Via regulations.gov

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

February 16, 2023

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

Dear Sir or Madam,

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) proposed rule to update the definition of the term "healthy" when used as a nutrient content claim in labeling. As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

Executive Summary

FMI supports FDA establishing an updated definition for the term "healthy" to better reflect updated dietary guidance. FMI also appreciates many of the proposed revisions, including the updates to the nutrients to limit to no longer cover total fat and cholesterol, and the flexibility provided for certain foods such as nuts that inherently contain saturated fat. However, as explained further in the comments that follow, FDA has proposed revisions that result in an overly restrictive definition that would allow very few foods to qualify and that could inadvertently signal that a broad swath of nutritious foods are "unhealthy." The proposed definition results in broad categories of foods that are considered healthy by consumers and dietitians/nutrition professionals alike, including yogurts, many 100% whole grain breads/buns, and bagged salads (with dressing), as being deemed misbranded if labeled as healthy. Many of the proposed changes go beyond updating the "healthy" definition to reflect the ways in which dietary guidance has changed over the past three decades. An overly restrictive definition that only allows an exceedingly small number of foods to bear a healthy claim, and very few

packaged foods, would be counter-productive to the agency's goal of improving dietary patterns in the United States because it would not encourage consumers to make small shifts towards overall healthier diets, nor would it provide incentives to reformulate. We urge FDA to more closely hew to federal dietary guidance and to ensure that the updated healthy definition reflects the broad range of foods that would be considered healthy per that guidance.

1. **Overall approach**
    a. Need to encourage shifts in behavior and innovation: FDA should reconsider its proposed approach of defining healthy in a very limiting way, in order to ensure the agency meets its legal obligations, and in light of the Dietary Guidelines for Americans' emphasis on meeting consumers where they are and encouraging small shifts in the diet.
    b. Scope: FDA should clarify that the "healthy" definition is limited to the implied nutrient content claim and its existing defined synonyms and does not affect other labeling claims; nor does it limit which foods should be considered part of a healthy dietary pattern. FDA should clarify that dietary guidance statements and other general statements about healthy dietary patterns should continue to be permitted so long as they are truthful and not misleading.

2. **Nutrients to encourage**
    a. Consistent with the current definition, a food that contains a meaningful amount of a beneficial nutrient, including dietary fiber, protein, vitamin D, calcium, potassium, or iron, should be able to qualify as healthy if it also meets the nutrients to limit.

3. **Food group equivalents**
    a. Combined contribution to food groups: The food group equivalents should be based on a combined contribution to multiple food groups, as this is more consistent with the Dietary Guidelines focus on the overall eating pattern rather than focusing on food groups in isolation. Consistent with this request, the individual foods and mixed products categories should be combined. We also ask FDA to consolidate the food groups for fruits and vegetables.
    b. First ingredient approach: For individual and mixed foods, as an alternative to the proposed FGE minimums, the food group equivalent criteria should be considered to be met if a food's first ingredient (or for foods other than beverages, the second ingredient if the first ingredient is water or broth) is in one of the food groups to encourage.
    c. Foods with small RACCs: Foods with small reference amounts should be subject to modified criteria.
    d. Guidance on food groups: In order to be implementable, significantly more guidance is needed on each of the food group equivalents.
    e. Fruits and vegetables: Dried fruit and vegetable powders not derived from juice should count toward the fruit and vegetable groups.

f. Grains: The food group equivalent requirement for grains should be a minimum of 8 grams of whole grain per ounce equivalent, consistent with the Dietary Guidelines for Americans
g. Protein foods: FDA should address the contributions of plant-based foods to the protein foods category.
h. Nuts: Additional clarity is needed for foods containing coconut.

4. Nutrients to limit

a. Added sugars: There is more room within a healthy dietary pattern to accommodate additional amounts of added sugars; limits of 30% DV for meals; 25% for main dishes, and proportionally smaller amounts for individual foods and foods with small RACCs, would be more consistent with the requirements of a healthy dietary pattern. The limits for added sugars should mirror those set for sodium.
b. Sodium: Likewise, there is more room within a healthy dietary pattern to accommodate additional amounts of sodium, and the sodium limits should also take into account potential consumer acceptance of lower levels of sodium.

5. Categories of foods considered under the definition

a. Beverages: We support FDA's recognition of plain water and plain carbonated water as automatically eligible for "healthy." Likewise, unsweetened coffee and tea (including whole, ground, and roasted coffee beans); and water beverages including those with added flavors, and other ingredients such as non-nutritive sweeteners or minerals added for taste should automatically qualify as healthy, consistent with the recognition in the DGA that these products play a role in providing consumers with hydration and will not contribute to calories or added sugars intake. Other beverages that meet the criteria in the healthy regulation, including nutrients to limit, should be able to qualify as healthy, consistent with the proposed rule.
b. Other categories: Raw whole fruits and vegetables that are cut and packaged should automatically qualify as "healthy".
c. Infants and children under age 2: FMI recommends that FDA establish a definition of healthy that would apply to foods for infants and children under 2 years of age because the DGA provide recommendations for this population group.

