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Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
Cooperative Milk Producers Association
Cortland Bulk Milk Producers Cooperative
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Ellsworth Cooperative Creamery
Farmers 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 Dairymen's Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Association
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto County Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative Creamery, Inc.
Swiss Valley Farms Company
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

October 13, 2015

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

Re: Docket No. FDA-2012-N-1210, RIN 0910-AF22; Food Labeling: Revision of the Nutrition and Supplement Facts Labels

Dear Sir or Madam:

The National Milk Producers Federation welcomes the opportunity to provide comments to the Food and Drug Administration (FDA) on the supplemental notice of proposed rulemaking published in the *Federal Register* of July 27, 2015, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions". The National Milk Producers Federation (NMPF), 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 more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

The FDA proposes to establish a Daily Reference Value (DRV) for added sugars (10 percent of total energy intake from added sugars) and proposes to require the declaration of the percent Daily Value (DV) for added sugars on the label. The new proposal for a DV responds, in part, to a recommendation in the scientific report of the 2015 Dietary Guidelines Advisory Committee (DGAC).

In the original proposed rule published in the *Federal Register* on March 3, 2014, the FDA noted that in requiring declaration of "added sugars" on the Nutrition Facts label, the decision was not based on the relationship of a specific nutrient to a chronic disease or health-related condition. Rather, it was based on consumers having additional nutrient information, citing a number of dietary recommendations encouraging consumers to limit their intake of added sugars which would otherwise displace the consumption of nutrient-dense foods. Further, in March 2014, after a review of evidence, FDA concluded that there was no sound scientific basis for the establishment of a quantitative intake recommendation upon which a DRV could be derived -- yet,

with little change in nutrition knowledge since that time, FDA has reversed their decision with the current supplemental proposal.

NMPF recognizes the rationale for a mandatory declaration of “added sugars” is atypical and is not based on a traditional nutrient-health outcome linkage, as well as that the strength of scientific evidence in establishing a DRV is weak. Notwithstanding the logic that FDA has used to attempt to justify their decision, NMPF does not support the current proposal as we disagree with FDA that a mandatory declaration of “added sugars” will assist consumers in maintaining healthy dietary practices. In addition, NMPF believes such a declaration should, in theory, aid in clarifying the role of lactose, a naturally-occurring sugar, in dairy-based ingredients and in formulated dairy products and other foods. However, the FDA’s proposed definition of “added sugars” falls woefully short in this regard and leaves our industry confused and ill-served with respect to comprehending the proposed regulation.

By extending the definition of added sugars beyond its common-sense scope – the addition to a food or beverage of nutritive sweeteners such as sucrose or high-fructose corn sweeteners – FDA has proposed a regulatory construct that will have anomalous results, both in the dairy sector and within the broader food industry.

The Nutrition Facts label is used by consumers in various ways, ultimately influencing or enabling them to make informed dietary choices and to develop healthful dietary habits. Toward that end, NMPF respectfully offers the following comments about FDA’s supplemental proposal, specifically as related to the definition of “added sugars” and the part of the definition that identifies added sugars as “naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component”.

As written, the current definition may suggest that the lactose in many dried and concentrated dairy ingredients qualifies as an “added sugar” when lactose is the constituent present in the largest quantity – which would include non-fat dry milk powder (51% lactose), whole milk powder (37% lactose), buttermilk powder (49% lactose), whey powder (70% lactose), etc. When these ingredients have been incorporated into a basic dairy substrate (i.e., milk) used to manufacture dairy products such as cheese, yogurt and ice cream, **NMPF maintains that the lactose contributed by dried and concentrated dairy ingredients should be excluded from the definition of “added sugars” on the Nutrition Facts label of dairy products** for the following reasons:

1. Lactose is not primarily added to dairy foods (for example, yogurt, ice cream) for the purpose of sweetening. Lactose differs from nutritive carbohydrate sweeteners used in foods in that it has a much lower relative sweetness (15-20% compared to

100% for sucrose on a typical sweetness scale) and is much less soluble (approximately 16 grams lactose per 100 grams water compared to 67 grams of sucrose per 100 grams of water). Both of these properties limit the functionality of lactose in dairy foods. Considering lactose as a substitute sweetener for sugar (sucrose) is not reasonable with respect to product formulation, nor from an economic perspective.

