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

Comments of Consumer Reports to the
Food and Drug Administration on the Notice and Request for Comments on
"Use of the Names of Dairy Foods in the Labeling of Plant-Based Products"
Docket No. FDA-2018-N-3522

Overview and Recommendations

Consumer Reports welcomes the opportunity to comment on the use of the names of dairy foods in the labeling of plant-based products. Consumer Reports is an independent, nonprofit member organization that works side by side with consumers to create a fairer, safer, and healthier world. One of our areas of focus is food labels, which should be clear, honest, and transparent.

The Food and Drug Administration (FDA) indicated in its Federal Register notice that it is "interested in learning whether consumers are aware of and understand differences between the basic nature, characteristics, ingredients and nutritional content of plant-based products and their dairy counterparts." The FDA requests this information in order to inform its "development of an approach to the labeling of plant based products that consumers may substitute for dairy foods"

We are pleased to share with the FDA the results of a nationally representative survey of over 1,000 U.S. adults conducted by Consumer Reports in October 2018 that probed consumers' understanding of plant-based milks. The results raise some important concerns. The survey indicates that approximately half of all American consumers (52%) lack an accurate understanding about the nutrients in plant-based milks, believing that these milks have the same or higher levels of nutrients as cow's milk, when in most cases this is not correct. Misunderstandings are even more prevalent among consumers who always or often purchased plant-based milk, compared to those who purchased cow's milk.

We urge the FDA to consider labeling options that will lead to consumers being better informed about the nutritional content of plant milks, compared to cow's milk. This is important in terms of the FDA's basic responsibility to ensure that labels are truthful and not misleading. It is also important in terms of the FDA's responsibility to protect public health, since misunderstandings could have

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adverse health consequences. A parent might, for example, substitute plant-based milk for cow's milk in a child's diet without adequate nutrient supplementation. Cases where this has occurred have been identified.

From the perspective of preventing consumer misunderstandings, we suggest two possible options that the FDA may consider for the labeling of plant-based products.

One option would be for the FDA to allow only beverages that have nutritional profiles similar to cow's milk to use the term "milk" on the label, as long as the plant source is plainly identified as part of the name. In terms of the nutritional criteria to use, we propose that the FDA determine the "key nutrients" that cow's milk provides. The FDA should consider not only these nutrients, but also differences in their bioavailability. To use this approach, the FDA would need to develop a standard of identity for plant-based milks that would require that they have a similar nutritional profile to cow's milk in terms of the "key nutrients" identified. Plant-based beverages that do not supply these "key nutrients" would be prohibited from calling themselves "milk."

In this regard, the FDA may want to consider how the USDA Dietary Guidelines for Americans addresses inclusion of plant milks in the dairy group. The Dietary Guidelines list key nutrients supplied by the dairy group, which include: calcium, phosphorus, vitamin A, vitamin D (in products fortified with vitamin D), protein, potassium, and magnesium.[1] At present, the only non-dairy product that is part of the dairy group in the Dietary Guidelines is soy milk fortified with calcium, vitamin A, and vitamin D.

A second option is for the FDA to require prominent labels on all plant-based products labeled as milk indicating how they deviate from cow's milk in terms of key nutrients that the agency has determined are provided by cow's milk. The FDA would require a front-of-package disclosure on the products that do not provide the levels of key nutrients typically found in cow's milk—naturally or by fortification—under the agency's general authority to prevent misleading labeling codified at 21 U.S.C. § 343(a)(1).

We submit additional, more detailed information below. We also provide, for the FDA's consideration, links in the references to studies that found that certain plant-based milks are not nutritionally equivalent to cow's milk, as well as studies that found adverse health effects in children when plant-based milks were substituted for cow's milk without adequate nutrient supplementation. We also present responses to the specific questions the FDA asks in its *Federal Register*

[1] https://health.gov/dietaryguidelines/2015-scientific-report/15-appendix-E3/e3-6.asp

notice, organized by question. Finally, our full survey results are appended to these comments.

Consumer Reports Survey Data

Consumer Reports conducted a nationally representative phone survey of 1,003 U.S. adults in October 2018 to provide insight into consumers' understanding and perceptions regarding the nutrient differences between cow's milk and plant-based milks, reasons for choosing plant-based milks, perceptions of front-of-package claims, and use of the ingredient list. Consumer Reports' survey asked about plant-based milks and not products that resemble other types of dairy foods, such as butter or yogurt. The results are summarized in the paragraphs below, and we provide answers to the FDA's specific questions at the end of this comment.