6. Recordkeeping and enforcement

a. Records of food group contributions: FDA should clarify that it does not have legal authority to access the complete product formulation, which is confidential, and that records may be stored centrally.
a. Rounding: FDA should clarify that either unrounded or rounded nutrient values may be used to assess compliance with the "healthy" definition.
b. Compliance and enforcement: FDA should make clear that products bearing the term "healthy" used in compliance with the existing regulation may be lawfully

sold and shipped in interstate commerce until the compliance date for the final rule.

c. FSIS-regulated products: FDA should coordinate with the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) to address healthy claims for FSIS-regulated products.

Detailed Comments

1. **Overall approach**

FMI generally supports the framework of the proposed rule, which takes into account food groups to encourage and nutrients to limit. We also appreciate that FDA has kept the definition focused on food group and nutrient content. Further, we support the updating of the definition to reflect dietary guidance, by removing the thresholds for total fat and cholesterol, and allowing for inherent saturated fat that is found in foods like dairy and nuts. Within this general framework, we have two initial comments on the scope and approach taken in the proposed rule.

a. FDA should reconsider its proposed approach of defining healthy in a very limiting way, in order to ensure the agency meets its legal obligations, and in light of the Dietary Guidelines for Americans' emphasis on meeting consumers where they are and encouraging small shifts in the diet.

In the proposed rule, FDA has taken an approach that is extremely limiting with respect to the foods that qualify to bear a healthy claim. While there are numerous potential places to draw a line with respect to the term healthy, the proposed rule represents a very strict interpretation that would significantly limit the types of foods that qualify. In fact, some of our members have found that their portfolios have gone from 80-95% "healthy"-eligible foods, to only 3-7% healthy eligible foods under the proposed rule. We expect that taking into account the entire food supply, fewer than 5% of products would qualify. Foods that would not meet the criteria include nutrient dense foods such as many 100% whole grain breads and buns, whole grain tortillas, hummus, salsa, and frozen meals that have qualified as healthy for decades, and bagged salads with dressing. It simply cannot be the case from a nutritional perspective that so few foods should be considered "healthy" and that the term "healthy" would be deemed misleading if used on any other food. Critically, FDA has not explained or provided the basis for its proposed decision, taking into account other alternative approaches not selected.

We urge FDA to adopt more flexible criteria as a way to better reflect the range of foods that would be considered healthy under dietary guidance. A more flexible definition is also more likely to encourage consumers to include more healthful foods, and to spur greater innovation in the food industry, whereby companies would be incentivized to formulate or reformulate products in order to qualify. Such an approach would be more consistent with the Dietary Guidelines for Americans 2020-2025 (DGA), which encourage small shifts in the diet to achieve a healthy dietary pattern. Indeed, if one significant goal of the healthy definition is to encourage

consumers to eat healthy foods, a system that allows only a very small subset of foods to be labeled as "healthy," is unlikely to shift behavior or encourage innovation. We describe in our comments below the types of changes that we believe would be necessary to meet FDA's legal obligations and that would be more likely to encourage shifts in consumer behavior and reformulation of foods.

b. FDA should clarify that the "healthy" definition is limited to the implied nutrient content claim and its existing defined synonyms and does not affect other labeling claims; nor does it limit which foods should be considered part of a healthy dietary pattern. FDA should clarify that dietary guidance statements and other general statements about healthy dietary patterns should continue to be permitted so long as they are truthful and not misleading.

We ask that FDA, in the preamble to the final rule, make several important clarifications about the scope of the updated healthy definition. These include clarifying that: (1) the "healthy" definition is limited to the implied nutrient content claim "healthy" and existing defined synonyms only (e.g., "healthier"), and does not cover health claims or other labeling claims; and (2) the FDA's work to update the "healthy" definition does not signal that other foods don't have a role to play in a healthy dietary pattern, or designate particular foods as "good" or "bad".

FDA should reaffirm in the final rule that the definition of "healthy" applies only to those terms expressly and currently defined as synonyms for a healthy nutrient content claim -- i.e., "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness" – and only in those circumstances where the requisite "nutritional context" is present on the label. It does not apply to other labeling claims, such as health claims, other nutrient content claims, or other undefined claims. Further, FMI does not support incorporating additional terms, such as nutritious, wholesome, or others, as synonyms for healthy. Consumers view these terms differently, and FDA has provided no information or consumer research to establish that they should be viewed as synonyms for healthy. FDA should also clarify in the final rule that, a claim such as "made with whole grains" or another claim that communicates something about the food or nutrient content of the food, without more, is not subject to the "healthy" criteria.

Relatedly, FMI requests that FDA reconsider its position that the mere inclusion of Facts Up Front, MyPlate, or other symbols on the label, would be considered nutritional context that would result in the term healthy on the label being considered to be presented in a nutritional context and therefore subject to the healthy nutrient content claim definition. FDA states in the proposed rule that examples of a nutritional context that would trigger the definition – in addition to including the term healthy on the label – include front-of-pack nutrition icons. The agency comments: "there may also be instances where the use of a graphic on the label of a food bearing "healthy" would place the term in a nutritional context; for example, if the label on a can of beans labeled "healthy" also used the MyPlate symbol (which graphically puts the food groups together in the context of an overall dietary pattern, as a translation of the *Dietary Guidelines*) or other front of pack labeling (such as the "Facts Up Front" labeling program) to

imply that the product meets nutritional needs." We disagree that the Facts Up Front program, MyPlate, or other symbols creates such a nutritional context. The Facts Up Front program represents the standardized and factual display of nutrient information about a food and doesn't create any sort of nutritional or health halo for the product. FDA has cited no consumer research or evidence to suggest that consumers view this type of information as creating a nutritional context.

