

VIA ELECTRONIC SUBMISSION (www.regulations.gov)

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

Re: Food Labeling: Nutrient Content Claims; Definition of Term “Healthy” (Docket No. FDA-2016-D-2335)

Dear FDA:

The Plant Based Foods Association (“PBFA”) submits these comments in response to the FDA’s proposed redefinition for the implied nutrient content claim “healthy” (the “Proposed Rule”).

PBFA is the first and only trade association in the U.S. representing the plant-based foods industry. We currently represent over 150 of the nation’s leading plant-based food companies. PBFA’s mission is to champion, strengthen, and elevate our members and the plant-based foods 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.

PBFA urges the FDA to define “healthy” in such a way that (i) is consistent with Dietary Guidelines and nutritional science that supports increased consumption of plant-based foods and (ii) in a way that fosters innovation in the plant-based foods industry. The Proposed Rule sets out an overly complex structure in which nutrient limits differ by food group categories and combinations thereof. These are based on a product’s role in the diet with unjustified higher allowances for animal-derived food products. PBFA urges the FDA to make the definition of the “healthy” nutrient content claim more inclusive of plant-based foods by providing for the same nutrition allowances across food groups. PBFA also urges the FDA to calculate food group equivalents by allowing for plant-based ingredients in various forms so long as they have similar nutrition profiles.

We discuss these issues in more detail below.

I. THE PROPOSED RULE IS INCONSISTENT WITH DIETARY GUIDELINES AND NUTRITIONAL SCIENCE

In its executive summary of the Proposed Rule, the FDA explains that its purpose is to “update the definition for... ‘healthy’ to be consistent with current nutrition science and Federal dietary guidance.” Yet, the Proposed Rule is inconsistent with both.

A. Dietary Guidelines Emphasize Consumption of Plant-Based Foods

The 2020-2025 Dietary Guidelines (“DGA”) released by the U.S. Department of Agriculture and the Department of Health and Human Services recommend dietary patterns that “provide the majority of energy from plant-based foods, such as vegetables, fruits, legumes, whole grains, nuts and seeds; provide protein and fats from nutrient-rich food sources; and limit intakes of added sugars, solid fats, and sodium.”¹

Specifically, the DGA finds and recommends as follows:

- Limiting saturated fat intake, stating that “replacing processed or high-fat meats with beans, peas, and lentils could help lower intake of saturated fat and sodium, nutrients that are often consumed in excess [of] recommended limits” (p. 34, DGA).
- Limiting dietary cholesterol intake, stating that dietary cholesterol consumption should be “as low as possible without compromising the nutritional adequacy of the diet.” (Page 44, DGA). This is consistent with the 2015-2020 DGA recommendation for Americans to consume as little dietary cholesterol as possible due to strong evidence of reduced risk of cardiovascular diseases.
- More than half of Americans do not meet the recommended intake amount for nuts, seeds, and soy products.

For the definition of “healthy” to be consistent with the DGA, it should encourage increased consumption of plant-based foods, such as vegetables, fruits, legumes, whole grains, nuts and seeds, in addition to plant-based dairy and meat alternatives, as well as decreased consumption of animal-based foods.

B. Nutritional Science Supports Consumption of Plant-Based Foods

The DGA’s recommendation that Americans transition to a plant-based diet is based on and aligns with nutritional science that overwhelmingly supports increased consumption of plant-based foods and reduced consumption of animal-based foods. Most notably:

- The World Health Organization has called out unhealthy diet and lack of physical activity as leading global risks to health. They define a healthy diet as one that includes an emphasis on fruit, vegetables, legumes, nuts and whole grains (e.g. unprocessed maize, millet, oats, wheat, and brown rice) and limits added sugars and saturated fats. Unsaturated fats (found in fish, avocado and nuts, and in sunflower, soybean, canola and

¹ Scientific Report of the 2020 Dietary Guidelines Advisory Committee, p. 12, available at https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf).

olive oils) are preferable to saturated fats (found in fatty meat, butter, palm and coconut oil, cream, cheese, ghee, and lard) and trans-fats of all kinds.²

- The EAT-Lancet Commission defines healthy diets as those that “have an optimal caloric intake and consist largely of a diversity of plant-based foods, low amounts of animal source foods, contain unsaturated rather than saturated fats, and limited amounts of refined grains, highly processed foods and added sugars.”³ This will require a significant change from current eating patterns in the United States, including increasing consumption of fruits, vegetables, whole grains, nuts, seeds, and legumes and decreased consumption of red meat and added sugars.

