



National Milk Producers Federation

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Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
California Dairies, Inc.
Cayuga Marketing
Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Ellsworth Cooperative Creamery
FarmFirst Dairy Cooperative
First District Association
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers
Maryland & Virginia Milk Producers Cooperative Association
Michigan Milk Producers Association
Mid-West Dairyman's Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Association
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.

July 20, 2020

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

Re: Docket No. FDA-1995-N-0062 (formerly 1995N-0294), Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period

Dear Sir or Madam:

These comments are submitted by the National Milk Producers Federation (NMPF) in response to the Food and Drug Administration's (FDA) reopening of the comment period on the proposed rule entitled "Food Standards; General Principles and Food Standards Modernization. NMPF was organized in 1916 to provide a forum for dairy producers and the cooperatives they own to participate in public policy discussions. NMPF advocates policies to Congress, U.S. and foreign government agencies, industry organizations, the news media, and the public.

NMPF has long been a supporter of the standards of identity. Standards of identity are central to consumers' perception of products, ensuring the product has the ingredients and nutrition they expect. A main function of these standards, which was acknowledged by FDA in 2005, is that they save consumers a considerable amount of time by not forcing them to engage in extensive reviews of ingredient statements and Nutrition Facts panels for every food they buy. Without the level of reassurance afforded by standards of identity for foods with similar composition and attributes, but marketed by a variety of competing firms, an average shopping trip could take hours to complete. Even under the best of shopping conditions, this is a burden for many busy consumers, but in the time of COVID-19, it has also become a very real health concern.

Overall, NMPF is supportive of the proposed action FDA is taking, which is listed as option #2 on page 29227 in the 2005 proposed rule. The proposed action has two primary components: (1) The establishment of a set of principles that FDA will use when assessing food standards, and (2) a statement of the system by which FDA intends to revise, eliminate, or establish standards in response to petitions submitted by external parties or on FDA's own initiative.

We believe option #2 is the correct option and concur with FDA's assessment of the benefits, which are reprinted below.

"Benefits. One benefit of establishing a set of principles for assessing food standards is that it simplifies our assessment of standards.

First, it eliminates the need for us to develop and explain the basis for accepting or rejecting proposed changes to standards in a piecemeal fashion. Establishing principles ensures that we use a consistent and systematic approach when assessing standards.

A second benefit is that the principles apprise external parties of the framework we intend to use when assessing standards, thereby reducing the costs for external parties to petition us to change standards. In the absence of principles, external parties would need to spend time reviewing past rulemakings to piece together the factors we consider relevant in assessing standards. Also, in the absence of established principles, external parties may expend resources developing petitions that we would be unable to accept, and we would expend resources evaluating such petitions. If the principles allow external parties to present more acceptable petitions, then we will be able to act on the petitions more quickly and make necessary changes to the standards regulations more quickly. This means that benefits for consumers and industry will take place more quickly than would otherwise have been the case.

A third benefit is that establishing the set of principles specified in this proposed rule ensures that we assess standards with respect to their ability to reduce consumers' search costs, while also reducing the likelihood that standards will impose unnecessary costs, or reduce competition and thereby increase prices¹."

The 13 stated principles to be used to revoke, revise or establish new standards of identity provide a framework with which industry can expect FDA to handle updating the standards of identity, allowing for greater transparency and trust between the agency and industry partners. We applaud FDA's efforts in attempting to make this a collaborative effort.

NMPF supports the submission of petitions by industry for reviewing, updating or implementing new standards, as long as they are in line with the principles laid out in this proposed rule. Furthermore, we could not agree more with FDA's point about the need for documentation supporting claims of interest groups about consumer expectations or beliefs when requesting a change to a standard of identity. FDA also states its hope for collaboration among industry on submitted petitions. NMPF has stated many times that no changes should be made to individual standards of identity without consensus among the affected industry participants.

