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Dr. Robert Califf
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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

Dear Commissioner Califf:

Sustainable Food Policy Alliance (SFPA) member companies Danone North America, Mars, Incorporated, Nestlé USA and Unilever United States appreciate the opportunity to review and comment on the Food and Drug Administration's (FDA) proposed rule on the "Use of the Term 'Healthy' in the Labeling of Human Food Products."

SFPA supports a comprehensive update of the definition of "healthy" to help people make the best choices for themselves and their families. Our member companies have long maintained that FDA's definition should be based on the preponderance of scientific evidence, reflect the recommendations from the most recent Dietary Guidelines for Americans (DGAs), and focus on foods and meals that fit within nutritious eating patterns and calorie needs of all Americans, including the full range of cultural diets and foods. We appreciate that the proposed rule reflects these priorities. In particular, SFPA was pleased to see the following in the proposal:

- The emphasis on consistency with the DGAs.
- The approach of using food group equivalents for determining product eligibility.
- The exclusion of limits for total fat, trans fat and dietary cholesterol.
- The promotion of fruits and vegetables under the definition, especially provisions that raw, whole vegetables and fruits meet the "healthy" criteria without needing a food group equivalent threshold or being subject to nutrients to limit requirements.

- The inclusion of plain and plain carbonated water and its exemption from food group equivalent and nutrients to limit requirements. We support consumer choice and encourage the consumption of water, whether bottled or from the tap.

When backed by a strong, clear, and science-based standard, the use of the word "healthy" on labels can be an effective decision-making tool for consumers to help them achieve a healthier eating pattern as recommended by the DGAs. Such a definition can also provide useful guidance for food and beverage manufacturers for product innovation and reformulation.

Certainly, strong, clear, and science-based dietary standards, in tandem with consumer research, must serve as the foundation for all government nutrition efforts. Consumers and food companies benefit from consistent terminology, definitions, data, and other factors across federal standards. As FDA works to finalize the "healthy" definition and consider other actions—including those prioritized by the National Strategy on Hunger, Nutrition and Health—the agency should ensure consistency among its standards and with the U.S. Department of Agriculture and other federal nutrition efforts.

The draft updated definition is an important step forward on providing more information for consumers and food companies. As FDA revises the proposal in preparation for finalizing the rule, SFPA recommends the following:

Set data-driven levels for nutrients to limit.
While SFPA supports the inclusion of limits on added sugars, sodium, and saturated fat in the updated definition, FDA should reconsider the levels for those nutrients and employ a more wholistic, data-driven approach in the final rule.

The current proposed levels for nutrients to limit may lead to unintended consequences and exclude some nutrient dense foods from falling within the definition. Take yogurt, for example: a level of $\leq$ 5% DV is feasible largely only for plain unsweetened yogurts. A small amount of added sugars or flavor results in greater consumer acceptance of these tart products that include under-consumed nutrients of public health concern. The proposed levels could also be prohibitive for some plant-based products that have key nutrients and would otherwise qualify as "healthy" if they contained inherent sodium or sugars similar to animal-derived products.

Continued taste acceptance and consumption of nutrient-dense categories is critical given their role in providing significant nutritional benefits such as nutrients of public health concern (fiber, calcium, vitamin D, and potassium), other under-consumed nutrients (vitamin A), nutrients of importance to consumers (B vitamins) and other key nutrients, cultures, and probiotics.

Finally, SFPA does not recommend that FDA use a limit for saturated fat based on the ratio of saturated fat to total fat, because this approach is not generally used in other dietary guidance.

Allow vegetable and fruit powders to count toward fruit and vegetable food groups.
The "healthy" definition should focus on the nutrient content and food group equivalents of a food or ingredient, and not the form. As such, dried fruit and vegetable powders not derived from juice (consistent with the "added sugars" definition), and therefore retaining the beneficial nutrients of the whole food, should count toward the fruit and vegetable groups. This approach is consistent with FDA's previous assessment on the nutritional contribution of fruit and vegetable powders detailed in its "Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry."[1]

Clarify that either unrounded or rounded nutrient values may be used to assess compliance.
In the final definition, FDA should clearly state that either unrounded or rounded nutrient values may be used to determine compliance. This would be consistent with the agency's approach for other absolute (i.e., non-relative) nutrient content claims, such as "fat free."[2]

Ensure clear and consistent labeling.
Clear and consistent labeling is needed to ensure consumer trust and clarity on products that meet the "healthy" standard. As such, the terms that can be used on the label should be limited to the implied nutrient content claim and its defined synonyms in 21 CFR 101.65(d)(2). Further, the agency should clarify that the "healthy" definition does not affect other labeling claims; nor does it limit which foods should be considered part of a healthy dietary pattern.

FDA should also create guidance for food makers who want to disclose relevant food groups for products labeled as "healthy" to help consumers understand the food group contributions. This voluntary guidance would ensure the consistency of such labeling.

Provide information on how new ingredients and technologies can fall into the definition.
As FDA finalizes and works to implement the updated definition, further information, clarity, and guidance are needed to prevent confusion by food makers. These issues include:

[1] 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.gov)
[2] 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 calculation of and underlying data behind the conversions for food group equivalents and how they will be calculated across various products to help food companies resolve issues that are not clearly addressed in the rule. For example, the proposed definition is unclear on how some plant-based food products and ingredients, such as plant protein isolates and concentrates, will fall into food group equivalents. Thus, further information is needed to determine if such foods and ingredients are eligible to be labeled as "healthy." Equivalents could be provided for each food category in a similar way to how Reference Amounts Customarily Consumed (RACCs) are defined in 21 CFR 101.12 and could apply across federal agencies nutrition standards.
- FDA's view on the role of the updated "healthy" definition in food product and ingredient innovation and any considerations for food makers as they develop new products. As new technologies are developed, FDA should assess how novel methods of processing, new sources of ingredients and nutrients and other advances can fall within the definition.

Finally, SFPA believes that the definition of "healthy should continue to evolve to address new product innovations and reflect the most current science. To do this, SFPA recommends FDA put a process in place to update the definition of healthy after each iteration of the DGAs are released to reflect the continuous evolution of science and consumer behavior.

We appreciate the opportunity to submit these comments on the proposed rule "Use of the Term 'Healthy' in the Labeling of Human Food Products." We hope that you will consider the SFPA as a resource as you move forward with finalizing the definition.

Sincerely,

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