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Dockets Management Staff (HFA-305)
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-2381 for Horizontal Approaches to Food Standards of Identity Modernization

The Good Food Institute (GFI) appreciates the opportunity to submit these comments on the Food and Drug Administration's effort to modernize food standards of identity.

GFI is a 501(c)(3) nonprofit organization working to build a sustainable, healthy, and just food system by harnessing the power of food innovation and markets to accelerate the transition of the world's food system to animal-free meat, eggs, and dairy. GFI supports FDA's goal of promoting industry innovation and flexibility to encourage manufacturers to produce more healthful foods. As detailed below, horizontal approaches to updating food standards of identity can support this goal, and we provide some suggestions on possible approaches. And where updating food standards is not feasible or desirable, we suggest that innovation can still be encouraged with a flexible approach to common or usual names, including names that reference standardized foods.

I. Updating Standards of Identity to Allow for Ingredients with Novel Production Methods

The modernization of standards of identity for dairy products (which account for a significant share of existing standards of identity) has been a topic of discussion for years. In particular, dairy food producers, the International Dairy Foods Association ("IDFA"), and FDA have all made various proposals for increased flexibility in standards for yogurt and cheese products. For example, IDFA has suggested expanding the list of "basic dairy ingredients" in yogurt to include

ultra-filtered (UF) milk, milk protein concentrate and isolate, and skim milk powder.[1] FDA in 2005 proposed permitting the use of UF milk in cheeses,[2] and in 2017 FDA issued a final guidance document announcing that it would exercise enforcement discretion on the use of UF milk in cheeses in accordance with that proposed rulemaking.[3] In that guidance document, FDA noted that "food standards should provide for flexibility in manufacturing procedures and ingredients, provided that the basic nature and essential characteristics of the food are preserved."

GFI supports an approach, such as that suggested by IDFA and FDA, that would allow flexibility to use modern dairy ingredients (such as UF milk or milk protein isolate) in standardized dairy foods like yogurt and cheeses. This could come in the form of a horizontal standard that would make these ingredients "basic dairy ingredients" across all classes of dairy foods. This horizontal approach would enable innovation so that dairy food producers could create higher-protein or lactose-free varieties of existing dairy products, for example. But this approach would still require that such new products retain the basic nature and essential characteristics of the food, as reflected in the physical, chemical, and compositional requirements of existing standards.

GFI also notes that some modern dairy ingredients are now being produced (and will soon be produced at greater scale) using precision fermentation technology.[4] Just as the overwhelming majority of enzymes used in cheesemaking in the United States are now produced through microbial fermentation,[5] it may not be long before a significant portion of milk proteins themselves are produced using the same technology. Proteins produced through fermentation are chemically identical to their animal-derived counterparts.[6] Therefore, to the extent that modern dairy ingredients (like milk protein isolate) are permitted in standardized dairy foods, fermentation-produced milk proteins should similarly be permitted in those foods.

And the efficient production of milk proteins is just one example of fermentation technology's potential to feed the world's growing population. Countless other food ingredients may be

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[1] IDFA, Comment from IDFA on FDA's Multi-Year Nutrition Innovation Strategy, Docket No. FDA-2018-N-2381, 2 (Oct. 8, 2018), https://www.regulations.gov/document?D=FDA-2018-N-2381-1120.

[2] 70 Fed. Reg. 60751 (Oct. 19, 2005).

[3] FDA, Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry (Aug. 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-ultrafiltered-milk-production-standardized-cheeses-and-related-cheese-products; *see also* 82 Fed. Reg. 37815 (Aug. 14, 2017).

[4] *See* Lana Boandoim, *Perfect Day Partners With ADM to Make Milk Without Cows*, Forbes (Nov. 16, 2018), https://www.forbes.com/sites/lanabandoim/2018/11/16/perfect-day-partners-with-adm-to-make-milk-without-cows/.

[5] *See* 21 C.F.R. § 184.1685. Most cheese standards allow the use of enzymes of "microbial origin." *See generally* 21 C.F.R. part 133.

[6] *See, e.g.*, FDA, Chymosin Enzyme Preparation Derived From E. Coli K-12, 55 Fed. Reg. 10932, 10933–34 (Mar. 23, 1990).

produced by the same methods, including for example egg proteins (albumen),[7] collagen proteins (gelatin),[8] and omega-3 fatty acids.[9] To the extent that these fermentation-produced ingredients are identical to conventional ingredients in terms of their basic and essential characteristics, a horizontal standard might allow their substitution in standardized foods. For example, FDA might permit fermentation-produced egg albumen to be used in any food with a standard that includes egg white or dried egg white.

Allowing for standardized foods to include fermentation-produced ingredients that are identical to their animal- or plant-produced counterparts would also accord with FDA's longstanding statutory interpretation and approach to labeling foods produced using different methods or new technology: if a food or ingredient is not significantly different when produced by a new method, the exact method by which it is produced is not considered "material information" within the meaning of section 201(n) of the Federal Food, Drug, and Cosmetic Act.[10] The standardized food name and ingredients list would continue to provide all facts that are material to consumers.