Plant-based milks are consumed by a significant number of Americans. Consumer Reports' survey found that while about two thirds, or 68%, of Americans say they usually or always purchase cow's milk, 18% say they purchase cow's and plant-based milk equally, and 10% say they usually or always purchase plant-based milk. Consumer Reports' survey found that about a third, or 35%, of Americans have purposely drunk or cooked with plant-based milk as a substitute for cow's milk.

Our survey results suggest that the majority of Americans are poorly informed about the nutrient content of plant-based milks versus cow's milk. When asked whether plant-based milk has more, the same, or less of the nutrients found in cow's milk (protein, calcium, vitamin A, and potassium), only 26% correctly responded that the plant-based milks had less. (This is true even for soy milk, which has a nutrient profile close to, but still not the same as, cow's milk.) Some 27% of Americans believed the plant-based milks had more nutrients, and 25% thought they were the same. Thus, a total of 52%, or about half of those surveyed, appeared to lack an accurate understanding about nutrients in plant-based milks compared to cow's milk. A substantial 20% of Americans just didn't know.

Misunderstandings were even more pronounced among consumers who said they usually or always purchase plant-based milk. In this group, 42% of consumers said they thought plant-based milks have more of these nutrients than cow's milk, compared with 22% of consumers who usually or always purchase cow's milk. Only 12% of consumers who report always or usually purchasing plant-based milks thought that these products have less of these nutrients. This suggests that a substantial segment of consumers who buy plant-based milk are not aware that some of the nutrients found in cow's milk are not present, or are not present in the same quantity or form, in the plant-based milks.

When those who purchase plant-based milk were asked to choose among eight possible reasons for why they did so, the most commonly selected reason, chosen by 58%, was that plant-based milk is "healthier than cow's milk."

Our survey also sought data on how claims that sometimes appear on plant-based milk products might affect consumer perceptions of the nutritional value of the product. We asked consumers to tell us, after reading the following actual front-of-package claims – "plant-powered protein," "heart-healthy protein," "cholesterol-free and heart healthy protein" and "original nutritious pea milk" – whether the claims suggested that plant-based milk is a "good substitute for cow's milk." Some 60% of respondents said yes. Thus, consumers appear to be influenced, at least to some degree, by statements on the package.

Studies Show Plant-Based Milks Are Not Nutritionally Equivalent to Cow's Milk

A number of studies have found that while plant-based milks vary in their nutritional value—depending on the product and whether it is fortified with vitamins and/or calcium—such milks generally do not provide the same nutrients as dairy milk. A study published in 2017 examined the protein and nutrient contents of dairy milk and a range of plant-based milks (almond, cashew, coconut, hazelnut, hemp, oat, rice, and soy) purchased in the Buffalo, NY, area and found that "cow's milk has higher protein content and quality compared with most of these [plant-based] products. ... These should not be considered nutritional substitutes for cow's milk."[2] The study also pointed out that even if the plant-based milk was fortified with calcium, vitamin D, and extra protein, the nutrient quality and bioavailability of those nutrients was not established as being equal to milk. Another recent study of plant-based milk also found that these milks aren't an adequate substitute for cow's milk: "The nutritional properties depend on the plant source, processing and fortification. As some products have extremely low protein and calcium contents, consumer awareness is important when plant-based milk substitutes are used to replace cow's milk in the diet."[3]

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[2] Pg. 799 in Singhal S, Baker RD and SS Baker. 2017. A comparison of the nutritional value of cow's milk and nondairy beverages. *Journal of Pediatric Gastroenterology and Nutrition* 64(5): 799-805.