C. The Proposed Rule Disadvantages Plant-Based Foods

Rather than encouraging consumption of plant-based foods, the Proposed Rule does just the opposite: it unfairly disadvantages plant-based foods by allowing them to be labeled as “healthy” under a narrower range of circumstances than their animal-based counterparts.

Specifically, the Proposed Rule allows plant-based foods to be labeled “healthy” if, among other conditions, they contain no more than 5% of the daily value (DV) of saturated fat per reference amount customarily consumed (RACC). Yet, it *doubles* this allowance for animal-based foods (including game meats, seafood, eggs, and dairy products), allowing these products to be labeled as “healthy” even if they contain 10% of the DV saturated fat per RACC. The Proposed Rule further limits many plant-based foods from being labeled as “healthy” unless they contain 0 grams added sugar, yet it allows dairy products to be labeled as “healthy” where they contain as much as 2.5 grams (5% DV per RACC) of added sugars.

The Proposed Rule rationalizes these higher allowances for animal-based foods by saying that certain plant-based foods are just inherently low in saturated fat and added sugar, and that without higher allowances for animal-based foods, they might be excluded from “healthy” labeling. As described further in Section II, this circular reasoning is flawed, and we urge the FDA to provide plant-based foods with at least the same allowances as animal-based foods under the Proposed Rule.

II. THE PROPOSED RULE IS CONTRARY TO FDA’S STATED POLICY OF FOSTERING INNOVATION

A. FDA Policy Purports to Encourage Innovation

In 2018, the FDA unveiled its Nutrition Innovation Strategy as a significant part of its efforts to reduce preventable death and disease related to poor nutrition. As Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition (CFSAN) has explained, “[o]ne way to achieve this is by encouraging industry innovation to create healthier products that consumers seek and

² World Health Organization, Healthy Diet Fact Sheet, available at <https://www.who.int/news-room/fact-sheets/detail/healthy-diet>.

³ Summary Report of the EAT-Lancet Commission, p. 9, available at [EAT-Lancet_Commission_Summary_Report.pdf \(eatforum.org\)](https://eatforum.org/EAT-Lancet_Commission_Summary_Report.pdf).

helping them identify those products.”⁴ Likewise, Douglas Stern, Deputy Director for Regulatory Affairs of CFSAN, has explained that a primary goal of the Nutrition Innovation Strategy is to “foster and support innovation already underway in the food industry that will allow industry to compete on the basis of healthful attributes.”⁵

The Proposed Rule itself states the intention for the “criteria to be appropriately flexible to allow for industry innovation, theoretically increasing the availability of foods in the marketplace that will meet dietary recommendations.”

Despite these commendable intentions, however, the Proposed Rule discourages innovation by disadvantaging plant-based food products as described above, and in Section III below, and though its inflexible calculation of food group equivalents, as described in Section II.C below.

B. Calculations of Food Group Equivalents Discourages Innovation

To allow for industry innovation, the Proposed Rule should also permit flexibility when calculating food group equivalents. The Proposed Rule is inconsistent on this front, as it allows for certain dehydrated foods and not others to meet food group requirements. It also fails to include all the plant-based sources for protein food products.

For example, it states that ¼ cup of raisins (dried grapes) would be the equivalent of ½ cup of fruit and therefore meet the food group equivalent requirement for the fruit food group, and that the fruit and vegetable food groups can include dried or pureed forms of fruits and vegetables. Paradoxically, it states that fruit and vegetable powders are – at least “tentatively” – not considered vegetables for the purposes of calculating food group equivalents because the products could be produced in a way that modifies the whole fruit or vegetable to an extent that removes some essential characteristics.

