



**Food Law and Policy Clinic, a Division of the Center for Health Law and
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Dockets Management Staff (HFA-305)
United States Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Docket No. FDA-2016D-2335

Sent via electronic submissions on the Federal eRulemaking Portal: www.regulations.gov

Re: Comments on the Proposed Definition of “Healthy” on Food Labels

To Whom it May Concern,

These comments are submitted on behalf of the Harvard Law School Food Law and Policy Clinic (FLPC) in response to the Food and Drug Administration’s (FDA) Federal Register notice on use of the term “healthy” in the labeling of human food products.

FLPC is an educational program at Harvard Law School that serves partner organizations and communities by providing guidance on food system issues and advocating for food systems change, while engaging law students in the practice of food law and policy. FLPC focuses on increasing access to healthy foods, supporting sustainable and equitable production, promoting community-led food system change, and reducing waste of healthy, wholesome food.

FLPC supports the adoption of an updated regulatory definition of “healthy.” Since the existing definition was adopted in 1993,¹ nutrition science for dietary guidance has evolved dramatically. It is essential that FDA bring the “healthy” definition in line with the latest Dietary Guidelines. It is also necessary for FDA to give “healthy” a meaning that is scientifically accurate, tailored to the needs of a wide range of consumers, and effectively empowers consumers with information to make healthier choices. Because the proposed rule largely accomplishes these goals, we are extremely supportive of the FDA’s proposed rule for the updated definition of “healthy.”

We believe that there are opportunities for FDA to use the “healthy” definition as a building block for a more robust regulatory structure aimed at helping consumers to make healthier choices in their daily lives. To ensure that the “healthy” definition is as comprehensive and effective as possible, FLPC also recommends the FDA incorporate the following changes (further detail for each recommendation is provided below):

- FDA should re-evaluate its added sugar limits and whole grain requirements
- The definition of “healthy” should include some consideration of whether a given food is processed and to what degree

¹ Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2375 (Jan. 6, 1993); 21 C.F.R. § 101.65(d) (2022).

- The “healthy” definition should explicitly exclude additives or contaminants known to be harmful to health
- FDA should establish a formal process for periodically revising the regulatory definition of “healthy” over time to align with the advances in nutrition science
- Products bearing the healthy label should provide additional information to inform consumers why a product is healthy, and for whom it is healthy
- Food bearing a “healthy” claim should be the same foods that are “green light” foods on a Front-of-Pack label

Overview of Proposed Rule

The proposed rule seeks to update the requirements for food to bear the nutrient content claim “healthy” on the label.² The existing rule imposes limits on the amount of total fat, saturated fat, cholesterol, and sodium (but not added sugar), and requires a minimum amount of vitamin A, vitamin C, calcium, iron, protein, and dietary fiber.³ The proposed “healthy” definition shifts attention away from satisfying minimum nutrient requirements and towards a more holistic approach to healthy by emphasizing eating whole, nutrient-dense foods.⁴ While the current rule focuses on nutrient deficiencies that were of public health concern 30 years ago, including vitamins A and C, the proposed rule emphasizes food consumption practices that can combat chronic disease.

Under the FDA’s proposed definition of “healthy,” a number of foods would automatically qualify as healthy such as whole fruits, whole vegetables, and water.⁵ Other foods are regulated according to food group. The food groups are vegetables, fruits, grains, dairy, protein foods, and oils,⁶ and are based on the 2020-2025 Dietary Guidelines.⁷ A food product may bear the term “healthy” if it contains a minimum “food group equivalent.” A food group equivalent is the amount of that food group an individual food must contain per serving⁸ to qualify under the “healthy” definition.⁹ For example, if the food product is a fruit product, it must contain at least a ½ cup equivalent of fruit.¹⁰ For some food groups, the proposed rule then also contains limits on the amount of added sugar, sodium, and/or saturated fat that the food product contains.¹¹ For mixed products, main dishes, and meals, eligibility for the “healthy” label are calculated by food group equivalent portions from multiple food groups.¹²

FLPC Recommendations

Overall, FLPC is supportive of the FDA’s proposed definition of healthy. As detailed above, the proposed rule aligns with current nutrition science, which emphasizes the importance of eating well-rounded meals

² Food Labeling: Nutrient Content Claims; Definition of Term “Healthy”, 87 Fed. Reg. 59168 (proposed Sept. 29, 2022) (to be codified at 21 C.F.R. pt. 101).

