



Institute of Food Technologists
525 W. Van Buren Street., Suite 1000
Chicago, IL 60607-3830 USA

+1.312.782.8424
+1.312.782.8348 Fax
ift.org

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Comments on Docket No. FDA-2016-D-2335 “Food Labeling: Nutrient Content Claims; Definition of the Term ‘Healthy’”

Dear FDA,

The Institute of Food Technologists (IFT) is thankful for the opportunity to provide comments on the proposed rule to update the definition of the implied nutrient content claim “healthy.” IFT is a global organization of approximately 12,000 members who are committed to advancing the science of food. We believe science is essential to ensure the global food system is equitable, sustainable, safe, and nutritious.

IFT commends the FDA on their efforts to update the healthy definition to align with current nutrition science and Federal dietary guidelines. We agree the healthy claim can be an opportunity to guide consumers towards food choices that are aligned with healthy practices. Additionally, as science of food professionals, we understand that the proposed criteria can help guide reformulation of foods to provide a diversity of healthy choices in the marketplace. To successfully achieve this, the proposed criteria for healthy must be feasible and result in foods acceptable to consumers that positively contribute to a healthy dietary pattern. Consumers should also be able to understand what healthy means on a label as confusion can lead to distrust of the claim. It is with these principles in mind that we provide feedback on the proposed definition of healthy.

As with any proposed rulemaking, potential unintended outcomes and consumer confusion should be considered and mitigated as much as possible. The proposed definition represents a major shift to focus on food groups instead of nutrients, thus there is considerable need for consumer education and monitoring for unintended outcomes. Below we discuss potential unintended outcomes and suggest possibilities that may alleviate some of these effects and improve consumer understanding.

Helping consumers understand how foods labeled as healthy fit into a healthy dietary pattern

We recognize the challenge that FDA faced in taking the DGA recommendations for overall healthy dietary patterns and attempting to apply these to individual food items. The proposed rule presents a good step in that direction, but consumers may not understand how foods with a healthy claim should fit into an overall healthy dietary pattern. As mentioned in our 2016

comments, “it is important to consider the amount and frequency of consumption of foods, including those labeled as “healthy,” in the context of overall eating patterns.” The proposed rule does not include provisions for communicating how many servings or food group equivalents (FGEs) of fruits, vegetables, dairy, protein foods, or grains to incorporate into a daily pattern, nor does it include a mention of staying within caloric requirements, both of which are key recommendations of the Dietary Guidelines for Americans (DGA). Even if an individual were to only purchase and consume foods labeled “healthy”, they may not achieve a healthy pattern if these foods are not consumed in the appropriate portions for each food group and within calorie limits.

We suggest additional on-pack communications, in addition to the term healthy, could help consumers identify how these foods fit into a healthy pattern. Identifying the food groups included may help with this, such as “Provides whole grains, part of a healthy eating pattern. Make half your grains whole grains.” or “Contributes to a healthy eating pattern with 25% of the daily recommendation for fruit and dairy.” This could also be done using the MyPlate infographic to highlight the food group equivalent within the context of the Dietary Guidelines for Americans communications. We also suggest that any consumer communications on the healthy claim include information on the recommendations for each food group and calorie considerations. It will also be important to monitor purchasing and intake of foods with the healthy claim to determine if there is improvement in recommended food group intake within caloric limits and if nutrients of concern (saturated fat, sodium, added sugar) are reduced.

Continuing to emphasize the importance of adequate nutrient intake for health

We understand the emphasis on food groups in the proposed rule; however, without requirements for positive nutrients, the intake of critical nutrients, particularly shortfall nutrients of public health concern, may not improve. These nutrients, including dietary fiber, calcium, iron, potassium, and vitamin D, play an important role in health and it is often difficult to obtain adequate amounts in the diet, particularly for certain sexes and life stages, even when following a healthy dietary pattern. A study from a group of experts with considerable experience in designing diets for clinical trials noted the challenge of meeting recommendations for vitamin D, sodium, potassium, and dietary fiber when a DGA healthy dietary pattern was scaled for individual energy intakes and food portions.¹ The authors note, “Considering the level of difficulty faced by dietitians and professionals to plan and execute this diet, this suggests that it would be even more challenging for non-specialists to follow these guidelines. In the future, practical implementations of the DGAs need to be tested for feasibility and ease of use.” Consumers also have an expectation that a “healthy” food will provide nutrients according to the most recent IFIC survey². Besides being good for you, the top

¹ Krishnan S, Lee F, Burnett DJ, et al. Challenges in Designing and Delivering Diets and Assessing Adherence: A Randomized Controlled Trial Evaluating the 2010 Dietary Guidelines for Americans. *Curr Dev Nutr.* 2020;4(3):doi 10.1093/cdn/nzaa022.

² <https://foodinsight.org/wp-content/uploads/2021/05/IFIC-2021-Food-and-Health-Survey.May-2021-1.pdf>

responses for defining a healthy food were “includes vegetables”, “includes fruits”, and “contains nutrients”.

Based on these concerns and consumer expectations, the FDA may want to consider the inclusion of beneficial nutrients, particularly shortfall nutrients of public health concern, in the proposed criteria for healthy to help consumers achieve nutrient adequacy in addition to meeting food group requirements. We understand the FDA’s concern about indiscriminate fortification; however, there are fortification policies in effect intended to prevent this and should continue to be enforced in the context of this revised definition.³ We also suggest monitoring the purchase and consumption of foods labeled as healthy to determine if there are positive increases in nutrient intake, particularly shortfall nutrients.

