

**PLANT BASED FOODS ASSOCIATION**

**COMMENTS  
RE LABELING OF PLANT- BASED MILK ALTERNATIVES AND VOLUNTARY  
NUTRIENT STATEMENTS: GUIDANCE FOR INDUSTRY**

**(DOCKET NO. FDA-2023-D-0451)**

**JULY 31, 2023**

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July 31, 2023

**VIA ELECTRONIC SUBMISSION ([www.regulations.gov](http://www.regulations.gov))**

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**Re: Labeling of Plant- Based Milk Alternatives and Voluntary Nutrient Statements:  
Guidance for Industry (Docket No. FDA-2023-D-0451)**

Dear FDA:

The Plant Based Foods Association (“PBFA”) submits these comments in response to the Draft Guidance issued by the U.S. Food and Drug Administration (“FDA”) on “Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements” (the “Draft Guidance”).

PBFA is the first and only trade association in the U.S. representing the plant-based food industry. We currently represent over 200 of the nation’s leading plant-based food companies. PBFA’s mission is to champion, strengthen and elevate our members and the plant-based food industry. 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.

Plant-based food products should be regulated in a manner consistent with the regulation of other food products. PBFA appreciates that, in its Draft Guidance, the FDA re-affirmed its long-standing position that standards of identity, like “milk,” may be used in the names of other foods, including plant-based milks, so long as such use is not misleading. This has been the FDA’s position for decades, but nevertheless we are glad the FDA has confirmed that it applies to plant-based milks. We also appreciate the FDA’s recognition that plant-based milks do not purport to be, nor are they represented as, cow’s milk.

We are concerned, however, by two items in the Draft Guidance that impose labeling requirements on plant-based milks that depart from longstanding FDA requirements and are inconsistent with requirements imposed on any other food product:

- (1) The FDA’s “recommendation” that plant-based milks that use the term “milk” – either in their name or in a relative claim comparing the product to cow’s milk – and do not meet minimums for nine cherry-picked nutrients present in cow’s milk should bear a “prominent” front-of-pack disclaimer describing how they are nutritionally different from cow’s milk (the “Nutrient Disclaimers”).
- (2) The FDA’s “recommendation” that plant-based milks include in their statement of identity a description of the nature or source of the characterizing or predominant ingredient(s) in the product (the “Naming Obligations”).

The Nutrient Disclaimers and Naming Obligations do not address any valid FDA concern. Although the FDA rationalizes these “recommendations” on supposed findings of consumer confusion and alleged public health risks, there is no evidence of either, nor would the “recommendations” even address these unsubstantiated concerns. The Nutrient Disclaimers and Naming Obligations are entirely without precedent and are inconsistent with existing regulation and guidance. They single out plant-based milks, regulate them unlike any other food product in the marketplace, and would effectively dissuade them from labeling with the term “milk.” In fact, they protect the dairy industry at the expense of its growing<sup>1</sup> plant-based competition.<sup>2</sup>

As we stated in comments previously submitted to the FDA, 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. Shifting to a plant-based diet is shown to be the single most effective way to reduce our impact on Earth.<sup>3</sup> 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.<sup>4</sup> 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.”<sup>5</sup> Given the immediacy of climate change, among other reasons, in our prior comments, we urged the FDA to issue guidance on the labeling of plant-based milks that supported, not hindered, our industry.

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<sup>1</sup> Appx. 1, Ex. A, Plant-based milk sales rose 40% between 2019 and 2022 and the sector accounted for 15% of all U.S. milk sales in 2022. *2022 U.S. Retail Sales Data for the Plant-based Foods Industry*, PLANT BASED FOODS ASS’N (2023), <https://www.plantbasedfoods.org/2022-u-s-retail-sales-data-for-the-plant-based-foods-industry/>.

<sup>2</sup> In fact, dairy milk industry groups have been lobbying FDA to crack down on their plant-based competitors for years. *E.g.*, Appx. 1, Ex. B, Letter from Jim Mulhern, President & Chief Exec. Officer, Nat’l Milk Producers Fed’n, to Robert M. Califf, Comm’r, Food & Drug Admin. (June 26, 2023), *available at* <https://www.nmpf.org/wp-content/uploads/2023/06/NMPF-letter-to-FDA-Commissioner-re-Synthetic-Dairy-Product-Labeling-06262023.pdf>; Appx. 1, Ex. C, *Fake Milk Guidance Generates NMPF Push*, NAT’L MILK PRODUCERS FED’N (June 2, 2022), <https://www.nmpf.org/fake-milk-guidance-generates-nmpf-push/>; Appx. 1, Ex. D, Letter from Jim Mulhern, President & Chief Exec. Officer, Nat’l Milk Producers Fed’n, to Sylvia M. Burwell, Sec’y of Health & Human Servs., and Thomas J. Vilsack, Sec’y of Agric. (May 8, 2015), *available at* [https://www.nmpf.org/wp-content/uploads/2015/06/file\\_NMPF-Comments-DGAC-Report-050815.pdf](https://www.nmpf.org/wp-content/uploads/2015/06/file_NMPF-Comments-DGAC-Report-050815.pdf).

<sup>3</sup> Appx. 1, Ex. E, J Poore & T Nemecek, *Reducing Food's Environmental Impacts Through Producers and Consumers*, 360(6292) *SCI.* 987 (2018), *available at* <https://pubmed.ncbi.nlm.nih.gov/29853680/>.

<sup>4</sup> Appx. 1, Ex. F, JAN LUNDQVIST ET AL., STOCKHOLM INT’L WATER INST., *SAVING WATER: FROM FIELD TO FORK* (2008), *available at* [https://www.siwi.org/wp-content/uploads/2015/09/PB\\_From\\_Filed\\_to\\_fork\\_2008.pdf](https://www.siwi.org/wp-content/uploads/2015/09/PB_From_Filed_to_fork_2008.pdf).

