

May 6, 2022

Julie Wise
Office of Management and Budget (OMB); Office of Information and Regulatory Affairs
(OIRA)
725 17th St NW
Washington, DC 20503

RE: Executive Order (EO) 12866 Meeting 0910-ZB08; OIRA Review of the Food and Drug Administration's (FDA) Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry

Dear Ms. Wise:

The Plant Based Foods Association (PBFA) is submitting these written comments on the OIRA's review of the FDA's proposed Draft Guidance for Industry titled Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements. PBFA is the first and only trade association in the US representing the plant-based foods industry. We currently have over 350 members, including the nation's leading plant-based food companies that produce plant-based milks, yogurts, meats, and eggs.

A draft guidance that recommends the inclusion of nutrient statements is unprecedented, unwarranted, and a solution in search of a problem. The FDA's long-standing position has been to allow use of the term "milk" with appropriate qualifiers like "soy," "almond," "oat," or "plant-based." There is no evidence that consumers are confused by plant-based milk labels.

The Ninth Circuit upheld dismissal of a class action suit alleging "that consumers will be deceived into thinking that almond milk has the same nutritional value as cow's milk."¹ Additionally, the district court found that "[n]o reasonable consumer could be misled by Defendant's unambiguous labeling or factually accurate nutritional statements. By using the term 'almond milk,' even the least sophisticated consumer would know instantly the type of product they are purchasing. If the consumer is concerned about the nutritious qualities of the product, they can read the nutrition label..."² In affirming dismissal, the Ninth Circuit, as noted above, found that no reasonable person could conclude that "almond milk is 'nutritionally inferior' to dairy milk . . . as two distinct food products necessarily have different profiles."³

¹ *Painter v. Blue Diamond Growers*, 757 F. App'x 517, 519 (9th Cir. 2018).

² *Id.*

³ *Id.*

The court's conclusions are supported by multiple consumer surveys. PBFA recently commissioned a survey of 756 consumers, attached hereto as Appendix I, which confirmed what previous studies have all shown: consumers are not confused by plant-based milk labels. The vast majority (95-98%, depending on the type of plant-based milk they purchased) of consumers surveyed understood that plant-based milks do not contain cow's milk. Our survey also showed that consumers are not confused about the ingredients in plant-based milks. When asked to describe the main ingredients in almond milk, only 3% mentioned a cow-derived ingredient.

Similarly, research conducted in 2018 by the International Food Information Council Foundation found that less than 1 in 10 consumers believed that plant-based milks contain cow's milk.⁴ In comparison, 15% of consumers incorrectly believed that peanut butter contains cow's milk, and 15-38% of consumers incorrectly believed that chocolate milk, organic milk, butter, and lactose free milk do not contain cow's milk. These findings demonstrate that there is even less confusion about plant-based milks than there is about conventional dairy products or products, like peanut butter, that have their own Standard of Identity (SOIs).⁵

Nor does research data show that consumers think plant-based milks have the same nutritional content as cow's milk. Academic research has shown that consumers are not confused about the nutritional differences between dairy milk and plant-based milk.⁶ In fact, this research found that consumers are "generally accurate at identifying nutritional differences between plant-based and animal-based milk and cheese products (50-62% accuracy)."⁷

There are two major issues in allowing the draft guidance to be published without further input from stakeholders or Congress. First, the draft guidance is likely to have a major effect on the economy and second, using draft guidance to create substantive policy is improper.

According to the Congressional Review Act (CRA), a regulatory action should be deemed "major" if it "has an annual effect on the economy of \$100 million or more;"

⁴ International Food Information Council Foundation, *Consumer Attitudes About Labeling Cow's Milk, Plant Based and Non-Dairy Alternatives* (Oct. 2018), https://foodinsight.org/wpcontent/uploads/2018/10/Milk-Nomenclature_PDF_1.pdf.

⁵ Food and Drug Administration (FDA), *Standards of Identity for Food*, <https://www.fda.gov/food/food-labeling-nutrition/standards-identity-food>.

⁶ UCLA School of Law, *Animal Law and Policy Program Comment Re Docket Number FDA-2018-N-2381*, <https://law.ucla.edu/sites/default/files/PDFs/Academics/Milk%20Literacy%20Comment%20to%20FDA%20Oct%205%202018.pdf>.