[3] Makinen OE, Wanhalinna V, Zannini E and EK Arendt. 2015. Foods for special dietary needs: Non-dairy plant based milk substitutes and fermented dairy type products. *Crit. Rev. Foo. Sci. Nutr.* At: https://www.researchgate.net/publication/270656365_Foods_for_Special_Dietary_Needs_Non-Dairy_Plant_Based_Milk_Substitutes_and_Fermented_Dairy_Type_Products

Protein content is of particular concern. The standard approach to evaluating protein quality for humans is by using the digestible indispensable amino acid score (DIAAS) or the protein digestibility corrected amino acid score (PDCAAS).[4] The DIAAS of cow's milk protein is 31% higher than that of soy protein, 100% higher than that of rice protein, and 118% higher than that of oat protein, showing that the protein quality of cow's milk protein is far superior to that of soy, rice or oats. Almond protein is of particularly low relative quality; while there is no DIAAS for almonds, the PDCAAS is 0.22 compared to a PDCAAS of 1.0 for cow's milk, meaning that the protein quality of cow's milk is almost four times that of almond protein.[5]

In addition, even when plant-based beverages have been fortified with extra protein or calcium, those nutrients might not be as bioavailable as they are in cow's milk. For example, studies have clearly shown that potential calcium fortificants varied in their bioavailability, meaning that the level stated on the label was not actually the level that was absorbed into the body.[6] As one study concluded, "each product must be explicitly tested to establish the degree to which its calcium is available to consumers."[7]

These and other relevant studies on nutritional content of plant milks should be considered by the FDA in developing labeling policy.

The FDA Should Explore Potential Public Health Hazards Associated With Current Labeling Practices and Consider Alternative Approaches

An initial look at the literature indicates that the difference in nutritional quality of some non-cow's milks can lead to adverse health effects if they are substituted in the diet of young children in place of cow's milk without adequate nutrient supplementation. We urge the FDA to investigate the degree to which this may be a public health hazard, the best ways to address it, and the potential effectiveness of addressing it through changes in labeling of plant milks.

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[4] Rutherfurd SM, Fanning AC, Miller BJ and PJ Moughan. 2015. Protein digestibility-corrected amino acid scores and digestible indispensable amino acid scores differentially describe protein quality in growing male rats. *The Journal of Nutrition* 145: 372-9. At: https://academic.oup.com/jn/article/145/2/372/4585766

[5] See Table 3 in Sousa A and KA Kopf-Bolanz. 2017. Nutritional implications of an increasing consumption of non-dairy plant-based beverages instead of cow's milk in Switzerland. *Journal of Advances in Dairy Research* 5(4). At: https://www.omicsonline.org/open-access/nutritional-implications-of-an-increasing-consumption-of-nondairy-plantbased-beverages-instead-of-cows-milk-in-switzerland-2329-888X-1000197.pdf

[6] Heaney RP, Rafferty K, Dowell MS and J Bierman. 2005. Calcium fortification systems differ in bioavailability. *Journal of American Dietetic Association* 105(5): 807-809.

[7] Rafferty K, Walters G and RP Heaney. 2007. Calcium fortificants: overview and strategies for improving nutriture of the U.S. population. *Journal of Food Science* 72(9): R152-R158.

For example, a 2014 study from Canada of 2,831 children one to six years of age found that increased consumption of non-cow's milk (e.g., soy, rice, goat) was associated with lower levels of vitamin D (Canada requires cow's milk to be fortified with vitamin D, while in the U.S., most cow's milk is voluntarily vitamin D fortified).[8] A 2017 cross-sectional study of 5,034 healthy Canadian children two to six years of age found a highly statistically significant "dose-dependent association between higher non-cow milk consumption and lower height"[9]; in other words, the more non-cow milk that a child drank, the shorter that child. The study found, the "height difference for a three-year-old child consuming three cups of non-cow milk per day, relative to a three cups of cow milk per day was 1.4 cm."

These health effects can also show up in more severe ways. Scientists and doctors at an Atlanta-area hospital reported on two case studies of toddlers with severe nutritional deficiencies due to consumption of plant-based milks in place of cow's milk, including a 22-month-old with severe kwashiorkor, a protein-energy deficiency disease, and a 17-month-old diagnosed with rickets, which is caused by inadequate vitamin D in the diet.[10] Furthermore, a study of twelve cases of kwashiorkor in US children found that half of the cases were due to a perceived intolerance to formula or cow's milk, leading to various nutritionally inadequate diets, including at least one that included substitution of formula with a rice milk.[11]

If a thorough FDA evaluation of current research on these and other potential health effects indicates significant nutritional shortfalls tied to substitution of plant beverages for cow's milk in specific populations, the agency should consider a health warning label. For example, the FDA could consider requiring a statement on plant milk products that are not nutritionally equivalent to cow's

