CENTER FOR
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Dr. Susan Mayne
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive, HFS-009
College Park, MD 20740-3835

Re: Use of the Names of Dairy Foods in the Labeling of Plant-Based Products (FDA–2018–N–3522)

Dear Dr. Mayne:

The Center for Science in the Public Interest appreciates the opportunity to comment on the Food and Drug Administration's request regarding the names of dairy foods in the labeling of plant-based products. The dairy industry has called on the agency to take enforcement action against plant-based products that compete with dairy products, such as "soy milk," "almond milk," "soy cheese," "rice yogurt," and others.[1] CSPI is a strong advocate for clear and non-misleading labeling of plant-based products (and all other products). We urge the agency to ensure that any actions taken to clarify the labeling of plant-based products prioritize public health considerations over the competitive or marketing concerns of any particular industry. As such, our comments focus on the role of plant-based products and dairy foods in meeting dietary recommendations and the implications for clear and non-misleading labeling of plant-based products.

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. Few purchasers of soy milk, for example, are surprised to discover that the product is not made from the lacteal secretions of cows. Many likely are seeking these products out because they are not dairy milk or animal-derived products. However, we are concerned that consumers may not understand the extent to which certain milk alternatives lack the key nutrients found in milk (or other dairy), or the degree to which milk alternatives vary in nutrient content. These concerns are heightened for populations who typically consume a larger proportion of nutrients from milk (*e.g.*, children). Clear, informative labeling can help ensure that consumers are aware of the nutritional differences between plant-based products and dairy, while also encouraging healthful innovation that will assist Americans in meeting dietary recommendations.

Minor changes to the names of dairy alternatives will not address this public health problem, because they will not help consumers understand the nutritional impact of substituting plant-based products for dairy. Therefore, rather than banning the terms "milk," "yogurt," or "cheese" from plant-based alternatives to dairy products by enforcing standards of identity as the dairy industry proposes, the FDA should require a front-of-package disclosure on the products that do

[1] National Milk Producers Federation. September 25, 2018. Available at: https://www.regulations.gov/document?D=FDA-2018-N-2381-1069.

not provide the levels of "key nutrients" typically found in dairy milk,[2] yogurt, or cheese—naturally or by fortification—under the agency's general authority to prevent misleading labeling in 21 U.S. Code § 343(a)(1). Furthermore, the FDA should extend this requirement beyond plant-based products named "milk," "yogurt," and "cheese" to include all products that are marketed as alternatives to those foods (*e.g.*, "non-dairy rice beverage," "cultured soy," or "vegan cheeze"). To identify which nutrients common to dairy foods are "key nutrients," the agency should consider dairy's nutrient content and contribution to nutrient intakes, population-wide nutrient shortfalls and health outcomes, consumer expectations, and potential harms. The FDA should then consider which key nutrients are typically present in significant amounts in each dairy product (milk, yogurt, and cheese), and set nutrient levels above which plant-based products will not have to provide such disclosures.

CSPI is a nonprofit consumer education and advocacy organization that, since 1971, has worked to improve the public's health through better nutrition and food safety. CSPI's work is supported by the 500,000 subscribers to its *Nutrition Action Healthletter*, one of the nation's largest-circulation health newsletters. CSPI is an independent organization that does not accept government or corporate grants or donations. For decades, CSPI has worked to ensure that food labeling claims are truthful, backed by evidence, and not misleading. CSPI previously commented on non-dairy plant-based products in response to the FDA's request for comment on the agency's Nutrition Innovation Strategy.[3] We present that position and its rationale in more detail here.

I. The FDA should not ban the use of terms such as "milk," "cheese," "yogurt," or other dairy terms from plant-based versions of these products. Instead, the FDA should require a front-of-package disclosure on the products that do not provide the levels of key nutrients typically found in milk, yogurt, or cheese.

Rather than banning the terms "milk," "yogurt," or "cheese" from plant-based versions of these products by enforcing standards of identity, the FDA should require a front-of-package disclosure on the products that do not provide the levels of key nutrients typically found in milk, yogurt, or cheese—naturally or by fortification—under the agency's general authority to prevent misleading labeling in 21 U.S. Code § 343(a)(1). The definition of "key nutrients" is provided later in this document.