However, NMPF also has concerns that given the lack of enforcement of the standards already in place, any moves towards "modernization" will prove of limited value. While the general principles are largely sound and unobjectionable, we question the utility of

¹ <https://www.federalregister.gov/documents/2005/05/20/05-9958/food-standards-general-principles-and-food-standards-modernization>

setting abstract principles for standards of identity if FDA does not intend to enforce standards where they already exist. We respectfully suggest that completing its analysis of comments received on dairy names last year (Docket No. FDA-218-N-3522), and then providing definitive guidance on the proper use of these names, should be a higher priority for FDA than re-opening a proposed rule that has lain dormant since 2005. More specifically, if FDA sincerely believes the employment of general principles is a sound and logical approach, the agency needs to acknowledge that the marketing of plant-based imitation dairy products utilizing standardized dairy terms is inconsistent with virtually every one of the principles. We illustrate this point in what follows. Much of the evidence that consumers are confused and misled by imitation dairy labels and marketing is derived from two large consumer surveys conducted by IPSOS in response to the dairy names docket. Attached to this letter are comments submitted to that docket last year by the National Dairy Council, a research and promotion organization overseen by the U.S. Department of Agriculture. The comments provide ample evidence from the IPSOS surveys that many Americans are misled and confused by the way dairy imitators are marketed. NDC's comments about how consumers perceive imitation products is objective, dispassionate – and devastating to the claims of those who profit from the sale of plant-based imitators. We do not repeat all the survey results in these comments, but commend them to FDA's attention as the agency considers the general principles.

The proposed general principles, and NMPF's comments on each, follow.

1. Promotes honesty and fair dealing in the interest of consumers.

Misleading, confusing names and claims (whether direct or indirect) are the very opposite of honesty and fair dealing, yet dairy imitators have benefitted handsomely from such conduct for years. It is simply not honest to claim or imply that plant-based beverages are more nutritious than dairy milk when they are clearly less so. It is not in the interest of consumers when the marketing of products creates confusion and misunderstanding – especially among consumers who exclusively or primarily purchase imitations, as documented in the NDC comments. For example, 55 percent of exclusive plant-based buyers viewed their beverages as a good protein source, while only 38 percent said that of real milk. But the reality is the opposite: Almond “milk”, which accounts for three-quarters of plant-based beverage sales, has only 2 grams of protein and is therefore not a “good” source in the sense of providing at least 10 percent of the Daily Value of protein. Real dairy milk has 8 grams of protein and is a good source. A recent article from the journal, *Nutrients*, entitled “*Got Mylk? The Emerging Role of Australian Plant-Based Milk Alternatives as A Cow's Milk Substitute*”² concluded:

“This cross-sectional survey of plant-based milk alternatives found substantial variability in the nutritional content of plant-based milk alternatives compared

² *Nutrients* **2020**, *12*, 1254; doi:10.3390/nu12051254

with cow's milk, supporting previous works from other geographical locations. Based on the nutrients we examined, legume-based (pea and soy) milks were the most mandatory fortification, prudent consumer selection of appropriately formulated products, regardless of the ingredient categories, is vital to avoid potential issues with reduced nutrient intake associated with substitution of cow's milk. This includes not only nutritional inadequacies commensurate to lower intake and/or bioavailability but also the casual consequences linked to displacement of dietary energy. Due to the high proportion of consumers selecting plant-based milk alternatives for non-dietary reasons, it is recommended that current legislations implement further advisory labelling, particularly for older women and adolescents. Additional formulations should target these age groups, taking into account protein content and quality, among adequate quantities of micronutrients, such as zinc and calcium. Nonetheless, in an age of plant substitution over animal products, prospective gaps in the nutritional value of plant-based milk alternatives must not be overlooked, particularly where bioavailability remains equivocal."

The authors viewed the issue to be so problematic that they suggested "advisory labeling" (aka a "warning label") and the publication Food Navigator wrote about it in an article entitled "*Disconcerting Discovery: Study shows plant-based milk lacking in calcium, protein, vitamins.*" This is a development that hardly reflects the promotion of honesty and fair dealing in the marketplace and the widespread misuse of standardized food terminology is clearly the root cause of the problem.

2. Describes the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers' expectations of product characteristics and uniformity.

In the marketing of plant-based dairy imitators, consumers are, in fact, "misled by the name of the food." Simply put, these imitation products are not milk, but they say that they are. Such products use the term "milk" in blatant violation of FDA's standard of identity for milk. Nor is the violation limited to a single dairy product category - plant-based products on the market also use standardized terms such as yogurt, cheese and butter.