⁷ *Id.*

causes a major increase in costs or prices for consumers or individual industries; or causes significant adverse effects on competition. The FDA's proposed draft guidance warrants this major designation as well as "significant" designation, defined by Executive Order (EO) 12866 as "any regulatory action that may adversely affect a sector of the economy in a material way."

There are several reasons why the draft guidance could have a major impact on the economy. Plant-based milk companies may incur significant expenses in relabeling or reformulating their products if the guidance advises them to include a new nutritional statement on their labels. FDA's draft guidance could also create a situation in which unwarranted and costly consumer class action lawsuits are brought against plant-based food companies.⁸

The draft guidance is also likely to have an anti-competitive effect and stifle innovation in the plant-based foods industry. Plant-based milk sales currently account for 16% of total milk sales and they continue to grow each year – in 2021 sales increased over 4%.⁹ The total milk market in 2021 accounted for \$16.25 billion in sales, and plant-based milks accounted for \$2.6 billion of those sales.¹⁰ Draft guidance implying that plant-based milk products are somehow inferior to dairy milk products in terms of nutritional content would be discriminatory and could jeopardize growth of the plant-based foods industry, especially because no other products - including different brands of dairy milk - are targeted by the draft guidance.

The FDA's standards of identity describe what a food must contain and sometimes describe necessary amounts or proportion of ingredients or components.¹¹ However, no standard of identity prescribes nutritional components for food products and the standard of identity for milk contains no requirements concerning any nutrients.¹²

Different brands of cow-derived milks can have different nutritional content.¹³ One cup of whole milk and skim milk typically have different quantities of these nutrients. What levels would be considered "typical"? Should cow's milk require such a disclosure

⁸ Elaine Watson, *A Tale of Two Evaporated Cane Juice Lawsuits*, Food Navigator (2017), <https://www.foodnavigator-usa.com/Article/2017/06/02/A-tale-of-two-evaporated-cane-juice-lawsuits-Stearns-and-Late-July>.

⁹ Plant Based Foods Association (PBFA), *2021 U.S. Retail Sales Data for the Plant-Based Foods Industry*, <https://www.plantbasedfoods.org/2021-u-s-retail-sales-data-for-the-plant-based-foods-industry/>.

¹⁰ *Id.*

¹¹ *See Standards of Identity*.

¹² *See id.*

¹³ *See e.g.*, Organic Valley Skim Milk (14g Sugars; 10g Protein) compared with Fairlife Skim Milk (6g Sugars; 13g Protein).

statement if it does meet these “typical” levels? What about flavored cow’s milk products? In short, nutritional equivalency is an inappropriate basis for distinguishing plant-based milk from dairy milk. They are different products with different intended uses and the nutritional labels of each product already make this clear.

The approach implied by the title of the draft guidance would create many questions and a significant administrative burden for the FDA, as well as a burden for all manufacturers of milk products – both cow-derived and plant-based. Moreover, there is no reason for it.

It is inappropriate for the FDA to announce a new and unprecedented policy via draft guidance. This was a concern of several members of Congress who, in 2014, communicated to the FDA that the use of draft guidance as a policymaking vehicle obviates stakeholder and congressional input.

As the DC Court of Appeals explained in a 2000 case brought against the Environmental Protection Agency (EPA), draft guidance can effectively become law without public participation or congressional oversight if an agency treats a regulatory document, such as draft guidance, as controlling in practice and if the document leads even private parties to believe it could affect market practices.¹⁴ Given that it can take FDA up to 1500 days to finalize its guidance, there is significant risk of the draft guidance becoming de facto policy.¹⁵

For all the reasons above, we urge you to reclassify this draft guidance as “major” under the CRA. The draft guidance is a solution in search of a problem and warrants further consideration by the FDA.

Sincerely,

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¹⁴ *Appalachian Power Co. v. EPA*, 249 F.3d 1032 (D.C. Cir. 2001).

¹⁵ Thomas Sullivan, *Senators Send FDA Letter with Concerns Over Draft Guidance Documents* (May 2018), <https://www.policymed.com/2016/06/senators-send-fda-letter-with-concerns-over-draft-guidance-documents.html>.



