November 16, 2021

VIA ELECTRONIC SUBMISSION (www.regulations.gov)

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

Re: Guidance Topic: Labeling of Plant-based Milk Alternatives; Draft Guidance for Industry (Docket No. FDA-2021-N-0553)

Dear FDA:

The Plant Based Foods Association ("PBFA") submits these comments in response to the FDA's notice that it intends to issue guidance on the topic of “Labeling of Plant-based Milk Alternatives; Draft Guidance for the Industry” by the end of June 2022, and as a supplement to PBFA’s previously submitted public comments on the “Use of Names of Dairy Foods in Labeling Plant-Based Products” (Docket No. 2018-N-3522), on “Horizontal Approaches to Foods Standards of Identity Modernization” (Docket No. 2018-N-2381), and in response to the Citizens Petition filed by the National Milk Producers Federation (Docket No. 2019-P-0777-0001).

PBFA is the first and only trade association in the U.S. representing the plant-based food industry. We currently represent over 220 of the nation’s leading plant-based food companies. PBFA’s mission is to build a strong foundation for the plant-based foods industry to scale and thrive. We empower the industry by advocating for government policies that allow fair competition, while expanding market opportunities for retail, distribution, and foodservice to support the industry’s continued growth.

PBFA urges the FDA to re-affirm its long-standing position allowing 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. Therefore, there is no valid basis for the FDA to reverse its long-standing approach regarding product naming.

As we stated in our comments on President Biden’s Executive Order on Tackling the Climate Crisis, encouraging an American transition to a plant-based diet supplied by American farmers is one of the leading ways we can cut greenhouse gases and mitigate climate change. Avoiding meat and dairy is shown to be the single most
effective way to reduce our impact on Earth.\(^1\) Plant-based diets are the most efficient way to feed to world: for every 100 calories of human-edible crops that we feed to animals, we only get 17-30 calories back in the form of meat or milk.\(^2\) The National Academy of Sciences is clear about the tremendous potential that plant-based diets have to affect climate change, concluding in a 2018 report that “shifting to plant-based diets confers substantial environmental savings, comparable to or even surpassing projected improvement in agricultural productivity.”\(^3\) Given the immediacy of climate change, among other reasons, we urge the FDA not to stifle innovation in the plant-based food industry.

We discuss these issues in more detail below.

I. FDA SHOULD CONTINUE TO SUPPORT INNOVATION WITH ITS FLEXIBLE APPROACH TO SOIS

A. The FDA Has a Long-Standing Position of Allowing SOIs With Qualifiers

For over fifty years, the FDA has shifted away from a strict interpretation of standards of identity to a flexible approach to support industry innovation. It has been decades since the agency has insisted that standardized names can only be used on foods that are, in all respects, the standardized foods. It abandoned this approach because it recognized that strict adherence to standards of identity stood in the way of innovation. We urge the agency not reverse course, especially at a time when innovation in the food industry is so crucial to planetary health.

In 1938, when the FDA was first given the authority to promulgate standards of identity, both food regulation and the food industry were much different than they are today. Consumers were just starting to purchase prepared foods at stores, and the products they were purchasing were simple ones for which they knew the ingredients. Ingredient labeling was not mandatory. Nutrition Facts panels did not yet exist. Standards of identity were the “recipes” understood by food consumers and, at the time, the only way to prevent manufacturers from passing off imitation foods as traditional staples.\(^4\)


\(^3\) A. Shepon et al., The Opportunity Cost of Animal Based Diets Exceeds All Food Losses, Proceedings of the National Academy of Sciences of the United States (April 2018), available at https://www.pnas.org/content/115/15/3804.

Over the next several decades, regulation evolved to accommodate an evolving industry. The 1969 White House Conference on Food, Nutrition and Health was a seminal, bipartisan event, chaired by Dr. Jean Meyer, that had significant and lasting policy impacts. The report that emerged from the conference recognized that standards of identity stood in the way of innovation and, subsequently, regulation shifted away from food standards to providing consumers with more complete information, such as ingredient and Nutrition Facts labeling.

