



September 25, 2023

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Comment on Draft Guidance for Industry re: Questions and Answers About Dietary Guidance Statements in Food Labeling (Docket No. FDA–2023–D–1027)

The Center for Science in the Public Interest (CSPI) appreciates FDA’s efforts to encourage manufacturers to leverage food labels for the purpose of nutrition education with this draft guidance for industry titled *Questions and Answers About Dietary Guidance Statements in Food Labeling*.¹

In this draft guidance, FDA establishes a new category of claims for food labeling (“Dietary Guidance Statements”) and defines Dietary Guidance Statements as statements in food labeling that “represent or suggest that an individual food or food group may contribute to or help maintain a nutritious dietary pattern” and provides examples of Dietary Guidance Statements such as:

- Make half your grains whole grain.
- Focus on whole fruit.
- Make half your plate fruits and vegetables.
- Vary your veggies.

The draft guidance also indicates that MyPlate visuals would constitute Dietary Guidance Statements.

The draft guidance has several strengths. We agree with FDA that Dietary Guidance Statements on food labels should be limited to statements based on “key or principal recommendations from a consensus report” as opposed to individual phrases or statements that could be taken out of context. We also agree with FDA that these statements are only appropriate on products with meaningful amounts of the referenced food or food group, and without excess saturated fat, sodium, or added sugars.

However, we have several recommendations to improve the guidance:

- FDA should specify what counts as a “consensus report”
- FDA should retain the recommendations for meaningful amounts of recommended foods or food groups, and consider applying these to other commonly used claims
- FDA should clarify what Dietary Guidance Statements are appropriate with respect to 100% juice
- FDA should amend its recommendations for Dietary Guidance Statements regarding whole grains
- FDA should align the maximum levels of saturated fat, sodium, and added sugars for products using Dietary Guidance Statements with the levels it sets for products making “healthy” claims
- FDA should amend its recommendation for disclosures on foods that use Dietary Guidance Statements but have excess saturated fat, sodium, or added sugars
- FDA should consider providing guidelines for recommended Dietary Guidance Statements regarding alcohol

Each of these recommendations is detailed below.

I. FDA should specify what counts as a “consensus report”

In this draft guidance, FDA defines a “consensus report” as:

a report that represents the consensus produced by a group of qualified experts whose bias and conflicts of interest have been minimized and that are convened to study a specific issue. The consensus report conveys agreed-upon recommendations that reflect widely accepted, objective views of current scientific evidence. The information presented in a consensus report about nutrition should reflect an objective view of the scientific evidence, should have been thoroughly reviewed for scientific rigor, and should be consistent with sound nutrition science. (p14)

It recommends further that “consensus reports used as the basis for Dietary Guidance Statements be published, for example, by U.S. Federal government agencies or U.S. scientific bodies or U.S. health organizations outside the Federal government,” lists examples of several agencies that may publish consensus reports, and suggests that other appropriate sources of consensus statements could include reports by public or private U.S. scientific bodies or health organizations that have the purpose of “protecting and promoting the public health of Americans,” whose work “directly relates to human nutrition,” and who are “neutral and objective without any conflicts of interest that may bias [their] review of the scientific evidence.”

The current definition of a consensus report is overly broad. The term “conflict of interest” is not defined, and we are concerned that a company could deem a private organization to meet the criteria for an appropriate source of a consensus statement with improper justification. We are also concerned that the current definition could allow for the use of Dietary Guidance Statements that conflict with recommendations in the Dietary Guidelines for Americans. It would be problematic for an agency within the Department of Health and Human Services to endorse the use of statements that are inconsistent with national guidelines issued by that very Department.

We recommend that FDA instead provide a limited list of published reports that may serve as the basis for Dietary Guidance Statements. The list should be updated at least every five years, in concert with the release of updated Dietary Guidelines for Americans. The guidance should explicitly discourage the use of Dietary Guidance Statements based on recommendations that conflict with the latest Dietary Guidelines for Americans.

