CENTER FOR Science IN THE Public Interest
*The nonprofit publisher of Nutrition Action*

February 16, 2023

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. FDA-2016-D-2335; Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"**

The Center for Science in the Public Interest (CSPI) commends the Food and Drug Administration (FDA) for issuing a proposed rule that would substantially improve the definition of the term "healthy" and better align the claim with evidence-based nutrition guidelines. While we expect that the proposed changes will provide benefit to consumers by better aligning the definition of "healthy" with foods that promote adherence to a healthy dietary pattern, the potential benefits of this voluntary marketing claim are limited. In this comment, we take the following positions:

- FDA should prioritize more effective public health interventions, such as mandatory front-of-package nutrition labeling, on which CSPI has filed a Citizen's Petition.
- The proposed limits for added sugars, sodium, and saturated fat are mostly appropriate, as is the adoption of a food group-based approach wherein "healthy" foods must provide minimum amounts of vegetables, fruits, whole grains, dairy, and/or protein foods.
- The proposal could be improved in several ways, including by strengthening the whole grain, fruit, and vegetable requirements and ensuring that terms like "wholesome," "nutritious," and "heart healthy" are considered implied "healthy" claims.
- Plain water and plain, carbonated water should be included under the definition of "healthy."
- FDA should review and revise the "healthy" rule every five years to ensure alignment with the latest Dietary Guidelines for Americans.

## I. The potential benefits of this proposed rule are limited.

The present rulemaking addresses the circumstances under which food manufacturers may voluntarily label foods using the implied nutrient content claim "healthy." According to FDA's Federal Register notice, "healthy" is an implied nutrient content claim because it indicates "that a food's level of nutrients may help consumers maintain healthy dietary practices."[1] It is important to define conditions for the use of this term so that consumers are not misled regarding which foods promote healthy diets. However, as a voluntary claim that companies may opt to use if

[1] 87 Fed. Reg. 59168-59202. September 29, 2022.

they believe it will increase their product's appeal to consumers, and which they can otherwise forgo, the potential benefits of the claim are limited.

Firstly, according to FDA, 14 percent of foods qualify for the existing "healthy" claim (or 15%, under current enforcement discretion[2]) but only about one-third of those foods (5% of all foods) currently bear the claim.[3] This estimated proportion of foods currently labeled "healthy" is likely an overestimate, as FDA's search for products using "healthy" nutrient content claims also captured claims such as the "heart healthy" health claim, which is not currently regulated as a "healthy" nutrient content claim. "Healthy" is a rarely used claim, and there is no indication that its use will increase after the term is redefined. In fact, FDA estimates that an even smaller proportion of products (4%) would be expected to bear the claim if the proposed rule were finalized in its current form.[4] A label that appears on such a small proportion of foods has limited utility in guiding consumers' choices.

Second, by nature of being voluntary, consumers will not be able to assess—based on the presence of the claim—whether a product labeled "healthy" is any healthier than other foods without the label, or if other products' manufacturers simply opted not to use the claim. In order for labels to be useful tools for promoting public health, they must be mandatory and implemented uniformly across the food supply.

In August 2022, CSPI filed a citizen petition calling for FDA to implement mandatory front-of-package labels that highlight when foods have high levels of overconsumed nutrients linked to chronic disease, including sodium, added sugars, and saturated fat.[5] Such labels have already been adopted in Mexico, Canada, and several other countries.[6] In Chile, where a law required labels stating "alto en [calorias/azúcares/grasas saturadas/sodio]" (which translates to "high in [calories/sugars/saturated fat/sodium]") starting in June 2016, a study found statistically significant effects on purchases from July 2016 through December 2017 versus January 2015 through June 2016, with a 3.5 percent decline in per capita calories, 10.2 percent decline in per capita calories from sugar, 3.9 percent decline in per capita calories from saturated fat, and 4.7

[2] FDA announced in a 2016 guidance to industry that it would exercise enforcement discretion on foods making "healthy" claims that are not low in total fat, but have mostly mono and polyunsaturated fats, and foods that contain at least 10% DV per RACC of potassium or vitamin D. See *Guidance for Industry: Use of the Term "Healthy" in the Labeling of Human Food Products*, September 2016: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-term-healthy-labeling-human-food-products

[3] U.S. Food and Drug Administration. Nutrient Content Claims; Definition of Term "Healthy" Preliminary Regulatory Impact Analysis. September 29, 2022. https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/nutrient-content-claims-definition-term-healthy-proposed-rule-regulatory-impact-analysis

[4] *Id.* Table 7 of the PRIA shows that under the proposed "healthy" claim, an estimated 10,741 UPCs out of a total 245,274 UPCs would label as "healthy" which is equal to 4.4%.

