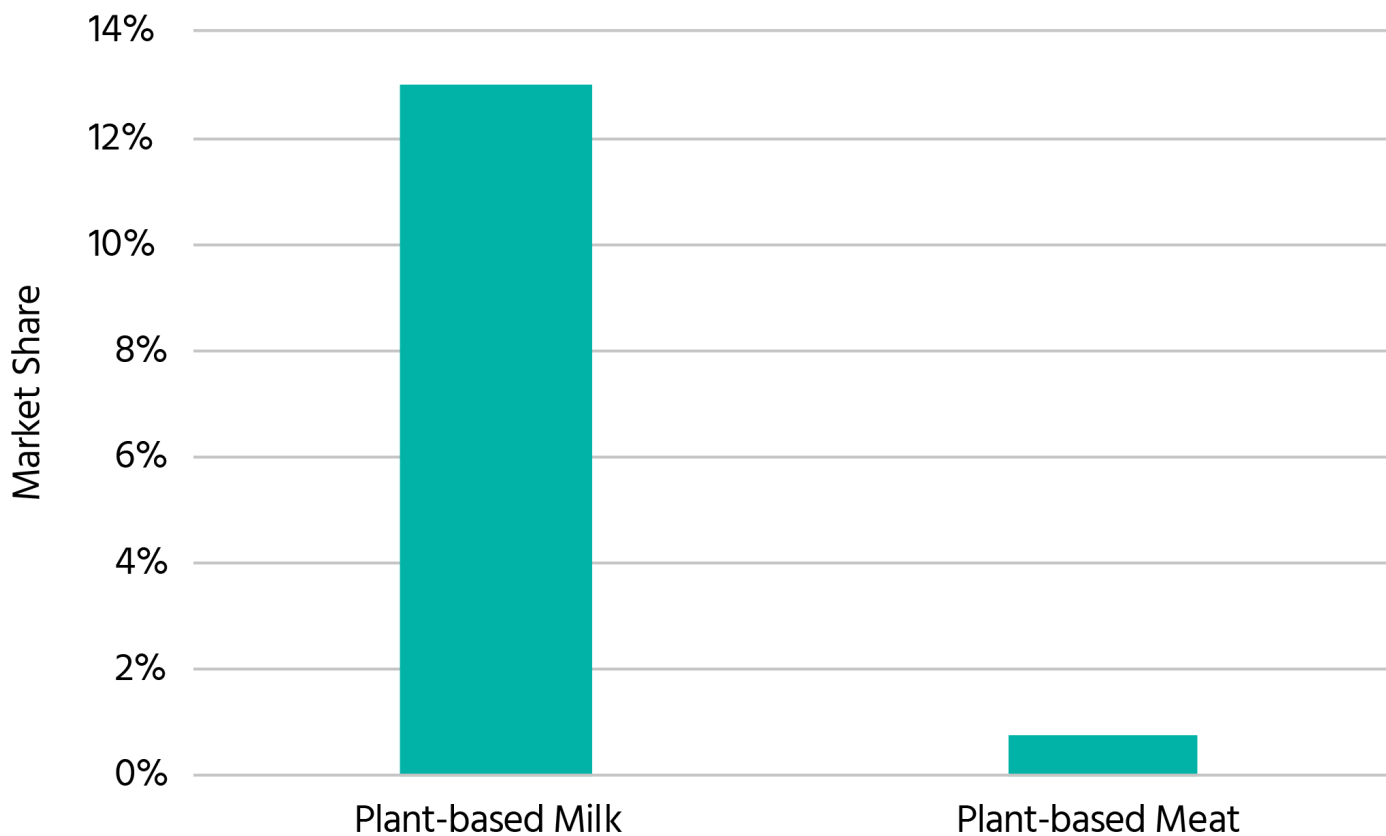
157MM+



Plant-based meat accounts for just under 1% of all retail meat dollar sales.

- The plant-based meat category today is reminiscent of the plant-based milk category a decade ago when it was in its early stages of rapid growth.
- Plant-based milk now accounts for 13% of all retail milk dollar sales. The opportunity for plant-based meat to gain 12 points of market share - reaching market share parity with plant-based milk - is worth over \$10B.