II. FDA should retain the recommendations for meaningful amounts of recommended foods or food groups, and consider applying these to other commonly used claims

A key component of this draft guidance is the recommendation for minimum food group equivalents in products making Dietary Guidance Statements. FDA recommends minimum food group equivalents for vegetables, fruits, whole grains, dairy, protein foods, and oils, as well as several protein food subgroups, and explains its rationale as follows:

If a product bearing a Dietary Guidance Statement about a food group (e.g., fruit) contains little or no amount of that food group (e.g., only 1 teaspoon fruit per serving), we would consider this information when evaluating if a Dietary Guidance Statement may be misleading or imply something false in product labeling. We are concerned that if a product bears such a Dietary Guidance Statement in those circumstances, consumers could be persuaded to purchase and consume the food believing that the product makes a meaningful contribution to a nutritious dietary pattern, when in fact, it does not. (p17)

We agree with this rationale and strongly support the recommendation of minimum food group equivalents for products making Dietary Guidance Statements.

We encourage FDA to also consider recommending minimum food group equivalents for additional claims that may not meet the definition of Dietary Guidance Statements, but where the same rationale applies. For example, products often indicate the presence or amounts of fruits and vegetables on their labels, using fruit and vegetable imagery and claims like “Made with whole fruit” (regardless of whether they contain meaningful amounts of fruit or vegetable).²⁻⁴ Grain-based foods like cereal, crackers, and bread often bear statements like “Made with whole grains” or “12 grams whole grains per serving,” as well as other terms like “multigrain” and “wheat” that consumers may perceive as whole grain claims.⁵

Research shows that fruit, vegetable, and whole grain claims influence consumers’ perceptions. One experimental study found that whole grain claims cause consumers to significantly overestimate whole grain content.⁵ Another study found that fruit claims and imagery made children significantly more likely to incorrectly believe that foods containing artificial fruit flavors but no real fruit did contain fruit.⁶ A third study found that consumers perceived products with labels listing “fruit sugar” instead of just “sugar” as being significantly healthier.⁷

Research also shows that combinations of fruit claims and other common label claims can mislead consumers and influence purchasing decisions. In an experiment where parents of young children were asked to select either a “fruit drink” (made primarily of water and high fructose corn syrup) or 100% grape juice for their children, parents were significantly more likely to select the fruit drink when the label stated “No artificial sweeteners,” “100% Vitamin C,” or “100% All Natural,” compared to a control fruit drink with no claim.⁸ A significantly higher percentage of parents who viewed fruit drinks with these claims believed that the drinks were 100% fruit juice or contained no added sugar compared to parents who viewed the control.⁸

FDA can help prevent fruit, vegetable, and whole grain claims from misleading consumers, and promote nutritious dietary patterns that are rich in these nutrient-dense foods groups, by defining “food group claims” along with Dietary Guidance Statements and recommending the same minimum food group equivalents for both new types of claims.

III. FDA should clarify what Dietary Guidance Statements are appropriate with respect to juice

We agree with FDA that only “key or principal recommendations from a consensus report” should serve as the basis for Dietary Guidance Statements. In the Dietary Guidelines for Americans, 2020-2025, the principal recommendation pertaining to fruits is that a healthy dietary pattern includes “Fruits, especially whole fruit.”⁹

In the draft guidance, FDA recommends amounts of foods or food groups that should be present in a product using a Dietary Guidance Statement about that food or food group. For Dietary Guidance Statements related to fruit, FDA recommends products should contain at least ½ cup equivalent of fruit per Reference Amount Customarily Consumed (RACC), which may take the form of ½ cup of fruit juice per RACC.

Given that the principal recommendation in the Dietary Guidelines is to focus on whole fruits, a Dietary Guidance Statement on a product containing fruit only in the form of juice could be confusing and

negates the Dietary Guidelines for Americans' emphasis on whole fruits. Furthermore, in the draft guidance, FDA states:

Current consensus report recommendations, including the Dietary Guidelines, encourage Americans to meet nutrient requirements through the consumption of whole foods (e.g., whole fruits and vegetables). Therefore, manufacturers should not use Dietary Guidance Statements on products labeled as or purporting to be dietary supplements. (p13)

By this same reasoning, manufacturers should not use Dietary Guidance Statements pertaining to fruits and vegetables on products containing fruit or vegetable ingredients only in the form of juice.

FDA should remove juice from the list of recommended amounts of foods or food groups that should be present in products using Dietary Guidance Statements, or clarify that Dietary Guidance Statements involving fruit should emphasize whole fruit over fruit juice.

IV. FDA should amend its recommendations for Dietary Guidance Statements regarding whole grains

In the Dietary Guidelines for Americans, 2020-2025, the principal recommendation pertaining to grains is to follow a healthy dietary pattern which includes "Grains, at least half of which are whole grain."⁹ This recommendation is not properly reflected in the example Dietary Guidance Statements related to whole grains in the draft guidance, nor by the minimum 12-gram per RACC amount of whole grain that this guidance recommends for products using a Dietary Guidance Statements about grains.