In the 1970s, the FDA took the position that: “The existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in connection with the name of a non-standardized food and ‘in some cases it may be necessary to include a standardized name in the name of a substitute food in order to provide the consumer with accurate descriptive and fully informative labeling.’” In 1983, the FDA stated that for “substitute” foods it is “reasonable and appropriate to include the name of a standardized food or other traditional food in the name of a substitute food” if the “name of the food [is] modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute.” The FDA also recognized that products that compete with a standardized food are not “purporting to be the standardized foods,” and therefore are not “imitations.”

In 2018, the FDA announced that it wanted to further “modernize standards of identity.” In this announcement, Former Commissioner Scott Gottlieb stated:

We are also looking at how we have been enforcing the FD&C Act with respect to food names and our own standard of identity for milk and what it means when milk is qualified with words like almond or soy. We recognize that, as a regulatory agency, it’s not appropriate to unilaterally change our regulatory approach if we have a history of non-enforcement. We also need to closely consider the potential First Amendment issues related to the different uses of these terms.

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7 See e.g., Nat’l Milk Producers Fed. v. Harris, 653 F.2d 339, 343 (8th Cir. 1981), citing Fed. of Homemakers v. Schmidt, 539 F.2d 740 (D.C. Cir. 1976) (unsuccessfully challenging the FDA’s position that cheese substitutes were not “imitation”).
In 2019, the White House convened a 50th Anniversary Conference in honor of the 1969 White House Conference on Food, Nutrition and Health. The report that emerged from the conference recognized that half a century later we now face a very different set of nutrition challenges, including threats to our climate exacerbated by global food production. The report further recognized support of innovation as a key policy priority, and as such, recommended incentivizing innovation of more sustainable foods and beverages and creating policies to reward private-sector innovation.

B. Public Comments Do Not Support a Change in the FDA’s Long-Standing Approach

In September 2018, the FDA invited public comment on the labeling of plant-based products with names that include the names of dairy foods such as “milk.” An analysis of the public comments received shows that an overwhelming majority (76%) of commenters favor continuing to allow plant-based foods to use dairy terms. Of those commenters who identify as consumers, an even greater majority (97.4%) favor this position, and 87% specifically stated that they are not confused by current labeling. Not surprisingly, however, the FDA also received comments from the dairy industry suggesting that the FDA change its approach regarding the labeling of their competition.

Many dairy industry representatives suggested that the FDA “enforce” the existing standard of identity for milk by prohibiting plant-based milk companies from using “milk” on their labels. This approach would diverge from the FDA’s established position, as explained in Section IA above. Moreover, as explained in Section III below, the FDA has no authority to ban the use of terms, especially in such a content-based way, when they are not misleading.

Other dairy industry representatives suggested that the FDA require plant-based milks to be labeled as “imitations,” pursuant to 21 C.F.R. 101.3(e), which defines a food as “imitation” if it is a substitute for and resembles another food but is nutritionally inferior to that food. Again, the FDA’s long-standing position conflicts with this approach. As the agency explained in 1973: “The courts have long recognized that the term ‘imitation’ suggests an inferior product….‘in the sense that

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it is cheapened by the substitution of ingredients.’ Vast strides in technology have taken place since...it is no longer the case that such food products are necessarily inferior to the traditional foods for which they may be substituted.”¹² Not surprisingly, modern courts agree. The Ninth Circuit recently found that:

Almond milk is not an “imitation” of dairy milk.... Notwithstanding any resemblance to dairy milk, almond milk is not a “substitute” for dairy milk as contemplated by section 101.3(e)(1) because almond milk does not involve literally substituting inferior ingredients for those in dairy milk.