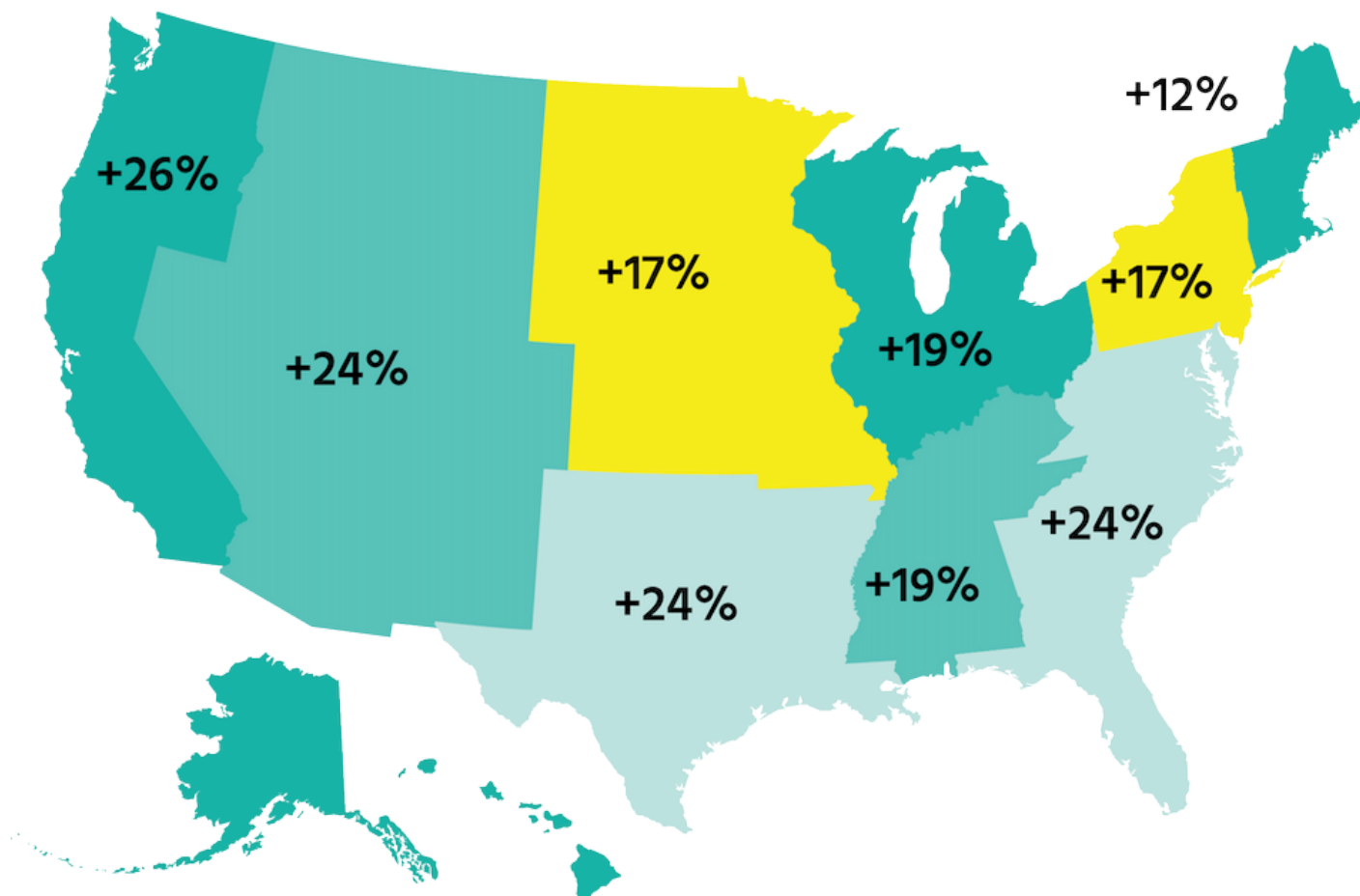
Plant-based meat and plant-based milk dollar market share



Source: Nielsen xAOC + WFM, 52 weeks ending 8/11/18.

Plant-based meat dollar sales are growing double-digits in every region of the country.

Plant-based meat dollar sales growth by region



Source: Nielsen xAOC + WFM, 52 weeks ending 8/11/18.

Growth in plant-based meat is not just coming from increases in distribution, category dollar velocity is up 20% (as measured by dollar sales per point of distribution).

- This indicates that plant-based meat is selling at a faster rate than it did one year ago. It also indicates that each shelf slot dedicated to plant-based meat is generating more revenue for retailers than it did one year ago.

Plant-based meat is sold in 79% of retail food stores and 95% of grocery stores (as measured by %ACV).

- This indicates room for plant-based meat distribution growth in retail stores outside of conventional grocery, such as convenience and drug.

Plant-Based Meat Segments

Frozen plant-based meat accounts for over 75% of all plant-based meat dollar sales and is more widely distributed than refrigerated plant-based meat.

Refrigerated plant-based meat dollar sales grew 49%, much faster than frozen plant-based meat dollar sales, which grew 17%.

- This reflects a shift in merchandising strategies as more plant-based meats are being shelved in the refrigerated case or adjacent to conventional meat.

Shelf-stable plant-based meat is a small category and accounts for just over 1% of total plant-based meat dollar sales.