As an example of a product with a Dietary Guidance Statement related to whole grains, FDA shows an image of a mock 100% Whole Wheat Bread product with a label stating "Make half your grains whole grain. This product contains 12g of whole grains per serving." This label statement should be better aligned with the consensus statement from the Dietary Guidelines for Americans in two ways. First, it should include the phrase "at least" (*i.e.*, "Make at least half your grains whole grain"). Second, it should provide context for how the food assists in achieving the referenced dietary recommendations. Instead of stating only the amount of whole grains per serving, it should state "12g of the 24g of grain in this product are whole grains" or "50% of the grain in this product is whole grain."

Moreover, the draft guidance recommends that companies may affix "Make half your grains whole grain" statements to products that undermine consumers' progress toward that goal (*i.e.*, products with large RACCs where 12g of whole grain could constitute only a small percentage of total grains). In addition to recommending that products using Dietary Guidance Statements about grains should contain at least 12 grams of whole grain per RACC, FDA should recommend that at least 50 percent of the total grains in such products must be whole grains.

V. FDA should align the maximum levels of saturated fat, sodium, and added sugars for products using Dietary Guidance Statements with the levels it sets for products making "healthy" claims

In this draft guidance, FDA recommends limits on saturated fat, sodium, and added sugar in products bearing Dietary Guidance Statements because "[e]xcess consumption of these nutrients can increase caloric intake and/or the risk of chronic disease and, therefore, diminish the potential public health impact of Dietary Guidance Statements." Similarly, in its recent proposed rule to define the "healthy" nutrient content claim, FDA proposed limits on saturated fat, sodium, and added sugar for products

using “healthy” claims and stated that its “proposed nutrients to limit criteria help ensure that foods bearing the ‘healthy’ claim do not contain excess saturated fat, sodium, or added sugars, which can increase calories and/or the risk of chronic disease and therefore diminish the potential beneficial impact of the ‘healthy’ claim.”¹⁰ Confusingly, the proposed limits on these three nutrients in the draft guidance on Dietary Guidance Statements and proposed rule on “healthy” claims are misaligned (Table 1).

These limits are being set for similar purposes and there is no compelling justification for them to diverge. FDA indirectly attempts to justify the inconsistency by stating that recommending lower limits for sodium and added sugar in products bearing Dietary Guidance Statements would “prevent foods that may contribute to a nutritious dietary pattern and are recommended by the Dietary Guidelines from bearing Dietary Guidance Statements.” However, some of the recommended limits are so high that they would allow for Dietary Guidance Statements on foods that are not consistent with nutritious dietary patterns. For example, Stouffer’s Macaroni & Cheese with Broccoli is a frozen meal product that contains 40% Daily Value (DV) of saturated fat (8 grams) and 40% DV of sodium (910 milligrams).¹¹ It would undermine the draft guidance’s stated goals for this product to state “Eat broccoli as part of a nutritious dietary pattern”—even if its side of broccoli is at least ½ cup—given that the food contains so much saturated fat and sodium that it would not be recommended as part of a healthy dietary pattern.

To prevent a confusing regulatory landscape where different claims have different recommended limits for the same nutrients, and to prevent misleading Dietary Guidance Statements on products with excess saturated fat, sodium, and added sugars, FDA should adopt the stricter limits from its proposed rule on “healthy” claims in its final guidance on Dietary Guidance Statements.

Table 1. Limits proposed by the U.S. Food and Drug Administration for nutrients to limit in products bearing “healthy” nutrient content claims and Dietary Guidance Statements

	“Healthy” Claim*			Dietary Guidance Statements		
	Saturated fat	Sodium	Added sugar	Saturated fat	Sodium	Added sugar
Individual food	0-5% DV	10% DV	5-10% DV	10% DV	15% DV	10% DV
Mixed product	0-5% DV	10% DV	5-7.5% DV	10% DV	15% DV	10% DV
Main dish	0-10% DV	20% DV	10-20% DV	30% DV	30% DV	20% DV
Meal	5-10% DV	30% DV	15-25% DV	40% DV	40% DV	30% DV

DV = Daily Value

*there are some exceptions to these limits depending on the food group components of the individual food, mixed product, main dish, or meal

