February 16, 2023

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

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

Dear Sir or Madam,

Soy Nutrition Institute Global (SNI Global) thanks the U.S. Food and Drug Administration (FDA) for the opportunity to comment on the Proposed Rule Food Labeling: Nutrient Content Claims; Definition of Term "Healthy." SNI Global is the leading voice representing soy industry producers, suppliers, and users up and down the soy value chain involved with soybeans and/or soy ingredients intended for human use.

We applaud the FDA for their inclusion of soyfoods and soymilk in this proposed rule and for aligning the "healthy" definition with the Dietary Guidelines for Americans, which encourages the consumption of fortified soymilk, yogurt, and soybean oil as part of a healthy diet.

SNI Global members are concerned that some soy products, such as soymilk, that receive high scores from a variety of nutrient profiling models would not qualify as "healthy" under the proposed definition. This is particularly concerning given this proposal includes another line of work on a corresponding icon, and the agency has plans for a future front-of-package nutrition labeling (FOPNL) system. Many processed soyfoods and soymilk are nutrient-dense functional food and beverage products that are designed to deliver health benefits and make a significant contribution to reduce the burden of nutrition-related chronic diseases. Therefore, such soy-based products should not be overlooked just because they do not meet the requirement for the minimum number of food groups. Given the important role soyfoods can play in the diet, we request FDA reconsider its proposal so that a wider variety of nutritious soyfoods and soymilk can qualify.

Overall Approach

SNI Global agrees that FDA should update this rule to align with the most recent nutrition science and federal dietary guidance. However, we suggest that the proposed rule's criteria are expanded to evaluate foods not only by nutrients to limit based on the food groups in which they belong, but also by nutrients to encourage. SNI Global is also requesting that soyfoods and soymilk that meet the requirements of the Authorized and Qualified Health Claims be able to use the "healthy" implied nutrient content claim even if they do not meet the food group or nutrients to limit requirements proposed by FDA.

SNI Global appreciates that FDA is updating the "healthy" implied nutrient content claim so that nutrient-dense foods that may exceed certain nutrient thresholds, like saturated fat, can still bear this claim. However, while this rule is supportive of whole foods, it does not account for nutrient-dense soyfoods and puts them at a disadvantage.

Further, FDA's proposal to eliminate nutrients to encourage does not achieve its goal of eliminating foods that are fortified just to meet the rule. This is because foods with a "healthy" implied nutrient content claim are already subject to FDA's fortification policy, which already discourages indiscriminate fortification of foods. SNI Global suggests that if FDA seeks to discourage unnecessary fortification, the agency instead update the fortification policy for foods - rather than exclude the use of the "healthy" implied nutrient claim on nutritious soy products.

As currently written, our members have shared that the proposed rule would not encourage food manufacturers to reformulate their food products to meet this definition because of the strict criteria. Below we expand further upon our recommendations for changes to the proposed food group criteria, and rationale for amending the agency's proposed thresholds for negative nutrients.

FDA Should Consider Small Reference Amounts Customarily Consumed (RACC)
SNI Global recommends FDA modify criteria for products with small RACCs that may not contribute a full food group equivalent. For example, some yogurts on the market with no added sugar may still contain a fruit puree or fruit pieces. As is, these yogurts are less than the ¾ cup equivalent for dairy but could meet the food group equivalent if the fruit portion is allowed to count as a combined food group equivalent by combining the food group equivalents for both fruit and dairy.

Additionally, products with smaller RACCs, like granola bars with concentrated soy protein, may provide a high amount of protein per gram but would not meet the individual proposed food group equivalents. Concentrated sources of soy protein have been extensively studied for their nutritional and health benefits, such as lowering elevated blood cholesterol levels.[2,3] SNI Global suggests these types of foods with small RACCs be considered separately for the "healthy" claim.

FDA Should Reconsider Nutrient Thresholds
SNI Global is in support of FDA including 'nutrients to limit' in the proposed healthy definition. However, as written, these thresholds are overly restrictive in their criteria. SNI Global proposes the below changes for added sugar, saturated fat, and sodium:

Added Sugar
SNI Global has concerns that the added sugar threshold is unnecessarily low and would disqualify many foods that are considered "healthy" by the 2020-2025 U.S. Dietary Guidelines for Americans (DGAs), and nutrition and health professionals. For example, some soyfoods that can help consumers achieve a healthy dietary pattern, such as soymilks, soy-based yogurt, meal replacement shakes, soy-based meat alternatives, soy nuts with flavor or soy-based breakfast cereals with added sugars, formulated as such to increase palatability, will not meet this proposed definition.

