National Milk Producers Federation

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April 26, 2017

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

(Submitted electronically: www.regulations.gov)

Re: Docket No. FDA-2016-D-2335, Use of the Term "Healthy" in the Labeling of Human Food Products

Dear Sir or Madam:

The National Milk Producer Federation (NMPF) is pleased to respond to your request in the *Federal Register* of September 28, 2016[1] for public comment on the term "healthy", generally, and as a nutrient content claim in the context of food labeling. NMPF appreciates the opportunity to provide information to the Food and Drug Administration (FDA) as the agency's nutrition labeling regulations are updated to reflect current federal dietary guidance and nutrition science.

When FDA announced the establishment of a docket to receive information and comments on the use of the term 'healthy' in the labeling of human food products, the agency also issued a guidance document[2] which stated that the agency will exercise enforcement discretion with respect to the requirement for a "healthy" food to be low in total fat, and with respect to the nutrients for which a good-source claim permits a "healthy" designation, effectively adding potassium and vitamin D to the existing nutrient list. Current requirements for use of "healthy" are laid out in FDA's regulations.[3]

[1] 81 FR 66562 ff

[2] Food and Drug Administration. Guidance for Industry: Use of the Term "Healthy" in the Labeling of Human Food Products. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm521690.htm

[3] 21 CFR 101.65(d)

1. Principles for "Healthy" Criteria and Executive Summary

As discussed below, NMPF encourages FDA to revise its regulations in line with the following key principles –

- FDA's criteria for "healthy" claims should be aligned with authoritative dietary guidance.
- Criteria must be drawn so that FDA can modify them without undue burden or delay as nutrition science evolves.
- General emphasis in the criteria should shift toward whole foods, but nutrient-based criteria remain important for some purposes.
- Foods recognized by authoritative dietary guidance as healthy, including those identified as nutrient-dense in the 2015-2020 Dietary Guidelines for Americans (DGA), as well as those food groups identified as under-consumed by the DGA, should be able to make a "healthy" claim without regard to other criteria in the current regulation.
- Consistent with the above principle, dairy foods should constitute a separate category in the regulations, as fruits and vegetables already do.
- Within the new dairy category, the reduced-fat forms of all dairy foods (as well as low-fat and fat-free forms) should be able to claim "healthy" status as long as they are a good source of one or more of the specified nutrients, without regard to criteria on total fat, saturated fat, cholesterol or sodium.
- Foods that otherwise meet criteria for "healthy" claims should not be prevented from making such claims because of the so-called "50 gram rule."
- If FDA chooses to add a criterion for added sugars, it should accommodate "healthy" claims for foods that contain no more than an amount recommended by an authoritative body such as the National Academies of Sciences, Engineering and Medicine (NASEM), which has recommended such levels for both flavored milk and yogurt.

2. Whether to Define the Term "Healthy"

Some have questioned whether the term "healthy" should be used on food packages at all, citing the potential for consumer confusion and other alleged problems. **NMPF believes that it is best for FDA to retain a definition of "healthy,"** but encourages FDA to modify it as recommended later in these comments.

First, any effort to bar the use of "healthy" on food labels would likely result in protracted litigation, given the number of products that presently use this claim. Regardless of the outcome of such suits, a lengthy period of regulatory uncertainty could lead to more consumer confusion, not less.

Second, there are ample standards that the agency can use in devising a rational template for making "healthy" claims. These standards and resources include the 2015-2020 Dietary Guidelines for Americans (DGA)[4]; the series of Dietary Reference Intakes (DRIs)[5] developed by the National Academies of Sciences, Engineering, and Medicine (NASEM); and the enormous published literature on the effects of foods and dietary patterns on nutritional outcomes and chronic disease risk, including recent research on the benefits of dairy foods. Because of the strong public interest in healthy foods and the available scientific resources, NMPF encourages FDA to continue to enforce regulations that define "healthy."

However, this recommendation comes with an important caveat. Nutrition science changes rapidly. Rigid regulations risk being perpetually out of date if they fail to keep up with the most recent relevant science. Indeed, FDA is implicitly acknowledging that this is the case in exercising enforcement discretion on total fat content.

Therefore, **NMPF strongly supports the concept that revised regulations should be structured so that FDA can make slight modifications to the exact criteria for use of a "healthy" claim as science evolves, without the need to go back through notice-and-comment rulemaking.** In NMPF's view, adequate

[4] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015 – 2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. http://health.gov/dietaryguidelines/2015/guidelines/.