³ 21 C.F.R. 101.65(d) (2022).

⁴ See Food Labeling, 87 Fed. Reg. at 59176–77.

⁵ Food Labeling, 87 Fed. Reg. at 59183–84, 59200.

⁶ Food Labeling, 87 Fed. Reg. at 59183 (Table 1); Food Labeling, 87 Fed. Reg. at 59200.

⁷ Food Labeling, 87 Fed. Reg. at 59177.

⁸ Note that the rule uses the term “reference amount customarily consumed” (RACC), which is a term used in nutrition labeling regulations to determine serving sizes. See 21 CFR § 101.9(b)(2), 101.12 (2022).

⁹ Food Labeling, 87 Fed. Reg. 59177–78.

¹⁰ Food Labeling, 87 Fed. Reg. at 59183 (Table 1).

¹¹ Food Labeling, 87 Fed. Reg. at 59200.

¹² Food Labeling, 87 Fed. Reg. at 59184 (Table 2), Food Labeling, 87 Fed. Reg. at 59192–93.

and whole, nutritionally dense foods.¹³ We support the structure of the proposed rule, which requires food products with a “healthy” label to contain a minimum amount of food products that contribute to such a diet.¹⁴

In particular, we applaud the proposed rule’s categorical inclusion of whole fruits and vegetables as “healthy.”¹⁵ Encouraging Americans to consume nutrient-dense foods, such as whole fruits and vegetables, supports nutrition science’s emphasis on developing healthy eating patterns, as opposed to merely consuming a minimum amount of nutrients.¹⁶

We also support the proposed rule’s restriction on the amount of saturated fat and elimination of the total fat amount. The current rule’s approach of restricting total fat has had adverse consequences. Foods high in healthy, unsaturated fats such as nuts cannot bear the “healthy” label because of the total fat maximum. Restricting the amount of saturated fat without addressing total fat content of food products will promote a consistent public health message that consumers should focus on building healthy dietary patterns.

Finally, we support the rule’s restriction on added sugar. This new part of the “healthy” label rule recognizes that consuming added sugars contributes to obesity in adults and children.¹⁷ This part of the rule also recognizes that increased consumption of some sugars can contribute to metabolic risk factors for type 2 diabetes, impair glucose metabolism, and increase the risk of cardiovascular disease.¹⁸ Limiting added sugars in foods with “healthy” labels is a welcome addition.

Though FLPC is overall supportive of the proposed rule in its current form, the following six sections outline recommendations for how the FDA could further strengthen the proposed rule to push industry to encourage healthy eating habits for Americans in accordance with existing science, while still aligning with realistic eating habits. Further, FLPC’s recommendations encourage the FDA to plan for updates to nutrition science and increase the “healthy” labels contribution to public education about what constitutes a healthy diet.

1. The definition of “healthy” should reduce the added sugar allowance for grains and increase the whole grain requirement.

In its current draft, the rule has codified that fruit products cannot have any added sugar (0% DV) in order to meet the threshold requirement for a “healthy” label; however, a single serving of grains can contain up to 5% DV and still meet the rule’s requirements.¹⁹ We think that these numbers should be changed to show greater consistency across categories and address the realities of how grains and fruit products are made. The fact that there are several whole-grain breads in the market with added sugar content *below* 5%

¹³ Food Labeling, 87 Fed. Reg. at 59169–72; *see generally* U.S. DEP’T. OF AGRIC., 2020-2025 DIETARY GUIDELINES FOR AMERICANS (2020), https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf.