The 2005 proposed rule stated:

"Under the proposed principles, a standard must reflect the basic nature of a food and its essential characteristics. Standards may accommodate certain variations of a food, provided those variations preserve the basic nature of the food and its essential characteristics. For example, shredded, grated, or diced forms of cheese would be permitted because they do not alter the basic nature of the food. However, this restriction may also generate certain costs. For example, if we did

not require that standards preserve the basic nature of the food and its essential characteristics, the information the standards provide for consumers might be reduced. Without such restrictions, a particular standard might be able to cover more diverse compositions of a particular food under a single name and thus address a greater variety of consumer health and dietary needs and preferences. Under this alternate approach, a “cheese” could be made with non-milk ingredients to be free of lactose or milk protein, and “bread” could be made using soy flour to improve the protein composition of the food. Under the proposed principles, such variations of these foods would not be permitted because they do not preserve the basic nature of these foods consistent with consumer expectations and beliefs. Such foods, however, can be marketed using non-standardized names (although we recognize that, in some cases, having to market under a non-standardized name may be costly and, therefore, may create a disincentive to create such foods). To the extent the proposed general principles lead to an increase in the number of foods covered by standards, the costs described here and other costs associated with standards will increase³.”

We agree that a “cheese” made with non-dairy ingredients would not reflect the basic nature of a food and its essential characteristics and is not consistent with consumer expectations. We also agree that such products can be marketed using non-standardized names and are in fact marketed in that fashion in most nations around the globe without any difficulty. In fact, many are already marketed in that fashion in the United States with seemingly reasonable success.

3. Reflects the essential characteristics of the food—or those that define or distinguish a food or describe the distinctive properties of a food and that may contribute to achieving the food’s basic nature or may reflect relevant consumer expectations of a food product.

An essential characteristic of milk is that it is a lacteal secretion from mammals. This essential characteristic is clearly not found in plant-based imitation products. Typically, the first ingredient among the long list of many ingredients found in these products is water. Consequently, they are largely nutritionally, organoleptically, and functionally lacking when compared to real milk.

Science increasingly recognizes the importance of the dairy food matrix- dairy foods are not simply the sum of their parts. Standards of identity establish clear process and composition differences, for example, between different types of cheese. The role of fermentation in products such as cheese and yogurt is also important. Protein quality differs as well, with real dairy foods providing complete, high-quality protein, in contrast to plant-based proteins, which are incomplete, providing only some of the

³ <https://www.federalregister.gov/documents/2005/05/20/05-9958/food-standards-general-principles-and-food-standards-modernization>

essential amino acids. And even though imitation products are frequently fortified with nutrients such as calcium that occur naturally in real dairy, health professional societies making recommendations for children's beverages in 2019 did not recommend plant-based beverages because the bioavailability of the fortified nutrients is not known. These societies include the Academy of Nutrition and Dietetics, the American Academy of Pediatric Dentistry, the American Academy of Pediatrics, and the American Heart Association.

4. Ensures food does not appear to be better or of a greater value than it is. May be used as a vehicle to improve the overall nutritional quality of the food supply.

If "value" includes nutritional value, then the marketing of plant-based beverages is inconsistent with this principle. NDC's comments clearly show, based on consumer responses, that there is widespread misunderstanding of imitators' nutritional value. Among consumers who exclusively purchase plant-based beverages, for example, a majority perceive them as having either more nutrients than, or the same amount as, real milk, even though this is untrue, as the NDC comments document. With respect to almond milk, for example, 79 percent of exclusive plant-based milk buyers say that their products have either the same amount of protein as milk, or more. The corresponding percentages who believe that plant-based products have more vitamins and key nutrients (calcium, potassium), respectively, were 86 percent and 74 percent.

5. Contains clear and easily understood requirements to facilitate compliance by food manufacturers.

NMPF concurs with this principle, but urges improved dialogue between the Agency and industry in support of its implementation. For example, NMPF requests that when clarification of provisions in existing standards is required by industry, responses by FDA to such requests be provided promptly to avoid potential and unnecessary confusion, delay, and expenditure of resources. Such delays are neither in the interest of FDA or industry.

6. Permits maximum flexibility in the technology used to prepare the food provided the technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality or safety, of the food. Provides for any suitable, alternative manufacturing process that accomplishes the desired effect, and describes ingredients as broadly and generically as feasible.

NMPF generally concurs with this principle, but cautions against the use of overly broad ingredient descriptors that may shortchange consumers understanding of the true nature of the ingredient. For example, terms like "plant protein" should be prohibited since the specific source of the protein is not disclosed.

