



## National Milk Producers Federation

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Agri-Mark, Inc.  
Associated Milk Producers Inc.  
Bongards' Creameries  
Burnett Dairy Cooperative  
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  
Mount Joy Farmers Cooperative Association  
Northwest Dairy Association  
Oneida-Madison Milk Producers Cooperative Association  
Prairie Farms Dairy, Inc.  
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Southeast Milk, Inc.  
Tillamook County Creamery Association  
United Dairymen of Arizona  
Upstate Niagara Cooperative, Inc.

February 16, 2023

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

### **RE: Docket No. FDA-2016-D-2335**

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) offers these comments in response to the proposed rule entitled "Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy'," published in the *Federal Register* September 29, 2022. 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.

The Food and Drug Administration (FDA) seeks to update the requirements for "healthy" claims to reflect newer science, and in particular the 2020-2025 Dietary Guidelines for Americans (DGA). The DGA recommends three daily servings of dairy for all Americans age 2 and older in the Healthy U.S. and Healthy Vegetarian dietary patterns, advises the introduction of cheese and yogurt as early as 6 months, and recommends whole milk from 12-24 months (1). Encouraging more consumers to consume recommended amounts of dairy would help Americans meet DGA recommendations for healthy, nutrient-dense foods.

Although alignment of "healthy" claims with the DGA is theoretically sound, a focus solely on current DGA recommendations (which are likely to be at least five years old by the time FDA finalizes and implements the present rulemaking) risks ignoring the best and newest science. It is widely accepted that past editions of the DGA badly missed their mark by placing strong emphasis on total fat, whereas we now know that total fat is not a relevant parameter, and more recent editions have not included recommendations on total fat.

FDA recognizes this development by proposing to eliminate total fat from the thresholds for “healthy” claims, but continues to maintain a threshold for saturated fat. The agency is surely aware of the vigorous debate about whether saturated fat is harmful, and how excessive carbohydrate intake may be cause for greater concern. This debate is especially salient for dairy, since many studies (as described later in these comments) show that dairy foods are beneficial or neutral at all fat levels. In particular, the dairy food matrix is increasingly viewed as having properties that distinguish dairy fats from other sources of saturated fat.

In fact, the Departments of Health and Human Services and Agriculture have implicitly recognized newer scientific findings in the proposed questions to be explored by the 2025 Dietary Guidelines Advisory Committee, one of which is: “What is the relationship between food sources of saturated fat consumed and risk of cardiovascular disease?” Obviously, many studies specific to dairy foods should be examined in the context of answering this question.

In this context, FDA’s proposed rule could unnecessarily restrict “healthy” claims on most dairy foods, even if the next DGA finally recognizes the obvious – that dairy foods are healthy at all fat levels, including foods with modest amounts of added sugars to enhance palatability. Because there will always be a lag between FDA’s rulemaking and the most recent DGA, the agency needs a way to encourage the consumption of healthy foods such as dairy. As discussed later in these comments, the answer is to recognize current science and permit “healthy” claims for milk, cheese and yogurt at all fat levels including those with modest amounts of added sugar.

### **Dairy foods supply essential nutrients and protect against chronic disease risk**

Dairy foods are essential to maintaining healthy dietary patterns.

- Milk is a good or excellent source of 13 essential nutrients (2).
- These nutrients include three of four nutrients of concern for underconsumption identified by the DGA – vitamin D, calcium and potassium (1). For children 2-18 years old, milk is the top dietary source of all three of these nutrients, and it is the top source of calcium and vitamin D for both children and adults (3).
- Dairy foods are affordable across income groups: Milk and dairy foods are the least expensive dietary sources of calcium and vitamin D in the American diet, and milk is among the three least expensive sources of potassium (4).

Research has associated dairy foods with multiple health benefits.

- A large and growing body of evidence published in recent decades shows that dairy consumption, regardless of fat level, may have a protective effect on CVD risk and in any case does not increase risk (7, 11).
- Dairy foods help children and adolescents to achieve peak bone mass (6).