[5] Citizen Petition from Center for Science in the Public Interest (CSPI), the Association of SNAP Nutrition Education Administrators (ASNNA), and the Association of Public Health Nutritionists (ASPHN). August 8, 2022. Available at: https://www.regulations.gov/document/FDA-2022-P-1832-0001

[6] University of North Carolina at Chapel Hill, Global Food Research Program. Front-of-package labeling map. August 2022. Available at: https://www.globalfoodresearchprogram.org/wp-content/uploads/2022/08/FOP_Regs_maps_2022_08.pdf

percent decline in per capita milligrams of sodium purchased from packaged foods.[7] In contrast, the Preliminary Regulatory Impact Analysis for the proposed rule to redefine "healthy" estimates that only 43,757 people (or 0.01% of the U.S. population) are "impacted by the use of the "healthy" nutrient content claim in a meaningful way to adhere to the *Dietary Guidelines*," thus confirming the agency's lack of confidence in any comparable population-wide benefits from updating the claim.[8] Mandatory front-of-package labeling is the best way to leverage food labels to promote healthier diets and should be FDA's top priority.

## II. CSPI largely supports the proposed amendments to the nutrient criteria.

### a. Added sugars

CSPI supports the proposal of a 5 percent Daily Value (DV) per Reference Amount Customarily Consumed (RACC) baseline limit for added sugars in foods labeled "healthy." We also support the proposed adjustments, including 0 percent DV for fruit, vegetable, and protein foods[9] and up to 10 percent DV for certain main dish and meal products. These levels are achievable and will help ensure that only nutrient-dense foods and beverages compatible with the Dietary Guidelines for Americans[10] may be labeled "healthy."

"Healthy" claims on foods that are loaded with added sugars currently confuse consumers and are out of step with the Dietary Guidelines' advice to limit added sugars in order to achieve a healthy dietary pattern without exceeding calorie limits. For example, the label of KIND LLC's Honey Almond Butter Nut Butter Filled Snack Bar describes it as a "healthy snack" despite containing 8 grams of added sugars (16% DV) per bar (*see* Figure 1). "Healthy" claims should be reserved for snack bars or nut snacks that are lower in added sugars, such as Whole Natural Almonds from Blue Diamond with 0 grams of added sugar (0% DV) per 1 ounce serving. As another example, the Healthy Choice Sweet & Sour Chicken Café Steamer frozen meal has 21 grams of added sugars (42% DV) per serving. Other Healthy Choice meals, like the Mexican-Style Street Corn Café Steamer, have substantially less added sugars and are deserving of the "healthy" claim.[11]

The adoption of stricter limits on added sugars for products making "healthy" claims will help restore consumer confidence in the integrity of the claim and prevent misleading "healthy"

---

[7] Taillie LS, Bercholz M, Popkin B, Reyes M, Colchero MA, Corvalán C. Changes in food purchases after the Chilean policies on food labelling, marketing, and sales in schools: a before and after study. *Lancet Planetary Health*. 2021;5(8):e526-e533.

[8] U.S. Food and Drug Administration. Nutrient Content Claims; Definition of Term "Healthy" Preliminary Regulatory Impact Analysis. September 29, 2022. https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/nutrient-content-claims-definition-term-healthy-proposed-rule-regulatory-impact-analysis

[9] We agree with FDA's rationale that "healthy" vegetable, protein, and fruit products should not contain any added sugars because vegetable products and protein food products generally do not contain added sugars, and most fruit products are naturally sweet. The "healthy" claim should not encourage addition of added sugars into otherwise nutrient-dense fruit and vegetable products.

[10] U.S. Department of Agriculture & U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025.* 2020.

[11] Although these products are regulated by USDA, we anticipate that USDA would adopt "healthy" regulations substantively similar to FDA's regulations, once finalized.

claims on products like sugary granola bars, frozen meals, shakes, cereals, and other foods and beverages with excess added sugars.

**Figure 1. Examples of higher added sugar products currently labeled "healthy," and alternatives that are lower in added sugars**

| Higher Added Sugars | Lower Added Sugars |
|---|---|
|  |  |
| 8 grams of added sugars per bar (16% DV) | 0 grams of added sugars per 1 oz. serving |
|  |  |
| 21 grams of added sugars per meal (42% DV) | 1 gram of added sugars per meal (2% DV) |

Sources:
https://www.kindsnacks.com/nut-butter-filled-bars/honey-almond-butter-M27362.html
https://www.walmart.com/ip/Kind-Breakfast-Filled-Bar-Honey-Almond-Butter-5-2-Oz-Pack-Of-4/756399896
https://www.bluediamond.com/brand/snack-almonds/classic-flavors/whole-natural
https://www.amazon.com/Blue-Diamond-Almonds-Whole-Natural/dp/B00GDVBHU2/
https://www.healthychoice.com/cafe-steamers/sweet-sour-chicken
https://stopandshop.com/groceries/frozen/frozen-meals-entrees-sides/frozen-dinners-entrees/frozen-poultry-meals/healthy-choice-cafe-steamers-sweet-sour-chicken-10-oz-pkg.html
https://www.healthychoice.com/cafe-steamers/mexican-style-street-corn