¹⁴ Food Labeling, 87 Fed. Reg. at 59178.

¹⁵ Food Labeling, 87 Fed. Reg. at 59183–84, 59200.

¹⁶ *See* U.S. DEP’T. OF AGRIC., 2020-2025 DIETARY GUIDELINES FOR AMERICANS 6 (2020), https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf

¹⁷ U.S. DEP’T OF AGRIC., SCIENTIFIC REPORT OF THE 2015 DIETARY GUIDELINES ADVISORY COMMITTEE 342 (2015), <https://health.gov/sites/default/files/2019-09/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf> (chapter 6); *see* Lisa Te Morenga et al., *Dietary Sugars and Body Weight: Systematic Review and Meta-analyses of Randomised Controlled Trials and Cohort Studies*, 346 *BMJ* e7492 (2013), <http://www.bmj.com/content/346/bmj.e7492>.

¹⁸ *See generally* Vasanti S. Malik & Frank B Hu, *Fructose and cardiometabolic health: What the evidence from sugar-sweetened beverages tells us*, 66(14) *J. OF THE AMERICAN COLLEGE OF CARDIOLOGY* 1615 (2015).

¹⁹ Food Labeling, 87 Fed. Reg. at 59187.

is proof that FDA could lower this number further, in order to ensure the healthy label is used to highlight which grain products truly *are* the healthiest available and push their competitors to reformulate. We recommend allowing only 2.5% DV added sugar in the grain category.

Similarly, grain products only have to contain $\frac{3}{4}$ oz whole grain equivalent per serving²⁰ in order to bear the “healthy” claim. FDA could increase this figure, requiring 100% whole grains in any qualified grain product, in order to create a higher bar for the “healthy” claim and push the market away from more refined products.

2. The definition of “healthy” should include some consideration of whether a given food is processed and to what degree.

As currently defined, the “healthy” label does not sufficiently differentiate between packaged foods with differing levels of processing. Though the rule does note in Table 2 that all raw, whole fruits and vegetables presumptively may bear the “healthy” claim, the remaining food categories—individual food products, mixed products, main dishes, and meals—are not further delineated based on the amount of processing they undergo prior to reaching consumers. In essence, the rule does not acknowledge any differences between the health value of a package of roasted nuts versus a frozen microwave meal, as long as each meets its food group requirements.

Failing to account for the level of processing a food can undergo when it bears a healthy label is a grave omission. Studies have shown that an ultra-processed diet can encourage excess caloric intake.²¹ Furthermore, ultra-processed foods are correlated with adverse health outcomes, such as metabolic diseases.²² A recent study involving thousands of children between the ages of 2 and 19 found that 67% of their caloric intake came from ultra-processed foods as of 2018.²³ As noted by the lead researcher of the aforementioned study, some highly-processed foods, such as whole grain breads, can still be part of a healthy diet.²⁴ However, overall, the proposed rule should encourage consumers to restrict the amount of processed foods they consume. To account for the health concerns associated with food processing, the final rule for the definition of “healthy” should include maximum processing requirements depending on the food group.

In order to strike a balance that discourages unnecessary preservatives and processing harms without punishing reasonable processing, FDA should add language to the rule to account for processing. The FDA could adopt a framework similar to the Academy of Nutrition and Dietetics—which has published a

²⁰ See *supra*, footnote 8 (discussing the serving vs. RACC, as used in the proposed rule).

²¹ See generally Kevin D. Hall et al., *Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake*, 30 CELL METABOLISM (2019), [https://www.cell.com/cell-metabolism/fulltext/S1550-4131\(19\)30248-7](https://www.cell.com/cell-metabolism/fulltext/S1550-4131(19)30248-7).

²² See generally Leonie Elizabeth et al., *Ultra-Processed Foods and Health Outcomes: A Narrative Review*, 12 NUTRIENTS 1955 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7399967/>.