<sup>5</sup> Appx. 1, Ex. G, Alon Shepon et al., *The Opportunity Cost of Animal Based Diets Exceeds All Food Losses*, 115(15) *PROC. NAT’L ACAD. SCIS.* U.S. 3804 (2018), *available at* <https://www.pnas.org/content/115/15/3804>.

Since the FDA released its Draft Guidance, the United Nations Intergovernmental Panel on Climate Change issued its 2023 Report.<sup>6</sup> The report recommended a shift to plant-based diets to prevent the worst of the climate crisis, stating that “plant-based diets can reduce GHG emissions by up to 50% compared to the average emission-intensive Western diet.”<sup>7</sup>

We are disheartened to see that the FDA is taking irrational action that would serve to discourage consumption of plant-based foods. We understand that this guidance is intended to increase consumer awareness and we remain hopeful that these comments will persuade the FDA to revise its Draft Guidance. We urge the FDA finalize its Draft Guidance without the Nutrient Disclaimers or Naming Obligations.

We discuss our concerns with these provisions in more detail below.

## **I. THE NUTRIENT DISCLAIMERS AND NAMING OBLIGATIONS ARE NOT REASONABLY RELATED TO ANY LEGITIMATE FDA CONCERN**

As we explained in prior comments, restriction of plant-based milk names – like the proposed Nutrient Disclaimers – would not survive a First Amendment challenge. The First Amendment “demands proof” that such restrictions are, at a minimum, reasonably related, to an actual FDA concern.<sup>8</sup> The FDA’s alleged concerns here are pretextual, but even if they were valid, the Nutrient Disclaimers do not address these concerns and are unjustified, unduly broad, and burdensome.

### **A. FDA’S CITED CONCERNS ARE NOT VALID**

The FDA rationalizes its recommended “Voluntary Nutrient Statements” through findings that: (a) consumers believe plant-based milk alternatives labeled with the term “milk” are nutritionally similar to cow’s milk, and (b) substituting plant-based milks for cow’s milk would “raise[] public health concerns” and “lead to inadequate intake of certain nutrients.” These findings are illegitimate and erroneous. In making them, the FDA relied on questionable research and information and failed to consider the substantial research and empirical evidence that undermines its predetermined conclusion.

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<sup>6</sup> Intergovernmental Panel on Climate Change, AR6 Synthesis Report: Climate Change 2023, *available at* <https://www.ipcc.ch/report/ar6/syr/>.

<sup>7</sup> Note, after lobbying by the meat industry, IPCC softened this reference. *See* Aurora Almendral, *The Meat Industry Blocked the IPCC’s Attempt to Recommend a Plant-based Diet*, QUARTZ (Mar. 24, 2023), <https://qz.com/ipcc-report-on-climate-change-meat-industry-1850261179#:~:text=As%20Thomas%20points%20out%2C%20the,draft%20leaked%20by%20Scientist%20Rebellion.>

<sup>8</sup> Appx. 1, Ex. H, *Miyoko’s Kitchen v. Ross*, No. 20-CV-00893-RS, 2021 WL 4497867 (N.D. Cal. Aug. 10, 2021).

## 1. THERE IS NO VALID EVIDENCE OF CONSUMER CONFUSION

Before attempting to impose unprecedented labeling obligations, unique to one category of products and inconsistent with existing regulation, the FDA must have well-grounded concerns—in this case, findings of consumer confusion. Such findings do not exist here – not even close. The FDA’s administrative file memorandum that summarizes the consumer research on which it relied (the “Research Memo”) lists six reports the agency reviewed related to “understanding how consumers...perceive the nutritional characteristics of plant-based milk alternatives and how their nutritional properties compare to those of milk.” Based solely on these six reports, the FDA concludes that consumers “do not understand the nutritional differences between milk and plant-based milk alternatives.”

PBFA engaged Dr. Joel Steckel, a Professor of Marketing at New York University’s Stern School of Business and well-regarded expert in consumer research, to review the six reports relied on by the FDA.<sup>9</sup> As described in Dr. Steckel’s report – and even as described by the FDA in its Research Memo – these reports do not support the FDA’s conclusion.

### Two Dairy Industry Reports

Two of the reports the FDA relied on – “Consumer Perceptions: Dairy Milk and Plant-based Milk Alternatives,” National Dairy Council, (“NDC Report”)<sup>10</sup> and “Consumer Perspective: Plant-based Beverages, Short Survey, April 2018,” WE ARE UNDENIABLY DAIRY, Dairy Management Inc., (“DMI Report”)<sup>11</sup> – were sponsored by Dairy Management, Inc. (“DMI”). DMI is trade association affiliated with the National Milk Producers Federation and the American Dairy Association and funded by the dairy industry, whose stated purpose is to “increase sales and demand for dairy.”<sup>12</sup>

As described in the Research Memo, the FDA relied only on the reports prepared by DMI, not the actual studies, which would describe the methodology and provide raw data---information crucial to analyze the legitimacy of the report itself. As such, the NDC Report and the DMI Report are inherently biased.<sup>13</sup> As the FDA explains of one study<sup>14</sup>: “the available methodology is insufficient for an assessment of the quality of the study” and “the small sample size of

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<sup>9</sup> Appx. 2, Ex. A, Report of Joel H. Steckel, Ph.D. Regarding Consumer Research Reports on Consumer Perceptions and Understanding of Plant-Based Milk Alternatives (July 31, 2023) [hereinafter “Steckel Report”].

<sup>10</sup> Appx. 2, Ex. C, NAT’L DAIRY COUNCIL, CONSUMER PERCEPTIONS: DAIRY MILK AND PLANT-BASED MILK ALTERNATIVES (Oct. 29, 2018).

<sup>11</sup> Appx. 2, Ex. D, DAIRY MGMT. INC., CONSUMER PERSPECTIVE: PLANT-BASED BEVERAGES (Apr. 2018).