VI. FDA should amend its recommendation for disclosures on foods that use Dietary Guidance Statements but have excess saturated fat, sodium, or added sugars

FDA’s draft guidance recommends that manufacturers may use Dietary Guidance Statements on products that exceed recommended limits on saturated fat, sodium, or added sugar but should add a disclosure statement about the nutrient(s) whose level(s) it exceeds. For example, for a hypothetical yogurt product with 20% DV of added sugars per serving (more than the recommended 10% limit) that bears the statement “Eat yogurt as part of a nutritious dietary pattern,” FDA recommends that such a

product also should bear a disclosure stating either “This product contains 10g (20% Daily Value) of Added Sugars per serving” or “See nutrition information for added sugars content.”

We do not agree that manufacturers should be able to make Dietary Guidance Statements on products with excess saturated fat, sodium, or added sugars because, in FDA’s words, this serves to “diminish the potential public health impact of Dietary Guidance Statements.” FDA should recommend against the use of Dietary Guidance Statements on such products. However, if it does recommend the use of disclosures, they should be more informative. Instead of simply stating the nutrient content, which, with some additional effort from consumers, can already be found on the Nutrition Facts label, the disclosure should state, “This product is high in [saturated fat/added sugars/sodium]. The Dietary Guidelines for Americans recommend to limit foods and beverages high in [saturated fat/added sugars/sodium].” The disclosure “See nutrition information for [saturated fat/added sugars/sodium] content” should not be an option, as the average consumer is not likely to understand why this disclosure is present and it provides no actionable information.

VII. FDA should consider providing guidelines for recommended Dietary Guidance Statement regarding alcohol

The draft guidance focuses on promoting a healthy dietary pattern. But one aspect of such an effort is to discourage elements of the diet that, at least at certain levels, could be injurious to health. Alcohol misuse or excessive alcohol intake increases the risk of several conditions such as liver disease, cardiovascular disease, injuries, and alcohol use disorder, and a key recommendation of the Dietary Guidelines for Americans is to “Limit alcoholic beverages.”⁹ Specifically, the guidelines recommend:

Adults of legal drinking age can choose not to drink or to drink in moderation by limiting intake to 2 drinks or less in a day for men and 1 drink or less in a day for women, when alcohol is consumed. Drinking less is better for health than drinking more. There are some adults who should not drink alcohol, such as women who are pregnant.

Americans may not be aware of the DGA’s specific guidelines on alcohol consumption, and research shows that including guidelines on labels of alcoholic beverages can increase awareness of lower risk drinking .¹² In other countries, including the United Kingdom and Canada, some manufacturers have opted to voluntarily include drinking guideline statements on alcoholic beverage labels (Figure 1).^{13,14}

Figure 1. Examples of voluntary dietary guidance statements on alcoholic beverage labels in the United Kingdom (left) and Canada (right)



Images: Portman Group, Courtney Shea/Macleans.ca

FDA should therefore amend its definition of Dietary Guidance Statements to include those that “represent or suggest that a food or food group may **or may not** contribute to or help maintain a nutritious dietary pattern.” With respect to alcohol-containing products specifically, permitted claims should reflect the latest Dietary Guidelines for Americans (*e.g.*, “The Dietary Guidelines for Americans recommend that if you drink, limit to no more than 1 drink in a day for women, 2 for men”). Dietary Guidance Statements regarding alcohol consumption should communicate recommended limits and should not in any way encourage drinking.

CSPI and other public health advocacy groups have previously advocated for conveying the Dietary Guidelines for Americans’ advice on moderate drinking on alcohol labels.^{15,16} We have primarily called for such labeling policies to be issued by the Alcohol and Tobacco Tax and Trade Bureau of the Treasury Department which regulates the labeling of most alcoholic beverages. But FDA has an opportunity to promote responsible drinking by recommending the use of Dietary Guidance Statements on the labels of alcoholic beverages that fall within its jurisdiction. FDA regulates a growing subset of beverages that are considered beers but are made from ingredients other than malted barley, including many hard seltzers. FDA-regulated hard seltzers accounted for 6 percent of total U.S. beer sales in 2020¹⁷ and, while beer sales are declining overall,¹⁸ hard seltzer sales are predicted to grow 16-31 percent annually over the next several years.¹⁹

Thank you for considering our recommendations to improve and expand this guidance.

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