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[8] Lee GJ, Birke CS, Parkin PC, Lebovic G et al. 2014. Consumption of non-cow's milk beverages and serum vitamin D levels in early childhood. *CMAJ* 186(17): 1287-1293. At: http://www.cmaj.ca/content/cmaj/186/17/1287.full.pdf; and Calvo MS, Whiting SJ and CN Barton. 2004. Vitamin D fortification in the United States and Canada: current status and data needs. *American Journal of Clinical Nutrition* 80(suppl): 1710S-1716S. At: https://academic.oup.com/ajcn/article/80/6/1710S/4690516

[9] Pg. 597 Morency ME, Birken CS, Lebovic, Chen Y et al. 2017. Association between noncow milk beverage consumption and childhood height. *American Journal of Clinical Nutrition* 106: 597-602. At: https://academic.oup.com/ajcn/article/106/2/597/4557638

[10] Carvalho NF, Kenney RD, Carrington PH and DE Hall. 2001. Severe nutritional deficiencies in toddlers resulting from health food milk alternatives. *Pediatrics* 107(4): At: http://pediatrics.aappublications.org/content/pediatrics/107/4/e46.full.pdf

[11] Keller MD, Shuker M, Heimall J and A Cianferoni. 2012. Severe malnutrition resulting from use of rice milk in food elimination diets for atopic dermatitis. *IMAJ* 14: 40-42. At: https://www.ima.org.il/FilesUpload/IMAJ/0/38/19354.pdf

milk that says “NOT A NUTRITIONAL SUBSTITUTE FOR COW’S MILK FOR....” and list any at risk populations.

Conclusion

In sum, Consumer Reports’ recent survey indicates that many consumers lack an accurate understanding of the relative nutritional quality of plant-based beverages identified as milk compared to cow’s milk. Consumers who purchase plant-based milks are especially prone to thinking they provide the same or higher levels of nutrients found in cow’s milk than cow’s milk, despite the meaningful disparity between them in terms of key nutrients. We urge the FDA to consider label changes in plant milks to ensure consumers are not misled by use of the term “milk” and to reduce misunderstandings.

We also urge the FDA to investigate whether there are public health issues it should address through label changes. A number of case studies have documented adverse health outcomes in children as a result of parents substituting plant-based milk for cow’s milk. The FDA should gather more data on this issue and consider how label changes may address this problem.

Therefore, to ensure consumers are properly informed, and to protect public health, Consumer Reports urges the FDA to make changes in its labeling policy for plant-based milks. Consumer Reports offers two possible options for the FDA’s consideration. For either option, the FDA would need to determine the “key nutrients” of public health concern that cow’s milk provides. Under the first option, the FDA would require plant-based milks to meet this nutritional standard in order to be labeled as “milk,” with an appropriate qualifier indicating the main plant-based source or sources (e.g., “soy milk,” “almond milk”). The second option would be for the FDA to require front-of-package labeling on plant-based milks that indicate the ways in which those products differ from cow’s milk in terms of key nutrients.

Consumer Reports survey results for specific questions posed by the FDA

The FDA’s notice includes many specific questions about consumer understanding, perception, purchase, and consumption of plant-based products that resemble dairy foods. Where the Consumer Reports 2018 survey sheds light on these questions, we provide answers below.

B. Consumer Understanding, Perception, Purchase, and Consumption of Plant-Based Products, Particularly Those Manufactured To Resemble Dairy Foods Such as, for Example, Milk, Cultured Milk, Yogurt, and Cheese

(B.1) Why do consumers purchase and consume these types of plant-based products?

In our survey, we presented a list of eight possible reasons why consumers might purchase plant-based milk. Respondents could select as many items on the list as they wanted. More than half of Americans who purchase plant-based milk say they do so because it's healthier than cow's milk (58%), tastes better than cow's milk (54%), is better for the environment (53%), and/or reduces exposure to antibiotics and hormones (53%).

Nearly half of Americans who purchase plant-based milk say they do so because they believe it has more nutrients that they need than cow's milk (48%). Forty four percent report they or someone in their household have allergies or sensitivities to cow's milk, 38% say they purchase plant-based milk to protect animals, and 21% report they or someone in their household is vegan.

(B.1) If consumers use these plant-based products as substitutes for dairy foods (for example plant-based beverages as alternatives to milk), what are their reasons?
Do consumers think they are healthier, and if so, why?