²³ Lu Wang et al., *Trends in consumption of ultraprocessed foods among US youths aged 2-19 years, 1999-2018*, 326 JAMA 519 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8356071/>.

²⁴ Sharon Reynolds, *Highly Processed Foods Form Bulk of U.S. Youths' Diets*, NATIONAL INSTITUTES OF HEALTH (2021), <https://www.nih.gov/news-events/nih-research-matters/highly-processed-foods-form-bulk-us-youths-diets> (quoting Dr. Fang Fang Zhang: “Some whole grain breads and dairy foods are ultra-processed, and they’re healthier than other ultra-processed foods.... But many ultra-processed foods are less healthy, with more sugar and salt, and less fiber, than unprocessed and minimally processed foods, and the increase in their consumption by children and teenagers is concerning.”).

spectrum from “minimally processed” to “heavily processed” food²⁵—in order to take a systematic approach to categorizing and evaluating products with respect to these factors. A maximum level of allowable processing should be selected for each food group and added to the chart of requirements. This inquiry should be conducted on a food group basis, so that, for instance, even if only “minimally processed” fruits and vegetables can receive the “healthy” label, “heavily processed” grains might still pass muster.

3. The “healthy” definition should explicitly exclude additives or contaminants known to be harmful to health when consumed in high quantities.

The FDA should consider how certain additives and contaminants are regarded under the scope of the “healthy” definition. While a product may be “healthy” due to low saturated fat or low salt content, it may be “unhealthy” because of additives or contaminants known to be harmful to health. This could include food products that are naturally high in harmful compounds, like fish that are high in mercury such as bigeye tuna and swordfish;²⁶ it could also include food products that have certain harmful additives, such as nitrates and nitrites in preserved meats.²⁷ The FDA should create a list of such compounds that may be present in foods that disqualify them from bearing the “healthy” claim.

4. FDA should establish a formal process for periodically revising the regulatory definition of “healthy” over time to align with the advances in nutrition science.

The forthcoming update to the definition of “healthy” by FDA would represent the first update of the term since 1993. As we have seen in the 2020 Dietary Guidelines and evolution in these guidelines over time, nutrition science is consistently evolving and shifting, changing the recommendations from public health experts for consumers.²⁸ While updating the existing “healthy” definition is a crucial first step to align with current scientific knowledge, the term must not ossify and remain unchanged as the science advances. To guard against this, FDA should develop a formal process to regularly revisit the “healthy” definition to reflect the latest guidance from the Dietary Guidelines. We suggest that FDA establish in this rule a plan to review the definition for the healthy claim every ten years, striking a balance between the administrative burden that aligning with each new Dietary Guidelines (every five years) would impose and the need for the definition to reflect the most accurate and up-to-date science.

5. Products bearing the “healthy” label should provide additional information to inform consumers why a product is healthy and for whom it is healthy.

Including a healthy claim on food packaging is helpful to quickly inform consumers that a product may be beneficial to their health and that they should purchase it over a substitute. However, standing alone, a healthy claim cannot serve the full purpose of creating a more informed public. To that end, FDA should require that any use of healthy be accompanied by some form of further information that explains to consumers why the product is healthy, briefly explaining what element of the healthy definition the product meets. This could be achieved by requiring foods with a healthy label to include a small

²⁵ Esther Ellis, *Processed Foods: What's OK and What to Avoid*, ACADEMY OF NUTRITION AND DIETETICS (Feb. 11, 2019), <https://www.eatright.org/food/nutrition/nutrition-facts-and-food-labels/processed-foods-whats-ok-and-what-to-avoid>.

²⁶ *EPA-FDA Advice about Eating Fish and Shellfish*, U.S. ENVIRONMENTAL PROTECTION AGENCY (Nov. 3, 2022), <https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish>.

²⁷ Leonardo Trasande et al., *Food Additives and Child Health*, 142 PEDIATRICS 1408 (Aug. 2018), <https://doi.org/10.1542/peds.2018-1408>.