Many vegetable or fruit powders are simply ground, dried vegetables or fruits. Therefore, it makes little sense to include vegetables and fruits in dried or pureed form, but not in dried *and* subsequently ground form or in any form where such vegetable or fruit retains its basic nutritional profile. Vegetable and fruit powders can be nutrient dense, made available in geographic areas where fresh fruits/vegetables are not, and serve to reduce food waste.⁶

⁴Susan Mayne, “FDA’s Nutrition Innovation Strategy Makes Great Process in First Year,” May 9, 2019, available at

<https://www.fda.gov/news-events/fda-voices/fdas-nutrition-innovation-strategy-makes-great-progress-first-year>

⁵ Douglas Stern, “FDA’s Nutrition Innovation Strategy,” FDLI Food Advertising Conference, September 26, 2018, available at

<https://www.fdpi.org/wp-content/uploads/2018/09/945-Doug-Stearn-Keynote-Address.pdf>

⁶Danyang Lin et al., Nutrient Dense Shelf-Stable Vegetable Powders and Extruded Snacks Made from Carrots and Broccoli, *Foods*. Oct. 2021, available at: [Nutrient-Dense Shelf-Stable Vegetable Powders and Extruded Snacks Made from Carrots and Broccoli - PMC \(nih.gov\)](#)

We propose that vegetable/fruit powders that are simply dried vegetables/fruits should qualify as the equivalent of the vegetable/fruit from which they were derived if, when hydrated, they have a similar nutritional profile.

Similarly, for the protein category, isolated or extracted proteins from foods within the protein food group (including beans, peas, lentils and soy) should qualify as the equivalent of the protein food from which they were derived if they have a similar protein profile when in their hydrated state.

The lack of inclusion of plant-based ingredients in alternative forms would be short-sighted and hinder forward momentum in the category. As the plant-based industry continues to innovate, products benefiting from advancements in innovation and technology should not be precluded from using the term “healthy.”

III. NUTRIENT LIMITS INCONSISTENTLY APPLIED

Inconsistent nutrient limits across product categories are not warranted.

A. Plant-Based Foods Should Have At Least the Same Allowance for Saturated Fat as Animal-Based Foods

The Proposed Rule rationalizes a higher saturated fat allowance for animal-based foods by noting that plant-based foods are just inherently low in saturated fat, that without higher allowances for animal-based foods, they might be excluded from “healthy” labeling, and that consumption of certain animal-based products should be encouraged because they provide important nutrients. Proposed examples of these “important nutrients” from animal-based foods are vitamin D and calcium from dairy products, beneficial fatty acids like eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from seafood, and choline from eggs. These rationales are not consistent with nutrition science or federal dietary recommendations.

While it is true that plant-based foods are generally lower in saturated fat, some do naturally contain saturated fatty acids and therefore would be excluded from the “healthy” claim, unless they comply with the more stringent saturated fat allowance for plant-based foods under the Proposed Rule. For example, soybeans contain 5 grams of saturated fat per cup and, as such, without the same saturated fat allowance, certain soy products would not be permitted to be labeled as “healthy.”

This organic tofu contains 14 grams of protein, no added sugar, and only 10 mg sodium, but because of it contains 1.5 grams of saturated fat per serving (or 1.4 grams saturated fat per RACC for the product category), would not be “healthy” under the Proposed Rule.



This tempeh contains 20 grams of protein, no added sugar, and only 10 mg sodium, but because of it contains 2 grams of saturated fat per serving (or 1.5 grams saturated fat per RACC for the product category), would not be “healthy” under the Proposed Rule.

The “important nutrients” that the Proposed Rule uses as a basis for concluding that animal-based foods should be afforded a higher saturated fat allowance to be “healthy” can also be found in plant-based foods.