b. Sodium

CSPI supports the proposed 10 percent DV per RACC baseline limit for sodium in individual foods labeled "healthy," and most of the proposed adjustments. However, we do not support the proposed increase in the sodium limit for meal products. Meal products already have higher limits than individual foods because they are intended to constitute an entire meal. Under current FDA regulations, a meal product or main dish product making a "healthy" claim must contain no more than 600 milligrams of sodium per labeled serving,[12] which is equivalent to 26 percent of the DV for sodium. Under the proposal, meal products would be allowed to contain 30 percent of the DV for sodium per labeled serving, or 690 milligrams. FDA should not increase this limit, as meals lower in sodium are healthier for consumers and more consistent with FDA's 2016 draft long-term Voluntary Sodium Reduction Goals. For example, according to FDA's draft sodium reduction goals, a typical 9 ounce (255 g) frozen meal would have a long-term sodium goal of 460 milligram per labeled serving (the proposed target mean was 180 mg/100 g).[13] Furthermore, there are already many meal products on the market with 600 milligrams of sodium or less, such as a variety of lines of meal products from Healthy Choice.[14] The company has demonstrated that it is both feasible and profitable to market these lower-sodium meals.

c. Saturated fat

CSPI supports the proposal of a 5 percent DV per RACC baseline limit for saturated fat in foods labeled "healthy," and most of the proposed adjustments, including the 10 percent DV allowance for dairy products, seafood, and game meats. We also support the proposal to exclude saturated fat from nuts and seeds from contributing to the overall saturated fat limit for nut and seed products (assuming that FDA does not consider coconut, which is unusually rich in saturated fat, to be part of the exempted nut-and-seed group).

Regarding FDA's request for comment on the alternative approach of using a ratio of saturated fat to total fat based on limits of 10% and 35% of calories (1:3.5) rather than a limit on saturated fat alone, we support the current proposal and not the alternative. The current proposed approach is simpler and better aligned with the DGA, which currently focus on limiting saturated fat as opposed to achieving a particular ratio. Because the "healthy" proposal is linked to the current DGA, the present approach is preferred, but a ratio-based approach may be appropriate if the DGA were updated to include a recommended ratio of saturated fat to total fat in the diet.

The alternative approach would allow manufacturers to manipulate their ratios by increasing total fat (e.g., by adding unsaturated oil) rather than by reducing saturated fat. This could lead to "healthy" claims on products with high levels of saturated fat, the consumption of which would

[12] 21 C.F.R. 101.65(d)(2)(ii)
[13] U.S. Food and Drug Administration. June 2016. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry. Draft Guidance. 2016.
[14] Healthy Choice. https://www.healthychoice.com/.

not help consumers adhere to the DGA recommendation to limit saturated fat to less than 10 percent of daily calories. It could also lead to products with increased calorie density and diluted nutrient density. Finally, it would exclude foods with small amounts of saturated fat (e.g., a trivial 1 gram), that do not have at least 3.5 grams of total fat, from bearing "healthy" claims. For all these reasons, we prefer the agency's proposed approach.

d. Total Fat and Trans Fat

CSPI supports FDA's decision not to include a limit for total fat in foods labeled "healthy." This is appropriately aligned with the removal of a recommended limit on total fat in the DGA, based on current nutrition science emphasizing that one's risk for diet-related disease is more closely related to the type of fat consumed rather than the overall amount of total fat consumed.

We also support FDA's decision not to include a limit for *trans* fat, given that partially hydrogenated oils are no longer allowed to be added to foods and products that are high in naturally occurring *trans* fat also contain high amounts of saturated fat and will be disqualified from bearing "healthy" claims based on the proposed saturated fat limits.

## III. CSPI generally supports the adoption of food group requirements, but the proposed requirements for whole grains, fruits, and vegetables are insufficient.

a. General Support

FDA has proposed that food products bearing "healthy" claims will need to contain certain amounts of food from recommended food groups (i.e., "food group equivalents" (FGE)). For example, one ½ cup equivalent of vegetable equals one FGE of vegetable, and one ¾ ounce equivalent of dairy equals one FGE of dairy.

CSPI agrees that the proposed food group approach is appropriate and aligned with the DGA. We agree that this approach has the potential to ensure that foods bearing the "healthy" label will contribute to nutrient-dense diets, even in the absence of separate requirements for minimum amounts of "nutrients to encourage."

We also support FDA's proposed method for calculating food group equivalent (FGE) requirements based on four eating occasions. This is appropriate given that 90 percent of Americans report four or more eating occasions per day.[15]

[15] Zeballos E, Todd JE, Restrepo B. Frequency and Time of Day That Americans Eat: A Comparison of Data From the American Time Use Survey and the National Health and Nutrition Examination Survey. U.S. Department of Agriculture, Economic Research Service. Technical Bulletin No. 1954. July 2019. https://www.ers.usda.gov/webdocs/publications/93514/tb-1954.pdf

b. Whole Grains

CSPI supports FDA's proposal to allow whole grains to count as a FGE for foods that make a "healthy" claim. However, we recommend that FDA also require that, in order to bear the claim, nearly 100 percent of the grains in any grain-containing food must be whole grains.