Put simply, while milk-derived ingredients that contain lactose are added to a variety of dairy and other foods, they are not primarily added because the lactose serves as a sweetener. The other milk components associated with milk-derived ingredients serve a variety of functional purposes (e.g., milk proteins contribute to aeration and gelation; milk salts often serve as sodium substitutes) and provide a “dairy flavor” to products. Likewise, lactose also contributes functional properties to foods (e.g., contributing to viscosity and mouthfeel, serving as a fermentation source in yogurt).

In FDA’s discussion of “added sugars”, yogurt and dairy-based desserts were cited as examples of foods that contain both naturally-occurring sugar (i.e., lactose) and added sugars. The functional properties of lactose are so different from other sugars used as sweeteners in the food industry that it would not be possible to make these foods if lactose were used as the sole sweetener in the formulation, replacing the traditional sugar (i.e., sucrose). The amount of lactose required to achieve the same level of sweetness would compromise basic attributes of the product itself. For example, if lactose were added to a typical ice cream – at a level to replace the sweetness contributed by sucrose – the amount of lactose that would have to be added (roughly 5 to 6 times the amount of sucrose) would either depress the freezing point of the ice cream mix such that the product would not be able to freeze under normal conditions or, if it did freeze, would result in an extremely “sandy” texture defect (lactose crystallization because of poor solubility) which would make the product unacceptable to consumers.

2. The standard of identity for many dairy products does not require sweeteners to be added, but does allow for lactose-containing dairy-based ingredients in “unsweetened” products. For standardized dairy products like milk and yogurt, current regulations do not require that a sweetener be added; the products may be manufactured and sold “unsweetened”. In the case of yogurt, per the standard, the product may be made by culturing cream, milk, partially skimmed milk, or skim milk¹ and other optional dairy ingredients, and without sweeteners. Not including dairy-based ingredients² (for example, concentrated skim milk, nonfat dry milk,

¹ 21 CFR 131.200 (c)

² 21 CFR 131.200 (d)(1)

buttermilk, whey, lactose, or modified whey) as “sweeteners”³ in the standard is tacit acknowledgement by FDA that the lactose in these dairy-derived ingredients is not primarily added to provide sweetness – dairy-based ingredients containing lactose and sweeteners are two clearly different categories of ingredients.

Similarly, “unsweetened” milk may be fortified by increasing the milk solids content with the addition of concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk⁴. The addition of dry whole milk or nonfat dry milk (containing 37% and 51% lactose, respectively) would not result in a “sweetened milk” simply because lactose-containing dairy-based ingredients were added to the milk. Likewise, “no-sugar-added” ice creams have been available in the marketplace for over two decades, despite the fact that many are formulated with dairy-based ingredients that contain lactose as the primary component (i.e., nonfat dry milk powder). This strongly suggests that the inherent lactose in dairy-based ingredients is different from “added sugars” from a regulatory perspective as well.

In addition, the names and nutrition panels together of these products would mislead consumers. A typical consumer would not understand why “unsweetened” or plain varieties of yogurt or milk made with dry or concentrated milk solids would include an “added sugars” declaration, as would be required per FDA’s proposed definition. The contradiction of a product labeled as “unsweetened” and clearly doesn’t taste sweet, but that also includes an “added sugars” declaration would confuse most Americans.