²⁸ See U.S. DEP’T. OF AGRIC., 2020-2025 DIETARY GUIDELINES FOR AMERICANS viii (2020), https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf.

additional statement with this information on the package, or on the seller’s website where consumers could obtain more information (perhaps with a required QR code linking to that page).

To account for nuance in nutrition, the FDA also should include an asterisked footnote with every “healthy” claim or label that clarifies that the product may not be considered “healthy” for all individuals, and that one should consult with their physician for customized dietary recommendations. The FDA should also identify populations that need special information and make it available via a QR code or link to the information on the seller’s website. These modifications to the healthy rule would ensure that the “healthy” claim has a more meaningful impact for all consumers.

6. Food bearing a “healthy” claim should be the same foods that are “green light” foods on a Front-of-Pack label.

FLPC is supportive of the standards set forth in the proposed “healthy” definition, especially since the current definition is outdated and needs to be amended to reflect current nutrition science. The proposed “healthy” standards can support healthy dietary patterns for Americans, though the actual impact of the label may be limited given only 5% of packaged foods use the label now.²⁹ Many manufacturers likely will continue to choose not to use the healthy label for various reasons. By contrast, FDA could require mandatory front of packaging labeling that would make health more salient to consumers. That is why we strongly support the FDA’s commitment to develop a required Front-of-Pack (FOP) label, as reiterated in the 2022 White House Conference on Hunger, Health and Nutrition Strategy.³⁰ To increase the impact on consumers and transparency in the food system, the FDA should use the new standards for the “healthy” label as a starting point for new FOP label requirements.

As the FDA and U.S. Department of Health and Human Services conduct research on standardized FOP labeling, it is essential that such labeling is concordant with “healthy” claims. FOP labeling has been shown to effectively convey information and guide purchasing decisions given that they are simple, identifiable, and easily remembered.³¹ A robust FOP labeling system is crucial to providing consumers with quick and accurate facts regarding their food. If a graduated “traffic light” labeling system is adopted for FOP labeling, we suggest that “healthy” foods are those that are also “green light” foods, as this would provide clear and consistent messaging that would appropriately guide the average consumer. Channeling the existing efforts of creating a healthy label towards synonymizing “healthy” with the highest tier of the labeling scheme would simplify labeling for consumers and could increase the potential impact of the new healthy label rule, as well as help FDA to roll out FOP labeling more quickly, as the “green light” tier would already be established.

Conclusion

Overall, FLPC is very supportive of the change that this rule represents. The definition of “healthy” has the potential to become the building block of a larger regulatory structure intended to push consumers to improve their eating habits. In addition to the impact the healthy label will have on individual consumer shopping decisions, the term may also serve as a criterion for procurement of certain foods and beverages

²⁹ Food Labeling, 87 Fed. Reg. at 59169.

³⁰ THE WHITE HOUSE, BIDEN-HARRIS ADMINISTRATION NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH 22 (Sept. 2023), <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>.

³¹ Shelley McGuire, *Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices*, 3 ADVANCES IN NUTRITION 332 (May 2012), doi:10.3945/an.112.001933.

in facilities like schools and hospitals. Furthermore, the standards outlined in the “healthy” label can and should be used as a starting point for required FOP labels.

To maximize the impact of the healthy definition as an industry pushing standard, the FDA should update the proposed rule to include more stringent added sugar requirements for grains, include maximum levels of processing a food may undergo, and limit harmful additives and contaminants. The FDA should also require food businesses to provide easily accessible information both about the definition of healthy and the rationale for the healthy labeling for that specific product. Finally, to ensure the definition of healthy continues to evolve with science over time, the proposed rule should include a strategy to routinely update the rule. In sum, these recommendations support a more comprehensive, responsive definition that accounts for the nuance of individual products as well as the ever-changing developments in the field of nutrition.

Thank you for your consideration of FLPC’s comments and recommendations.

Sincerely,

A handwritten signature in black ink that reads "Emily Broad Leib". The signature is written in a cursive, flowing style.

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