The DGA recommend that at least half of one's daily grains should be whole grains and note that nearly all Americans underconsume whole grains and overconsume refined grains.[16]Therefore, it is essential that grain-containing foods labeled "healthy" are 100 percent or near-100 percent whole grain to ensure that grain-containing foods labeled "healthy" will be whole-grain-rich (defined by USDA as foods that are at least 50 percent whole grain).[19] There are three reasons why the proposed FGE requirement is insufficient in this respect: 1) under the current proposal, grain-based individual foods with large RACCs could qualify as "healthy" but contain predominantly refined grains; 2) combination foods could qualify as "healthy" by meeting the whole grain food group requirement while still containing substantial amounts of refined grains; and 3) combination foods could qualify as "healthy" based on food groups other than whole grains and contain only refined grains. Each of these concerns is discussed in greater detail below. In order to ensure that foods eligible for "healthy" claims encourage Americans to replace refined grains with whole-grains, FDA must add a requirement for a minimum percentage of total grains that must be whole grains in order for a product to qualify as "healthy." We recommend that FDA set this percentage requirement at near-100 percent whole grain.

1. Under the current proposal, grain-based "individual foods" with large RACCs may contain predominantly refined grains and still qualify as "healthy"

In the proposed rule, FDA proposes that a ¾ ounce equivalent of whole grain (equal to 12 grams of whole wheat flour or 21 grams of uncooked whole grains)[17] represents 1 FGE of grains. To be eligible for the "healthy" claim based on the FGE for the grains food group, individual foods (defined as "foods that are comprised entirely or almost entirely of one food group") must have at least 1 FGE of whole grains per RACC. However, if a food has a large RACC and contains more than 24 grams of flour or 42 grams of uncooked grains per RACC, this whole grain requirement does not ensure that most of the product's grains must be whole grains in order for it to qualify for a "healthy" claim.

RACC weights vary substantially across grain-based products, from as low as 7 grams (croutons) to more than 100 grams (*e.g.*, bagels) (Table 1).[18] While the proposed whole grain FGE requirement would ensure that most of the grains in foods with smaller RACCs must be whole

[16] U.S. Department of Agriculture & U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025.* 2020.
[17] Bowman SA, Clemens JC, Friday JE, Moshfegh AJ. Food patterns equivalents database 2017-2018: Methodology and User Guide. U.S. Department of Agriculture Agricultural Research Service. October 2020. https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/fped/FPED_1718.pdf
[18] U.S. Food and Drug Administration. Reference Amounts Customarily Consumed: List of Products for Each Product Category: Guidance for Industry. February 2018. https://www.fda.gov/media/102587/download

grains in order for those products to be labeled "healthy," foods with larger RACCs could contain 1 FGE of whole grains and an even larger amount of refined grains while still qualifying as "healthy."

**Table 1. Examples of grain-based individual food categories by RACC size and implications of FDA's proposed rule**

| Product Category | RACC | Implications of proposed rule |
|---|---|---|
| Bagels | 110 g | Likely to qualify as "healthy" even if grains are predominantly refined grains |
| Waffles | 85 g | |
| Pasta | 55 g | |
| Breads and rolls | 50 g | |
| Grain-based breakfast bars | 40 g | Unclear whether proposed rule ensures that products labeled "healthy" will be predominantly whole grain (depends on products' other ingredients besides flour) |
| Hard taco shells | 30 g | |
| Dry, ready-to-eat pastas | 25 g | |
| Eggroll wrappers | 20 g | Must be predominantly whole grain to qualify for "healthy" |
| Hard bread sticks | 15 g | |
| Croutons | 7 g | Ineligible for "healthy" claim (RACC too small) |
| Source: https://www.fda.gov/media/102587/download | | |

For example, Thomas' 100% Whole Wheat Bagels contain 64 grams of whole wheat flour per 110-gram RACC (Figure 2).[19] A similar hypothetical product that is not 100% whole grain could contain a mix of 12 grams of whole wheat flour plus 52 grams of refined flour (therefore containing only about 19 percent of its total grains from whole grains) and still qualify for the "healthy" claim under the current proposal.

[19] Thomas' Breads. Thomas' 100% Whole Wheat Bagels. https://thomasbreads.com/products/thomas-100-whole-wheat-bagels

**Figure 2. Example of an individual grain-based food that could be formulated with at least 1 FGE of whole grains yet contain predominantly refined grains**


Thomas' 100% Whole Wheat Bagels contain 55 g whole grain per 95 g bagel (equivalent to 64 g whole grain per 110 g bagel RACC). If a hypothetical "healthy" bagel containing a mix of whole and refined grains contained only the minimum amount of whole grains for 1 FGE (12 g per 110 g RACC), it would contain only 19% of its total grains as whole grains (12 g whole/64 g total).