Plant-based seafood accounts for just \$9.3MM (1.4%) of total plant-based meat dollar sales.

- Approximately 95% of plant-based seafood dollar sales are from the frozen section.
- Several new brands of plant-based seafood will be launching soon or recently launched, including Good Catch, Ahimi, and New Wave.

Plant-Based Meat Purchase Dynamics

11.9% of all U.S. households purchase plant-based meat, which equates to approximately 15 million households.

- Last year 10.5% of U.S. households purchased plant-based meat. This is an increase of 1.4 points or 13%.
- Compared to household penetration of plant-based milk at 37%, there is clear upside for the number of households purchasing plant-based meat to increase threefold.

The projected number of household trips to purchase plant-based meat is over 79MM annually.

- This is an increase of almost 12 million household trips from last year.

Footnotes:

¹ SPINS: Total US - Natural Channel, Plant Based Positioned, 52 weeks ending 8/12/18.

² Nielsen: Total US Household Panel, 52 weeks ending 10/6/18.

Additional details on Nielsen custom dataset:

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Plant-Based Milk

Plant-Based Milk Category Sales

The plant-based milk category is worth \$1.8B.

- Plant-based milk alone accounts for almost half of the total plant-based food market.
- With the additional of natural channel sales data, the total plant-based milk category is worth over \$1.9B.

 **SPINS** In the natural channel, the plant-based milk category is worth an additional \$110MM.¹

Dollar sales of plant-based milk grew 8.8% in the past year.

Over 567MM units of plant-based milk were sold in the past year.

567MM+

Plant-based milk accounts for 13% of all retail milk dollar sales.

Plant-based milk is sold in 89% of retail food stores and 100% of grocery stores (as measured by %ACV).

- This officially makes plant-based milk ubiquitous.

Growth in plant-based milk is not being driven by increases in distribution. Rather, category dollar velocity is driving the increase, up over 7% from last year (as measured by dollar sales per point of distribution).

Plant-based milk is the most developed plant-based category and is also the most promoted of all plant-based food categories.

- Plant-based milk is the one plant-based category that is consistently shelved adjacent to similar animal-based products.

Plant-Based Milk Segments

Refrigerated plant-based milk makes up 88% of all plant-based milk dollar sales.

- Refrigerated plant-based milk dollar sales increased more (+9.7%) than shelf-stable plant-based milk dollar sales (+2.3%) over the past year.
- The shelving change many years ago that saw plant-based milk move to the refrigerated set was key to introducing these products to a much larger consumer base and thus, rapidly growing category sales.

Almond milk is the category leader with the majority of dollar sales and its sales are still increasing. Oat milk is the fastest growing type of plant-based milk.

Plant-Based Milk Purchase Dynamics²

37% of all U.S. households purchase plant-based milk, which equates to over 45 million households.



The projected number of household trips to purchase plant-based milk is 335MM annually.

Households that purchase plant-based milk exhibit high cross-purchase behavior across all other plant-based alternative categories.

- This indicates that plant-based milk is the entry point for many consumers into other plant-based categories.

Footnotes:

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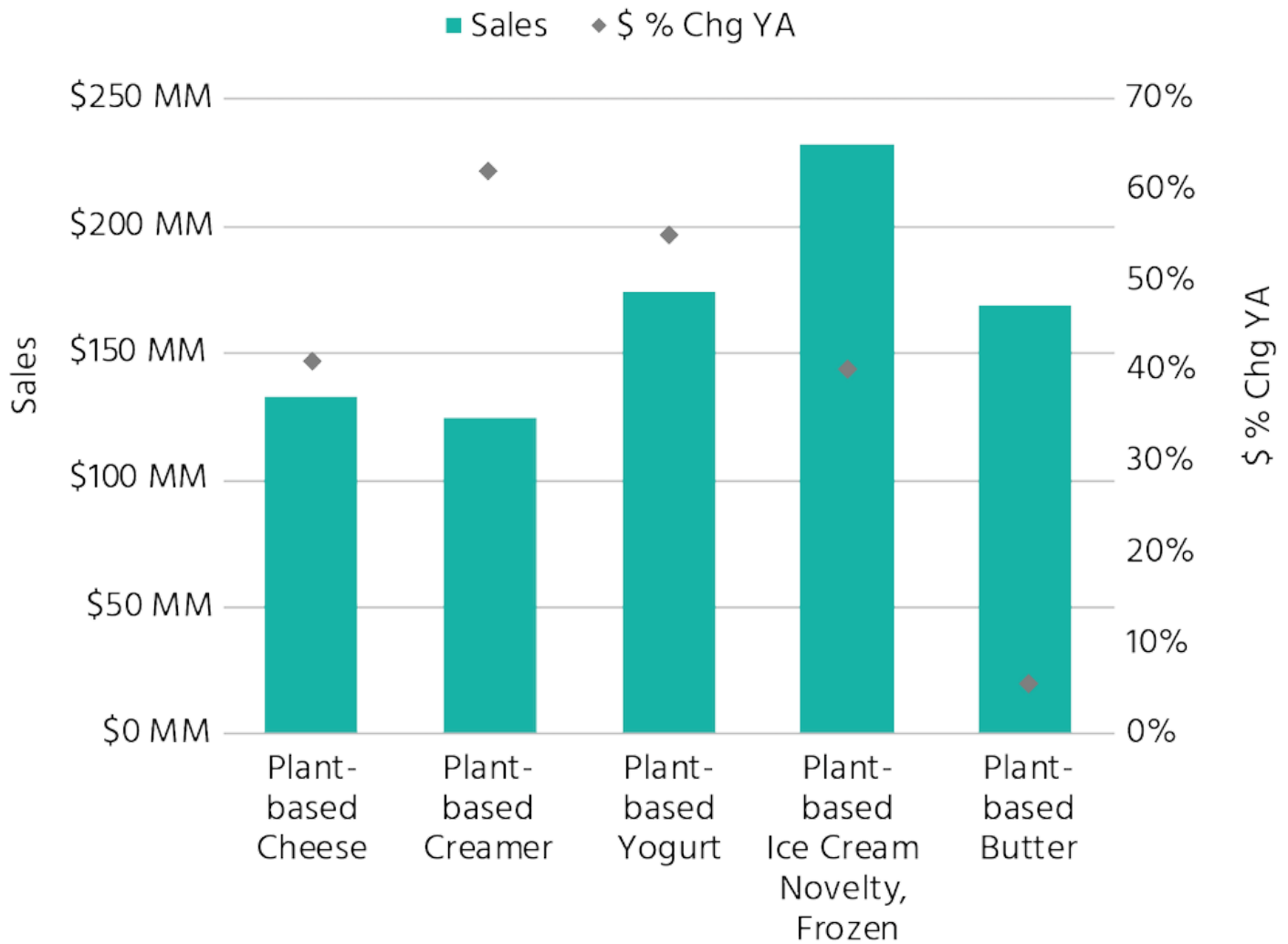
Other Plant-Based Dairy

Emerging plant-based dairy categories have experienced the greatest dollar sales growth.

- The growth of plant-based milk - now purchased by approximately 1 in 3 households - has laid the groundwork for other plant-based dairy categories.

Together, these “other plant-based dairy” categories are worth \$833M.

Dollar sales and percent sales growth for “other plant-based dairy” categories



Source: Nielsen xAOC + WFM, 52 weeks ending 8/11/18.

Ice Cream and Frozen Novelty

The plant-based ice cream and frozen novelty category is worth \$232MM.

Dollar sales of plant-based ice cream and frozen novelty grew 40% in the past year.

Plant-based ice cream and frozen novelty is sold in 70% of retail food stores (as measured by %ACV).

Yogurts

The plant-based yogurt category is worth \$174MM.

Dollar sales of plant-based yogurt grew 54% in the past year.

Plant-based yogurt is sold in 61% of retail food stores (as measured by %ACV).

Butter

The plant-based butter category is worth \$169MM.

Dollar sales of plant-based butter grew 6% in the past year.

Plant-based butter is sold in 73% of retail food stores (as measured by %ACV).

Cheese

The plant-based cheese category is worth \$133MM.

Dollar sales of plant-based cheese grew 41% in the past year.

Plant-based cheese is sold in 61% of retail food stores (as measured by %ACV).

Creamer

The plant-based creamer category is worth \$125MM.

Dollar sales of plant-based creamer grew 62% in the past year.

Plant-based creamer is sold in 65% of retail food stores (as measured by %ACV).

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Plant-Based Meals

The plant-based meal category is worth \$209MM.

- The majority of plant-based meal dollar sales are from the frozen foods section. Refrigerated ready-to-eat plant based meals appear to be an untapped opportunity.

Dollar sales of plant-based meals grew 25% in the past year.



Plant-based meals are sold in 72% of retail food stores (as measured by %ACV).

Footnotes:

¹ SPINS: Total US - Natural Channel, Plant Based Positioned, 52 weeks ending 8/12/18.

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Plant-Based Eggs and Mayo

The plant-based egg and mayo category is worth \$42MM.

- This sales data is from before the launch of JUST's new eggless scramble.

Dollar sales of plant-based egg and mayo grew 15% in the past year.

↑ 15%



Plant-based eggs and mayo are sold in 62% of retail food stores (as measured by %ACV).

Footnotes:

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