7. Harmonizes with international food standards to the extent feasible.

It is widely recognized that regulatory agencies in other countries apply stricter rules for the labeling of dairy imitators and vigorously enforce them -- unlike what is currently experienced in the United States. NMPF urges FDA to consider the implementation of labeling regulations found in Canada, the European Union and elsewhere, which permit the very same kinds of products to be freely marketed, but with forthright rather than deceptive nomenclature.

8. Is simple, easy to use, and consistent among all food standards. Includes only those elements that are necessary to define the basic nature and essential characteristics of a particular food, without unnecessary details.

The goals of simplicity, ease of use and consistency cannot be achieved if companies and consumers are either confused or misled about what common terms mean. But as the NDC comments amply document, consumers are in fact confused and misled when it comes to many standardized dairy product imitators. Not only do many consumers think plant-based dairy imitators are more nutritious than they really are, but according to a survey by the International Food Information Council, up to a quarter of consumers either think plant-based “milk” contains cow’s milk, or are not sure.

9. Allows for variations in the physical attributes of the food. Where necessary to provide for specific variations in the physical attributes of a food within the standard, variations are consolidated into a single food standard.

As proposed, NMPF cannot support this principle. In the absence of a clear understanding of FDA’s position on the use of defined terms, the degree of permissible “variations in the physical attributes of the food” remains unknown. This uncertainty contributes to confusion in the marketplace, a situation obviously at variance with this principle. However, NMPF believes that standards may accommodate certain physical variations of a food, provided those variations preserve the basic nature of the food and its essential characteristics. For example, shredded, grated, or diced forms of cheese would be permitted because they do not alter the basic nature of the food.

10. Incorporates general requirements that pertain to multiple food standards of a commodity group into general regulatory provisions that address the commodity group whenever possible.

NMPF generally concurs with this principle, but cautions against overextension of the principle and wider interpretation of what is meant by “commodity group”. For example, NMPF can likely support the extension of general regulatory provisions in the commodity group encompassing cheese standards, but due to possible unique circumstances, such extension may not be appropriate to all dairy commodity standards.

11. Considers other relevant regulations. Any specific requirements for foods intended for further manufacturing are incorporated within the reference standard rather than provided as a separate standard.

NMPF concurs with this principle and offers no further comment.

12. Provides terms that can be used to name a food and allows terms to be used in any order that is not misleading to consumers.

Once again, the use of defined terms like “milk” on labels of products that are not milk is “misleading to consumers” regardless of the “order of terms.” Defenders of the imitation products assert that because “milk” is modified by a term like “almond,” consumers are not misled. This is false. The previously cited IFIC survey in our comment on principle 8 above showed that approximately one out of four people either think that the imitators do in fact contain cow’s milk or are not sure.

13. Names of ingredients and functional use categories in a food standard should be consistent with other food standards and relevant regulations in this chapter, and, when appropriate, incorporate current scientific nomenclature.

Consumers are confused about both the ingredients and the functionality of plant-based dairy imitators, as documented in the NDC comments. For example, more than half of exclusive plant-based beverage buyers said that they were “substitutable for cooking and baking.” Similarly, consumers think the ingredients in plant-based beverages make them healthier and more nutritious than they actually are. Since the products do not themselves have a standard of identity, consumers cannot have expectations of consistency in ingredients.

Lastly, we would like to emphasize that NMPF is not completely supportive of the previously opened docket, “Horizontal Approaches to Food Standards of Identity Modernization.” As stated in our comments, NMPF worries about the implications horizontal standards may have on the quality and nutritional value of food and find them to be unnecessary. For example, food companies have still been able to create new and innovative products with the same standards in place. A better approach, which is outlined in this proposed rule, is that general principles would incorporate general requirements that pertain to multiple food standards of certain commodity groups into general regulatory provisions that address the commodity group whenever possible and updating that group together. To reiterate our previous example, FDA could create a standard that applied to all standards of identity involving cheese. This would simplify the current standards of identity without running the risk of a manufacturer being able to use a horizontal standard meant for one food on another.

NMPF appreciates FDA’s efforts in trying to streamline and update the standards of identity, but urges proceeding with caution. Furthermore, NMPF firmly believes that the

lack of enforcement of standards of identity, whether “modernized” or not, is a significantly larger issue and one that is causing consumers far greater harm through misperceptions and the illegal use of standardized terms. We appreciate the opportunity to submit these comments and look forward to continuing to work with FDA on this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen". The signature is written in a cursive style with a prominent vertical stroke on the left side.

Clay Detlefsen
Senior Vice President, Regulatory Affairs & Staff Counsel