In addition, a reasonable jury could not conclude that almond milk is “nutritionally inferior” to dairy milk within the meaning of 21 C.F.R. 101.3(e)(4), as two distinct food products necessarily have different nutritional profiles. As the district court concluded, it is not plausible that a reasonable consumer would “assume that two distinct products have the same nutritional content.”¹³

One organization suggested that the FDA require plant-based milks that do not provide equivalent amounts of vitamin D, calcium, potassium, or protein or vitamin B-12 to be labeled with front-of-package disclosures stating that the products do not provide the levels of these “key nutrients” typically found in milk. As explained in Section III below, the FDA certainly lacks authority to compel this type of content-based speech. Even narrowing such an approach to “milk” products would be quite convoluted and would create consumer confusion. The standard of identity for milk contains no requirements concerning these “key nutrients.” Different brands of cow-derived milks can have different nutritional content.¹⁴ 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 statement if it does meet these “typical” levels? What about flavored cow’s milk products? This approach 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-based and plant-based. Moreover, there is no reason for it.

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¹³ Painter v. Blue Diamond Growers, 757 F. App’x 517, 519 (9th Cir. 2018)
¹⁴ See e.g., Organic Valley Skim Milk (14g Sugars; 10g Protein) compared with Fairlife Skim Milk (6g Sugars; 13g Protein).
II. CONSUMERS ARE NOT CONFUSED BY PLANT-BASED MILK LABELS

As the purported basis for their proposals, the dairy industry asserts that any use of the term “milk” on a food or beverage somehow confuses consumers into thinking that the product is cow’s milk and/or nutritionally equivalent to cow’s milk. These assertions are baseless.

A. Courts Find Even the “Least Sophisticated” Consumers Would Not Be Confused

Courts have consistently rejected claims that the word “milk” confuses consumers – about its source or its nutritional content. In fact, these courts have found that not only would no “reasonable” consumer be confused, not even the “least sophisticated” consumers would be confused.

In dismissing a proposed class action challenging the product names “soy milk” and “almond milk,” a court found the claim that the names mislead consumers “stretch[e]d the bounds of credulity,” stating further “it is simply implausible that a reasonable consumer would mistake a product like soymilk or almond milk with dairy milk from a cow. The first words in the products’ names should be obvious enough to even the least discerning of consumers. Adopting Plaintiffs’ position might lead to more confusion, not less, especially with regard to other non-dairy alternatives, such as goat milk or sheep milk.”

Likewise, in dismissing a nearly identical class action, another judge concluded that, “The reasonable consumer (indeed, the least sophisticated consumer) does not think soymilk comes from a cow. To the contrary, people drink soymilk in lieu of cow’s milk.”

The Ninth Circuit upheld dismissal of a yet another similar proposed class action – this one alleging “not that consumers will confuse almond milk for cow’s milk, but rather that consumers will be deceived into thinking that almond milk has the same nutritional value as cow’s milk.” The district court found that “the distinction is without a difference. No 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...” In affirming dismissal, the Ninth Circuit, as noted above, found that no reasonable person could

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conclude that “almond milk is ‘nutritionally inferior’ to dairy milk... as two distinct food products necessarily have different profiles.”18

B. Research Shows Consumers Are Not Confused

Courts’ conclusions that even the “least sophisticated” consumers are not misled are also evidenced by research, which shows that consumers understand that plant-based milks are sourced from plants, not cows, and that the products have different nutritional profiles. Multiple surveys demonstrate this.

PBFA recently commissioned a survey of 756 consumers, attached hereto as Appendix 1, which confirmed what previous studies have all shown: that 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. In comparison, 45% of consumers and 24% of consumers, respectively, did not understand that lactose free and nonfat milk in fact 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.

Research conducted in 2018 by the International Food Information Council Foundation found, similarly, that less than 1 in 10 consumers believed that plant-based milks contain cow’s milk.19 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. Even the Center for Science in the Public Interest, in comments supporting front-of-pack disclosures for plant-based milks, stated: “We are not aware of any evidence that the current labeling of non-dairy plant-based foods and beverages are contributing to widespread consumer confusion.”20

18 Painter v. Blue Diamond Growers, 757 F. App’x 517, 519 (9th Cir. 2018).
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 cow and plant-based milk products.\textsuperscript{21} 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).”