With this approach, plant-based products that are not misbranded would fall into one of two groups:

1) **Plant-based products that are marketed as alternatives to dairy products and provide equivalent amounts of key nutrients in dairy versions.** These products should be allowed to continue to use their current names and labeling, including the terms "milk," "yogurt," or "cheese" or imagery suggesting that the products resemble or are interchangeable with dairy products, so long as their names and other elements of the label clearly distinguish these products as non-dairy (*e.g.*, by calling the product "almond milk" and showing imagery of almonds rather than simply calling the product "milk").[4] These products would not be required to provide any additional front-of-package disclosure related to nutrient content.

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[2] Our comment uses the general term "milk" throughout; however, we note the FDA's standard for "cultured milk" and encourage the agency to extend our suggested approach to such products.

[3] Center for Science in the Public Interest. October 11, 2018. Available at: https://www.regulations.gov/document?D=FDA-2018-N-2381-1249.

[4] We are unaware of examples of plant-based products currently on the market that use terms such as "milk" without distinguishing the products as non-dairy by using additional terms and/or imagery.

2) **Plant-based products that are marketed as alternatives to dairy products but do not provide equivalent amounts of key nutrients found in dairy versions.** These products should also be clearly distinguishable from dairy by their labeling. In addition, the packaging should include a prominent front-of-package disclosure adjacent to the product name that indicates it contains less of particular key nutrients found in dairy milk, yogurt, cheese, etc. The disclosure on these products should list the key nutrients that are present in lower amounts than the comparable dairy product. An example of this suggested disclosure language would read: "**Contains less [name key nutrient(s)] than dairy [milk *or* yogurt *or* cheese, etc.].**"

This approach would alleviate consumer confusion and promote public health more effectively than a ban on the use of the terms "milk," "yogurt," or "cheese" for three reasons:

First, it is unlikely that consumers are being misled about the lack of dairy ingredients in non-dairy versions, precisely because those products are commonly marketed as alternatives to dairy. While it is conceivable that non-dairy products could be marketed in a way that makes it hard to distinguish them from dairy, we are not aware of any current examples of such marketing, nor of any compelling evidence that consumers misunderstand the current labeling of non-dairy alternatives or are confused about the nature of this class of products.

Mere use of the term "milk," "yogurt," or "cheese" alone will not necessarily lead to consumer confusion, provided that other aspects of the label make clear that the product is being marketed as a non-dairy alternative. For example, a product named "almond milk," with a picture of almonds and the phrase "non-dairy" stated prominently on the front of the package, would likely be enough to prevent would-be purchasers from confusing this product with cow's milk.

However, there may be circumstances under which use of the name "milk" or "cheese" may lead to confusion in light of the overall product labeling. For example, a "Nut Cheese Log" (in which the "cheese" is made of nuts) marketed with an image of a cheese-like log covered with crushed nuts and no other clarifying labeling may lead to confusion if consumers believe that "nut" refers only to the crushed nuts rather than the non-dairy "cheese." Were the FDA to identify specific examples of non-dairy products being marketed in a manner that leads consumers to believe the foods are made with dairy, the agency may be justified in taking enforcement action against those specific products, as it has done previously with other types of plant-based foods.[5]

Second, as committed as CSPI is to preventing consumers from being misled, the more important public health concern related to these products is not that some people may mistake them for dairy products, but that consumers may knowingly substitute plant-based products for dairy without understanding that certain of these products have a *nutrient profile* that is lacking in key nutrients provided by the relevant dairy counterpart,[6] or that plant-based products themselves can vary widely in nutrient content (Table 1). To the extent that consumers expect plant-based dairy substitutes to contain the key nutrients found in dairy products, non-dairy products could be misleading. Furthermore, when these nutrients are "nutrients of concern" due to underconsumption,[7] or when dairy foods supply a substantial proportion of nutrient intake across

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[5] Food and Drug Administration. August 12, 2015. Warning Letter to Hampton Creek Foods. Available at: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm458824.htm.

[6] The potential for misunderstanding is supported by a recent survey funded by the Dairy Management Inc. and the National Dairy Council. The FDA should conduct its own consumer research to confirm those results and examine the dairy industry's survey design for potential sources of bias. *See* Dairy Management Inc. and National Dairy Council. Consumer Insights. Available at: https://www.usdairy.com/trends-and-initiatives/community-focus.