Source: https://thomasbreads.com/products/thomas-100-whole-wheat-bagels

Allowing products predominantly comprised of refined grains to qualify for "healthy" claims departs from the DGA's attempt to encourage whole grain consumption. On the contrary, the healthiest grain-based foods contain 100 percent of their grains from whole grains, and plenty such 100 percent whole grain foods—including cereals, breads, tortillas, bagels, English muffins, crackers, pastas, rice, and other grains—are widely available to consumers and deserving of eligibility for the "healthy" claim. Given the widespread underconsumption of whole grains and overconsumption of refined grains and availability of 100% *refined*-grain products in the United States,[20] consumers should be encouraged to consume 100 percent whole grain products to achieve overall healthful dietary patterns. Therefore, we recommend that FDA add a requirement that, in order to bear the "healthy" claim, near-100 percent of the grains in any grain-containing food must be whole grains. FDA could establish an acceptable trivial amount of refined grain, flour, or starch—for example, a few percentage points—that could account for additives, such as cultured wheat flour used as a preservative in many breads.

If FDA declines to establish a near-100-percent whole grain requirement for all foods eligible for "healthy" claims, at the very least the agency should require that at least 50 percent of a product's total grains be whole grains. While this would not ensure that the "healthy" claim is

[20] U.S. Department of Agriculture & U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025.* 2020.

only used on the healthiest foods, it would prevent "healthy" claims on foods that would make it harder for consumers to meet the DGA recommendation that at least half of total grains should be whole grains.

FDA could also consider increasing the FGE size for whole grains for increasingly larger RACCs. However, given the substantial variation of RACC size across grain-based and potentially grain-containing products, a blanket requirement is likely the most feasible and simplest approach.

2. Under the current proposal, "combination foods" could qualify as "healthy" by meeting the whole grain FGE requirement while still containing substantial amounts of refined grains

In the current proposal, "combination foods" (or foods "comprised of meaningful amounts of more than one food group"[21]) may be eligible for the "healthy" claim based on the FGE for whole grains if they are a mixed product (*i.e.*, a product "similar in size to an individual food but contain[ing] more than one food group"[22]) with ½ FGE of whole grains and ½ FGE from another food group (vegetables, fruits, dairy, or protein); a main dish (*i.e.*, a product larger in size than an individual food or mixed product and "intended to make a major contribution to a meal"[23]) with 1 FGE of whole grains and 1 FGE from another food group; or a meal product (i.e., a product larger in size than a main dish product and "intended to comprise all of the food for a single eating occasion"[24]) with 1 FGE of whole grains and 1 FGE from at least two other food groups.

This means, for example, that a soft-baked cereal bar (mixed product) containing a mere 6 grams of whole-wheat flour (equal to ½ FGE whole grains) plus 11 grams of dried apple (equal to ½ FGE fruit)[25] per 40-gram RACC could qualify for a "healthy" claim based on its whole grain and fruit content. However, the ½ FGE whole grain requirement leaves ample room for additional refined grains (potentially up to 23 grams, or more than three times the amount of whole grains).

As another example, a mixed bread product could contain 6 grams of whole-wheat flour plus 7 grams of nuts or seeds (1/2 FGE nuts/seeds)[26] per 50-gram RACC and qualify for a "healthy" claim, again leaving room for a substantial amount of refined grain/flour, which could comprise most of the remaining 37 grams of the product.

[21] 87 Fed. Reg. 59168-59202. September 29, 2022.
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] Bowman SA, Clemens JC, Friday JE, Moshfegh AJ. Food patterns equivalents database 2017-2018: Methodology and User Guide. U.S. Department of Agriculture Agricultural Research Service. October 2020. https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/fped/FPED_1718.pdf
[26] *Id.*

3. Under the current proposal, "combination foods" qualifying as "healthy" based on non-grain FGE could contain *only* refined grains

FDA's proposed rule provides an option for combination foods that contain some grains, but also contain meaningful amounts of multiple other food groups, to qualify as "healthy" based on minimum FGE from those other food groups while containing only refined grains. It appears from the proposal that *none* of the grains in combination products that meet FGE requirements based on vegetables, fruits, dairy, or protein content would need to be whole grains. For example, a "healthy" soup containing chicken, vegetables, and white pasta that meets the criteria for a "main dish," and contains at least 1 FGE of chicken and 1 FGE of vegetables, could contain pasta that is 100% refined grain. These products could still contribute substantial amounts of grains to the diet and, if only providing refined grains, hinder an individual's ability to adhere to the DGA recommendation to make at least half of one's grains whole grains. Therefore, FDA should establish a blanket requirement that all products containing more than a certain amount of grains must contain a minimum percentage (100 percent or near-100 percent) of their total grains as whole grains.

c. Fruits and Vegetables

CSPI supports the inclusion of fruit and vegetable FGE in determining which foods are eligible to bear "healthy" claims, but the current proposal is overly permissive regarding which forms of fruit and vegetable may count toward the FGE.