Consumer Survey Report

The enclosed report includes the results of a survey conducted by Moonshot Collaborative LLC on behalf of the Plant Based Foods Association. The purpose of the survey was to better understand consumer knowledge and beliefs regarding ingredients, nutrition, and labeling of cow-based and plant-based milk products.



OCTOBER 7, 2021

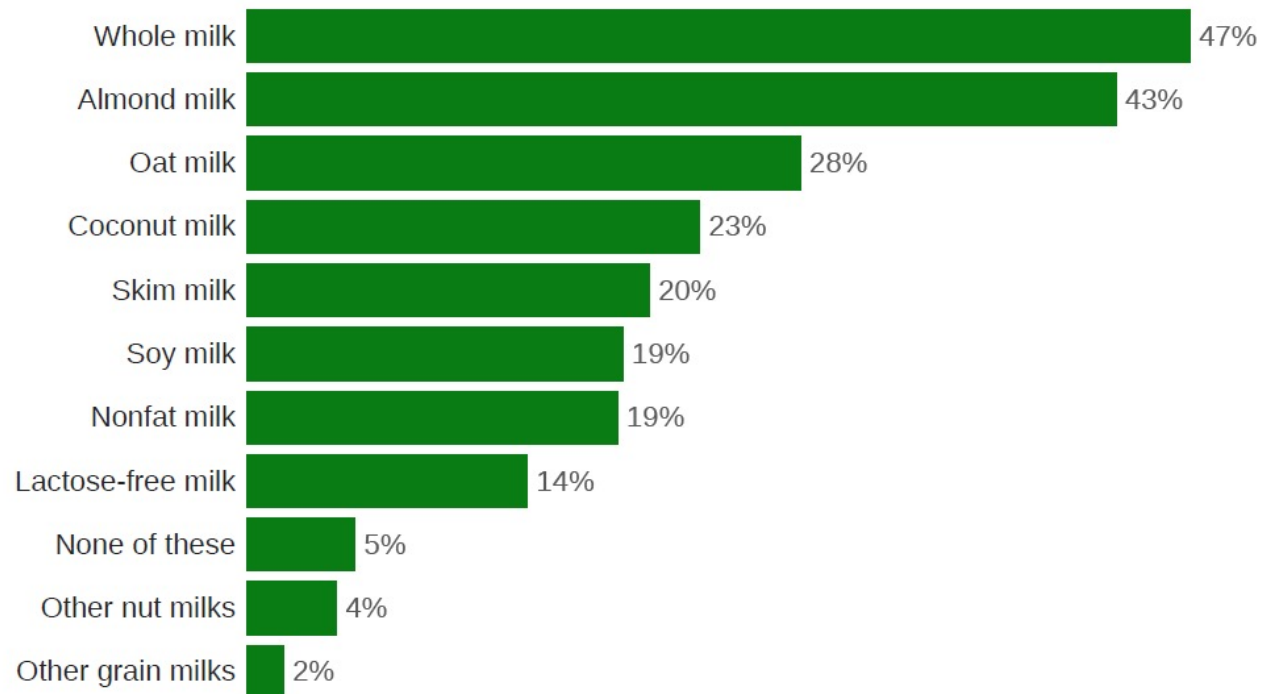
METHODS:

The enclosed results are from an online survey conducted from September 21-24, 2021, with a total sample size of 756 individual respondents. Participants were randomly selected from Prolific's panel of pre-qualified survey respondents, which employs Census-based sampling to achieve a representative sample of the adult United States population. Attention checks and other methods were employed to identify and eliminate lower quality responses. All analysis was conducted in Qualtrics.

Types of Milk Purchased Recently

Question: Which of the following products have you purchased for yourself or others in your household in the past 3 months? Please choose all that apply.