Further, FDA should educate consumers about the purpose of redefining the term healthy. Many consumers likely are not aware of the purpose of FDA defining the term healthy, but may hear in the news that certain foods have been deemed by FDA to be "healthy" or "no longer healthy". Consumers may not understand that the rulemaking is quite narrow and is limited to the voluntary use by food companies of the term "healthy" in their labeling when used in scenarios that constitute an implied nutrient content claim. The healthy definition doesn't represent a determination by FDA that Americans should avoid other foods, should only consume foods that qualify as "healthy", or some other broader policy recommendation. Indeed, as FDA recognized in the proposed rule, "nearly all foods can be incorporated into a healthy dietary pattern to a greater or lesser extent." We ask the agency to similarly include language in the preamble to the final rule making clear that the scope of the rulemaking is limited and narrow in nature and that doesn't deem particular foods as "unhealthy".

FDA should clarify that dietary guidance statements and other general statements about healthy dietary patterns should continue to be permitted so long as they are truthful and not misleading. Indeed, we understand the agency intends to issue guidance on dietary guidance statements.

2. Nutrients to Encourage

a. Consistent with the current definition, a food that contains a meaningful amount of a beneficial nutrient, including dietary fiber, protein, vitamin D, calcium, potassium, or iron, should be able to qualify as healthy if it also meets the nutrients to limit.

FMI asks FDA to retain the existing provision that allows a food to qualify as healthy if it meets both nutrients to encourage and nutrients to limit. For clarity, this would mean foods (other than those categorically exempt) would need to meet *both* (1) nutrients to limit, and (2) *either* the food group equivalent criteria, OR the minimum nutrients to encourage criteria.

As an initial comment, FDA has not provided an adequate basis for its proposal to depart from the "nutrients to encourage" approach that has been in place for decades. FDA's only stated rationale in proposing to eliminate this part of the healthy criteria is that it could encourage indiscriminate fortification of foods. Yet, under the current and proposed healthy criteria, foods that bear a healthy claim are subject to the binding effect of FDA's fortification policy in 21 CFR 104.20, which otherwise would be non-binding guidance. The fortification policy discourages the indiscriminate fortification of foods, and this policy has mandatory effect for foods bearing

healthy claims. And the Dietary Guidelines recognize that fortified foods are contributors of important nutrients and may be necessary for some populations to help achieve nutrition recommendations (e.g., vitamin D, fortified soy beverages, folic acid). FDA cites a single example to illustrate its concern, "white bread fortified with calcium." But FDA's standard of identity for enriched bread requires the addition of B vitamins to bread, making it clear that bread is not a food that the agency considers inappropriate to fortify. Further, to the extent there are particular foods for which FDA wishes to discourage fortification for purposes of qualifying for the healthy claim, the appropriate regulatory remedy would be to modify the fortification policy or the enriched bread standard of identity, not to prohibit healthy claims on a broad swath of foods that are properly fortified. FDA's proposal to eliminate the nutrients to encourage criteria is therefore overly broad and not appropriately tailored to achieve its stated goal.

Importantly, in updating the "healthy" nutrient content claim definition, FDA has stated that the goal is to have the updated definition reflect current dietary guidance. Nothing has changed about dietary guidance that would result in a situation where a food that contains meaningful amounts of at least one nutrient to encourage, and also meets nutrients to limit criteria, should no longer be considered healthy. To the contrary, the only change in dietary guidance related to the nutrients to encourage is that vitamins A and C are no longer considered nutrients of public health significance; instead, vitamin D and potassium are classified as such nutrients. The DGA continue to discuss nutrients of public health significance and recommend that consumers increase intake of these important nutrients in their diet.

Continuing to recognize the role of nutrients to encourage would also help to address many of the serious considerations raised below regarding the food group equivalents, including the lack of clarity on how to conduct food group equivalent calculations, and how to treat ingredients such as soy protein isolate, whey protein isolate, etc. It also is easier for FDA to implement, as nutrient content can be assessed using the Nutrition Facts Panel on the label, and easier for consumers to understand than the food group equivalent approach.

Accordingly, FDA should maintain the ability for foods to qualify as healthy based on meeting criteria for both nutrients to limit and nutrients to encourage. We believe this approach is required by the FFDCA given that FDA is defining the term "healthy" as a nutrient content claim. The FFDCA allows FDA to define terms that expressly or implicitly characterize the nutrient content of a food, but does not provide authority for FDA to require foods bearing nutrient content claims to have a minimum amount of food groups, or for the claim criteria to be based on something other than nutrients.

For the reasons discussed above, FDA should retain the nutrients to encourage criteria. In particular, FDA should maintain the existing structure for nutrients to encourage, where meals must provide at least a good source of three nutrients to encourage, main dishes must provide at least a good source of two nutrients to encourage, and individual foods/mixed products must provide at least a good source of one nutrient to encourage.