3. FDA’s common or usual names for dairy ingredients would cause confusion with “added sugars” declarations. NMPF urges FDA to clarify how the proposal to label added sugars would operate in situations involving dairy foods with lactose-containing milk-based ingredients. Otherwise, dairy products having identical compositions and identical ingredient statements would have different nutrition labels based on which ingredients are sourced. For example, FDA allows manufacturers to identify skim milk, concentrated skim milk, and nonfat dry milk as “skim milk” or “nonfat milk” in an ingredients listing⁵. Two nonfat yogurt products could be formulated to the same final product composition, and the ingredient statements for both could read “nonfat milk and culture”. However (as stated above regarding standard of identity implications), with the definition of “added sugars” as proposed, a yogurt made using fluid skim milk as the sole dairy ingredient would have zero added sugars, while a yogurt made using both skim milk and nonfat dry milk powder as sources of dairy solids would have to declare “added

³ 21 CFR 131.200 (d)(2)

⁴ 21 CFR 131.110 (a)

⁵ 21 CR 101.4 (b)(3)

sugars” on the nutrition label. Not only would this require manufacturers to constantly have to adapt their nutrition labels due to sourcing different ingredients, this would also be confusing to consumers who would see different nutrient declarations that are not reflected with differences either in the final product (i.e., no differences in taste or sweetness level) or in the ingredient statement. This directly contradicts one of FDA’s justifications in proposing an added sugars declaration “for consumers to have a consistent basis on which to compare products”.

While we recognize that FDA wanted to include products like fruit juice concentrates in the definition for “added sugars”, it would be easier to simply specify that fruit juice concentrates are included in the definition of “added sugar” (which is the example given of “naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component”).

In addition to being used in formulations for dairy foods, lactose-containing dairy-based ingredients are also used in a variety of other non-dairy applications. The primary use of these dairy-derived ingredients is not for the sweetening power of lactose (as noted above), but for the functional properties of the other concomitant dairy components (proteins, milk salts) or for other functional properties of lactose itself (e.g., the browning on the crust of baked goods). Clearly, it is unreasonable to categorize the lactose in dairy-based ingredients as an added sugar in non-dairy foods as well. Therefore, should this proposal be finalized, NMPF would emphasize that **FDA should amend the rule to provide that the lactose in dairy-derived ingredients is not considered an added sugar.**

Examples of inherent flaws in FDA’s proposed definition of “added sugars” are not limited to dairy foods. Dried fruits and vegetables (for example, sun-dried tomatoes, raisins, freeze-dried blueberries) do not contain “added sugars” the in common-sense meaning of the term but, when these are used as ingredients in other foods, could be interpreted as such by the phrase “naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component”. Consider the Nutrition Facts panels (NFP) of two instant oatmeal products – one product that is plain/unsweetened versus another product that also contains dried milk powder (added for taste, texture and nutritional benefits) and fruit pieces that have been processed and freeze-dried. The latter oatmeal product would have a greater amount of “added sugars” declared on the NFP due to the naturally-occurring lactose and fructose in these ingredients (which would be the primary component of the ingredient), and a typical consumer may opt for what is overall a less nutrient-dense food in an attempt to minimize or avoid “added sugars”. NMPF strongly encourages FDA to re-write the

definition of “added sugars” or risk significant consumer misunderstanding and confusion.

The 2015 report from the World Health Organization (WHO)⁶ does not use the term “added” sugars, but instead refers to “free sugars” as including “monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, fruit juices and fruit juice concentrates”, which exempts naturally-occurring sugars in fruits, vegetables and milk. Similarly, the American Heart Association, in their Heart-Check food certification program nutrition requirements⁷, does not count sugar from fruit toward the total sugars limit of cereals or breads when determining whether or not a product is eligible to participate in the Heart-Check Program. Both of these illustrate acknowledgement that naturally-occurring sugars should not be viewed as a negative by consumers striving to make healthy dietary choices.