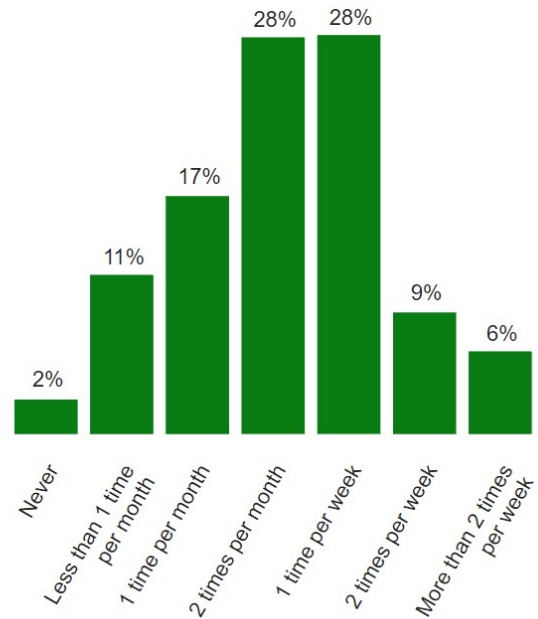
756 Responses



Purchase Frequency: Cow-Based Milk and Plant-Based Milk

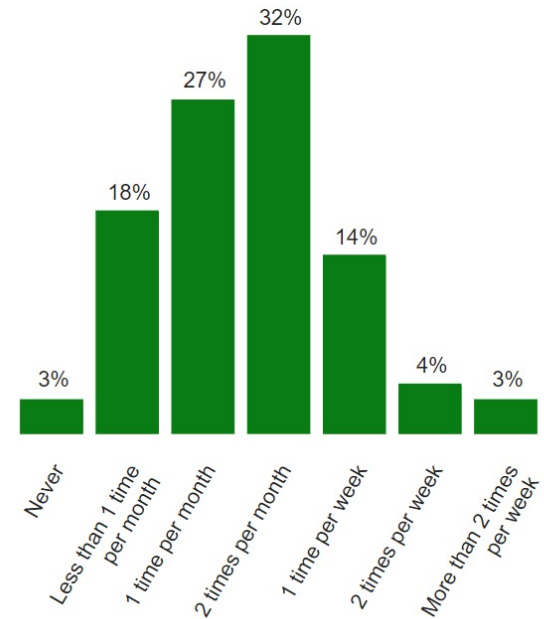
How often do you typically purchase any kind of milk made from cows?

541 Responses



How often do you typically purchase any kind of plant-based milk (made from nuts, beans, or grains)?

506 Responses



Main Ingredients of Almond Milk

When asked to describe the main ingredients in almond milk, 97% of consumers listed only plant-based ingredients. Only 3% mentioned some form of dairy. The following are the responses from those who mentioned dairy.

Milk, water and sugar
Almonds, cream
almond and milk
Water, sugar, milk, almonds
Almond and Milk
almonds and milk
milk
Cheese, egg and pure milk
milk
almonds, sugar, water, regular milk
Almond & milk
Almond, soy, milk
Almonds and dairy
I think water, starch and milk
milk

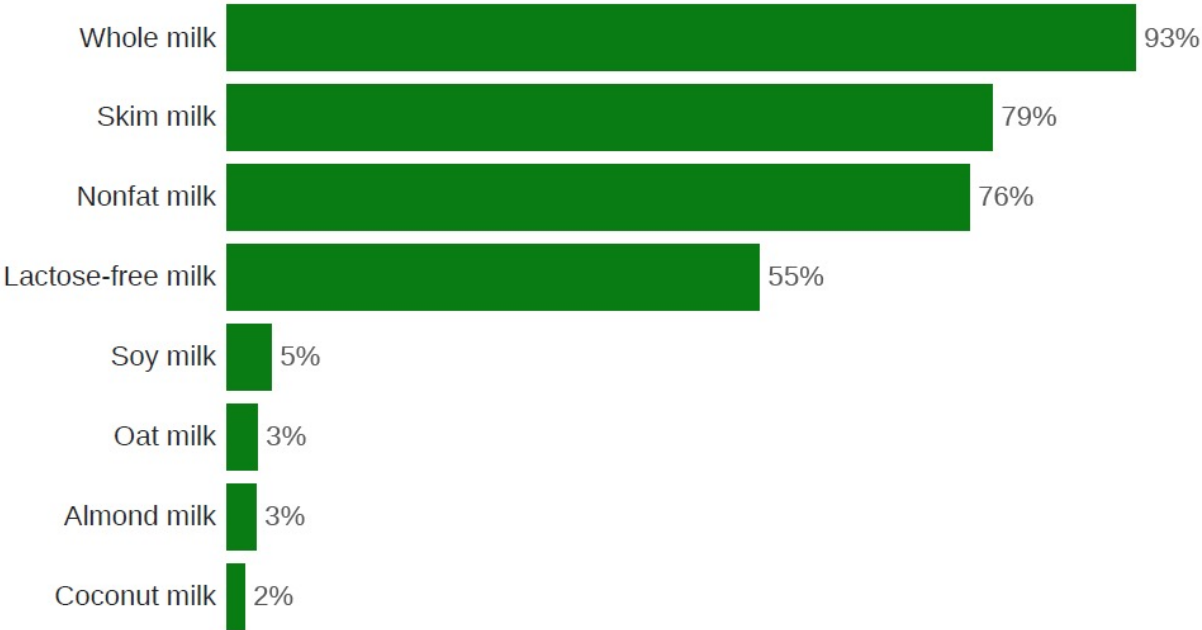
Raw milk, sugar and preservatives
Regular milk mixed with granulate almond powder I guess.
almond extract and milk
almond , sugar, milk
Almond and cream of some sort.
almonds, milk, sugar
dairy and almond extract
milk and almond
Milk and water
Milksugar
almonds, sugar, cream
almonds, lactose, soy