FDA should also continue to recognize that fortification is an appropriate way to qualify for the claim. As discussed above, under the current healthy definition, the use of a healthy nutrient content claim triggers the binding effect of FDA's fortification policy, which provides protection against the indiscriminate fortification of foods and establishes that the purpose of fortification is to provide for the rational addition of beneficial nutrients to foods. Fortification also serves as a means for manufacturers to improve the nutritional quality of foods that can assist consumers construct a diet that conforms to the DGA. Fortification that is consistent with the fortification policy and that is used to further improve the nutritional quality of certain foods should be an appropriate way to qualify for the nutrients to encourage under the healthy definition.

3. **Food group equivalents**

    a. **The food group equivalents should be based on a combined contribution to multiple food groups, as this is more consistent with the Dietary Guidelines focus on the overall eating pattern rather than focusing on food groups in isolation. Consistent with this request, the individual foods and mixed products categories should be combined. We also ask FDA to consolidate the food groups for fruits and vegetables.**

FMI supports FDA's proposed approach of focusing both on food group contribution and also on nutrients to limit, provided that the food group contribution is framed as an alternative to meeting the nutrients to encourage criteria, as discussed above. However, the proposal to require at least one food group equivalent (FGE) from at least one food group, rather than allowing for all food group equivalent contributions to count toward a collective total, is arbitrary, unnecessarily limiting, and inconsistent with dietary guidance. A food need not contain a full FGE from a single group to be nutrient dense or make a significant positive contribution to the diet. Rather, it might contribute smaller amounts to multiple different groups to encourage and still be a healthy choice. Indeed, the DGA emphasize the importance of not focusing on food groups *in isolation*, but rather looking at them as part of an overall dietary pattern:

> "Researchers and public health experts, including registered dietitians, understand that nutrients and foods are not consumed in isolation. Rather, people consume them in various combinations over time—a dietary pattern—and these foods and beverages act synergistically to affect health. The Dietary Guidelines for Americans, 2015-2020 puts this understanding into action by focusing its recommendations on consuming a healthy dietary pattern. The 2020-2025 Dietary Guidelines carries forward this emphasis on the importance of a healthy dietary pattern as a whole— rather than on individual nutrients, foods, or food groups in isolation."

If an individual food or mixed product contains at least one FGE combined from one or more different groups, it should be considered to meet the FGE requirement. This would logically follow because it would not matter whether a product contained one full FGE from a single group, or ½ FGE from two different groups. Similarly, combined contributions should count for

main dishes and meals, rather than requiring proportional amounts of exactly one full FGE from two or three different groups, respectively. For example, instead of requiring at least two full FGE from two different groups for a main dish, it would be appropriate to have 1 ½ FGE from one group and ½ FGE from another group. This approach is consistent with the framework for school meals, where the dietary pattern is assessed more holistically over the course of the week, rather than requiring individual foods to contribute precise amounts of the food group equivalents. Accordingly, this type of approach is also more consistent with a healthy definition that recognizes that foods are part of overall dietary patterns. Further, any concerns about ensuring a balanced main dish or meal would be addressed by the requirements for nutrients to limit.

To take a few examples of the arbitrariness of the proposal that result from not counting collective contributions to multiple food groups, a 100% fruit juice or 100% vegetable juice would both qualify as healthy, as would a 100% juice that is precisely 50% fruit juice and 50% vegetable juice. However, a blend of 100% fruit and vegetable juice that has mostly fruit juice or mostly vegetable juice would not qualify. A mixed product, per the proposed rule, must contain at least ½ of a FGE from two different food groups, or at least ¼ cup 100% fruit juice and ¼ cup 100% vegetable juice. If a 100% juice contained, for example 1/8 cup vegetable juice and 7/8 cup fruit juice, it would not qualify as an individual food or as a mixed product. Similarly, a smoothie product that contains yogurt and fruit would have to contain precise amounts of each component (at least ¼ cup fruit and at least 3/8 cup yogurt) to qualify as healthy. To avoid these arbitrary distinctions, we urge FDA to assess the combined contribution of a food to multiple food groups, rather than requiring proportional amounts of individual food groups.

We also ask FDA to combine the fruit and vegetable food groups to avoid arbitrary distinctions for products that contain a mixture of fruits and vegetables. A product that contains a meaningful amount of fruits, vegetables, or fruits and vegetables together should be treated similarly regardless of the precise contribution to the fruit group vs. the vegetable group.

b. For individual foods and mixed products, as an alternative to the proposed FGE minimums, the food group equivalent criteria should be met if a food's first ingredient (or second ingredient if the first ingredient is water or broth) is in one of the food groups to encourage.

For foods with small RACCs (30 g/ 2 Tbsp or less), and individual foods and mixed products with a RACC greater than 30 g/ 2 Tbsp, we encourage the agency to include the option of using "first ingredient" (whole grain, fruit, vegetable, dairy, or protein food) as a way to identify food group contributions, as an alternative to the proposed FGE minimums. If the food's first ingredient is in one of the food groups to encourage (or for foods other than beverages, its second ingredient after water or broth), it should be viewed as meeting the food group requirements.