[5] http://nationalacademies.org/hmd/activities/nutrition/summarydris/dri-tables.aspx

discretion should be provided in the regulatory text to allow the agency's criteria to keep pace with science. As described below, this flexibility is highly relevant to potential future claims for dairy foods, where science is rapidly evolving and increasingly appears to contradict long-held assumptions.

3. Dairy Foods and "Healthy" Claims

Milk and other dairy foods are widely recognized as nutrient-dense, healthy sources of key nutrients. The 2015-2020 DGA recommends increasing consumption of low-fat and fat-free milk, cheese or yogurt to support healthy eating patterns. Dairy foods make significant nutrient contributions to all the recommended DGA eating patterns, two of which include three daily servings for adults and older children and adolescents, while the third pattern includes two. Dairy's nutrient package includes nutrients under-consumed by most Americans—calcium, vitamin D and potassium—as well as high-quality protein, phosphorus, magnesium, zinc, vitamin B-12, vitamin A, riboflavin and choline.[6]

In addition to nutrient contributions, dairy foods have been recognized by the last two Dietary Guidelines Advisory Committees (DGAC) as contributing a reduced risk of serious chronic diseases. The 2010 DGAC wrote that dairy consumption was associated with a lower risk of cardiovascular disease (CVD) and type 2 diabetes (T2D) and, in adults, with lower blood pressure.[7] In addition to re-stating dairy's beneficial impact on CVD and T2D, the 2015 DGAC also noted benefits with respect to the metabolic syndrome and obesity.[8] As we explain further in the section entitled "Recent Science on Dairy Foods, Fat Levels and Health Outcomes," these benefits seem increasingly likely to be associated with all forms of dairy foods, not just low-fat or fat-free versions.

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[6] National Dairy Council. Science Brief: Whole and Reduced-Fat Dairy Foods. https://www.nationaldairycouncil.org/content/2016/science-brief-whole-and-reduced-fat-dairy-foods

[7] Dietary Guidelines Advisory Committee. 2010. Report of the 2010 Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, D.C.

[8] Dietary Guidelines Advisory Committee. 2015. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2015, to the Secretary of Agriculture and the Secretary of Health and Human Services. Washington, DC: U.S. Department of Agriculture, Agricultural Research Service.

Nevertheless, few dairy foods can make a "healthy" claim under current regulations, largely because of fat content (and, in the case of some cheeses, the impact of the FDA's so-called "50-gram rule"). Most dairy foods are not low in total fat or saturated fat (though some are). Dairy foods are, by contrast, good sources of several nutrients in both the FDA's current regulations and its new guidance document (vitamin D in the latter case).

4. Discussion of Criteria for Revising Regulations on "Healthy" Claims

As noted earlier in these comments, NMPF recommends that FDA use certain overarching principles to revise its definition of "healthy" with respect to foods generally, and to dairy foods in particular. Below we provide our rationale for each principle.

FDA's criteria for "healthy" claims should be aligned with authoritative dietary guidance. Under federal law, the DGA constitute the official dietary advice of the U.S. government. The DGA, in turn, benefit from the DRIs and other federal information resources. The leading role of the DGA provides a clear and compelling argument to eliminate the total-fat criterion from FDA's current regulations, as well as to add those nutrients of public health concern (i.e., vitamin D and potassium) that are not presently listed in the regulations.

General emphasis in the criteria should shift toward whole foods, but nutrient criteria remain important for some purposes. It is often said that people do not eat nutrients; they eat foods. At the same time, it is also a fact that some specific nutrients are significantly lacking in typical diets. Regulations that are built around whole foods, but still require the presence of certain nutrients in a "good-source" amount, will bring balance to FDA's approach.

In general, foods recognized by authoritative dietary guidance as healthy, including those identified in the DGA as nutrient-dense, and those food groups identified by the DGA as under-consumed should be able to make a "healthy" claim without regard to other criteria in the current regulation. This principle flows logically from the one above. Alignment with the DGA

should mean that consumers can use "healthy" as a signpost to consuming a diet that is more consistent with current recommendations. Where the DGA text identifies foods as healthy, the presumption should be that those same foods can also call themselves healthy.

Consistent with the above principle, dairy foods should constitute a separate category in the regulations, as fruits and vegetables already do. According to the DGA, dairy foods are underconsumed by Americans to about the same extent as vegetables, and to a greater degree than fruits.[9] For comparison, according to the 2015 DGAC report, the percent of all Americans over one year of age consuming recommended amounts of dairy (or greater) is well below 20%, and the percentage consuming recommended vegetable servings or greater is likewise below 20%. Slightly more than 20% of Americans one year and over consume at or above recommended fruit serving levels. Likewise, when evaluating the proportion of the mean intake of various food groups relative to their recommended levels, the percentage for dairy is comparable to that for fruits and vegetables (~50-60%).