<sup>12</sup> *About Us*, DAIRY MGMT. INC., <https://www.usdairy.com/about-us/dmi>.

<sup>13</sup> Appx. 2, Ex. A, Steckel Report at ¶ 70.

<sup>14</sup> Appx. 2, Ex. C, NAT’L DAIRY COUNCIL, CONSUMER PERCEPTIONS: DAIRY MILK AND PLANT-BASED MILK ALTERNATIVES (Oct. 29, 2018).

exclusive plant-based milk alternative buyers raises concerns about the reliability for this group of respondents.” And, as it says of the other:<sup>15</sup> “[The] [r]eport provides little information of the sampling method used. Many results are not subject to statistical test of group differences. Relatively small sample sizes of plain almond buyers make reliability of some results uncertain.”

Dr. Steckel found further that the NDC Report and the DMI Report contained vague research objectives<sup>16</sup> and were too outdated to be useful or relevant.<sup>17</sup> He also found that the NDC Report used ambiguous language (e.g., “key nutrients”), which respondents would not uniformly understand, thus rendering the results unreliable.<sup>18</sup>

### Consumer Reports Survey

With regard to the “Plant-Based Milk Survey: 2018 Nationally Representative Phone Survey, October 31, 2018,” CR Consumer Reports Survey Research Report (“CR Survey”),<sup>19</sup> even the FDA concluded that it has questionable methodology. In its assessment, the FDA states, “it is not clear whether the weighted data are generalizable to the U.S. population” and that “the relatively small size of plant-based milk alternative respondents casts uncertainty on the representativeness of data for this group of consumers.”

The *sole* question in the study related to consumers’ perceptions of nutritional equivalence asked generally: “Compared to cow’s milk, do you think unsweetened plant-based milks have more, the same, or less nutrients (i.e., protein, calcium, vitamin A, and potassium) than cow’s milk?” Although the question provides examples of “nutrients” it asked about them collectively, and asked about plant-based milks collectively, when there are a variety of products on the market with a myriad of nutrition profiles. As the FDA’s Research Memo explains, “It is hard to draw conclusions on how respondents compare nutrients between cow’s milk and individual plant-based milks because the survey did not ask which specific plant-based milks respondents referred to.” Likewise, Dr. Steckel explains: “[T]he question bundles four nutrients. Since there is only one question, it is not clear what a respondent should do if she thinks one type has more protein or less calcium. Also the question does not make clear whether these nutrients are the only ones to consider or just examples.”<sup>20</sup> Again, Dr. Steckel found that such ambiguous language rendered the results unreliable.<sup>21</sup> He also found that the CR Report was too outdated to be useful or relevant.<sup>22</sup>

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<sup>15</sup> Appx. 2, Ex. D, DAIRY MGMT. INC., CONSUMER PERSPECTIVE: PLANT-BASED BEVERAGES (Apr. 2018).

<sup>16</sup> Appx. 2, Ex. A, Steckel Report at ¶ 42.

<sup>17</sup> *Id.* at ¶¶ 52-54.

<sup>18</sup> *Id.* at ¶¶ 54, 58.

<sup>19</sup> Appx. 2, Ex. B, CONSUMER REPS., PLANT-BASED MILK SURVEY: 2018 NATIONALLY REPRESENTATIVE PHONE SURVEY (Oct. 31, 2018).

<sup>20</sup> Appx. 2, Ex. A, Steckel Report at ¶ 57.

<sup>21</sup> *Id.* at ¶ 55.

<sup>22</sup> *Id.* at ¶¶ 52-54.

## RTI Focus Groups Report, Commissioned by FDA

The “Focus Groups on Consumer Understanding and Behaviors Related to Plant-based Products and Foods: Final Report, August 2019,” (“RTI Focus Groups Report”)<sup>23</sup>, commissioned by the FDA, is just a collection of focus groups, asking open-ended questions of 110 participants. As the FDA’s Research Memo explains, “these findings are qualitative and cannot be projected to the whole population of plant-based milk alternative users in the US.” The FDA describes only three findings from the RTI Focus Groups Report related to nutrition, two of which actually contradict the FDA’s conclusion:

- *“There were frequent mentions that plant-based milk alternatives may be healthier than milk because they are lower in fat and cholesterol, and do not contain animal ingredients.”*
- *“Participants who knew that plant-based milk alternatives can be lower than milk in protein and calcium did not consider this an issue due to other benefits of plant-based milk alternatives.”*

Moreover, the FDA’s Research Memo failed to describe other insights and results from the RTI Focus Groups Report that contradict its conclusion, namely:

- Participants in most groups (8 out of 12) said plant-based milks were less nutritious than cow’s milk.<sup>24</sup>
- Ten groups mentioned reasons why they felt that plant-based milks were not healthy or less healthy than dairy milk. The reasons were fewer nutrients (e.g., calcium or vitamin D; 4 groups), less protein (3 groups), more additives (3 groups), or more sugar (4 groups).<sup>25</sup>

Dr. Steckel further found that the RTI Focus Group Report contained vague research objectives<sup>26</sup> and was based on a convenience homogenous sample of participants, with the many problems inherent in focus groups.<sup>27</sup>

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<sup>23</sup> Appx. 2, Ex. F, RTI INT’L, FOCUS GROUPS ON CONSUMER UNDERSTANDING AND BEHAVIORS RELATED TO PLANT-BASED PRODUCTS AND FOODS (Aug. 2019).

<sup>24</sup> *Id.* at 5, 13.

<sup>25</sup> *Id.* at 5, 17.

<sup>26</sup> Appx. 2, Ex. A, Steckel Report at ¶ 43.

<sup>27</sup> *Id.* at ¶¶ 65-66.