Academic research has also shown that consumers are no more likely to think that plant-based products come from an animal if the product’s name incorporates words traditionally associated with animal products than if it does not, and that omitting words that are traditionally associated with animal products from the name of plant-based products causes consumers to be significantly more confused about the taste and uses of these products.\textsuperscript{22}

Furthermore, academic research examining consumers’ ability and tendency to use products’ Nutrition Facts panels supports the idea that consumers can determine nutritional differences between plant-based and animal-based milk products without any more information than is currently required to be on their labels (72% of consumers read the Nutrition Facts panel, as confirmed by eye-tracking studies).\textsuperscript{23}

Taken together, these findings demonstrate that requiring label changes for plant-based milks would not advance any interest in preventing consumer confusion.

**III. STRICT CONSTRUCTION OF STANDARDS OF IDENTITIES WOULD NOT WITHSTAND LEGAL CHALLENGE**

Restriction of plant-based milk names would not survive a First Amendment challenge. Where commercial speech is not inherently misleading – as has already been decided by the Ninth Circuit here\textsuperscript{24} – regulations restricting such speech must directly advance a legitimate government interest and be no more extensive than necessary.\textsuperscript{25} The First Amendment “demands proof.”\textsuperscript{26}


\textsuperscript{24} Painter v. Blue Diamond Growers, 757 F. App’x 517, 519 (9th Cir. 2018).


\textsuperscript{26} Miyoko’s Kitchen v. Ross, No. 20-CV-00893-RS (N.D. Cal. Aug. 10, 2021).
To satisfy the First Amendment, the FDA would first have to show that a significant number of consumers are confused by plant-based milk labels. Based on court precedent and existing consumer research data, this would likely be impossible to show. Second, even if the FDA could show such confusion, it would also have to show that other, less restrictive regulatory approaches do not or could not address it. For example, the FDA would have to evaluate existing nutrition labels and the use of appropriate qualifiers like “plant-based” and demonstrate that neither sufficiently prevent any alleged consumer confusion.

A recent court decision is directly on point here. In December 2019, the California Department of Food and Agriculture did just what the dairy industry has been urging: it sent Miyoko’s Kitchen, maker of a “vegan butter” product, a letter citing the federal definition of “butter” and demanding that, among other things, the company remove the term from the product’s labeling. Miyoko’s challenged the agency’s enforcement on First Amendment grounds and the Court ruled in favor of Miyoko’s – first on preliminary injunction and then on summary judgement – making clear that its decision was not even a close call.  

Recent developments in First Amendment jurisprudence might require an even greater level of judicial scrutiny. The Supreme Court has recently held that “content-based” restrictions are subject to “heightened” judicial scrutiny, even in the context of commercial speech.

Proposals to ban use of the word “milk” on plant-based milk labels would certainly fall within this category. After all, the term “milk” is used on the labels of many other foods and beverages that do not meet the standard of identity for “milk” (“the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows”) – such as goat’s milk, sheep’s milk, buffalo milk, camel milk, or even Muscle Milk®.

IV. PROPOSED GUIDANCE

For all the foregoing reasons, PBFA urges the FDA to issue guidance stating as follows:

Consumers understand food names such as “almond milk,” “coconut milk,” “oat milk,” “plant-based milk,” and “soy milk.” These terms are appropriately descriptive and beneficial to consumers as they inform them about the taste of and uses for the

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28 Sorrell v. IMS Health, 564 U.S. 552 (2011) (invalidating a state law prohibiting the sale of pharmacy data as an impermissible restriction on free speech under the First Amendment).
29 21 C.F.R. 131.110(a).
product. Furthermore, under 21 C.F.R. 102.5, FDA regulations permit the establishment of a common or usual name by common usage. Given the longstanding and increasingly widespread use of names like “soy milk,” “coconut milk” and “almond milk” in the marketplace and the extent to which these names are recognized and used by consumers and the FDA itself, such names have been established as common or usual names through common usage.

The FDA has long recognized that strict adherence to standards of identity hampers innovation. Likewise, perceived legal uncertainty about labeling requirements serves to increase regulatory burdens on emerging industries.