Fruits and vegetables provide the greatest health and nutritional benefits when consumed whole (fresh, frozen, or canned). Whole fruits and vegetables are nutrient-dense and their intact dietary fiber, hard texture, and slow ingestion rate promote satiety.[27,28,29] The Dietary Guidelines for Americans advise people to "Focus on whole fruits" and specify that "At least half of the recommended amount of fruit should come from whole fruit, rather than 100% juice."[30]

Under the current proposal, a FGE of fruit is one ½ cup-equivalent of fruit and a FGE of vegetable is one ½ cup-equivalent of vegetables. An individual food in the Fruits or Vegetables food group would be eligible to bear a "healthy" claim if it contained one FGE of fruit or vegetable. A mixed product could have ½ a FGE of fruit or vegetable and ½ a FGE from another food group. According to the proposed rule:

> "The vegetables food group can include fresh, frozen, canned, and dried forms of vegetables, as well as 100% vegetable juice. FDA considers concentrated vegetable

[27] Flood-Obbagy JE, Rolls BJ. The effect of fruit in different forms on energy intake and satiety at a meal. *Appetite.* 2009;52(2):416-422.
[28] Teo PS, Lim AJ, Goh AT, R J, Choy JYM, McCrickerd K, Forde CG. Texture-based differences in eating rate influence energy intake for minimallyprocessed and ultra-processed meals. *Am J Clin Nutr.* 2022;116(1):244-254.
[29] Forde CG, Mars M, de Graaf K. Ultra-Processing or Oral Processing? A Role for Energy Density and Eating Rate in Moderating Energy Intake from Processed Foods. *Curr Dev Nutr.* 2020;4(3).
[30] U.S. Department of Agriculture & U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025.* 2020.

> purees and vegetable pastes to be vegetables for the purpose of calculating food group equivalents since these products are essentially whole vegetables that have been processed to change the physical form of the vegetable to remove moisture. We tentatively do not consider vegetable powders to be vegetables for the purpose of calculating food group equivalents. These products could be produced or used in a way that modifies the whole vegetable to an extent that removes some essential characteristics that are beneficial when consuming the whole vegetable, which could impact nutrient content."[31]

The proposed rule includes parallel language with respect to which forms of fruit may count toward an FGE of fruit.

Only whole fruits and vegetables should count toward FGE of fruit and vegetables for foods to qualify as "healthy." Concentrated purees, pastes, and especially 100 percent juice should not count toward FGE of fruit and vegetables for the same reasons that FDA has decided not to count powders—their processing typically removes some of the beneficial characteristics of whole fruits and vegetables. For example, 100 percent fruit or vegetable juices typically contain less (in most cases, 70% or less) dietary fiber than whole fruit and vegetables (*see* Table 2) and may contribute to excess calorie consumption and weight gain.[32,33] Fruit puree concentrates are similarly often lower in fiber than whole fruit. Even non-concentrated fruit purees and sauces (like applesauce) are often made without the edible, fiber-containing parts of the whole fruit, such as edible skin, peels, and seeds, causing them to be less nutrient-dense (Table 2).[34] If FDA allows fruit and vegetable purees to count toward fruit and vegetable FGE, it should specify that the purees must include all edible parts of the whole fruit or vegetable and have similar naturally occurring fiber content (from the fruit or vegetable, not from added processed fiber ingredients) as the whole fruit or vegetable.

[31] 87 Fed. Reg. 59168-59202. September 29, 2022.
[32] Houchins JA, Burgess JR, Campbell WW, Daniel JR, Ferruzzi MG, McCabe GP, Mattes RD. Beverage vs. Solid Fruits and Vegetables: Effects on Energy Intake and Body Weight. *Obesity.* 2012;20(9):1844-1850.
[33] Auerbach BJ, Dibey S, Vallila-Buchman P, Kratz M, Krieger J. Review of 100% Fruit Juice and Chronic Health Conditions: Implications for Sugar-Sweetened Beverage Policy. *Adv Nutr.* 2018;9:78-85.
[34] Fruit juices and purees may be less beneficial than whole fruit in terms of their effect on satiety. While we recognize that the impact on satiety is not formally part of a nutrient content claim such as "healthy," we wish to draw the agency's attention to this attribute that can influence a food's effect on the total daily diet. *See* Krishnasamy S, Lomer MCE, Marciani L, et al. Processing apples to puree or juice speeds gastric emptying and reduced postprandial intestinal volumes and satiety in healthy adults. *Journal of Nutrition.* 2020.; Flood-Obbagy JE, Rolls BJ. The effect of fruit in different forms on energy intake and satiety at a meal. *Appetite*. 2009;52(2):416-22.