## Mintel Report

Likewise, the “Non-Dairy Milk US, September 2017,” (“Mintel Report”)<sup>28</sup> appears to contradict the FDA’s conclusion. In its Research Memo, the FDA’s only description of a finding in the Mintel Report related to consumers’ understanding of nutrition is that the report “mentions respondents consider milk better than plant-based milk alternatives in vitamins, minerals and protein.”

Dr. Steckel found that the Mintel Report was not designed to address consumer perceptions of nutrient content and was, like the other reports, outdated.<sup>29</sup>

## Online Anthropology Report

Finally, the “Plant-Based Diets are Here to Stay!, Proprietary consumer insights based on results from ‘Plant-Based Eating’ and ‘Plant-Based Behaviors & Motivations: Online Anthropology, conducted by HealthFocus® International and MotiveQuest, respectively,” (“HealthFocus Anthropology Report”)<sup>30</sup> is a review of online consumer conversations. As the FDA states in its Research Memo, the “sample is skewed toward opinions by individuals who are interested in the topic... and are willing to offer their unsolicited opinions on social media” and “the findings cannot be generalized to the U.S. population.”

Furthermore, Dr. Steckel found that the HealthFocus Anthropology Report disregarded certain online sources, lacked a research objective, and suggests findings that contradict the FDA’s conclusion (suggesting that dairy milk is perceived as having greater protein content than plant-based beverages).<sup>31</sup>

\* \* \*

Dr. Steckel concluded that “the six research reports, individually, and collectively, do not contain valid scientific evidence about how consumers perceive the nutrient contents of plant-based milk alternatives relative to those of dairy or cow’s milk.”<sup>32</sup> Notably, he opines as follows:

- “[D]rawing any conclusions about perceptions of relative nutrient content from the six research reports at issue can only be the result of what is often referred to as ‘confirmation bias’ on the part of the FDA.”<sup>33</sup>

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<sup>28</sup> Appx. 2, Ex. E, MINTEL, NON-DAIRY MILK: US, SEPTEMBER 2017 (2017).

<sup>29</sup> Appx. 2, Ex. A, Steckel Report at ¶ 71.

<sup>30</sup> Appx. 2, Ex. G, HEALTHFOCUS INT’L, PLANT-BASED DIETS ARE HERE TO STAY! (2019).

<sup>31</sup> Appx. 2, Ex. A, Steckel Report at ¶¶ 67, 73

<sup>32</sup> *Id.* at p. 16.

<sup>33</sup> *Id.* at ¶ 38.

- That “none of the six reports” were adequately designed to test the research objective at hand.<sup>34</sup>
- “[N]o coherent consistent story about consumer perceptions of the nutritional content of plant-based milk alternatives relative to dairy milk emerges from the six reports. As such, there can be no scientifically valid conclusion on the subject from the six reports.”<sup>35</sup>
- “Even if they were collected and reported properly and addressed the question of interest directly, the data that formed the basis of the six reports are as out of date as the Blackberry.” Adding, “I know of no marketing manager that would base product or advertising decisions on data that are that old.”<sup>36</sup>

Finally, Dr. Steckel, points out that – as recognized by the FDA – the reports are missing critical details. In its Research Memo, the FDA states, “(w)hile we often did not have sufficient information to conduct a thorough, critical review of these studies, we gained useful and relevant insight into consumers’ perceptions and understanding of plant-based milk alternatives.” Dr. Steckel finds this statement “curious,” opining “The FDA appears to be accepting at least some results presented in the six reports without knowing how they were obtained. No scientist worth his or her salt would ever do that.”<sup>37</sup>

\* \* \*

At the same time, the FDA failed to consider empirical research that directly addressed the issue of consumers’ understanding of nutritional differences between plant-based milk and cow’s milk.<sup>38</sup> Research conducted by University of Oklahoma professors Silke Feltz Adam Feltz found no confusion on the part of consumers about differences between cow’s milk and plant-based milks labeled with the term “milk.”<sup>39</sup> One major result from this study was: “Consistently, participants performed better on the subscale measuring differences between plant and animal-

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<sup>34</sup> *Id.* at ¶¶ 40-45.

<sup>35</sup> *Id.* at ¶¶ 46-51.

<sup>36</sup> *Id.* at ¶¶ 52-54.

<sup>37</sup> *Id.* at ¶¶ 60-63.

<sup>38</sup> Appx. 1, Ex. I, Silke Feltz & Adam Feltz, *Consumer Accuracy at Identifying Plant-based and Animal-based Milk Items*, 4 FOOD ETHICS 85 (2019). The Feltz study was submitted in its entirety by UCLA School of Law Animal Law and Policy Program as a comment on October 5, 2018 (Docket Number FDA-2018-N-2381-1104).

<sup>39</sup> See Appx. 1, Ex. J, Expert Report of Professors Adam Feltz, Ph.D. and Silke Feltz, Ph.D., *Turtle Island Foods, SPC v. Stitt*, No. CIV-20-938-F (2023); Appx. 1, Ex. K, Expert Declaration on Miyoko’s Labeling Conventions, Dr. Adam Feltz, Dr. Silke Feltz, *Miyoko’s Kitchen v. Ross*, No. 20-CV-00893-RS, 2021 WL 4497867 (N.D. Cal. Aug. 10, 2021); Appx. 1, Ex. L, Expert Report of Professors Adam Feltz, Ph.D. and Silke Feltz, Ph.D., *Turtle Islands Foods, SPC v. Thompson*, 425 F. Supp. 3d 1131 (W.D. Mo. 2019).

based milk products (M = 3.47 out of 6) than the subscale measuring differences among animal-based milk products (M = 1.89 out of 6).<sup>40</sup>

## 2. THERE ARE NO VALID PUBLIC HEALTH CONCERNS

The FDA's finding that substituting plant-based milks for cow's milk would "raise[] public health concerns" and "lead to inadequate intake of certain nutrients" is similarly suspect. There is no evidence—empirical, reliable, or otherwise—that indicates that plant-based milk consumers are at risk of nutrient deficiency or that a shift in consumption to plant-based milks would create some sort of public health risk.

