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

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Docket No. FDA-1995-N-0062
Food Standards: General Principles and Food Standards Modernization

The Good Food Institute (GFI), an international 501(c)(3) nonprofit organization, appreciates the opportunity to submit these comments regarding food standards modernization. Together with the signatories below, GFI supports FDA's efforts to establish a modernized food standards framework that reflects the current marketplace, including significant changes in consumer preferences.

GFI's team of scientists, entrepreneurs, lawyers, and policy experts advocate for research into plant-based and cultivated meat in order to build a sustainable, healthy, and just food system. GFI encourages innovation in plant-based and cultivated foods and supports their availability to meet increasing consumer demand.

American dietary preferences have evolved considerably over the years with consumers continually seeking greater variety, including alternatives to foods that consist of or contain conventional ingredients like cow's milk, eggs, and other animal proteins. In particular, American consumers are increasingly interested in consuming plant-based foods including plant-based milks, like oat milk and hemp milk, and alternatives to conventional meat made from plant proteins or other non-animal¹ ingredients. Additionally, technological advancements are beginning to enable the production of some foods or ingredients (including animal meat and other ingredients of animal origin) by methods with lower environmental impact, such as the use of cell cultures or fermentation.

Recognizing these developments in consumer preferences and food science, GFI supports FDA's proposal to issue principles for evaluating new and existing standards of identity.² GFI also

¹ These may include proteins from fungi, algae, or cultivated microorganisms.

² FDA, Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period, 85 Fed. Reg. 10,107 (Feb. 21, 2020).

proposes herein an additional principle to be incorporated into the final rule. The proposed principles together provide a valuable framework to interested parties who may seek revision or elimination of certain food standards, and these principles would further ensure that new standards may only be established when reasonable and consistent with consumer expectations.

As GFI proposes below, the principles should account for both the possibility of innovation in the ways we produce our food, and the major role that nonstandardized foods play in the American diet, including many distinct foods with similar uses to standardized foods. (For this purpose, any food that does not conform to an existing standard of identity may be considered a nonstandardized food.) As FDA noted in reopening the proposed rule for additional comment, inflexible standards may sometimes “impede technological innovation.”³ Indeed, when innovative new ingredients or production processes preserve all the essential features of a standardized food, food standards should be flexible enough to permit the use of such new ingredients or processes, or should be easily and quickly updated to allow for such use. The principles also should require consideration of each standard in the context of the broader food supply, which often includes many functionally similar nonstandardized foods that are familiar to consumers. It is not always necessary to update a standard to include similar or innovative products — sometimes they may be considered (and marketed as) separate nonstandardized products, though the name of the new or distinct product may reference a standardized product in a manner that is not misleading to consumers.

I. GFI’s Proposed Principle

GFI proposes adding the following principle for establishing or revising a food standard:

The food standard should not unreasonably limit innovation in the ingredients or processes for producing the food, and it should have narrow application to the standardized food and not to similar but distinct foods. Where one standard cannot reasonably account for the full variety of similar foods, the name or names provided in the standard should not foreclose non-misleading uses of similar terms or qualified uses of such terms to refer to nonstandardized foods.

This proposed principle illustrates a common and necessary limitation of many existing food standards, as a few examples may show. Significantly, FDA’s standard for “bread”⁴ does not account for all breads readily available to Americans, nor does it purport to do so; it only accounts for loaves of bread weighing at least one-half pound and made with at least 97% wheat flour. That definition excludes rye bread, potato bread, cornbread, multigrain bread, several flatbreads, and many other breads from the standardized definition of “bread.” It would be impractical to incorporate every variety of bread into a single standard. Instead, the standalone

³ *Id.* at 10,108 (quoting FDA, Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214, 29,226 (May 20, 2005)).

⁴ 21 C.F.R. § 136.110.

term “bread” is used for the common bread described in the standard, while other breads are appropriately qualified (“_____ bread”) to distinguish these products for consumers.