[7] Dietary Guidelines Advisory Committee. 2015. *Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture*. Available at: https://health.gov/dietaryguidelines/2015-scientific-report/.

the population or for vulnerable subgroups (*e.g.*, young children), the potential for consumers to be misled may impact public health.

Table 1. % Daily Value (DV) of Eight Nutrients in an 8 oz. Serving of Selected Varieties of Plant Milk and Dairy Milk

	Bolthouse Original Plant Protein Milk[1]	Silk Original Soymilk	Westsoy Organic Original Plain Soymilk[2]	365 Organic Chocolate Almondmilk	Wegmans Original Unsweetened Almondmilk	Oatly Oatmilk	1% Dairy Milk[3] *(for comparison)*
Vitamin D	20%	15%	0%	25%	15%	20%	15%
Calcium	35%	30%	2%	4%	35%	25%	25%
Potassium	8%	8%	6%	<2%	4%	8%	8%
Protein	10g (15%)	8g (16%)	8g (16%)	1g (<2%)	1g (<2%)	3g (<6%)	8g (16%)
Vitamin B-12	110%	120%	0%	25%	0%	50%	50%
Vitamin A	10%	15%	NA	10%	15%	20%	15%
Magnesium	NA	10%	NA	NA	4%	NA	6%
Riboflavin	NA	30%	NA	NA	NA	45%	35%

[1]Made with pea protein. [2]Not fortified. [3]Vitamins A and D added. Dairy milk % DVs are rounded per FDA rounding rules for comparison to plant milks' labeled values. All other milks are fortified in varying amounts. NA: Number not available on Nutrition Facts label.
Source: Company websites, Label Insight, and U.S. Department of Agriculture National Nutrient Database for Standard Reference.

For these reasons, merely changing the standard of identity to prevent unfortified products from using the term "milk," "yogurt," or "cheese" would be insufficient to prevent misleading labeling and avoid consumer confusion, because non-dairy alternatives could still be marketed as substitutes for dairy using label imagery to draw visual comparisons to milk (Figure 1).

Figure 1. Plant-based alternatives to milk that include imagery resembling dairy milk on the package. The Silk Almond and Blue Diamond Almond Breeze are fortified with calcium and vitamins A, E, and D. (Blue Diamond Almond Breeze also adds potassium.) The Rice Dream and Edensoy products are unfortified.

Third, a disclosure policy would encourage rational fortification to improve public health in a popular and growing segment of the market. Such a disclosure would encourage manufacturers to fortify products with all of the key nutrients (or as many as possible given specific product

constraints), likely resulting in shorter or absent disclosures and reformulated products that would support public health. In addition, the disclosures would clearly inform consumers about the nutritional differences between dairy and plant-based versions of products, as well as the nutritional differences among various plant-based products.

II. To identify "key nutrients" that merit disclosure, the FDA should consider population-wide nutrient shortfalls and related health outcomes, dairy's nutrient content and contribution to overall nutrient intakes, consumer expectations, and potential harms.

The FDA should select "key nutrients" that would have the greatest public health impact (while considering what is feasible to prominently disclose in the space available on the front of a package). The agency should also consider encouraging manufacturers (*e.g.*, as guidance on recommended fortification levels or developing standards of identity for plant-derived milks) to voluntarily fortify with additional nutrients found in dairy that may not merit mandatory disclosure.

To select key nutrients, the FDA should consider:

1) Whether the nutrient is a shortfall nutrient; that is, one underconsumed by a significant proportion of the general population or among vulnerable subgroups (*e.g.*, young children or older adults);
2) Whether the nutrient shortfall is associated with a health outcome ("nutrients of concern for underconsumption" identified by the 2015 Dietary Guidelines Advisory Committee);
3) Whether dairy milk, yogurt, and/or cheese contribute a substantial proportion of the nutrient to overall average intakes at current consumption levels;
4) Whether dairy milk, yogurt, or cheese are rich in the nutrient (*e.g.*, approximately a "good" or "excellent" source);
5) Whether consumers expect dairy to be a good source of the nutrient; and
6) Whether fortification with the nutrient and at certain thresholds could pose potential harms.

Below, Table 2 summarizes information relevant to the first three of the above considerations, and Table 3 summarizes information relevant to the fourth. We address the fifth and sixth factors separately in the following sections.