As discussed further in Section I(B) below, only three of the nine comparative nutrients for the Nutrient Disclaimers are considered "nutrients of public health concern": Potassium, Vitamin D and Calcium.

With regard to Potassium, cow's milk does not meet the FDA definition of a good source of the mineral based on the updated DV of 4700 mg. According to United States Department of Agriculture ("USDA") nutrition data, one cup of cow's milk contains a modest 8% of the FDA's DV for Potassium.<sup>41</sup> There are many fruits and vegetables that contain much more potassium than milk.<sup>42</sup> These include leafy greens, dried beans and peas, potatoes, yams, squash, citrus fruits and melons, just to name a few.<sup>43</sup>

Fortified foods provide most of the Vitamin D in American diets and there are numerous fortified food sources in addition to cow's milk. In addition, natural sources of Vitamin D, include sunlight, fish, and mushrooms.<sup>44</sup>

With regard to Calcium, although cow's milk is a good source of the mineral, there is no sound evidence that failing to consume cow's milk leads to the health condition associated with calcium deficiency, osteoporosis. As described by the National Institutes of Health (NIH): "Because dairy products are a major source of calcium, you might assume that people with lactose intolerance who avoid dairy products could be at increased risk for osteoporosis. However, research exploring the role of lactose intolerance in calcium intake and bone health has produced conflicting results."<sup>45</sup> The NIH goes on to state: "Besides low-fat dairy products, good

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<sup>40</sup> Appx. 1, Ex. I, Feltz & Feltz.

<sup>41</sup> Appx. 1, Ex. M, *Milk, fluid, 1% fat, without added vitamin A and vitamin D*, USDA AGRIC. RSCH. SERV., <https://fdc.nal.usda.gov/fdc-app.html#/food-details/173441/nutrients>.

<sup>42</sup> Appx. 1, Ex. N, *Potassium*, NAT'L INST. HEALTH, <https://ods.od.nih.gov/factsheets/Potassium-HealthProfessional/#h3>.

<sup>43</sup> Appx. 1, Ex. O, *Food Sources of Potassium*, DIETARY GUIDELINES FOR AM.S., <https://www.dietaryguidelines.gov/food-sources-potassium>.

<sup>44</sup> Appx. 1, Ex. P, *Vitamin D*, NAT'L INST. HEALTH, <https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/>.

<sup>45</sup> Appx. 1, Ex. Q, NAT'L INST. HEALTH, WHAT PEOPLE WITH LACTOSE INTOLERANCE NEED TO KNOW ABOUT OSTEOPOROSIS (2006).

sources of calcium include dark green, leafy vegetables and calcium-fortified foods and beverages.”<sup>46</sup>

Furthermore, as discussed in Section I(A)(1) above and Section I(B)(2) below, there is no evidence that consumers think plant-based milk has similar Calcium or Vitamin D content as cow’s milk such that a disclaimer with regard to these nutrients would provide clarification.

## **B. THE NUTRIENT DISCLAIMERS WOULD NOT ADDRESS FDA’S ALLEGED CONCERNS**

Even if the FDA’s findings were valid, the Nutrient Disclaimers do not address the FDA’s stated concerns. The Nutrient Disclaimers are overly broad because they relate to nutrients that are, admittedly, not of public health concern, and are unnecessary because existing regulations already address the stated underlying concerns.

### **1. THE NUTRIENT DISCLAIMERS RELATE TO NUTRIENTS THAT ADMITTEDLY ARE NOT OF PUBLIC HEALTH CONCERN**

The Nutrient Disclaimers concern nine cherry-picked nutrients: Calcium, Protein, Vitamin A, Vitamin D, Magnesium, Phosphorus, Potassium, Riboflavin, and Vitamin B12. Of these nine nutrients, only three (Potassium, Vitamin D and Calcium) have been identified as “nutrients of public health concern” in the Dietary Guidelines. Five (Vitamin A, Magnesium, Phosphorus, Riboflavin, and Vitamin B12) are not even considered significant enough by the FDA to be required on the Nutrition Facts panel (“NFP”).

The FDA acknowledges this in the FAQ section of its Draft Guidance:

**Q 2.6. If my plant-based milk alternative contains the same amount of nutrients of public health concern as milk, but has lower levels of magnesium, which is not under-consumed, does FDA recommend that my product still bear a voluntary nutrient statement?**

A. Yes, if a manufacturer chooses to use the term “milk” in the name of a plant-based milk alternative that has a lower amount of magnesium than milk, we recommend the product bear a voluntary nutrient statement on the PDP, such as “Contains a lower amount of magnesium than milk.”

Incredibly, the FDA is admittedly obligating plant-based milk producers to use Nutrient Disclaimers even where no public health concern is raised. If nutrients do not raise public health concerns, there is certainly no justification for an unprecedented, unique, disparaging disclaimer alerting consumers to lower levels of them.

Regarding the three “nutrients of concern” at issue (Potassium, Vitamin D, and Calcium), as discussed in Section I(A)(2) above, substituting cow’s milk for plant-based milks would not lead

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<sup>46</sup> *Id.*

to increased deficiencies of these nutrients. Moreover, for all three, if consumers want more information, they can look to the NFP.

## **2. EXISTING REGULATIONS ARE SUFFICIENT TO ADDRESS FDA'S ALLEGED CONCERNS**

As discussed in Section II below, the Nutrient Disclaimers and Naming Obligations would be unprecedented. No other food product is subject to similar “recommendations” because, among other reasons, existing regulations sufficiently convey necessary information to consumers.