Just as bread may be made from different grains, so may other staples such as noodles and pasta. Standardized “noodles” and “macaroni products”⁵ call for wheat flour (and in the case of “noodles,” egg products), but rice noodles, buckwheat noodles, and gluten-free spaghetti are just a few examples of nonstandardized noodles. Similarly, the standalone term “milk” was standardized for cow’s milk,⁶ but milks from other animals (such as goats or sheep) and plants (such as coconuts or almonds) are well-established food products with a long history of use. Standards for many other dairy products (like yogurts and cheeses) also require cow’s milk exclusively, but this does not prevent variants made from other animal milks from using “yogurt,” “cheese,” and other conventional dairy terms in their product names.

In some instances, it may be reasonable and appropriate for a food standard to be broadened to encompass foods that would otherwise be nonstandardized. For example, in promulgating the standard for “milk,” FDA did not initially intend for it to include flavored milks such as chocolate milk, noting that flavored milks could continue to be marketed as nonstandardized foods in absence of a standard for them. But in the final rule, FDA reconsidered this approach and ultimately included flavored milks within the standard for “milk” by specifying optional “characterizing flavoring ingredients” in that standard.⁷ In that instance, flavored cow’s milk was easily accounted for within the standard for milk, but other nonstandardized milks (such as goat’s milk, buttermilk, or coconut milk) could not reasonably be incorporated into the standard in the same way.

As these examples show, food standards play a limited role in the broader food supply. The decision of whether to create or revise a food standard should include careful consideration of this larger context; this is the purpose behind GFI’s proposed principle. In many instances, nonstandardized variants are common and familiar to consumers, and these nonstandardized foods are optimally named in a manner that references a standardized food but makes clear that they are something different.⁸ In such cases, it is unnecessary to account for these variants in the food standard — indeed, an expectation that such variants must be specified in a standard could impede innovation.

⁵ 21 C.F.R. §§ 139.150, 139.110.

⁶ 21 C.F.R. § 131.110.

⁷ FDA, Milk & Cream, 38 Fed. Reg. 27,924, 27,925 (Oct. 10, 1973).

⁸ Elsewhere, GFI has proposed a unifying regulation for the naming nonstandardized foods. 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/3ai4o5w>. The principle proposed here is intended to complement that approach by requiring the consideration of a standard’s impact on the broader category of similar or related foods, and whether such other foods should be incorporated into any standard.

By contrast, where potential nonstandardized variants cannot be described easily to consumers, incorporation of such variants into a standard may be the best approach. For example, the standard for milk chocolate requires the inclusion of dairy ingredients from cow's milk.⁹ A chocolate that is made with almond milk instead of cow's milk might reasonably be called "almondmilk chocolate," and incorporating a variation like this into the standard for milk chocolate is unnecessary because any consumer would know that it is a distinct product. If, however, a food producer were to make chocolate with an innovative dairy ingredient such as milk protein isolate or ultrafiltered milk, it would not comport with the standard for "milk chocolate," nor would there be any other straightforward way to name the product in a manner clear to consumers. Further, the product might be chemically and organoleptically indistinguishable from ordinary milk chocolate, having all the essential characteristics but still not meeting the standard due to use of a novel ingredient. In such a circumstance, revising the standard to account for innovative new ingredients is the most logical approach, and as discussed next, follows from the full set of proposed principles.

II. Revisions of Standards to Reflect Innovative Ingredients

The third principle in the proposed rule is that a food standard "should reflect the essential characteristics of the food."¹⁰ These essential characteristics "define or distinguish a food or describe the distinctive properties of a food."¹¹ Under this principle, standardized foods are often defined by ingredients or compositional characteristics. Further, in the sixth principle, FDA writes:

The food standard should permit maximum flexibility in the technology used to prepare the standardized food so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality or safety, of the food. The food standard should provide for any suitable, alternative manufacturing process that accomplishes the desired effect, and should describe ingredients as broadly and generically as feasible.¹²

The principles' emphasis on maximum flexibility in technology and broad or generic ingredients would account for common ingredients produced by new methods. For instance, some ingredients are now being produced (and will soon be produced at greater scale) using precision fermentation — using microbes or other cell cultures to express specific proteins. Just as the overwhelming majority of enzymes used in cheesemaking in the United States are already

⁹ 21 C.F.R. § 163.130.