II. Another Horizontal Approach: Clarifying That Common or Usual Names for Nonstandardized Foods May Include Standardized Terms with Qualifiers

The discussion above only accounts for situations where new food ingredients may be incorporated into standardized foods without any resulting material differences in the finished products. But standardized food recipes are sometimes modified in ways that *do* result in some material difference that can be measured. And still other foods may be produced from entirely new methods or ingredients to serve as effective substitutes for familiar standardized foods. These nonstandardized foods need descriptive names that consumers understand, and FDA has recognized that sometimes "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."[11]

GFI has proposed a regulation to codify existing FDA policy in a 2017 Citizen Petition.[12] Similar to FDA's regulation for foods named by use of a nutrient-content claim and a standardized term (codified at 21 C.F.R. § 130.10, which may itself be considered a "horizontal approach"), GFI's

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[7] *See, e.g.*, Elaine Watson, *Clara Foods Completes Series B, Joins Forces with Ingredion to Commercialize Egg Proteins… Minus the Chicken*, Food-Navigator USA (Apr. 25, 2019), https://bit.ly/34VXkcw.

[8] *See, e.g.*, Elaine Watson, *Geltor Teams Up with GELITA to Commercialize Animal-free 'Biodesigned' Collagen for Supplements*, Food-Navigator USA (Oct. 17, 2019), https://bit.ly/2O175zq.

[9] *See, e.g.*, GRAS Notice for Ulkenia DHA Oil Derived from Ulkenia Sp. Microalga, GRN No. 319 (Aug. 4, 2010), https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=319.

[10] *See, e.g.*, FDA, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992); FDA, Citizen Petition Denial Response, Docket No. FDA-2011-P-0723 (Nov. 19, 2015).

[11] 44 Fed. Reg. 3964–65 (Jan. 19, 1979) (quoting 38 Fed. Reg. 20702–03 (Aug. 2, 1973)).

[12] 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://www.gfi.org/images/uploads/2017/03/GFIpetitionFinal.pdf.

proposed regulation would permit nonstandardized foods to be labeled using standardized names with appropriate qualifying terms that inform consumers of the materially different nature of a new product.

As explained in GFI's petition, the proposed regulation aligns with longstanding history and practice. For example, a variety of nonstandardized foods — such as rye bread, cornbread, rice noodles, goat milk, or soy milk — do not conform to the identity standards for bread,[13] noodles,[14] or milk.[15] In each instance, the product name uses a standardized term together with appropriate qualifying language that informs consumers of the product's distinct nature or origin. Under this framework, if any food deviates from a standard of identity in some material way but is similar to a standardized food in terms of function or intended use, an appropriate qualifier can inform consumers about the material difference.

As the above examples show, this framework has been applied for decades without question or controversy. More recently, this framework has been used successfully to meet consumers' growing demand for a variety of new products. While innovative plant-based foods are some of the most visible examples of rapid growth, conventional meat and dairy producers have also begun to meet consumer demand by creating new variations on "traditional" foods. For example, Live Real Farms, a brand of Dairy Farmers of America, recently introduced a blended milk product labeled as "Dairy + Almond Milk Blend" — where both "dairy" and "almond" modify the word "milk."[16] Similarly, the major chicken producer Perdue has recently released a line of blended chicken products such as "chicken breast & vegetable tenders," which do not conform to USDA's standard for poultry tenders.[17] In each case, appropriate qualifying terms are used to modify standardized terms, resulting in names that directly and accurately inform consumers of the basic nature of the products.

FDA must recognize that Americans' dietary preferences have evolved considerably over the years, with consumers continually seeking greater variety. In particular, American consumers have shown increasing interest in consuming plant-based foods, such as plant-based burgers and plant-based milks. This growing interest is reflected in a 31% increase in plant-based food dollar sales in the past two years,[18] a consumer trend that is in line with public health objectives.[19]

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[13] 21 C.F.R. § 136.110.

[14] *Id*. § 139.150.

[15] *Id*. § 131.110.

[16] *See* Catherine Lamb, *Dairy Farmers of America Brand Launches First Ever Blended Milk Product: 50% Dairy, 50% Plants*, The Spoon (Aug. 19, 2019), https://thespoon.tech/dairy-farmers-of-america-brand-launches-first-ever-blended-milk-product-50-dairy-50-plants/.

[17] *See* Press Release, Perdue Foods, Perdue Foods Launches CHICKEN PLUS™ with Vegetable Nutrition New Chicken Nuggets, Tenders and Patties Meet Demand for Flexitarian Families (June 12, 2019), https://bit.ly/36ZfU5p.

[18] GFI, U.S. Plant-Based Market Overview (Apr. 21, 2019), https://www.gfi.org/marketresearch.

[19] Tao Huang et al., *Cardiovascular Disease Mortality and Cancer Incidence in Vegetarians: A Meta-Analysis and Systematic Review*, Ann Nutr Metab 2012;60(4):233-40. doi: 10.1159/000337301. Epub 2012 Jun 1 (noting that

Continuing to allow innovative producers to use qualified standardized terms on the labels of new foods will promote regulatory efficiency and flexibility and give consumers the opportunity to make more healthful food choices. Given that innovative producers are continually adding new foods to the marketplace,[20] it would not be feasible or efficient for FDA to evaluate and approve new standards of identity for every new food product that seeks to refer to a standardized term. An inflexible approach may also suppress truthful and non-misleading speech, while chilling innovation in new — and sometimes healthier and more sustainable — foods. Instead, as described in GFI's petition, FDA should simply clarify that nonstandardized foods may be named using standardized terms with qualifying language that informs consumers of the distinct nature of the food. This will be consistent with FDA's historical practice, consumers' expectations and demands, and FDA's goal of promoting industry innovation and flexibility.

Again, GFI thanks FDA for the opportunity to submit these comments and would welcome the opportunity to discuss further.

Sincerely,

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diets lower in animal-based foods and higher in plant-based foods result in lower mortality from certain causes such as heart disease, which is the leading cause of death in the U.S.).

[20] USDA & Econ. Research Serv., *New Products*, https://bit.ly/2KgmlHt (last updated Aug. 20, 2019).