Therefore, dairy foods constitute a food group for which FDA should encourage healthy claims to provide much-needed guidance to consumers. A separate regulatory category is appropriate for this purpose. Although fruits and vegetables are not required to meet a "good-source" test for any nutrients in order to call themselves "healthy," we do not request such treatment for dairy, but recommend that the current nutrient requirements (with the addition of potassium and vitamin D) continue to apply.

Within the new dairy category, the reduced-fat forms of all dairy foods (as well as low-fat and fat-free forms) should be able to claim "healthy" status as long as they are a good source of one or more of the specified nutrients, without regard to criteria on total fat, saturated fat, cholesterol or sodium. NMPF believes that as nutrition science develops further, it is possible the full-fat form of dairy products, such as full-fat cheese, may also be deemed to merit a "healthy" claim. However, NMPF recognizes that FDA desires to

[9] U.S. Department of Health and Human Services and U.S. Department of Agriculture, *op. cit.*

encourage the reduction of saturated fat content generally – in part to reduce caloric intake and in part because the health effects of the unique set of fatty acids in dairy foods may not be identical to the effects of saturated fat consumption.

NMPF believes that requiring some reduction in fat content and therefore caloric levels – namely to the "reduced-fat" level – will provide the appropriate balance of the newer science of dairy foods with FDA's more traditional concerns. The agency has already recognized, through its use of enforcement discretion on total fat, that the science of fat has changed. Allowing healthy claims for reduced-fat dairy would be completely consistent with that recognition, while the more flexible regulatory structure we have suggested would preserve the agency's ability to recognize the "healthy" status of full-fat dairy foods if science continues to point in that direction.

Foods that otherwise meet criteria for "healthy" claims should not be prevented from making such claims because of the so-called "50 gram rule." For purposes of several FDA regulations, foods with a Reference Amount Customarily Consumed (RACC) of less than 50 grams must meet regulatory criteria per 50 grams. However, this requirement seems inconsistent with dietary patterns (RACCs are supposed to represent typical amounts consumed). Further, as the RACCs were recently updated in 2016 and now reflect the most current food consumption data, the 50-gram rule is no longer needed. The reference point for a "healthy" claim should be an amount normally consumed on one occasion in order to maximize consumer understanding.

Criteria must be drawn so that FDA can modify them without undue burden or delay as nutrition science evolves. The text of the regulations themselves should permit the Commissioner of FDA to make reasonable modifications – without subsequent notice-and-comment rulemaking – that are consistent with the overall principles of the "healthy" criteria and are made in response to continued evolution in our understanding of nutrition science and the impact of foods, nutrients or dietary patterns on specific health outcomes. This structure will give FDA flexibility when the DGA themselves change.

If FDA chooses to add a criterion for added sugars, it should accommodate "healthy" claims for foods that contain no more than an amount recommended by an authoritative body such as the National Academies of Sciences, Engineering and Medicine (NASEM), which has recommended such levels for both flavored milk and yogurt. Although NMPF does not advocate the use of added sugars as a criterion, we note that FDA has received numerous comments on this topic and will presumably consider those comments.

In the event that the agency determines there is a sound basis for referencing added sugars in its regulations, FDA should be aware that the use of moderate amounts of these sugars in otherwise nutrient-dense foods is received favorably by the DGA. In addition, in the course of reviewing nutrition assistance programs, NASEM has made specific recommendations for total sugars in flavored milk (22 grams per 8-ounce serving) and yogurt (30 grams per 8-ounce serving). Calculating the corresponding amount of added sugars is easily done because of the known amount of naturally-occurring lactose in each food. Reflecting as they do the views of experts empaneled by the nation's premier source of scientific advice, these maximum sugar levels deserve deference as being consistent with the consumption of healthy foods.

5. Recent Science on Dairy Foods, Fat Levels and Health Outcomes

In recent years, a wide variety of published, peer-reviewed studies, systematic reviews and meta-analyses have challenged previous thinking on fat and saturated fat. It appears that not all fats are created equal.

The fat in dairy foods has either a beneficial or neutral effect on various parameters of interest for public health, including chronic disease risk, chronic disease biomarkers and related conditions such as adiposity.

