



July 31, 2023

Submitted electronically via www.regulations.gov

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

Re: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request [Docket No. FDA-2023-D-0451]

Dear Sir or Madam,

The International Dairy Foods Association (IDFA), located in Washington, D.C., appreciates the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA) draft guidance titled "*Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry.*" IDFA represents the nation's dairy manufacturing and marketing industry, which supports more than 3.2 million jobs that generate \$49 billion in direct wages and \$794 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies and dairy companies and cooperatives to food retailers and suppliers. Together, our members represent most of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. More information about IDFA can be found at www.idfa.org.

IDFA appreciates FDA's efforts to support consumer choice and innovation in the marketplace and specifically the agency's actions to ensure that the labeling of plant-based milk alternatives (PBMA, henceforth) is truthful and does not mislead or confuse consumers. IDFA is fully aligned with the FDA's goal for issuing this guidance as stated by FDA Commissioner Califf: "The draft recommendations should lead to providing consumers with clear labeling to give them the information they need to make informed nutrition and purchasing decisions on the products they buy for themselves and their families."

With that said, IDFA does have the following specific concerns with and suggestions for improvements to the FDA's aforementioned draft guidance:

- **The draft guidance does not adequately address the noted concern that consumers believe PBMA are healthier than milk.**

IDFA does not agree that the voluntary declaration of up to nine select nutrient differences between PBMA and cow's milk (hereinafter referred to as "milk") sufficiently addresses the FDA's concern that consumers "believe plant-based milk alternatives are healthier than milk and expect that products labeled with the term 'milk' in the name are comparable in nutrition to milk."

Based on the FDA's own consumer research regarding PBMA (FDA reference 1), when consumers mentioned comparisons of PBMA to milk or specifically compared the nutrition of PBMA to milk, they focused their remarks on the following nutrients: calcium, protein, potassium, vitamin D, added sugars, fat

(see pages 3, 8, 9). These mentions may indicate that consumers do not have a good understanding of the nutritional contributions of milk or PBMA to the diet. Milk is a good source of thirteen (13) essential nutrients¹, which include three of the four nutrients identified as nutrients of public health concern in the 2020-2025 Dietary Guidelines for Americans (DGA)—calcium, vitamin D, and potassium. Without additional education on the nutritional content and levels of nutrients in milk and PBMA, we believe the FDA’s proposal to include all nine nutrients on the USDA’s Food and Nutrition Service’s list in a voluntary nutrient statement would fail to accomplish the aforementioned goal of this guidance and has the potential to instead cause consumer confusion.

- **The draft guidance does not consider the bioavailability of the nutrients in milk as compared to PBMA.**

Milk and milk products have a range of health benefits associated with their long-term consumption and are nutritionally distinct from non-dairy based alternatives. Emerging science suggests that nutrients, within their natural food matrix, function differently as compared to their isolated forms.² The FDA recommends in its draft guidance a nutrient comparison of up to nine vitamins and minerals, and protein, between the PBMA and milk, on the front of the package. IDFA is concerned that this approach does not address nor consider differences in the bioavailability of nutrients in milk and PBMA; other nutrients and bioactive compounds that are also present in these products; or long-term health benefits. We recommend that the FDA take these additional factors into consideration when finalizing this guidance.

- **A concise disclaimer is recommended.**

IDFA does not agree with the FDA’s proposed approach of including the specific nutritional differences between PBMA and milk on the Principal Display Panel (PDP) of a product’s label (on the front of the package). We believe that consumers should continue to obtain information on the nutrients in food products using the Nutrition Facts Panel (NFP), which is typically found on the back of the food package.

As an alternative, IDFA recommends that the FDA suggest the inclusion of a disclaimer, such as “This product is nutritionally different than milk,” positioned in close proximity to the NFP to provide additional nutrition-related information to consumers. We believe this construct will prompt consumers that want to compare the nutritional value of milk and PBMA to use information that is already available on the NFP, which is where consumers are accustomed to looking for nutrition-related information on the foods they consider for purchase.

- **Using the FDA’s proposed approach, the list of nutrients should include only those on the NFP and Vitamin A.**

If IDFA’s recommended approach is not accepted and the FDA’s proposed approach is included in final guidance, IDFA suggests that the nutrient comparison statements include only those nutrients that are required to be on the NFP with the addition of vitamin A, given milk is an important source of vitamin A and it is standard industry practice to fortify reduced milkfat versions of milk with vitamin A so that the product is not nutritionally inferior, as defined in 21 CFR 101.3(e)(4), to the standardized food “milk.” Additionally, we recommend the comparison statements be provided on the back panel of the package, near the NFP, instead of on the PDP or front of package.

¹ Protein, calcium, potassium, vitamins D, B12, A, riboflavin, phosphorus, niacin, zinc, iodine, selenium and pantothenic acid. More information can be found here: <https://www.usdairy.com/getmedia/0caf28ce-c6ce-4be0-adfd-dbc208f942a3/13-nutrients-in-milk-infographic-2021.pdf>

² Harnessing the Magic of the Dairy Matrix for Next-Level Health Solutions: A Summary of a Symposium Presented at Nutrition 2022. <https://pubmed.ncbi.nlm.nih.gov/37396060/>

- **FDA should continue and even enhance efforts to educate consumers on the NFP.**

IDFA recommends that the FDA continue and even enhance its efforts to educate consumers on how to use the NFP. This will serve to improve the nutrition literacy of consumers and help them make more informed decisions based on their consumption preferences and individual dietary needs.

* * *

IDFA appreciates the opportunity to share our comments on this draft guidance. We look forward to working with the agency to provide consumers with the easy-to-understand nutrition information they need to make informed purchasing decisions as novel foods continue to enter the marketplace. Please contact us if you have any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John T. Allan". The signature is written in a cursive style with a large, looping initial "J".

John Allan, MS
Vice President, Regulatory Affairs & International Standards