For some categories, the focus on added sugars does not account for the amount of added sugar required for certain products to be palatable to consumers. Equally important, is that the 5-8 grams of added sugar in many soymilks is half the amount of total sugar present in dairy milk (see table1), and yet, these soymilks would not qualify. It is clear that fortified soymilk can provide the same nutrients that dairy milk can and is an inclusive solution for the many Americans who limit or avoid dairy milk for a variety of reasons. This proposed rule would exclude sweetened fortified soymilk that would otherwise help consumers meet their nutrition needs. SNI Global suggests soymilk and other food categories that use sugar for palatability should have their own total sugar limit rather

than an added sugar limit, as is currently suggested in the proposed rule to update the WIC food package.

Table 1. Total and added sugar comparisons between dairy and soymilk

Dairy Milk Type (Per 236 ml)	**Total Sugar (source: Naturally Occurring)**	**Soymilk Type (Per 236 ml)**	**Total Sugar (source: Added Sugar*)***
1% dairy milk	12 grams	Original (sweetened) soymilk	5 grams
2% dairy milk	12 grams	Vanilla soymilk	8 grams

**Data for dairy pulled from Walmart Great Value products and data for soymilk, from Danone Silk soymilk products*

SNI Global recognizes that current nutrition science suggests limiting added sugar intake, but as written, this rule allows less than half the daily value (DV) of added sugar to be consumed across four eating occasions. Assuming most "healthy" foods must contain no more than 5% DV added sugars per RACC or per serving, and meals must contain 0-10% DV, and assuming the typical consumer eats three meals and a snack per day,[1] then a consumer's total intake would ≤35% DV added sugars.

Additionally, FDA's 0-10% DV criteria for added sugar across food groups and mixed products is in conflict with the 2020-2025 DGAs that recommends limiting added sugar consumption to 10% of total calories or 200 calories (based on a 2,000-calorie diet). As a result, there seems to be more room for added sugars within a healthy dietary pattern. Based on the above discussion, we propose that FDA increase the threshold for added sugar to at least 5-10% DV of added sugar. Particularly for single products that are nutrient-dense, at least 10% DV would be reasonable to improve the palatability of nutrient-dense foods and make a positive contribution to the diet.

Saturated Fat and Sodium

There are some soy-based meat alternatives that can fit under the "healthy" definition, especially those with lower amounts of saturated fat and sodium than their animal-based counterparts. However, the proposed saturated fat and sodium levels would disqualify many soy-based products from meeting the healthy definition, such as plant-based burgers for sodium, as well as some tofu products for saturated fat levels.

While some soy-based meat alternatives do not meet the definition for 'mixed products' or 'main dishes' based on weight, options like soy-based burgers are meant to be served as a main course, so higher thresholds are warranted to account for their role on the plate.

Additionally, some soyfoods, such as certain types of tofu, have a saturated fat content that is above the 5% DV threshold. These products that are higher in saturated fat can provide higher amounts of protein. Furthermore, their fatty acid profile (approximately 60% of total fat is polyunsaturated, and only 15% is saturated) is consistent with those that have been associated with heart health. SNI Global suggests FDA increase the saturated fat thresholds for the beans, peas, and soy products

food group to align closer with the other protein foods and also increase the sodium thresholds in general so that more protein-rich plant-based products made with soy protein, such as black bean burgers or plant-based chicken can qualify.

Food Group Equivalents

FDA Should Allow Contributions from Multiple Food Groups
SNI Global suggests that rather than allowing one food group to count toward a food group equivalent, FDA should allow multiple food groups, as a collective group, to count toward a single food group equivalent across individual foods, mixed foods, etc. For example, a meal replacement shake that has a food group equivalent from more than one group (e.g., protein and fruit) could meet the food group equivalent if both the protein and fruit food group equivalents combine to equal a single food group equivalent value. However, since many meal replacement shakes would fit under the meal category, they would not meet the requirement to contain three composite food group equivalents. Since these products are formulated with nutrients to deliver a certain amount of calories required for the human body to function, SNI Global suggests that these meal replacement shakes are excluded from the food group equivalent criteria.