Table 2. Intake of Eight Nutrients and the Proportion of Total Nutrient Intakes from Dairy Foods Across the U.S. Population and in Young Children

				Average % from All Dairy[2]		Average % from Milk		Average % from Cheese	Average % from Yogurt
Nutrient	**Shortfall Nutrient?**	**Nutrient of Concern?**	**% <EAR[1]**	**All 2+ yrs.**	**2-5 yrs.**	**All 2+ yrs.**	**2-5 yrs.**	**All 2+ yrs.**	**All 2+ yrs.**
Vitamin D	Yes	Yes	94%	55.7%	75.5%	45.1%	67.8%	9.1%	1.6%
Calcium	Yes	Yes	42%	53.6%	67.8%	24.2%	43.8%	26.9%	2.5%
Potassium	Yes	Yes	>97%[1]	14.4%	30.6%	11.3%	26.0%	1.9%	1.3%
Protein	No	No	3%	17.8%	32.9%	8.3%	21.5%	8.3%	1.1%
Vitamin B-12	No	No	<3%	27.4%	50.9%	18.4%	40.9%	7.4%	1.6%
Vitamin A	Yes	No	40%	29.0%	43.6%	16.8%	33.2%	11.5%	0.7%
Magnesium	Yes	No	49%	11.6%	25.2%	7.7%	20.1%	3.0%	0.9%
Riboflavin	No	No	<3%	24.5%	44.7%	17.2%	36.7%	5.7%	1.6%

[1]Percentage of population that consumes less than the EAR. Percentage for potassium is the % below the Adequate Intake (AI) because no Estimated Average Requirement (EAR) is set. [2]All dairy is the sum of milk (which includes flavored milk), cheese, and yogurt. Sources: Dietary Guidelines Advisory Committee. *Scientific Report of the 2015 Dietary Guidelines Advisory Committee*, Appendix E-2.1 (shortfall nutrients, nutrients of concern, and proportion of the population aged 1+ yrs below the EAR, excluding breast-fed children and pregnant or lactating females), and National Dairy Council. NHANES 2011-2014. Data Source: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services (proportion of total nutrient intakes from dairy foods).

Table 3. % Daily Value (DV) of Eight Nutrients in a Single Serving of Milk, Cheese, & Yogurt

	Milk *(1 cup)*	**Cheese** *(30 g)*	**Yogurt** *(6 oz.)*
Example product	*1%, Vit. A & D added*	*Mozzarella, full-fat*	*Vanilla, low-fat*
Vitamin D	15%	1%	0%
Calcium	23%	12%	22%
Potassium	8%	0%	8%
Protein	16%	13%	17%
Vitamin B-12	48%	28%	38%
Vitamin A	16%	6%	2%
Magnesium	6%	1%	6%
Riboflavin	35%	7%	26%

Source: U.S. Department of Agriculture National Nutrient Database for Standard Reference.

III. Vitamin D, calcium, potassium, protein, and vitamin B-12 should be named key nutrients in front-of-package disclosures on plant-derived dairy alternatives.

Based on the material in Tables 2 and 3, and the additional considerations discussed below, the FDA should require plant-based products that are named or marketed as alternatives for dairy products to disclose five key nutrients—vitamin D, calcium, potassium, protein, and vitamin B-12—when they are present at lower levels than in dairy:

- **Vitamin D, calcium, and potassium:** The Dietary Guidelines Advisory Committee identified all three as nutrients of concern for underconsumption because of significant shortfalls and their link to important health outcomes. Ninety-four percent of Americans consume less than the Estimated Average Requirement (EAR) for vitamin D and 42 percent consume less than the EAR for calcium, both of which are critical for preventing osteoporosis and low bone mineral density. Adequate intake of potassium—which helps lower blood pressure—is critical at a time when nearly half of American adults have hypertension, yet nearly all (more than 97 percent) of Americans consume less than the Adequate Intake (AI). Dairy products contribute a significant amount of these nutrients to Americans' diets, including more than half of calcium and vitamin D intakes.