- Dairy is linked to healthy blood pressure in adults and adolescents, according to multiple studies, including recent systematic reviews and meta-analyses (7, 8).
- Consuming dairy foods is associated with lower risk of T2D (7).
- Dairy intake is inversely associated with the risk of cardiovascular disease (CVD) in numerous studies, and the association also holds with cheese (9).
- Dietary patterns that include low-fat and fat-free dairy are associated with lower risk of all-cause mortality, cardiovascular mortality, type 2 diabetes (T2D) and certain cancers, according to the 2020 Dietary Guidelines Advisory Committee (5).

### **Americans under-consume dairy and “healthy” claims could encourage more adequate consumption**

About 90 percent of the U.S. population under-consumes dairy. Average daily consumption is only about 1.5 servings. Moreover, there are disparities related to race and ethnicity: Non-Hispanic Black and Asian children and adults consume the least, compared to other groups (10).

The ability to make “healthy” claims on dairy foods holds the potential to educate consumers about dairy’s nutritional value and could improve consumption closer to DGA recommendations. In the proposed rule, FDA recognizes dairy’s prominence in DGA recommendations and evinces a desire to allow forms of dairy favored in the DGA to bear “healthy” claims.

### **Dairy is healthy at all fat levels and with moderate amounts of added sugars**

A large and growing body of evidence published in recent decades shows that dairy consumption, regardless of fat level, may have a protective effect on cardiovascular disease (CVD) risk and in any case does not increase risk (7, 11). The authors of a systematic review on this subject stated that “the recommendation to focus on low-fat in place of reduced- or full-fat dairy is currently not evidence-based (7).”

- A 2021 meta-analysis of 55 prospective cohort studies found that total dairy consumption was associated with lower risk of coronary heart disease (CHD), stroke and hypertension (12).
- A 2021 systematic review and meta-analysis found that total, full-fat and low-fat dairy had no association with CHD or ischemic stroke (13).
- Three other recent meta-analyses of prospective cohort studies reported that dairy consumption was *inversely* associated with CVD risk and CVD mortality or was neutral with respect to CHD risk (14, 15, 16).
- A 2016 systematic review of meta-analyses concluded that total dairy consumption was not associated with CVD risk (17).
- In 2017, a meta-analysis of 29 cohort studies with almost 1 million participants reported no association between total dairy consumption, including full-fat varieties, and the risk of CVD and CHD (18).

Flavored milk and yogurt do contain added sugars, but as the American Academy of Pediatrics has pointed out, there is a balance to be struck between limiting added sugars and promoting nutrient-rich foods. The AAP's policy statement supports the addition of small amounts of sugars to nutrient-dense foods like milk in order to increase children's consumption (19). A study published last year used national dietary intake data to show that the nutritional benefits of flavored milk outweighed the added sugar content (20). The 2020 DGA states explicitly that "sweetened milk and yogurt products may be included in a healthy eating pattern" within overall calorie limits when amounts of sweeteners and moderate (1).

### **FDA should consider authorizing "healthy" claims for more dairy foods**

NMPF recognizes FDA's proposal to modestly increase the allowable portion of the Daily Value (DV) for saturated fat to 10 percent in the case of dairy products. This will permit unflavored low-fat milk to bear a "healthy" claim. It is also consistent with meeting the dietary patterns recommended by the DGA, since a key recommendation is to keep saturated fat content in the total diet below 10 percent of calories (1).

As noted above, dairy foods have been increasingly associated with protective or neutral effects on chronic disease risk. In light of this fact, NMPF urges FDA to treat dairy foods (milk, cheese and yogurt) as a whole, similar to the agency's proposed approach to raw fruits and vegetables, i.e., permit healthy claims for milk, cheese and yogurt without additional criteria. Like fruits and vegetables, dairy is recommended by the DGA but under-consumed by a large majority of the population. (Indeed, dairy is less adequately consumed than fruits and about equally under-consumed as vegetables (1).) The protective effect of dairy with respect to chronic diseases appears to be associated with the dairy food matrix, more so than with levels of individual nutrients, bolstering the argument for a blanket authorization for milk, cheese and yogurt to make healthy claims.