- A recent meta-analysis found a 12% overall reduction in CVD risk from the consumption of dairy foods. Eight of nine studies considered in the analysis showed a lower risk. The dairy foods consumed included all fat levels.[10]
- The same meta-analysis found a 13% lower overall risk of stroke, with (a different) eight of nine studies again showing a reduced risk.[11]
- Consistent with several recent studies, meta-analyses and reviews, Li and colleagues found no association between saturated fat intake and coronary heart disease (CHD) risk.[12]
- In the MESA study, a higher intake of dairy fat was associated with a lower CVD risk.[13]
- A review by Chen and colleagues found no association between dairy fat intake and CHD risk.[14]
- A meta-analysis associated cheese consumption with lower risk for CVD, CHD and stroke.[15]
- In a clinical study, cheese consumption was found to have no impact on serum LDL cholesterol levels after 12 weeks.[16]
- A meta-analysis found that butter intake was not associated with CVD, CHD or stroke, and was associated with a 4% reduction in risk for T2D.[17]
- Two variants of the Dietary Approaches to Stop Hypertension (DASH) diet – one with low-fat and one with full-fat dairy – conferred the same benefit in reducing blood pressure. The full-fat DASH diet resulted in the more favorable serum lipid profile.[18]
- Dairy fat biomarkers reduced the risk of incident T2D in a study published last year.[19]
- Although full-fat versions of dairy foods certainly contain more calories, a study found that women with the highest consumption of full-fat dairy actually had the *smallest* change in weight over a 17-year period.[20]

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[10] Qin et al. Asia Pac J Clin Nutr 2015
[11] Ibid.
[12] LI et al Am JAAC 2015
[13] de Oliveira Otto et al. AJCN 2012
[14] Chen et al Am J Clin Nutr 2016
[15] Chen et al. EurJ Nutr2016
[16] Raziani et al. AJCN 2016
[17] Pimpin et al. PloSOne 2016
[18] Chiu et al. AJCN 2016
[19] Yakoob et al. Circulation 2016
[20] Rautiainen et al Am J Clin Nutr 2016

- Kratz and colleagues reviewed 16 studies of dairy intake and adiposity. None showed an increase in adiposity and 12 showed a decrease (four were neutral). Of the four studies with a specific fatty acid marker, all showed a decrease.[21]
- A systematic review published at the end of 2016 found that "there is no evidence from this extensive review that the consumption of dairy fat or of regular- and high-fat dairy is detrimental to cardiovascular-related clinical outcomes" and concluded that "the recommendation to focus on low-fat in place of regular- and high-fat dairy is currently not evidence-based."[22]

These and other results suggest that dairy fats are different from other sources of saturated fat in the diet. Some indicate that dairy fat may actually be protective, while others find it to be neutral, raising the possibility that a non-fat component(s) of dairy foods is key to risk reduction.

NMPF believes that FDA should recognize this science and not require dairy foods to be low in total fat, saturated fat, or sodium in order to make a "healthy" claim. The studies listed above, and others, focus on the very outcomes that FDA and other authorities have in mind when they promote "healthy" foods: less weight gain, less adiposity, and reduced risk of CVD, CHD, stroke, T2D and other chronic diseases. As mentioned above, NMPF submits that it is consistent with FDA's goals to promote the consumption of dairy – at least at the reduced-fat level or less – to balance current science with FDA's traditional concerns about intake of saturated fat and calories.

The distinguished scientist Dariush Mozaffarian, Dean of the Tufts Friedman School of Nutrition Science & Policy, put the current state of science succinctly: **"No long-term studies support harms, and emerging evidence suggests some potential benefits, of dairy fat or high-fat dairy foods such as cheese. Together these findings provide little support for the prevailing recommendations for dairy intake that are based largely on calcium and vitamin D contents, rather than complete cardiometabolic effects; that emphasize low-fat dairy based on theorized influences on obesity and CHD,**

[21] Kratz et al.; Eur. J. Nutr. 2013; 52: 1-24

[22] Drouin-Chartier J-P et al. Systematic Review of the Association between Dairy Product Consumption and Risk of Cardiovascular-Related Clinical Outcomes. Adv Nutr 2016;7:1026–40.

rather than empirical evidence; or that consider dairy as a single category, rather than separately evaluating different dairy foods."[23]

NMPF urges FDA to take this expert advice and use this opportunity to revise its "healthy" definition to promote the consumption of dairy and other nutrient-dense, under-consumed foods.

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Thank you for your consideration of our perspectives. NMPF would be happy to discuss further development of a definition of "healthy", specifically how it might be applied to nutrient-dense dairy products. Please contact NMPF for additional information.

Respectfully submitted,

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The National Milk Producers Federation, established in 1916 and based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies. NMPF provides a forum through which dairy farmers and their cooperatives formulate policy on national issues that affect milk production and marketing.

[23] Mozaffarian D. Dietary and Policy Priorities for Cardiovascular Disease, Diabetes, and Obesity: A Comprehensive Review. Circulation 2016;133:187-225.