- **Protein:** Although protein is not a shortfall nutrient in the general population, dairy contributes a substantial proportion—fully one-third—of protein intakes in young children (age 2-5 years) at current levels of consumption. Approximately 20 percent comes from milk alone. However, many plant-based substitutes for dairy—such as coconut milk or almond milk—contain 0 grams or 1 gram of protein per serving, far less than dairy milk's 8 grams (Table 1). Therefore, simply replacing dairy milk with certain plant-based milks could lead to suboptimal protein intakes that could impair a young child's growth and development. Furthermore, many consumers of all ages expect milk to be a good source of protein and may fail to realize that certain non-dairy milks, particularly nut or rice milks, contain negligible amounts.[8] In contrast, many soy milks roughly match the protein in dairy milk. The U.S. Department of Agriculture's standards for milk alternatives approved for use in schools[9] and the *2015-2020 Dietary Guidelines for Americans*[10] both acknowledge that these products, when fortified appropriately, are suitable nutritional substitutes for dairy milk.[11] A clear disclosure would help consumers who rely on plant-based

[8] In a recent dairy industry survey, 77% of respondents said that almond milk contains as much or more protein than dairy milk. Dairy Management Inc. and National Dairy Council, op. cit.
[9] 71 Fed. Reg. 65753 and 73 Fed. Reg. 52903
[10] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at: https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#dairy-1.
[11] In addition to soy milk, plant-based milks made from pea protein can contain as much protein as dairy milk.

milks or other non-dairy products for protein select an appropriate product.

- **Vitamin B-12:** Although vitamin B-12 is not a shortfall nutrient in the general population, dairy foods contribute a substantial proportion of B-12 intakes at current levels of consumption: approximately a quarter of B-12 consumed by the general population, and fully one-half of B-12 consumed by children aged 2-5 years. However, older adults would also stand to benefit significantly from plant-based products fortified with vitamin B-12. Older adults are at greater risk of vitamin B-12 deficiency and its irreversible neurological damage because 10 to 30 percent of them may be unable to absorb the naturally occurring, food-bound vitamin B-12 in animal foods. The National Academy of Medicine therefore advises that individuals older than 50 years meet the Recommended Dietary Allowance (2.4 micrograms) mainly by consuming foods fortified with vitamin B-12 or a supplement.[12] In addition, strict vegans—who consume no animal foods and often consume plant-based milk substitutes—must supplement with vitamin B-12 or consume fortified foods to prevent deficiency.[13]

IV. The FDA should encourage the *voluntary* addition of vitamin A, riboflavin, and magnesium to plant-based products.

Vitamin A, riboflavin, and magnesium are not nutrients of concern for underconsumption and are not all supplied by dairy foods to the same degree as calcium, vitamin D, potassium, protein, and vitamin B-12. Thus, the FDA could encourage manufacturers of plant-based products that are named or marketed as alternatives for dairy products to *voluntarily* add those nutrients, instead of requiring a disclosure when they are present at lower levels than in dairy:

- **Vitamin A:** The 2015 Dietary Guidelines Advisory Committee identified vitamin A as a shortfall nutrient—because 40 percent of Americans consume less vitamin A than the EAR—but not a nutrient of concern. The primary dairy source of vitamin A is milk, which is typically voluntarily fortified with vitamin A. Americans consume about 29 percent of their vitamin A from dairy. For children aged 2-5 years, the proportion rises to 43 percent.

- **Riboflavin:** Dairy—especially milk—is rich in riboflavin and supplies a quarter of Americans' overall intake (44 percent among children aged 2-5 years). However, riboflavin is not a shortfall nutrient, and riboflavin deficiency is extremely rare in the United States.[14]

- **Magnesium:** Magnesium is a shortfall nutrient, but dairy is not a particularly rich source of magnesium, unlike many beans (including soy milk), whole grains, and nuts.[15] Because young children consume more dairy, it supplies a greater proportion of their overall magnesium intakes, which led the USDA to require milk substitutes approved for use in schools to match milk's levels.[16]

The FDA should also consult plant-based manufacturers to understand the technical feasibility of fortifying their products with these nutrients at the levels found in dairy, because riboflavin and magnesium are not added to many plant-based products on the market (Table 1).