This approach is consistent with USDA standards for Smart Snacks in School, which require a food to meet nutrients to limit criteria and to contain as the first ingredient a grain, fruit, vegetable, dairy, or protein food (or if the first ingredient is water, the second ingredient is one

of the listed food groups).[1] Further, looking to the first ingredient is an approach that is easier for FDA to implement, companies to comply with, and consumers to understand. The "first ingredient" approach is also used under the Dietary Guidelines to help consumers identify whole grain-rich foods, and accordingly will be helpful in educating consumers about how to identify healthful foods by looking at ingredient lists.[2]

As discussed further below, it also could help eliminate/ minimize the existing small RACC/FGE discrepancy problem where a significant number of foods have RACCs that are smaller than the food group equivalent requirement, making it mathematically impossible for the food to meet the "healthy" criteria. It also is appropriate to look to the first ingredient for individual foods/mixed products with RACCs of 30 g/2 Tbsp or more. This approach would ensure a significant amount of the food group is within the food and the criteria threshold goes up proportionally as the RACC increases in size. For example, a 110 g bagel will need to have more whole grain than a 40 gram cereal.

c. Foods with small reference amounts should be subject to modified criteria.

Foods with small reference amounts customarily consumed (RACCs) should be subject to a proportionally smaller FGE and nutrients to limit requirements. Under the proposed rule, foods like salsa, hummus, dips, cottage cheese, most other cheeses, whole grain croutons, some crackers/cereals with a 15 g RACC, and avocado could not qualify as healthy because their RACC is too small for them to contain a full FGE in the RACC. As discussed above, FDA should instead consider the FGE requirements to be met if either the proposed FGE minimums are met, or if the first ingredient (or the first ingredient after water for foods other than beverages) is a food in one of the food groups to encourage. Such an approach would appropriately recognize the proportionally smaller contribution to dietary patterns made by foods with small RACCs, and would avoid arbitrary results where foods are ineligible for a healthy claim simply because they are commonly consumed in small quantities. As discussed further below, foods with small RACCs should also be subject to proportionally lower nutrients to encourage and nutrients to limit criteria.

d. In order to be implementable, significantly more guidance is needed on each of the food group equivalents.

---

1 7 CFR 210.11(c)(2)(ii)-(iii).

2 See page 32 of the DGA ("Choose 100% whole-grain foods for at least half of all grains consumed. The relative amount of whole grain in the food can be inferred by the placement of the grain in the ingredient list. The whole grain should be the first ingredient—or the second ingredient after water. For foods with multiple whole-grain ingredients, they should appear near the beginning of the ingredient list.").

The proposed rule provides strikingly little guidance on what counts toward each of the food groups or on how to calculate FGE equivalents when cooked, dried, or frozen foods are used. In order for the rule to be implementable, this guidance is critical. For example:

- Generally, it is unclear how to calculate the food group equivalent contribution of a food because the proposed FGE amounts are in volume, and the volume will vary considerably based on the form of the food. FDA should clarify how to treat changes in density that result from processing and cooking steps (e.g., chopping, grating, slicing, pureeing, and many others).
- We support FDA's comments that concentrated vegetable and fruit purees and pastes are considered vegetables/fruits for purposes of calculating food group equivalents. However, it is unclear how the amount of the FGE that a puree contributes would be calculated. Indeed, there are numerous forms of fruits and vegetables where it is not clear how to calculate the FGE volume, including fruit and vegetable purees and pastes, processed vegetables, riced vegetables, and many others.
- It is unclear whether dried lentil or chickpea powder would be considered a vegetable or a protein food. The DGA state that dry beans and peas may be considered a vegetable or protein. For purposes of the "healthy" definition, we believe these could appropriately qualify as either group, and we ask FDA to clarify this.
- The protein food category in particular needs greater clarity.
    - It is unclear whether it is restricted to whole protein foods such as soybeans and tofu or tempeh from soy or could also include other soy derivatives that would be common in plant-based foods and that contain meaningful amounts of protein (e.g., soy protein isolate, soy protein concentrate, and others). We encourage FDA to take an inclusive approach to the protein foods category in recognition that the protein foods category is a broader, more nutrient-based category than some of the others.
    - It is unclear how chopped, diced protein foods/ingredients would be considered, particularly if these processing steps change the volume of the product.

The preamble language also reads as though it is an exhaustive list (e.g., "a 1 oz-eq **is** …") instead of providing a list of examples. FDA should make clear that the lists of ounce equivalents are merely non-exhaustive examples. Without such qualifying language, as an example, the grains category could be interpreted as not including whole wheat flour, whole oat flour, or foods made from whole grains (e.g., whole wheat bagels, whole grain crackers, brown rice crisps, etc.), since these foods are not specifically listed.

e. The food group equivalent requirement for grains should be a minimum of 8 grams of whole grain per ounce equivalent, consistent with the DGA.

FMI recommends that the whole grain threshold set by FDA should align with the recommendations in the 2020-2025 Dietary Guidelines for Americans: 8 g whole grain per ounce equivalent. The DGA recommend that one way to meet the recommended intake of grains (6 ounce-equivalents of grain foods per day, at least half of which are whole grains) is to choose

foods with 8 grams of whole grain per ounce equivalent. However, under FDA's proposed definition of healthy, foods with 8 g whole grain per ounce equivalent and that meet all other established nutrient limits for saturated fat, added sugars, and sodium, would not qualify for a "healthy" claim as currently proposed.