If this approach is adopted, SNI Global recommends that FDA establish a minimum amount of ¼ of a food group equivalent that must count toward the total food group equivalent collective. Additionally, as mentioned above, SNI Global suggests that in addition to the amounts outlined for food group equivalents in the proposed rule that the food group equivalent criteria could be met if a food's first ingredient in a food product is one of the food group equivalents. This would allow products such as plant-based meat alternatives that 1) meet thresholds for nutrients to limit and 2) contain concentrated soy protein as their first ingredient to meet the healthy proposed rule.

FDA Should Provide Guidance for Calculating Food Group Equivalents
While the updated "healthy" criteria refer to food groups and subgroups in the Dietary Guidelines, the examples provided for the food group equivalents do not give a prescriptive view of what it would take for a food product to be seen as equivalent. The calculations for complex multicomponent foods that undergo processing will be complicated to assess, and more clarity in this area would be helpful. Specifically, guidance on how to appropriately calculate the "food group equivalents" for the below food products will be necessary to help soyfood and beverage makers comply with this rule:

> *Concentrated Soy Protein*
> Calculations are difficult when the products contain ingredients that are not in the cup-equivalent form, such as soy protein isolate, which is approximately 90% protein. The proposed rule does not make it clear how soy derivatives like soy protein isolate or soy protein concentrate would be calculated as a food group equivalent. SNI Global members would appreciate more clarity around calculating concentrated soy protein in food group equivalents.

FDA Should Align the Healthy Proposed Rule with Current Food Labeling Regulations
Under the proposed regulation, many soyfoods that are not eligible for the new "healthy" implied nutrient content claim are still eligible for FDA Authorized Health Claims and Qualified Health Claims that acknowledge their role in a healthy diet. Since FDA has stated that the goal of this voluntary implied nutrient content claim is to help improve diet quality and reduce chronic disease

risk, we propose that products that meet the food substance and disqualifying nutrient requirements for the Authorized and Qualified Health Claims (such as soy protein bars with soluble fiber or soy protein shakes) under 21CFR101.14 should qualify for the voluntary "healthy" implied nutrient content claim. Otherwise, this can create inconsistency in FDA's messaging and lead to confusion for consumers.

FDA Should Further Clarify Nutrition Facts Label Calculations for Recordkeeping Requirements

SNI Global members believe FDA should provide further clarity around the recordkeeping requirements outlined in the proposed definition, specifically around calculating values for the designated thresholds. In instances where the proposed requirements cannot be verified with the label and manufacturers have to provide information to determine whether the product meets the food group equivalent requirements, food formulators/food companies need clarification regarding whether unrounded values would need to be at or below thresholds and to what decimal place. Finally, SNI Global is also asking for more clarity around the amount and type of nutrients that would need to be included to label soymilk as "fortified."

Summary

In summary, soy-based beverages, yogurts, bars, meat alternatives, cereal and some meal replacements provide high-quality protein and are nutrient-dense options that can help consumers achieve a healthy dietary pattern. These products have the potential to improve access to healthy choices for consumers across the U.S. SNI Global and our members look forward to the agency's work on the definition of the term "healthy" and appreciate the opportunity to comment on this proposed rule. Should you have any questions about these comments, please contact me.

Respectfully,

Julie Ohmen
Chief Executive Officer
SNI Global

1. 87 Fed. Reg. at 59177
2. Astbury NM, Piernas C, Hartmann-Boyce J, Lapworth S, Aveyard P, and Jebb SA. A systematic review and meta-analysis of the effectiveness of meal replacements for weight loss. Obesity Review. 2019; 20:569-587.
3. Blanco Mejia S, Messina M, Li SS, Viguiliouk E, Chiavaroli L, Khan TA, Srichaikul K, Mirrahimi A, Sievenpiper JL, Kris-Etherton P, et al. A meta-analysis of 46 studies identified by the FDA demonstrates that soy protein decreases circulating LDL and total cholesterol concentrations in adults. J Nutr 2019;149:968-81.