The FDA already requires macronutrients, as well as vitamins and minerals that are “nutrients of concern” to be labeled in the NFP. For the “nutrients of concern” at issue (Potassium, Vitamin D and Calcium), a product’s NFP must state the amount of nutrient, as well as the percent daily value (“DV”) – indicating to consumers both the amount of each nutrient they are recommended to consume daily and the percent of that DV they would be gaining by consuming a serving of the product.

To the extent that plant-based milks compare their nutrient content to the nutrient content of cow’s milk, FDA regulations concerning “relative claims” already require them to (a) state the percentage or fractional difference of the nutrient compared and (b) make an immediately adjacent disclaimer stating the amount of that nutrient in cow’s milk.<sup>47</sup>

## **3. THE NUTRIENT DISCLAIMERS WOULD CONFUSE CONSUMERS**

The Nutrient Disclaimers would just serve to confuse consumers and undercut their informed choices. In the Draft Guidance, the FDA cites research showing that some consumers purchase plant-based milks because they believe they are healthier than cow’s milk, and that the reason consumers think plant-based milks are healthier is “because they are lower in fat and cholesterol, and do not contain animal ingredients.” These consumer understandings are accurate. Plant-based milks are lower in fat and cholesterol than cow’s milk and, of course, they do not contain animal ingredients. None of these facts are disputed. Whether these facts render plant-based milks “healthier” than cow’s milk is, at least somewhat, subjective. The Nutrient Disclaimers would simply function to point out to consumers the ways in which cow’s milk may be “healthier” than plant-based milks – many of which are fairly insignificant and many of which are misleading.

Six nutrients at issue in the Nutrient Disclaimers, including Protein, Vitamin A, Magnesium, Phosphorus, Riboflavin, and Vitamin B12, are not under-consumed “nutrients of concern.” A prominent front-of-pack disclaimer (quite possibly the only nutrition information on the PDP) stating “Contains lower amounts of [nutrients] than milk.” would give consumers the false impression of the importance of those nutrients.

For two nutrients at issue in the Nutrient Disclaimers, Magnesium and Potassium, cow’s milk is not even a “good source” of them. According to USDA nutrition data, a cup of cow’s milk

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<sup>47</sup> 21 CFR § 101.13(j)(2).

contains 6% of the FDA’s DV for Magnesium and 8% of the FDA’s DV for Potassium.<sup>48</sup> Here too, a prominent front-of-pack disclaimer (again, quite possibly the only nutrition information on the PDP) stating “Contains lower amounts of Magnesium [or Potassium] than milk.” would give consumers a false impression: that cow’s milk is a good source of Magnesium or Potassium.

Moreover, with regard to any nutrient, a prominent front-of-pack disclaimer stating, “Contains lower amounts of [nutrients] than milk.” is intended to give consumers of plant-based milks the impression that cow’s milk would be better for them. The Nutrient Disclaimers require more than simply factual, accurate and uncontroversial information. The implication that cow’s milk is healthier than plant-based milk is subjective – and likely to confuse consumers, who for other subjective, but accurate, reasons think plant-based milk is healthier.

### **C. FDA PROVIDES NO BASIS FOR THE NAMING OBLIGATIONS**

The FDA provides no justification for the Naming Obligations. It simply concludes that “omitting a descriptor of a particular legume may be confusing to consumers as the product would not be readily distinguishable from other types of plant-based milk alternatives,” and that “consumers should be able to easily determine the plant source just from looking at the name of the food on the label.”

As discussed in Section II(B) below, absent specific and limited circumstances, FDA regulations do not require a product’s “characterizing ingredient” to be in its statement of identity. The FDA gives no reason why consumers of plant-based milks would be any more “confused” about their ingredients than consumers of other food products that do not list their ingredients in their product name. For example, “gluten free” breads or noodles have no obligation to include their “characterizing ingredients” in their product names, even though “conventional” breads and noodles are made with wheat flour.

To the extent consumers want more information about the ingredients in any food product, they can look to ingredient list.

## **II. THE NUTRIENT DISCLAIMERS AND NAMING OBLIGATIONS ARE UNPRECEDENTED**

The Draft Guidance creates unprecedented obligations that are inconsistent with existing regulations and that refer to school nutrition standards inappropriate for market regulation.

### **A. NUTRIENT DISCLAIMERS ARE NOT RECOMMENDED FOR ANY OTHER PRODUCT CATEGORY**

The Nutrient Disclaimers would be an obligation unique to plant-based milks; no similar disclaimers are recommended for any other product category. In fact, the FDA does not currently mandate *any* nutrition information on a product’s principal display panel (“PDP”).

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<sup>48</sup> Appx. 1, Ex. M, *Milk, fluid, 1% fat, without added vitamin A and vitamin D*.

Under existing FDA regulation, unless a product makes additional optional claims, only a discrete amount of information is mandatory on its label. On the PDP the only two requirements are the statement of identity and net quantity statement. On the information panel, there are three requirements: nutrition labeling, the ingredient list with requisite allergens, and name and address information.

The statement of identity must be the standardized name established by any applicable law or regulation, or if there is none, the common or usual name of the food, or if there is none, an appropriately descriptive term.<sup>49</sup> In the Draft Guidance, the FDA explains that because no standardized names have been established for plant-based milks, they must be labeled with either their common or usual names, which have been established by common usage in some cases, like “soy milk” and “almond milk,” or, in absence thereof, by an appropriately descriptive term. The FDA has placed not placed any restrictions – through regulation or guidance – on “appropriately descriptive terms” for statements of identity, except that they should not be misleading.