Extending this logic, NMPF would support an exemption in the definition of “added sugars” for lactose and dairy ingredients. As stated above, lactose is a poor sweetener substitute and dairy ingredients are often used to contribute nutritional benefits to foods, actually boosting the overall nutrient density of a product. Additionally, the evidence cited in the 2015 DGAC report as suggesting an association between a reduced intake of added sugars and a reduced risk of cardiovascular disease relied on a narrower definition of added sugars than what would be included under the definition in FDA’s supplemental proposed rule which, again, suggests the current definition may be inappropriate.

Regardless of if or how FDA opts to redefine the term “added sugars”, even where dairy products are formulated in such a way that they do clearly contain “added sugars” in the common-sense meaning of the term, FDA’s consumer studies demonstrate a high potential for consumer confusion. The July 15, 2015 memorandum entitled “Experimental Study on Consumer Responses to Nutrition Facts Labels with Declaration of Amount of Added Sugars (OMB No. 0910-0764)” states that “the incorrect answer that was most frequently observed was an amount equal to the sum of the product’s total sugars and added sugars...” Consider how such an error might affect the way that a typical consumer would perceive flavored milk:

Flavored milk has all the nutrients of unflavored milk, and has been cited in the Dietary Guidelines for Americans as a nutrient-dense food where modest amounts of

⁶ WHO. 2015. Guideline: Sugars intake for adults and children. Geneva: WHO Press.

⁷ http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/Heart-CheckMarkCertification/Heart-Check-Food-Certification-Program-Nutrition-Requirements_UCM_300914_Article.jsp, Accessed September 21, 2015.

added sugars may increase palatability and therefore advance better nutrient intakes, especially among children and adolescents. As an example, a serving of flavored milk (8 ounces) may have a total sugars content per serving of 25 grams, approximately 13 grams of lactose and 12 grams of “added sugars”. At 4 calories per gram of sugar, it would account for a relatively modest 24% of the DV for added sugars, assuming a 200-gram DV (10% of calories in a 2,000-calorie diet).

However, consumers could get quite a different impression if they mistakenly added total sugars (25 grams) to “added sugars” (12 grams) to arrive at 37 grams of sugars. The DV would still say 24%, but the (incorrect) number in the consumer’s mind is approximately equal to the amount of sugars in the leading sugar-sweetened carbonated beverage (all of which are “added” in any conceivable sense of that term). In this case, the mistake could lead the consumer to view flavored milk in the same light as soda – surely not a result that FDA would wish to encourage.

If FDA determines to proceed with a DV for added sugars, it is critical that the agency revise the definition of added sugars to prevent the anomalous labeling outcomes described previously. In addition, it is essential that FDA design the wording on the Nutrition Facts panel so that it prevents consumer confusion and does not unintentionally portray dairy foods (as well as other nutrient-dense foods, including fruits and vegetables) in a negative light.

In conclusion, NMPF urges FDA not to move forward with the supplemental proposed rule without significant revision. As currently drafted, NMPF is unable to support the proposal. Especially with respect to a key part of the definition of “added sugars”, NMPF has concerns about unintended consequences with respect to dairy foods and dairy ingredients to which we respectfully call attention. Without modification, an “added sugars” declaration may result, at best, in meaningless information and, more likely, may increase consumer confusion and hinder the ability of Americans to make truly informed decisions in building an overall healthy dietary pattern. We encourage FDA to re-evaluate their proposal in light of currently available scientific studies, to assure that the proposal will accomplish the objectives set by the agency, as well as to be certain that this proposal will assist consumers in maintaining healthy dietary practices.

NMPF appreciates the opportunity to submit comments and looks forward to continuing to work with the agency to provide Americans with a variety of dairy foods and to effectively communicate nutrition information through accurate labeling.

Thank you for the opportunity to share our perspectives. Please contact us if you have additional questions.

Sincerely,

A handwritten signature in black ink that reads "Beth Panko Briczinski". The signature is written in a cursive, flowing style.

Beth Panko Briczinski, PhD
Vice President, Dairy Foods & Nutrition