Given the assumption of 4 eating occasions per day and the recommended 6 ounce-equivalents of grain foods, people would have to eat multiple ounce equivalents of grain foods at certain eating occasions. It is therefore not necessary for just four foods to deliver the full recommended 3 ounce-equivalents of whole grain. Rather, if each of the 6 ounce-equivalents of grain foods consumed per day was a source of at least 8 g of whole grains, consumers would meet the recommendation. FDA should amend the whole grain equivalent requirement so that it is aligned with the 8 g whole grain per ounce equivalent recommended in the DGA. This could be accomplished by explicitly recognizing that a 1 oz equivalent of whole grains is 16 g, as stated in the DGA, and that ½ FGE equals 8 g of whole grains. Such an approach would also be more consistent with the DGA's recommendation that half of grain intake should be whole grains.

f. Dried fruit and vegetable powders not derived from juice should count toward the fruit and vegetable groups.

FMI recommends that dried fruits and vegetables, including those in powder form, should count toward the fruit and vegetable groups when they are made by drying and crushing whole fruits and vegetables (as opposed to those made from drying juice concentrates into a powder). FDA has recognized in its guidance on added sugars that fruit and vegetable powders that are not made from juices "are essentially whole fruits and vegetables that have been processed to change the physical form of the fruit or vegetable and to remove moisture."[3] Accordingly, FDA recognized they "contribute to the diet the same way that sugars found in whole fruits or vegetables do, and do not have to be declared as added sugars." Similarly, powdered fruits and vegetables that are not derived from juice should be eligible to contribute toward the fruit and vegetable groups.

Relatedly, FDA should provide guidance on how to convert dried fruits and vegetables, including those in powdered forms, into the whole equivalent for purposes of determining the food group contribution.

g. FDA should address the contributions of plant-based foods to the protein foods category.

As discussed above, additional guidance is needed on the protein foods category. We understand that fortified soy beverages and soy yogurt alternatives would count as a dairy food,

---

[3] Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals | FDA.

and certain soy foods (e.g., tofu made from soybeans, tempeh) would count as protein foods. Beyond those examples, however, the proposed rule does not give much guidance related to plant-based foods, including how ingredients like chickpea powder or legume powder would be treated; whether soy protein isolate and similar ingredients would be considered protein foods; and whether fortified pea milk, fortified almond milk, and other fortified plant-based milks would be considered protein foods. We ask FDA to provide additional guidance that would assist plant-based food companies in determining whether their products are eligible. Finally, we note that this issue would be addressed if FDA adopts our recommended "nutrients to encourage" approach, as plant-based foods that contain a good source of protein would be eligible under this approach.

h. Additional clarity is needed for foods containing coconut.

We ask FDA to clarify the treatment of foods containing coconut (other than coconut oil), given that coconut is currently classified as a tree nut under the Food Allergen Labeling and Consumer Protection Act (FALCPA). Would products containing coconut be subject to the same standards as nut products? Given the saturated fat content of coconut, which is inherent to the nut, we believe it should be subject to the same standards as other nuts.

Further, we understand that coconut water would be considered juice and a 100% coconut water with no added sugars would qualify as healthy.

4. Nutrients to Limit

As previewed above, the proposed criteria for added sugars and sodium are so excessively restrictive that many foods commonly viewed as "healthy" by consumers and collectively encouraged as part of "healthy" dietary patterns by health professionals, dietitians, nutrition scientists, and the DGA will not meet the agency's proposed definition. Further, the criteria are not attainable in many categories of foods and will not result in the desired innovation or reformulation intended by the Agency.

Examples of nutrient dense foods not meeting the agency's proposed "healthy" definition include: whole grain and 100% whole grain breads and buns, 100% whole grain tortillas, many 100% whole grain cereals, fat free/low fat cottage cheese, hummus, nearly all bagged salad with dressing, frozen vegetables with very small amounts of added sugar/sodium, frozen whole grain and vegetable bowls with very small amounts of added sugar/sodium, and reduced fat milk and cheeses. To clarify, these foods deliver a wide range of nutrients in consumer-friendly ways with minimal added sugar, sodium, or saturated fat, and are often encouraged as healthful choices by nutrition professionals when working with consumers looking for more nutrition from food.

a. There is more room within a healthy dietary pattern to accommodate additional amounts of added sugars; limits of 30% DV for meals; 25% for main dishes, and proportionally smaller amounts for individual foods and foods with small RACCs, would be more consistent with the requirements of

a healthy dietary pattern. The limits for added sugars should mirror those set for sodium.

For added sugars, there would be an ability to accommodate greater amounts within a healthy dietary pattern; limits of 30% DV for meals; 25% for main dishes, and proportionally smaller amounts for individual foods/mixed products, and foods with small RACCs, would be more consistent with the requirements of a healthy dietary pattern. The limits for added sugars should mirror those set for sodium. The proposed added sugars limits generally range from 0% to 5% DV (though a few categories may contain up to 10% DV per serving if they are meals or main dishes and contain dairy and whole grain). These limits are quite conservative given the 50 gram daily value that FDA established for added sugars, which is based on the DGA recommendation to limit added sugars to 10% of total calories (using a reference of a 2,000 calorie diet). If most "healthy" foods must contain no more than 5% DV added sugars per RACC or per serving (with some at 0% DV), this would mean a total intake of no more than 35% DV added sugars in most diets that consist only of healthy foods.

Simply, there is room within a healthy dietary pattern that includes no more than 50 g added sugars to accommodate slightly higher amounts of added sugars in each category. The 50 g daily value was based on food pattern modeling and was considered the amount of added sugars per day that would allow consumers to meet nutrient needs within calorie limits and construct a healthy dietary pattern. With limits of 10-20% DV in certain categories, and four eating occasions per day, consumers would consume only a portion of the daily reference intake for added sugars. This would also leave room in the dietary pattern to consume other foods that may not meet the healthy definition.