Though we didn't specifically ask about substituting dairy foods with plant-based products, in our survey the most commonly selected reason for purchasing plant-based milk is that it is "healthier than cow's milk" (58%).

Are consumers purchasing these plant-based products because they may be allergic to dairy or are lactose-intolerant?

According to our survey results, 44% of consumers who purchase plant-based milk do so because they, or someone in their household, has allergies or sensitivities to cow's milk.

Are consumers purchasing these plant-based products for reasons related to their personal consumption habits, such as a vegan diet?

Just 21% say they purchase plant-based milk because they or someone in their household is vegan.

If consumers do not use these plant-based products as substitutes for dairy foods, what are their reasons for choosing these products? (For example, do these products provide unique taste, flavor, or texture?)

Though we did not specifically ask about substituting plant-based milk for cow's milk, some 54% of Americans said they purchase plant-based milk because it tastes better than cow's milk. Some 53% said it was better for the environment and 38% said they bought it to protect animals.

(B.2) Do consumers perceive these plant-based products to be more nutritious, as nutritious, or less nutritious than their dairy counterparts?

Americans have a wide range of views on whether plant-based milk has more, the same, or less protein, calcium, vitamin A, and potassium than cow's milk.

Our survey found that compared to cow's milk, 27% of Americans say plant-based milks have more of these nutrients, 25% say plant-based milk have the same amount of these nutrients, and 26% say plant-based milks have less of these nutrients. Twenty percent of Americans say they just don't know.

We also compared these responses about the nutritional equivalency of plant-based and cow's milk by whether consumers say they usually or always purchase cow's milk, plant-based milk, or both cow's milk and plant-based milk equally. Consumers who buy plant-based milk have a much more favorable view of its nutrient value than those who don't. Forty two percent of consumers who always or usually purchase plant-based milk said they thought plant-based milks have more of these nutrients than cow's milk, compared with 22% of consumers who usually or always purchase cow's milk. Only 12% of consumers who report always or usually purchasing plant-based milks thought that these products have less of these nutrients, compared with 31% of consumers who buy cow's milk. This suggests that consumers who buy plant-based milk may not be aware that those products lack some of the nutrients found in cow's milk.

(B.4) How do consumers perceive or understand labeling of these plant-based products? For example, do consumers perceive the labeling as suggesting that these plant-based products are equivalent to or can be substituted for their dairy counterparts? Do consumers perceive the labeling as suggesting that plant-based products are different or distinct from their dairy counterparts?

To better understand how common claims on plant-based milk are perceived, we read some of these claims to our respondents and asked whether these claims suggest that plant-based milk is a good substitute for cow's milk, healthier than cow's milk, nutritionally equivalent to cow's milk, or pure. We read the following claims: "plant-powered protein," "heart-healthy protein," "cholesterol-free and heart healthy protein," and "original nutritious pea milk."

Six in 10 Americans say that the claims suggest that plant-based milks are a good substitute for cow's milk and half of Americans say that they suggest that plant-based milks are pure and, therefore, only contain the specific plant-based ingredient.

C. Consumer Understanding Regarding the Basic Nature, Characteristics, and Properties of Plant-Based Products

(C.3) What is consumers' understanding of the amount or proportion of plant-based ingredient(s) relative to other ingredients in plant-based products? Are consumers aware that other ingredients (e.g., emulsifiers, thickeners, sweeteners, and added nutrients such as vitamins and minerals) are used in the manufacture of these plant-based products? How does the use of these ingredients impact consumer perception of these products? Please provide any data or evidence to support your answer.

We did not ask about specific other ingredients, but in our survey, we did ask about the use of the ingredient list, where these other ingredients would be listed. The ingredients list is important for understanding that some plant-based milks are not comprised solely of the featured plant-based food (e.g., soy, almond) and water, but may include other ingredients. We asked respondents whether they read the ingredients list on the label the last time they purchased a plant-based milk they had not purchased before. More than half (53%) said no. The remainder, 47%, said yes. Of them, more than a quarter (28%) said it affected their purchasing decision, while 19% said it did not affect the decision.

Since half of respondents never looked at the ingredient list, we cannot assume consumers will necessarily be aware of additional ingredients beyond the main one in the product, listed on the front of packaging. The ingredients list remains a useful tool, however, since almost half of respondents did review it.

APPENDIX: Consumer Reports Survey Research Report, Plant-Based Milk Survey, 2018