Under existing regulation, the only circumstance in which nutrient disclaimers are required (or even recommended) is when a product chooses to make a voluntary “nutrient content claim.” “Nutrient content claims” are defined by regulation as claims “that expressly or impliedly characterize the level of a nutrient of the type required to be in nutrition labeling”<sup>50</sup> – namely for seven categories of nutrients: calories, total fat, saturated fat, cholesterol, sodium, sugars, and fiber. FDA regulations require that where a nutrient content claim is made on a food label and a nutrient in that food exceeds certain prescribed levels of certain nutrients (total fat, saturated fat, cholesterol, sodium and, for certain nutrient content claims, calories), the food label must include a disclosure statement that identifies that nutrient through a disclaimer stating, “See nutrition information for [exceed nutrient] content.”<sup>51</sup>

With the newly proposed Nutrient Disclaimers, the FDA is essentially equating the word “milk” (but only when used by plant-based milks) to a nutrient content claim, saying that usage of the word gives rise to the obligation for a nutrient disclaimer. This is totally unprecedented. No such statement is recommended when using any other standardized name.

Furthermore, the Nutrient Disclaimers for “milk” are more expansive than disclosure statements for nutrient content claims for at least three reasons. One, the word “milk” would bring with it an implication of minimums for nine nutrients – twice the number implicated for nutrient content claims. Two, for “milk” the implicated nutrients would include nutrients not even required to be labeled in the Nutrition Facts panel. Nutrient content claims only implicate mandatory nutrients. Three, the Nutrient Disclaimers for “milk” obligate the plant-based milks to characterize their levels of the implicated nutrients in a way that disparages the product when compared with milk, *i.e.*, “Contains a lower amount of \_\_\_ than milk,” whereas the disclaimers for nutrient content

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<sup>49</sup> 21 CFR § 101.3 (b).

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*



claims just require a reference to the product’s Nutrition Facts Panel, *i.e.*, “See nutrition information for \_\_\_ content.”

Per the logic of the Draft Guidance, in which the Nutrition Facts Panel and ingredients list are insufficient to provide consumers with comparative nutritional information, similar nutrient disclaimers should be recommended for many other categories of food products in the market. For example, the FDA should recommend that “juice drinks” disclaim that they “Contain more added sugar and lower amounts of vitamins and minerals than 100% juice,”<sup>52</sup> that beef burgers disclaim they contain more cholesterol than plant-based burgers,<sup>53</sup> and that breads that are not 100% whole grain disclaim that they “Contain lower amounts of fiber and vitamins and minerals than 100% whole grain bread.”<sup>54</sup>

## **B. THE NAMING OBLIGATIONS ARE INCONSISTENT WITH EXISTING REGULATION**

The Naming Obligations are also inconsistent with existing regulation. As described in Section II(A) above, existing regulations require a product’s statement of identity to be the standardized name established by any applicable law or regulation, or if there is none, the common or usual name of the food, or if there is none, an appropriately descriptive term.<sup>55</sup> FDA regulations do not generally require a product’s “characterizing ingredient” to be in its statement of identity, except in the case of specific common or usual names for non-standardized foods established by regulation, which do not apply to plant-based milks.

## **C. SCHOOL NUTRITION STANDARDS ARE INAPPROPRIATE FOR MARKET REGULATION**

For the nutrition composition of cow’s milk that plant-based milks must meet or else disclaim, the FDA refers to the USDA’s Child Nutrition Programs (“CNP”) standard. These school nutrition standards are not appropriate for market regulation as they designed for a unique environment that is separate and distinct from the consumer marketplace.

The CNP, established “to safeguard the health and well-being of the Nation’s children” and promote consumption of surplus agricultural commodities, provide free and reduced-cost meals to American school children and set forth nutritional guidelines schools must follow to receive

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<sup>52</sup> Appx. 1, Ex. R, *Don’t Be Fooled by Misleading Juice Labels*, CONSUMER REPS. (Apr. 7, 2008), <https://www.consumerreports.org/media-room/press-releases/2008/04/consumer-reports-warns-dont-be-fooled-by-misleading-food-labels/>.

<sup>53</sup> See Moira Lawler, *Are Plant-Based Alternatives to Meat Actually Healthier?*, EVERYDAY HEALTH (May 27, 2022), <https://www.everydayhealth.com/diet-nutrition/are-beyond-burgers-impossible-burgers-healthier-than-meat/>.

<sup>54</sup> Appx. 1, Ex. S, Katherine D. McManus, *Whole Grains or No Grains? Food Labels Can be Misleading*, HARVARD MED. SCH., <https://www.health.harvard.edu/blog/whole-grain-or-no-grain-food-labels-can-be-misleading-2020093021025>.

<sup>55</sup> 21 CFR § 101.3 (b).



such funding.<sup>56</sup> Since 1994, federal law has required school meals to be “consistent with” the USDA’s Dietary Guidelines for Americans.<sup>57</sup>

The USDA reports that school meals represent the bulk of the caloric and nutritional intake for many students, particularly those from food insecure households.<sup>58</sup> Sadly, USDA research has shown that “school meals are the healthiest meals children eat in a day.”<sup>59</sup> For many students, school meals may be the only nutritious meals they receive that day. As such, the USDA sets nutrition standards for school meals to ensure that school children have the right balance of foods for adequate nutrient intake.<sup>60</sup> In other words, the nutrition standards for each food type are based on the other foods being offered in the school meals and assume children are not getting nutrition from sources other than these school meals.

By law, cow’s milk is required to be served in CNP meals.<sup>61</sup> Schools may offer “nondairy beverages” as substitutes for cow’s milk only if they are “nutritionally equivalent” to cow’s milk and meet nutrition standards set by the USDA.<sup>62</sup> The “Fluid Milk Substitutes Nutrient Criteria” appended to the Draft Guidance are these USDA-determined nutrition standards.

The “Fluid Milk Substitutes Nutrient Criteria” was designed specifically for use in the CNP, which must meet specific nutrient recommendations for each meal and snack, including having a fluid milk serving on the tray to receive federal reimbursement. In that context, the requirement that non-dairy beverages be nutritionally equivalent to cow’s milk has some logic: to help children, some of whom may not have other sources of nutrition, meet daily nutrition requirements.