As such, to provide certainty to manufacturers, the FDA re-affirms its long-standing position that a food shall not be considered to purport to be or be represented as “milk,” under 21 U.S.C. 343(g), solely because its label bears the term “milk” in its statement of identity or elsewhere on the label, provided that the label clearly indicates that the product is plant-based or otherwise not cow-derived by using one or more of the following words or phrases, or a comparable qualifier: plant-based, vegan, animal-free, almond, cashew, coconut, oat, or soy.

V. CONCLUSION

In conclusion, PBFA urges the FDA to truly “modernize” its approach to standards of identity by re-affirming a position it has held for half a century: that standardized names can be used on foods that are not, in all respects, the standardized foods and, more specifically, that the term “milk” may be used with appropriate qualifiers like “soy,” “almond,” “oat,” or “plant-based.”

Sincerely,

Nicole Negowetti
Senior Director of Policy
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.

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

- Whole milk: 47%
- Almond milk: 43%
- Oat milk: 28%
- Coconut milk: 23%
- Skim milk: 20%
- Soy milk: 19%
- Nonfat milk: 19%
- Lactose-free milk: 14%
- None of these: 5%
- Other nut milks: 4%
- Other grain milks: 2%
Purchase Frequency: Cow-Based Milk and Plant-Based Milk

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

- Never: 2%
- Less than 1 time per month: 11%
- 1 time per month: 17%
- 2 times per month: 28%
- 1 time per week: 28%
- More than 2 times per week: 6%

541 Responses

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

- Never: 3%
- Less than 1 time per month: 18%
- 1 time per month: 27%
- 2 times per month: 32%
- 1 time per week: 14%
- More than 2 times per week: 4%

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.

<table>
<thead>
<tr>
<th>Plant-based ingredients</th>
<th>Dairy ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk, water and sugar</td>
<td>Raw milk, sugar and preservatives</td>
</tr>
<tr>
<td>Almonds, cream</td>
<td>Regular milk mixed with granulate almond powder I guess.</td>
</tr>
<tr>
<td>almond and milk</td>
<td>almond extract and milk</td>
</tr>
<tr>
<td>Water, sugar, milk, almonds</td>
<td>almond, sugar, milk</td>
</tr>
<tr>
<td>Almond and Milk</td>
<td>Almond and cream of some sort.</td>
</tr>
<tr>
<td>almonds and milk</td>
<td>almonds, milk, sugar</td>
</tr>
<tr>
<td>milk</td>
<td>dairy and almond extract</td>
</tr>
<tr>
<td>Cheese, egg and pure milk</td>
<td>milk and almond</td>
</tr>
<tr>
<td>milk</td>
<td>Milk and water</td>
</tr>
<tr>
<td>almonds, sugar, water, regular milk</td>
<td>Milksugar</td>
</tr>
<tr>
<td>Almond &amp; milk</td>
<td>almonds, sugar, cream</td>
</tr>
<tr>
<td>Almond, soy, milk</td>
<td>almonds, lactose, soy</td>
</tr>
<tr>
<td>Almonds and dairy</td>
<td></td>
</tr>
<tr>
<td>I think water, starch and milk</td>
<td></td>
</tr>
</tbody>
</table>
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

- Whole milk: 93%
- Skim milk: 79%
- Nonfat milk: 76%
- Lactose-free milk: 55%
- Soy milk: 5%
- Oat milk: 3%
- Almond milk: 3%
- Coconut milk: 2%
Knowledge of Plant-Based Milks  

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

756 Responses

- Coconut milk: 85%
- Soy milk: 85%
- Almond milk: 83%
- Oat milk: 82%
- Lactose-free milk: 15%
- Skim milk: 4%
- Nonfat milk: 2%
- Whole milk: 1%
Knowledge of Cow-Based Milks

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

- Product B: 95%
- Both products: 3%
- Product A: 2%
- Neither product: 0%
- Do not know: 0%

Product A

Product B
Knowledge of Plant-Based Milks

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

756 Responses

- Product B: 91%
- Product A: 5%
- Neither product: 3%
- Both products: 1%
- Do not know: 0%

Product A

Product B