If FDA does not adopt this view, NMPF urges the agency to include greater flexibility in with respect to criteria for saturated fat, sodium and added sugars in dairy products as a means of increasing consumption of the important nutrient package provided by dairy.

### **FDA's proposed move to a food group approach supports flexibility for dairy**

FDA proposes moving to a food group approach, consistent with recent editions of the DGA, whereas existing rules for "healthy" claims focus on specified levels of desirable nutrients. NMPF agrees that the proposed rule is more consistent with the DGA's general approach, but we would make two points. First, the fact that milk is a good or excellent source of 13 essential nutrients strengthens our position in favor of a blanket authorization for dairy products. Specifically, milk, cheese and yogurt as called out in the DGAs for their health benefits, should be able to make "healthy" claims, similar to the proposal for fruits and vegetables, which also supply many essential nutrients. Second, the reliance on food groups in place of favorable nutrients exists in some tension with the proposed rule's maintenance of highly specific thresholds for avoidance nutrients. FDA's recognition that single nutrients

are not the sole focus of “healthy” claim criteria would argue in favor of what we suggested above, namely, claim eligibility for dairy foods at all fat levels, or failing that, additional flexibility for dairy products (milk, cheese and yogurt) with respect to the criteria for added sugars and sodium, given dairy’s unmatched profile of positive nutrients.

### **Plant-based beverages are not nutritionally equivalent to dairy**

Finally, NMPF urges FDA to take no actions which would imply that plant-based beverages are nutritionally equivalent to real dairy, since they are not.

This view is amply supported by nutrition science. The DGA state that beverages such as almond, rice, coconut or hemp “milks” are not nutritionally equivalent to milk and therefore not included in the dairy foods group (1). To the extent that FDA wants healthy criteria to reflect the DGA, it would be blatantly inconsistent with this goal to accord equivalence to highly-processed plant-based beverages that are, factually, not equivalent to milk.

There are real-world health consequences. The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) notes numerous adverse effects on young children when plant-based imitation milks are served, including failure to gain weight, decreased stature, kwashiorkor, electrolyte disorders, kidney stones and nutrient deficiencies (21).

Other prominent nutrition and medical groups also do not recommend plant-based milk imitators. These groups include the Academy of Nutrition and Dietetics (AND), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Pediatrics (AAP), and the American Heart Association (AHA) (22).

Finally, the Food and Nutrition Service (FNS), which operates the nation’s child nutrition programs, is clear in its judgment about dairy imitators: “Most commercial almond, coconut and rice beverages are not nutritionally equivalent to fluid milk.” Accordingly, beverages like these which are not nutritionally equivalent may not be credited toward reimbursements in the school meal programs (23).

NMPF recognizes the need for choices for individuals who are lactose-intolerant. Cheese and yogurt may be better tolerated than milk while providing many of the same nutrients – a consideration which strengthens our contention that FDA should consider a blanket claim authorization for all dairy foods. In addition, lactose-free milk is now widely available and is a good way for lactose-intolerant individuals to avoid digestive problems without sacrificing the essential nutrients in milk.

### **NMPF feels modifications are necessary to the proposed rule**

In summary, NMPF recognizes FDA is attempting to modernize the criteria for “healthy” claims. However, we feel modifications are necessary in order to permit more dairy products to make claims. Allowing claims for all milk, cheese and yogurt will increase the

chances that the claim rules will actually encourage consumers to consume more adequate amounts of dairy, in line with the DGA recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen". The signature is written in a cursive style with a long horizontal stroke at the end.

Clay Detlefsen, Esq.  
Senior Vice President,  
Environmental and Regulatory Affairs and Staff Counsel

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