**Table 2. Comparison of the fiber per 100 calories of select whole fruits and vegetables and corresponding 100% juice, puree, and puree concentrate ingredients**

| | Fiber (g) per 100 calories | Percent of fiber compared to whole form |
|---|---|---|
| **Apples, raw (whole, *unpeeled*)** | 4.6 | (ref) |
| Applesauce, canned | 2.6 | 57% |
| Apple Purée Concentrate, commercial ingredient (Tree Top) | 2.5 | 55% |
| Apple Juice | 0.4 | 9% |
| **Apricots, raw (whole)** | 4.2 | (ref) |
| Apricot Puree, commercial ingredient (Tree Top) | 2.6 | 63% |
| Apricot Puree Concentrate, commercial ingredient (Tree Top) | 2.6 | 63% |
| Apricot Juice (Raley's) | 1.7 | 42% |
| **Beets, raw** | 6.5 | (ref) |
| Beet Juice | 4.4 | 68% |
| **Blueberries, raw (whole)** | 4.2 | (ref) |
| Blueberry Purée, commercial ingredient (Tree Top) | 2.3 | 55% |
| Blueberry Purée Concentrate, commercial ingredient (Tree Top) | 2.4 | 57% |
| Blueberry Juice (Better Way Farms) | 0.0 | 0% |
| **Carrots, mature, raw** | 6.5 | (ref) |
| Carrot Juice, canned | 2.0 | 31% |
| **Raspberries, raw (whole)** | 12.5 | (ref) |
| Raspberries, puree, seedless | 2.2 | 18% |
| Raspberry Purée Concentrate, commercial ingredient (Tree Top) | 2.6 | 21% |
| Raspberry Juice (Tazah) | 0.0 | 0% |
| **Squash, winter, butternut, raw** | 4.4 | (ref) |
| Squash Puree, butternut (Target) | 5.1 | 115% |
| **Strawberries, raw (whole)** | 6.3 | (ref) |
| Strawberry Puree, commercial ingredient (Tree Top) | 4.4 | 70% |
| Strawberry Purée Concentrate, commercial ingredient (Tree Top) | 2.2 | 35% |
| Strawberry Juice | 0.3 | 4% |
| **Tomato** | 4.5 | (ref) |
| Tomato Puree, canned, without salt added | 5.0 | 110% |
| Tomato Juice, canned, without salt added | 2.4 | 52% |

Sources: https://fdc.nal.usda.gov/ ; https://www.treetop.com/

The need for stricter requirements for fruit and vegetable content in foods labeled "healthy" is heightened by the prevalence of misleading fruit and vegetable claims in the current marketplace. Foods containing processed forms of fruits and vegetables are often marketed using claims like "contains real fruit" and images of whole fruits and vegetables despite their lack of equivalence to whole fruits and vegetables with respect to dietary fiber and satiety (*see* Figure 3). These foods should not be permitted to augment these implicit claims by bearing "healthy" claims that would further confuse consumers about their appropriateness as substitutes for whole fruit or vegetables in the diet.

**Figure 3. Examples of foods marketed using images of whole fruits and vegetables, despite only containing juice, concentrated juice, pastes, purees, concentrated purees, or powders**

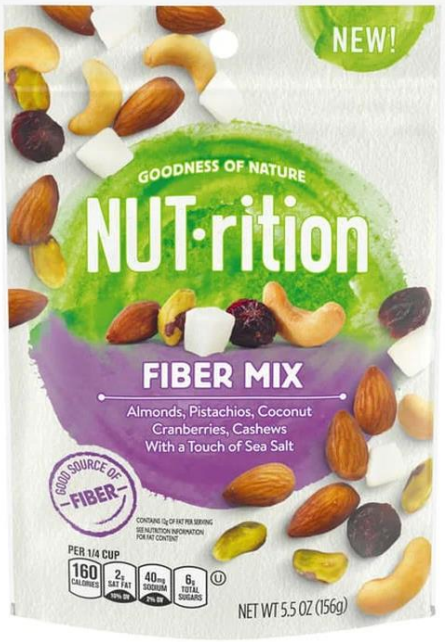

Sources: https://welchsfruitsnacks.com/products/berries-n-cherries/; https://www.nutrigrain.com/en_US/products/soft-baked-breakfast-bars/kellogg-s-nutri-grain-cereal-bars-strawberry-product.html; https://www.bolthouse.com/product/berry-boost/; https://www.kroger.com/p/simple-truth-organic-strawberry-mango-strips/0001111008610; https://ortega.com/product/cauliflower-and-flour-tortillas/; https://www.naturesbakery.com/oatmeal-crumble-bars-strawberry

## IV. FDA should regulate additional terms as "healthy" claims

In the proposed rule, FDA outlines nutrient and food group requirements that a food must meet in order to use the term "healthy" or related terms, including "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness," as implied nutrient content claims. FDA requested comments on whether there are any additional terms synonymous with "healthy" that the agency should consider in its final rulemaking.

There are several terms other than "healthy" and its derivatives that consumers may interpret as indicating that the levels of nutrients in a food are such that the food may help maintain healthy dietary practices. The most obvious of these terms is "nutritious" and its derivatives, such as "nutrition," "nutritional," "nutritiously," and "nutritionally." Additional terms include "nutrient-dense," "good for you," "nourishing" and "wholesome." Consumers likely perceive these claims as synonymous with "healthy" and they should be regulated as implied "healthy" claims. We therefore request that FDA expressly add "nutritious," "nourishing," "wholesome," and their derivatives, and any other equivalent terms, to the proposed rule as examples of terms that are synonymous with "healthy."