¹⁰ FDA, Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214, 29,235 (May 20, 2005).

¹¹ *Id.*

¹² *Id.*

produced through microbial fermentation,¹³ it may not be long before a significant portion of the milk proteins themselves are produced using the same technology.¹⁴ Proteins can be produced through fermentation that are chemically identical to their animal-derived counterparts, and ingredients derived from such proteins may thus share all the basic and essential characteristics of certain conventional ingredients.¹⁵ Where standards call for milk proteins or milk solids, for example, fermentation-derived milk proteins may reasonably be permitted in those foods. Where necessary, some standards may also need to be revised to account for these new sources of dairy ingredients.

And the efficient production of milk proteins is just one example of fermentation technology's potential to satisfy consumers' demand for variety. Countless other food ingredients may be produced by the same methods, including egg proteins (albumen),¹⁶ collagen proteins (gelatin),¹⁷ and omega-3 fatty acids like EPA and DHA that have historically been sourced from fish oil.¹⁸ And innovations in efficiently producing animal proteins are not limited to fermentation. Other new technologies that produce food ingredients historically derived from animals may continue to emerge, and FDA will want to ensure that standards are inclusive of the ingredients produced with such innovative technologies. To the extent that ingredients produced through fermentation or other novel technologies share the basic and essential characteristics of conventional ingredients, it would be consistent with the proposed principles to revise applicable standards to allow these new ingredients. 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 ingredients that share the essential characteristics of their conventional animal- or plant-produced counterparts but are produced in new ways 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,

¹³ 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.

¹⁴ See, e.g., Perfect Day, GRAS Notice for Non-Animal Whey Protein from Fermentation by *Trichoderma reesei*, GRN No. 863 (Mar. 29, 2019), <https://bit.ly/2wOmL4w>.

¹⁵ See, e.g., FDA, Chymosin Enzyme Preparation Derived From *E. Coli* K-12, 55 Fed. Reg. 10,932, 10,933–34 (Mar. 23, 1990).

¹⁶ See, e.g., Elaine Watson, *Clara Foods Completes Series B, Joins Forces with Ingredient to Commercialize Egg Proteins... Minus the Chicken*, Food-Navigator USA (Apr. 25, 2019), <https://bit.ly/34VXkcw>.

¹⁷ 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>.

¹⁸ See, e.g., Lonza, GRAS Notice for *Ulkenia* DHA Oil Derived from *Ulkenia* Sp. Microalga, GRN No. 319 (Jan. 6, 2010), <https://bit.ly/2Vhwaeg>.

Drug, and Cosmetic Act.¹⁹ The standardized food name and ingredients list would continue to provide all facts that are material to consumers.

III. Conclusion

As consumers' dietary preferences continue to evolve, it is critical that food standards of identity do not interfere with or limit innovation. Food standards cannot reasonably account for the full variety of similar foods, nor should food standards be so inflexible as to include only conventionally produced ingredients. FDA's principles should account for the full variety of foods, including nonstandardized foods named with a standardized term paired with a qualifier. Further, standards should be readily adaptable to allow for new production technologies, such as fermentation technology. Both of these suggestions are consistent with consumer expectations, FDA's goal of supporting innovation, and the reality of the marketplace today.

GFI thanks FDA for the opportunity to submit these comments. We appreciate your efforts to support industry innovation and flexibility to the benefit of consumers. Please let us know if we can be of assistance in any way.

Sincerely,



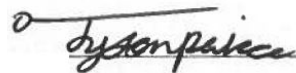
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¹⁹ See, e.g., FDA, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992); FDA, Petition Denial, FDA to Center for Food Safety, Dkt. No. FDA-2011-P-0723 (Nov. 19, 2015).



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