Illustrating just how restrictive the proposed limits are, in some cases, the proposed added sugars limits don't reflect an accurate understanding of the products available on the marketplace. For example, in its consumer-facing materials on the proposed healthy rule, FDA lists "Greek vanilla yogurt" as an example of a product that would qualify as healthy.[4] Yet we are not aware of *any* Greek vanilla yogurts that contain 2.5 g or less added sugars per RACC, unless they are sweetened exclusively with high-intensity sweeteners. Accordingly, one of the key examples of products that FDA intended to qualify as healthy would generally *not* qualify. This suggests that FDA may not have vetted its proposed criteria against products in the marketplace and that the agency is taking an approach that is stricter than it intended.

FMI asks that FDA establish added sugars criteria that mirror those for sodium on a % DV basis. For sodium, FDA has proposed a 30% DV threshold in meals. It would make sense to impose the same standard for added sugars in meals, and then to set correspondingly smaller limits in smaller food categories – i.e., 25% DV for main dishes, and proportionally smaller levels for individual foods/mixed products with larger RACCs, and foods with small RACCs.

---

[4] See Use of the Term Healthy on Food Labeling | FDA.

Further, there are some categories where the exclusive focus on added sugars, as opposed to total sugars, would seem to unfairly penalize certain foods. One example is tart juices such as cranberry juice that require sugar for palatability. FMI supports the proposal to allow 100% juices to bear a healthy claim, as it encourages the consumption of whole fruits and vegetables. Yet the total sugars in a 100% cranberry juice could be less than other 100% juices but the product would not qualify as healthy because it would have more than 0% added sugars. Similarly, certain dairy alternatives would not contain the total sugars that are inherent to dairy foods, so could have total sugars comparable to traditional dairy products but would not qualify because they exceed the added sugars limits. We ask FDA to consider whether a modified requirement that is based on total sugars, rather than added sugars, would be more appropriate for these foods.

b. The proposed sodium limits are unrealistic in terms of consumer acceptance.

Likewise, there is more room within a healthy dietary pattern to accommodate additional amounts of sodium, and the sodium limits should also take into account potential consumer acceptance of lower levels of sodium. The proposed thresholds for sodium are 23-50% lower than the current criteria, whereas the daily value for sodium has only decreased by 100 mg (4%) in the time since the healthy rule was first issued. The current daily value of 2300 mg reflects the most recent science and is only 100 mg lower than the previous daily value of 2400 mg.

The reductions in the sodium limits should be more commensurate with the change to the daily value. Such an approach would also avoid a situation where the limits are set so strictly that consumers would reject products with those levels of sodium, as such an outcome would not further the goals of the rulemaking to encourage more healthful eating. Thresholds of 30% DV for meals – consistent with what FDA has proposed – 25% DV for main dishes, and proportionally smaller levels for individual foods/mixed products with larger RACCs, and foods with small RACCs, would allow for more gradual adoption by consumers of lower sodium foods.

5. Categories of foods considered under the definition

a. We support FDA's recognition of plain water and plain carbonated water as automatically eligible for "healthy." Likewise, unsweetened coffee and tea (including whole, ground, and roasted coffee beans); and water beverages including those with added flavors, and other ingredients such as non-nutritive sweeteners or minerals added for taste should automatically qualify as healthy, consistent with the recognition in the DGA that these products play a role in providing consumers with hydration that will not contribute to calories or added sugars intake.

FMI supports the recognition that plain water, including carbonated or noncarbonated water without added ingredients, qualifies as healthy. This is consistent with the DGA, which recommends water as one of the primary beverages consumed, and the extensive science on water and hydration.

However, plain coffee and tea, and water beverages with added flavors, and other ingredients such as non-nutritive sweeteners that do not contribute added sugars should also qualify for categorical/automatic eligibility for "healthy." The DGA encourage consumption of these beverages, explaining that coffee, tea, and flavored waters are good options and that the most nutrient-dense beverages options include little, if any, sweeteners or cream. By recognizing plain coffee (including both whole, ground and roasted coffee beans, as well as plain unsweetened coffee) and tea, and flavored carbonated or noncarbonated waters (including those with non-nutritive sweeteners) as "healthy," FDA would be aligning its healthy definition with those beverages that are recommended choices under the DGA. There is no logical distinction for excluding waters with added flavors or non-nutritive sweeteners, which don't contribute calories or sugar, but make drinking water easier and more enjoyable.

Other beverages that meet the criteria in the healthy regulation, including nutrients to limit, should be able to qualify as healthy, consistent with the proposed rule.

b. Raw whole fruit and vegetables that have been cut and packaged, should automatically qualify as "healthy."

FMI supports the proposed categorical exemption for raw, whole fruits and vegetables. However, FDA states that such foods are categorically exempt *unless they are processed in any way*. The agency has clarified that cut and packaged fruit and vegetables are not subject to this exemption and therefore must meet the FGE and nutrients to limit criteria. However, cutting and packaging a food does not in any way change its nutrient content, so we recommend that such processing steps not result in the food no longer being considered a raw, whole fruit and vegetable for purposes of the healthy definition. We recommend that FDA adopt the USDA's Agricultural Marketing Service's (AMS's) approach under country of origin labeling, where activities such as "trimming, cutting, chopping, and slicing" are not considered to change the character of the product.[5]

c. <u>Infants and children under age 2</u>: FMI recommends that FDA establish a definition of healthy that would apply to foods for infants and children under 2 years of age because the DGA provide recommendations for this population group.