- Vitamin D. The Proposed Rule uses Vitamin D as an example of an important nutrient allegedly needed to be consumed from dairy products. Yet, Vitamin D is not even a naturally-occurring nutrient in milk; it needs to be added. The DGA notes that vitamin D recommendations are difficult to achieve through natural sources from diet alone and often require consuming foods and beverages fortified with vitamin D (DGA, p. 36). While there are limited natural food sources of vitamin D, there are numerous fortified food sources of vitamin D available to consumers in addition to dairy products, including many plant-based dairy alternatives.
- Calcium. Numerous plant-based foods are important food sources of calcium, including a wide range of leafy greens as well as fortified plant-based milks and yogurts.
- EPA and DHA. The Dietary Guidelines encourages consumption of seafood as a source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). However, EPA can be found in marine plants, such as seaweed. In addition, many plant-based foods, including nuts, seeds, and oils are sources of alpha-linolenic acid (ALA) which the body can convert into DHA and EPA.
- Choline. While the main dietary sources of choline in the United States consist primarily of animal-based products, there are numerous plant-based sources as well.⁷ Plant-based sources of choline include cruciferous vegetables, certain beans, nuts, seeds, and whole grains. The DGA notes that meeting recommended protein intakes can help meet choline needs.

Plant-based foods should be permitted a higher saturated fat allowance than animal-based foods because plant-based foods have a healthier fat profile overall, with no cholesterol and a higher proportion of unsaturated fatty acids. Plant-based foods also have other beneficial nutrients that are lacking in animal-based foods. For example:

- Fiber. The DGA identified fiber as a nutrient of concern because low intakes are associated with health concerns. More than 90 percent of women and 97 percent of men do not meet recommended intakes for dietary fiber (DGA, p. 101). Dietary fiber intake is associated with reduced risk of coronary heart disease, as well as supporting bowel health. Fiber is only found in plant-based foods, and is not present in animal-based foods. As noted in the DGA, shifts are needed within the protein foods subgroups (p. 34). Replacing meats with vegetable-based proteins would ensure adequate protein intake while also increasing fiber intake.

⁷ Choline Fact Sheet for Health Professionals, available at [Choline - Health Professional Fact Sheet \(nih.gov\)](https://www.nih.gov)

- Phytonutrients. Plant foods contain thousands of natural chemicals called phytonutrients or phytochemicals. These chemicals help protect plants and also appear to have benefits to human health serving as antioxidants and anti-inflammatories.

Moreover, there is no need to encourage greater consumption of animal-based foods by facilitating their use of the “healthy” label. The DGA finds that adolescents and adults meet or exceed recommended intakes for meat, poultry and eggs, but do not meet recommendations for plant-based foods.

B. Added Sugar Allowances Should Be Consistent Regardless of Source

The Proposed Rule provides for higher added sugar allowances for dairy and grain products (5% DV) than it does for vegetable, fruit, and protein products (0% DV). Although it explains that there are no “special circumstances to require deviation from baseline levels” for dairy or grain products, it reduces the baseline for vegetable, fruit, and protein products explaining that vegetable and protein products generally do not contain added sugar and fruit products are generally already naturally sweet.

Added sugars are by FDA definition “added during the processing of foods” and are not inherent in any food product. Dairy and grain products should not be permitted higher allowances of added sugars on the basis that such products are often sweetened. While sugars are added to many dairy and grain products, many such products contain no added sugars. Milk contains 12 grams of sugar per cup and is – just as the Proposed Rule describes fruit products – already naturally sweet. While plant-based dairy alternatives often do not contain inherent sugars, they typically contain a lower total sugar level than their dairy counterparts.

Many plant-based alternatives will fall under the food product categories of vegetable, fruit and protein products. There is no reason to allow their dairy-derived counterparts higher levels of added sugar. Doing so, could lead to inequitable consequences where, for example, a dairy beverage, but not its or soy or nut-based counterpart with the same level of added sugars, would be permitted to be labeled as “healthy.”

If the intent of this rule is to promote consumption of food groups that are under-consumed, the same qualifying standards should apply across all food group equivalents including the plant-based foods that are included in those categories.

IV. CONCLUSION

In conclusion, “healthy” should be defined in a way that does not disadvantage plant-based foods, especially when both the Dietary Guidelines and nutrient science support increased consumption of them, or disadvantage innovation in the food industry at a time when it is most needed.

Sincerely,



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