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[12] National Academy of Sciences, Institute of Medicine, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes and its Panel on Folate, Other B Vitamins, and Choline. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. Washington, DC: National Academies Press, 1998. Available at: https://www.ncbi.nlm.nih.gov/books/NBK114302/.
[13] Ibid.
[14] Office of Dietary Supplements, National Institutes of Health. August 20, 2018. Riboflavin Fact Sheet for Health Professionals. Available at: https://ods.od.nih.gov/factsheets/Riboflavin-HealthProfessional/.
[15] Most almond milks contain too few almonds to be a good source of magnesium.
[16] 71 Fed. Reg. 65753 and 73 Fed. Reg. 52903

V. The FDA should not name phosphorus or other nutrients as key nutrients.

Phosphorus is not a shortfall nutrient. Moreover, emerging evidence suggests that an excess of phosphorus-containing additives in the food supply,[17] and high blood phosphorus levels are associated with an increased risk of arterial stiffness, calcification of the arteries, and heart failure.[18] Furthermore, high phosphorus intakes may be linked to a higher risk of lethal prostate cancer.[19] Although there is insufficient evidence to demonstrate a causal relationship between excess phosphorus and disease risk, given the potential harms and current adequate intakes, the FDA should not give companies an incentive to introduce more phosphate additives into the food supply.

The FDA also should not encourage manufacturers to formulate plant-based products that meet or exceed levels of other undesirable nutrients present in many dairy products (*e.g.*, saturated fat, cholesterol, or sodium). The fact that nut or soy milks, for example, are lower in saturated fat and higher in healthier unsaturated fats than dairy milks is a clear benefit of these products. While such a benefit may still be declared on the label on a voluntary basis, it need not be required.

VI. The FDA should let the nutrient composition of typical dairy counterparts dictate which key nutrients must be present—and in what amounts—to avoid disclosure statements on categories of plant-based products.

On average, milk and cheese contribute the vast majority of key nutrients from dairy to American diets (Table 2). Yogurt lags far behind, reflecting its lower average levels of consumption. However, the FDA should require yogurt to carry the same disclosures as milk or cheese to protect frequent yogurt consumers who might assume that plant-based yogurts are nutritionally comparable to dairy yogurt.

Conversely, if a nutrient is not naturally present in a significant amount in cheese or yogurt, its absence from the corresponding plant-based product should not require disclosure (Table 3). Therefore, the absence of vitamin D, potassium, and magnesium from cheese should not require disclosure. The absence of vitamins A and D from yogurt also should not require disclosure.

For the remaining key nutrients, the FDA should base the amounts required to avoid disclosure on typical dairy counterparts, because these levels align with consumer expectations and dietary recommendations. These amounts are straightforward for milk and most cheeses. For yogurt's nutrient minimums, FDA should consider whether the non-dairy yogurt is marketed as Greek-style, which is strained and therefore significantly higher in protein and lower in calcium than non-Greek yogurt, and develop nutrient standards accordingly.

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[17] Calvo MS, Uribarri J. Contributions to total phosphorus intake: all sources considered. *Semin. Dial.* 2013;26:54. doi:10.1111/sdi.12042.

[18] Kendrick J, Ix JH, Targher G, Smits G, Chonchol M. Relation of serum phosphorus levels to ankle brachial pressure index (from the Third National Health and Nutrition Examination Survey). *Am. J. Cardiol.* 2010;106:564. doi:10.1016/j.amjcard.2010.03.070. Dhingra R, Gona P, Benjamin EJ, et al. Relations of serum phosphorus levels to echocardiographic left ventricular mass and incidence of heart failure in the community. *Eur. J. Heart Fail.* 2010;12:812. doi:10.1093/eurjhf/hfq106.

[19] Wilson KM, Shui IM, Mucci LA, Giovannucci E. Calcium and phosphorus intake and prostate cancer risk: a 24-y follow-up study. *Am. J. Clin. Nutr.* 2015;101:173. doi:10.3945/ajcn.114.088716.

As part of the FDA's fortification policy[20] and food additive regulations,[21] the agency should assess whether *upper* limits, in addition to minimums, are warranted for certain nutrients (*e.g.*, vitamin D limits to reduce the risk of hypercalcemia or calcium limits to reduce the risk of kidney stones) to ensure rational fortification of the food supply and prevent potential harms from overconsumption.

VII. The FDA should not take the same approach to plant-based "butter," "veggie meat," or other products for which plant-based substitutes present significant nutritional advantages.