Gradual changes in some requirements may promote consumer acceptance

We agree with the need to reduce the intake of several nutrients/components of public health concern, including saturated fat, sodium and added sugars. However, compared to the current healthy criteria, the reduction for sodium for individual foods is more than half (480 mg to <230 mg), which will impact taste and potentially safety for some foods. Consumers that already purchase foods labeled as healthy, may reject new formulations if they do not meet taste expectations. Further, they may opt for higher sodium options in the same food category that do not qualify as healthy.

To help minimize taste impact and improve consumer acceptance the FDA could consider the option of slowly reducing sodium content over time, similar to the Voluntary Sodium Reduction Goals recommended by the FDA. The Voluntary Sodium Reduction Goals⁴ were based on the principles that “reduction in sodium levels should progress gradually to allow time for product reformulation” and “sodium intake reduction should progress at a pace such that consumer preferences and expectations for saltiness in foods adjust.” These same principles could apply to reduction of sodium in foods qualifying for the healthy claim. Should the FDA maintain the <230 mg criterion, it would be critical to monitor consumer acceptance of reformulated foods and if possible, determine alternative foods purchased to make sure sodium intake is not inadvertently increasing.

Encouraging intake of enriched grains to help meet nutrient adequacy

We agree with the inclusion of whole grains in the recommendation for food groups, but there is no mention that any refined grains should be enriched, as recommended by the DGA. Enrichment and fortification of grains improves intake of several nutrients, including nutrients such as iron and folate, critical for women of childbearing age.

³ 21 CFR 104.20

⁴ Center for Food Safety and Applied Nutrition. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry. In: U.S. Department of Health and Human Services - Food and Drug Administration, ed. Rockville, MD, 2021.

FDA may want to consider, in addition to the whole grain criterion, that any refined grains in the food should also be enriched.

Avoiding consumer confusion around calorie-free beverages

While we agree on the importance of water for health, we also consider that including a healthy claim on plain or plain, carbonated water, to the exclusion of other calorie-free beverages, may lead to consumer confusion. As FDA noted, the DGA recommends that the primary beverages consumed should be “calorie-free—especially water—or that contribute beneficial nutrients....” To include only plain or plain carbonated water under the definition of healthy would exclude other beverages, such as coffee, tea, flavored waters and diet sodas, that could meet the DGA recommendation for “calorie-free.” For beverages such as flavored waters or diet sodas, the primary differences from plain or carbonated water are flavors, colors, and possibly no-calorie sweeteners. To include a healthy label on water, but not these other calorie-free beverages could imply to consumers that flavors, colors, and no-calorie sweeteners are not healthy – an implication that is not confirmed or discussed in the DGA and not supported by the current scientific evidence. This could create considerable confusion for consumers.

To ensure alignment with the DGA and avoid consumer confusion, the FDA may want to consider either 1) not permitting water or any calorie-free beverages to carry a healthy claim as they do not provide nutrients or a food group or 2) all calorie-free beverages be permitted to carry a healthy claim. It may also be helpful, prior to the final rule, to conduct a consumer study evaluating consumer understanding of healthy on water and calorie-free beverages.

Ensuring the criteria is broad enough to encompass new technologies and innovations

We note that plant-based dairy products were discussed in the definition, but other plant-based foods, such as plant-based meat alternatives (other than soy), were not discussed. We encourage the FDA to consider if the proposed definition is broad enough to encompass new technologies and innovations in the food system. For example, would plant-based meats be expected to follow the requirements of protein foods, or would they be considered by the plant sources they are composed of (e.g., vegetables, grains)?

Protecting the safety of individuals with allergies

The proposed definition would exclude saturated fat from nuts and seeds in the total limit of saturated fat for combination foods. FDA should consider if this could increase the use of nuts as a source of saturated fat in foods that previously may not have contained nuts, due to the flexibility in saturated fat limits. As one of the top allergens in foods, this could pose issues for individuals with nut allergies who may not be aware of product changes that include nuts.

Ensuring that healthy foods remain affordable for consumers

The proposed changes to the healthy definition will likely require substantial reformulation of existing healthy foods which may increase the cost of some existing foods with the healthy

claim. We suggest that the FDA monitor the affordability of foods bearing the healthy claim going forward and examine key drivers of cost and potential mitigation strategies to ensure healthy foods are available and affordable for all.

Ensuring the healthy claim is trusted by consumers

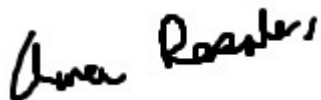
The complexities of how a food qualifies for a healthy claim will not be easily understood by consumers. Therefore, consumers will likely evaluate and compare products carrying the healthy claim to determine if it is trustworthy. We ask the FDA to monitor foods within and across categories that qualify and do not qualify for the healthy claim and evaluate consumer perception and confusion. For example, the allowance for oils will now permit some 100% oils and high-fat oil-based salad dressings to qualify for a healthy claim. However, low-fat or fat free salad dressings of the same variety will not qualify because they do not contain sufficient oil or a food group to qualify for healthy. Will this confuse consumers since the high-fat oil-based dressing will have more calories? Will it encourage consumption of excess calories? Will it achieve the goal of consumers *substituting* oils for saturated fats, or will they only start consuming more oils? This may be another reason to include additional communications on-pack beyond the word “healthy” to help consumers understand how to fit these foods into a healthy dietary pattern within individual calorie limits.

Establishing a regular cadence for updating the healthy claim

We recommend that the FDA initiate a plan for regular updates to the healthy definition based on the DGA recommendations, prevailing scientific evidence, and consensus.

IFT appreciates the opportunity to provide comments on these proposed criteria for the healthy claim. We thank you for considering our comments. Please contact Anna Rosales, Senior Director Government Affairs and Nutrition (arosales@ift.org) if IFT may be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Anna Rosales". The signature is written in a cursive, slightly slanted style.

Anna Rosales, RD
Senior Director Nutrition and Government Affairs
Institute of Food Technologists