Outside such a program, however, consumers purchase plant-based milks for a wide range of reasons other than nutrition—including taste, allergies, personal beliefs, religious practices, and cost. While some consumers may be driven by nutritional content, in an open marketplace, nutrients of interest vary widely, and consumers have a wide range of options for meeting their daily nutrition requirements.

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<sup>56</sup> Richard B. Russell National School Lunch Act, Pub. L. No. 79-396, 60 Stat. 230 (1946) (codified as amended at 42 U.S.C. §§1751-1769j (2019)).

<sup>57</sup> Healthy Meals For Healthy Americans Act of 1994, Pub. L. No. 103-448, § 107, 108 Stat. 4699, 4704 (1994).

<sup>58</sup> Appx. 1, Ex. T, *National School Lunch Program*, USDA ECON. RSCH. SERV., <https://www.ers.usda.gov/topics/food-nutrition-assistance/child-nutrition-programs/national-school-lunch-program/>.

<sup>59</sup> Appx. 1, Ex. U, *Strengthening School Meals for Healthier Kids*, USDA FOOD & NUTRITION SERV., <https://www.fns.usda.gov/cn/strengthening-school-meals-healthier-kids>.

<sup>60</sup> *Id.*

<sup>61</sup> National School Lunch Act (NSLA), 42 U.S.C. § 1758(a)(2).

<sup>62</sup> *Id.*

In addition, the “Fluid Milk Substitutes Nutrient Criteria” include several nutrients that are not identified as nutrients of public health concern in the Dietary Guidelines for Americans, including Protein, Vitamin A, Magnesium, Phosphorus, Riboflavin and Vitamin B12. The proposed rule notes that the USDA identified cow’s milk as the primary food source for Riboflavin, Vitamin B12, Magnesium, Phosphorus, and Potassium for children, and thus included those nutrients in the standard. Again, this rationale does not align to the diversity of the population and dietary patterns of the general population and disregards that there are many other food sources of these nutrients beyond cow’s milk. For example, Magnesium is widely available in foods and beverages, with green leafy vegetables, legumes, nuts, seeds, and whole grains, containing more Magnesium than a serving of cow’s milk.<sup>63</sup>

### **III. THE NUTRIENT DISCLAIMERS WOULD EFFECTIVELY DISSUADE PLANT-BASED MILKS FROM USING THE TERM “MILK”**

The Draft Guidance purports to allow plant-based milk companies to continue using the term “milk.” As the FDA states therein, there is no legal basis on which to explicitly disallow plant-based milks from using the term “milk” because (a) plant-based milks do not purport to be, nor are they represented as cow’s milk, (b) the FDA has long-allowed standardized names of foods to be used in the names of other foods, so long as such use is not misleading, and (c) such a prohibition would be a clear violation of the First Amendment. Instead, the FDA “recommends” “voluntary” disclaimers of purportedly, objective factual nutrition information.

Yet, the Nutrient Disclaimers are tantamount to requirements, as companies that do not follow the FDA’s “recommendations” risk consumer class action. Although these lawsuits should not succeed – a similar lawsuit was dismissed on early motion practice and affirmed by the Ninth Circuit<sup>64</sup> – the cost of defense could put a small plant- based milk company out of business.

The Nutrient Disclaimers are also disparaging (not purely factual) and are unduly burdensome.<sup>65</sup> As discussed in Section I(B)(3), the disclaimers function to point out to consumers nine ways in

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<sup>63</sup> Appx. 1, Ex. V, *Magnesium*, NAT’L INST. HEALTH, <https://ods.od.nih.gov/factsheets/Magnesium-HealthProfessional/>.

<sup>64</sup> Appx. 1, Ex. W, *Painter v. Blue Diamond Growers*, No. CV 17-02235-SVW-AJW, 2017 WL 4766510 (C.D. Cal. May 24, 2017), *aff’d*, 757 F. App’x 517 (9th Cir. 2018) (Upholding dismissal of consumer class action alleging “consumers will be deceived into thinking that almond milk has the same nutritional value as cow’s milk.” The district court found that “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 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.”

<sup>65</sup> Commercial disclosure requirements, including disclaimers, are constitutional only if they are (“reasonably related to the State’s interest in preventing deception of consumers,” (b) require “purely factual, accurate, and uncontroversial information” about the product, and (c) are not “unjustified or unduly burdensome.” Appx. 1, Ex. X, *Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626, 651(1985).

which cow's milk may, subjectively, be more nutritious than plant-based milks and none of the ways in which plant-based milks more nutritious than cow's milk. And, as discussed in Section III, these disclaimers are unprecedented, apply only to plant-based milks, with no analogous disclaimers recommended for any analogous "substitutes."

If this proposal is made final, many plant-based milk companies will effectively be dissuaded from using the term "milk" on their label. For this reason, among others, the Nutrient Disclaimers will not withstand First Amendment scrutiny.<sup>66</sup>

#### IV. CONCLUSION

In conclusion, PBFA urges the FDA to finalize its Draft Guidance without the unsupported and unprecedented Nutrient Disclaimers or Naming Obligations.

Sincerely,



Nicole Negowetti  
Vice President, Policy and Food Systems

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<sup>66</sup> See e.g., Appx. 1, Ex. Y, *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136 (1994) (finding incompatible with First Amendment restraints a government requirement that lawyers who stated they were specialists on their business cards and letterhead include a disclaimer that was so detailed, it effectively ruled out their ability to use the designation). In its review of "First Amendment Considerations" in the Draft Guidance, the FDA notes that "some courts have held that a state can require that the labeling on the plant-based alternative product include a prominent disclosure indicating that the product is plant-based" – implying that the Draft Guidance would survive a First Amendment challenge. This implication is flawed. For one, in none of the court cases cited has a final opinion been issued upholding the regulation that was challenged. Moreover, requiring a "plant-based" disclaimer is entirely different than obligating plant-based milks to include a disparaging comparison to nine cherry-picked nutrients in cow's milk.