CSPI cautions against extending the disclosure approach that we have outlined above to products—such as butter—that contribute relatively few key nutrients to the American diet and can be replaced by non-misleading plant-based versions that are substantially more healthful (*e.g.*, certain plant-based "butter" spreads made of largely unsaturated oils), contrary to the American Butter Institute's position that such products are "misbranded" and should be subject to FDA enforcement action.[22] We also caution against extending the approach outlined in our comment to non-misleading veggie burgers and other plant-based products marketed as substitutes for meat, poultry, or seafood. Many of these products have distinct health advantages precisely because they use legumes, vegetables, gluten, or other ingredients to replace red and processed meats, which are linked to an increased risk of heart disease[23] and colorectal cancer.[24]

VIII. FDA should consider whether there should be a mandatory warning that non-dairy milks are not adequate substitutes for infant formula or breastmilk.

FDA Commissioner Scott Gottlieb noted in a July 2018 statement about modernizing the standards of identity for dairy products, "There are reports that indicate this issue needs examination. For example, case reports show that feeding rice-based beverages to young children resulted in a disease called kwashiorkor, a form of severe protein malnutrition. There has also been a case report of a toddler being diagnosed with rickets, a disease caused by vitamin D deficiency, after parents used a soy-based alternative to cow's milk."[25]

These cases appear to be relatively rare, although they are undoubtedly serious. Reported U.S. cases of kwashiorkor associated with rice milk have occurred largely in infants who were consuming primarily or exclusively rice milk as an inappropriate substitute for infant formula, due to perceived food allergies or feeding problems.[26] Many non-dairy milks already voluntarily

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[20] Food and Drug Administration. November 2015. Questions and Answers on FDA's Fortification Policy: Guidance for Industry. Available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm470756.htm.

[21] Food and Drug Administration. Vitamin D for Milk and Milk Alternatives. Available at: https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm510522.htm. 81 FR 46578.

[22] National Milk Producers Federation, American Butter Institute, Attachment 2. October 15, 2018. Available at: https://www.regulations.gov/document?D=FDA-2018-N-2381-1192.

[23] Pan A, Sun Q, Bernstein AM, et al. Red meat consumption and mortality: Results from 2 prospective cohort studies. *Arch. Intern. Med.* 2012;172:555. doi:10.1001/archinternmed.2011.2287.

[24] International Agency for Research on Cancer (IARC) Working Group on the Evaluation of Carcinogenic Risks to Humans. Red Meat and Processed Meat (Volume 114). Lyon, France: International Agency for Research on Cancer, 2018. Available at: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono114.pdf.

[25] Food and Drug Administration. July 26, 2018. Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency's standards of identity for dairy products. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm614851.htm.

[26] Tierney EP, Sage RJ, Shwayder T. Kwashiorkor from a severe dietary restriction in an 8-month infant in suburban Detroit, Michigan: case report and review of the literature. *Int. J. Dermatol.* 2010;49:500. Rogers AS, Shaughnessy KK, Davis LS. Dermatitis and dangerous diets: A case of kwashiorkor. *JAMA Dermatol.* 2014;150:910. Keller MD, Shuker M, Heimall J, Cianferoni A. Severe malnutrition resulting from use of rice milk in food elimination diets for atopic dermatitis. *IMAJ* 2012;14:40.

bear warnings that they are not a substitute for infant formula. However, because these warnings vary in their placement and prominence, the FDA should consider the optimal format to promote consumer understanding as part of its rulemaking. The FDA could also develop materials to help inform the public and medical practitioners that plant milks are an inadequate substitute for infant formula or breastmilk and can result in malnutrition.

Dairy products such as milk, evaporated milk, and powdered milk are also not suitable substitutes for infant formula or breastmilk. If the FDA engages in rulemaking that mandates a warning to inform consumers that plant-based products should not be substituted for infant formula, the agency should also consider whether such a warning is warranted for similar dairy products.

IX. Conclusion

In conclusion, CSPI recognizes the importance of labeling that is clear and non-misleading and urges the FDA to adopt a labeling disclosure requirement that focuses on public health considerations, rather than the competitive or marketing concerns of any particular industry. Rather than banning the terms “milk,” “yogurt,” or “cheese” from plant-based versions of these products, the FDA should require a front-of-package disclosure on products that do not provide the levels of key nutrients typically found in dairy versions. Such an approach would alleviate consumer confusion and, by encouraging fortification with key nutrients, promote public health more effectively than a ban on the use of specific words, which would have only minor impact on labeling, consumer understanding, and public health.