Knowledge of Cow-Based Milks 1 of 2

Of the products below, which do you think contain milk from a cow? Select all that apply.

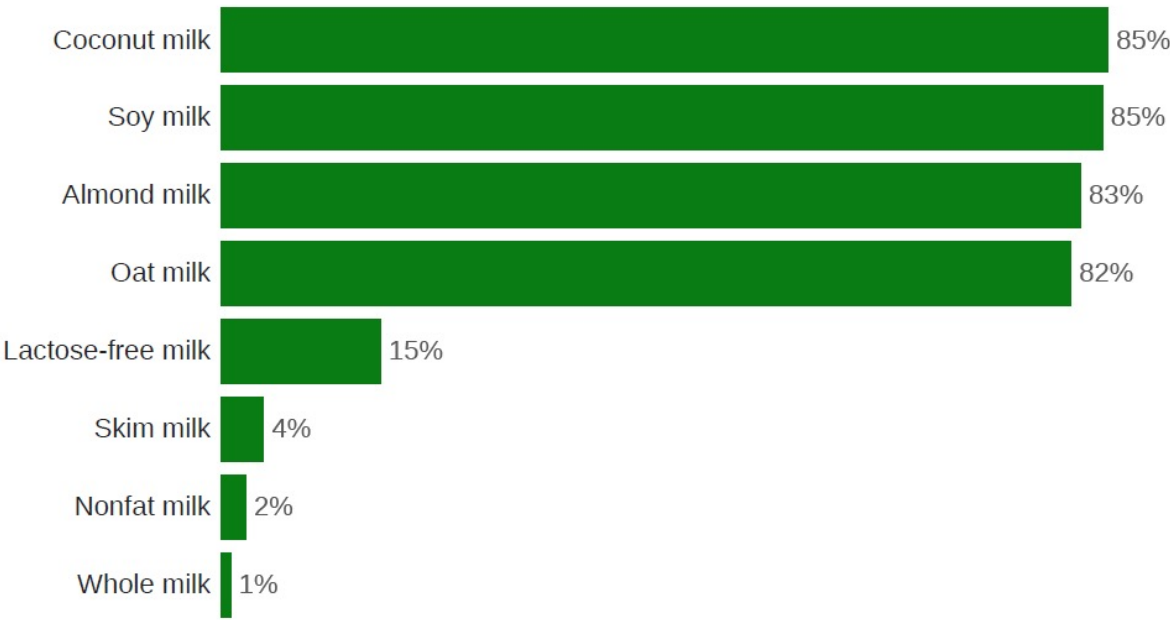
756 Responses



Knowledge of Plant-Based Milks 1 of 2

Of the products below, which do you think contain milk made from plants? Select all that apply.

756 Responses



Knowledge of Cow-Based Milks 2 of 2

Which of the following two products do you think is made from cow's milk?

756 Responses



Product A



Product B

Knowledge of Plant-Based Milks 2 of 2

Which of the following two products do you think is made from plants?

756 Responses



Product A



Product B