FDA should provide for "healthy" nutrient content claims for infants and children under two years of age, rather than limiting the claim to foods for older children and adults. The DGA 2020-2025 – unlike past editions of the DGA – provide recommendations for this population group, so there is no reason to restrict use of the claim, nor has FDA provided any such reason in the proposed rule. In the definition of "healthy" for infants and children under two years of

---

[5] See *Country of Origin Labeling (COOL) Frequently Asked Questions | Agricultural Marketing Service (usda.gov).*

age, we recommend that FDA either include household measures or standardize an alternate approach for assessing food group equivalents.

6. **Recordkeeping and enforcement**

    a. **With respect to recordkeeping, FDA should clarify that it does not have legal authority to access the complete product formulation, which is confidential, and that records may be stored centrally.**

We ask FDA to clarify that records kept to verify the food group contributions need not include the complete product recipe or formulation, as this is confidential and trade secret information, but instead would be limited to the specific information regarding the food group component contribution. Relatedly, as FDA noted in the proposed rule, we agree that manufacturers should be permitted to demonstrate compliance using the records they best believe accomplish this and not required to produce any specific form or document, similar to FDA's recordkeeping approach for nutrition labeling of added sugars and other nutrients for which no analytical test method exists. We also note that to the extent FDA adopts our recommended approach of considering nutrients to encourage, as an alternative to food groups, this would meaningfully reduce the significant administrative burden that would otherwise be associated with the proposed recordkeeping requirements.

FDA should also recognize that records required under the proposed rule may be stored centrally and need not be available at the manufacturing facility. Allowing for central storage of records would be consistent with the approach FDA has taken in numerous other situations. *See, e.g.,* 21 CFR 117.315(c).

Additionally, we ask FDA to clarify which party is responsible for keeping records in a situation where a contract manufacturer produces a product on behalf of another party and maintains the product recipe as confidential and proprietary. In this situation, we believe it should be sufficient if the manufacturer provides to the distributor/own-brand company a signed statement confirming that the product is eligible for the "healthy" definition.

    b. **FDA should clarify that either unrounded or rounded nutrient values may be used to assess compliance with the "healthy" definition.**

FMI asks FDA to expressly state that either unrounded or rounded nutrient values may be used to determine compliance with the healthy definition. This would be consistent with FDA's approach for other absolute (i.e., non-relative) nutrient content claims, such as "fat free," where FDA has explained that "because there is no nutritional difference between rounded and unrounded values of a nutrient in a food, the agency does not see a need to specify which value should be used in determining whether or not a food qualifies to make a nutrient content claim." 58 Fed. Reg. 44020, 44024 (Aug. 18, 1993). The same standard should apply to assessing the nutrients to limit standards for the healthy definition, since healthy is an absolute claim, where you could use either the rounded or unrounded amount to assess compliance. As an

example, the proposed added sugars threshold for many products is 5% DV or 2.5 g. It is important to allow the use of unrounded values, because grams of sugar round to the nearest gram in the Nutrition Facts Panel, so using only rounded values could mean a food effectively must have 2 g or less, which is 4% DV, rather than 5% DV.

c. FDA should make clear that products bearing the term "healthy" used in compliance with the existing regulation may be lawfully sold and shipped in interstate commerce until the compliance date for the final rule.

FMI urges FDA to state clearly and unequivocally that following the issuance of the final rule, and during the 3-year compliance period, the term healthy may continue to be used consistent with the existing regulation, and products bearing the term healthy may continue to be sold and shipped in interstate commerce and are compliant with the Federal Food, Drug, and Cosmetic Act.

Relatedly, we ask that FDA provide for an effective date that is the same as the compliance date, i.e., 3 years after issuance of the final rule, in order to help make clear that existing uses of healthy under the current regulation may continue until the compliance date. This is allowed under FDA's administrative regulations, which require that the effective date be at least 30 days after publication of the final rule, but don't restrict longer effective dates. See 21 CFR 10.40. FDA should also recognize it will exercise enforcement discretion for products that comply with the new revised healthy rule to allow such products to bear a "healthy" claim prior to the compliance date.

d. FDA should coordinate with the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) to address healthy claims for FSIS-regulated products.

Before finalizing the rule, FDA should coordinate with USDA's FSIS and seek input from the agency on the updated healthy definition, so as to ensure an approach that would work equally for FDA-regulated and FSIS-regulated products. We also ask FDA to encourage FSIS to provide enforcement discretion for products that would qualify for the FDA's updated definition to bear a "healthy" claim, assuming that meat or poultry would be considered part of the protein foods group, as is the case under the DGA.

* * *

FMI thanks FDA for the opportunity to submit comments on this important rulemaking. Please do not hesitate to contact FMI with any questions.

Sincerely,

Krystal Register, MS, RDN, LDN
Senior Director, Health & Well-being

Dana Mullen Graber
Senior Counsel, Legal and Regulatory Affairs