**Figure 4. Examples of products currently using claims that are likely perceived as synonymous with "healthy" without meeting the proposed "healthy" definition**




Labeled with "nutrition" claim
Contains 4 grams of added sugars (9% DV) per serving


Labeled with "wholesum" claim
Contains 8 grams of added sugars (16% DV) per serving

Sources:
https://www.instacart.com/products/19758997-planters-fiber-mix-mixed-nuts-with-almonds-pistachios-coconut-cranberries-cashews-sea-salt-5-5-oz
https://shop.wegmans.com/product/253024/wegmans-organic-chocolate-brownie-wholesum-kids-bars-6-pack

## V. CSPI supports the broadening of what the use of "healthy" in a "nutritional context" entails and recommends it be broadened further

Under current regulations, "healthy" claims are only considered implied nutrient content claims when made in connection with a statement about a nutrient, for example "healthy, contains 3 grams of fat."[35] FDA's new proposed rule states:

> "[FDA] propose[s] revis[ions that …] would no longer require that an implied nutrient content claim be used "in connection with an explicit or implicit claim or statement about a nutrient." Instead, […] "healthy" constitutes a nutrient content claim where the term "healthy" is used to characterize the food itself and "where *there is also* implied or explicit information about the nutrition content of the food. [… FDA] propose[s] to make clear that any information on the label or labeling that puts the term "healthy" into a nutritional context would make "healthy" an implied nutrient content claim when it is used to characterize the food. For example, where "healthy" appears on the front of a cereal product that is described elsewhere on the label or labeling as high in dietary fiber (e.g., on the back of the package, or on a website), the "healthy" claim would constitute a nutrient content claim."

CSPI supports this broader interpretation of when a "healthy" claim constitutes a nutrient content claim. We also recommend that the term "healthy" (and equivalent terms) be considered an implied nutrition content claim even when it is utilized as part of a health claim (*e.g.*, "heart healthy") or structure-function claim (*e.g.*, "brain health"). In other words, the term "heart healthy" should be considered an implied nutrient content claim whenever the labeling includes any voluntary implied or explicit information about the nutrition content of the food (*e.g.*, if another nutrient content claim appears on the package or product website). This is important because the average consumer cannot be expected to understand that the term "healthy" is regulated differently when used as part of a health claim, structure-function claim, or implied nutrient content claim. If consumers come to trust that products with "healthy" claims must adhere to requirements for maximum levels of added sugars, sodium, and saturated fat, they may be misled into purchasing, for example, a product labeled "heart healthy" that is high in added sugars, unless such products making health claims using the term "healthy" are held to the same nutrient standards as all other products bearing "healthy" claims.

[35] 21 CFR 101.65(d)(1)(ii)

**Figure 5. Examples of products with "heart healthy" claims that would not qualify for the "healthy" implied nutrient content claim under FDA's proposed definition**

| | | |
|---|---|---|
|  |  |  |
| Contains 10 grams of added sugars (19% DV) per 1-cup serving | Contains 9 grams of added sugars (18% DV) and 270 mg of sodium (12% DV) per 1-cup serving | Contains 12 grams of added sugars (24% DV) per 1-cup serving |

Sources:
https://www.quakeroats.com/products/cold-cereals/life-cereal/cinnamon
https://www.target.com/p/basic-4-breakfast-cereal-19-8oz-general-mills/-/A-78364685
https://www.greatgrains.com/products/cranberry-almond-crunch/

## VI. CSPI supports including plain water and plain, carbonated water under the definition of "healthy"

FDA's proposed rule notes that, "Under the existing regulation... water cannot be labeled "healthy" because it does not meet the existing nutrient-related criteria."[36] FDA's new proposal would allow plain water and plain, carbonated water to qualify as "healthy" under the updated definition. CSPI agrees that these beverages should qualify for the "healthy" claim. Plain and sparkling water without added caloric, low-calorie, or calorie-free sweeteners or other caloric ingredients are among the healthiest beverages, and consumers should be encouraged to consume them.

[36] 87 Fed. Reg. 59168-59202. September 29, 2022.

## VII. FDA should review and revise the "healthy" rule every five years

FDA has not updated its regulations pertaining to the "healthy" nutrient content claim since it was first defined in 1994.[37] Since then, there have been five updates to the DGA, which evolve in alignment with the latest nutrition science. Going forward, the "healthy" claim should be amended more regularly. Although the "healthy" definition may not need to be amended with every update to the DGA, we urge FDA to review and (if needed) revise the rule every five years to ensure the criteria used for the "healthy" claim continues to be based on the current scientific evidence and latest edition of the DGA.

## VIII. Conclusion

CSPI appreciates the opportunity to comment on FDA's proposal to update the "healthy" claim. We urge the agency to rapidly conclude this regulatory process while also prioritizing front-of-package nutrition labeling regulations.

[37] 81 Fed. Reg. 33742 at 33791