



GENERAL MILLS

August 1, 2014

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

Comments Re:

- **Docket No. FDA-2012-N-1210** “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” 79 Fed. Reg. 11880 (March 3, 2014);
- **Docket No. FDA-2004-N-0258** “Food Labeling: Serving Sizes of Products that Can Reasonably be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes” 79 Fed. Reg. 11990 (March 3, 2014)

Dear Sir or Madam:

General Mills (GMI) is a major packaged-food manufacturer engaged for over 80 years in the development and production of food products including ready-to-eat-cereals, yogurts, vegetables, soups, snacks, flour, cake and other dessert mixes, refrigerated dough products, and numerous other products. Our mission is Nourishing Lives® — making lives healthier, easier and richer — and our 41,000 employees around the world work to carry out this mission every day. GMI has been committed to nutrition labeling for over 40 years, and today we provide nutrition information for more than 2000 retail food products in the U.S., representing approximately 4500 Nutrition Facts labels.

We support the Food and Drug Administration’s (FDA) efforts to update nutrition labeling and serving sizes and appreciate the opportunity to provide written comments on both FDA proposals addressing revisions to the Nutrition and Supplements Facts Labels, Serving Sizes of foods that can reasonably be consumed at one-eating occasion, dual-column labeling and updating, modifying and establishing certain reference amounts customarily consumed. General Mills appreciates the Agency’s commitment to revise nutrition labeling regulations and the significant work that FDA has completed to evaluate and update nutrition labeling regulations in light of the currently available evidence.

We have long supported consistent, science-based nutrition labeling practices and have acted in accordance with the Agency’s various regulations, including the 1990 Nutrition Labeling and Education Act (NLEA). Like the Agency, we agree in the importance of helping consumers maintain healthy dietary practices and believe that any changes made to the

Nutrition Facts label should be based on the most current scientific evidence and recent dietary recommendations. We recognize that significant changes have occurred since the Agency issued regulations related to the Nutrition Facts label in 1993, including shifts in the public health profile of Americans, availability of new nutrition research, changes in reference intake values for various nutrients, improvements in analytical methods, and new dietary recommendations. We agree with the Agency that these new scientific developments should be considered when updating the Nutrition Facts label. Additionally, we believe that it is equally important that proposed changes are useful, understandable and relevant to the consumer, and that these changes can be consistently interpreted and implemented across the food industry.

The primary purpose of the Nutrition Facts label is to help consumers make informed food choices and maintain healthy dietary practices. Any changes must take a science and fact-based approach to nutrition information. Updates should not be based on subjective opinions, which would deviate from the original intent of the 1990 Nutrition Labeling and Education Act, and be a disservice to consumers seeking to make well-balanced, informed, healthy food choices. *General Mills' positions on the proposed rules are supported by the following key, underlying principles:*

- Reducing obesity and improving health are common goals for both public and private sector initiatives. Nutrition Facts label changes should focus on providing consumers with the necessary information, in particular, an emphasis on calories and serving sizes, to meet those goals.
- All changes to the Nutrition Facts label and its components must take into account the totality of credible and relevant evidence-based research.
- Proposed changes, particularly nutrient definitions, must remain objective and grounded in analytical methods in order to yield consistent labeling practices across the food industry and ease in compliance measurements by the Agency.
- Any change must focus on the benefit to the consumer, and importantly their use and understanding of the Nutrition Facts label. Given the broad scope of the proposals, the collective changes should aim to assist consumers in making healthy dietary choices.
- Comprehensive and thorough consumer research on the totality of the proposed changes and the various Nutrition Facts label formats must be completed and published before issuing a final rule. This research would ensure proposed revisions would be easy for consumers to understand, meaningful and useful in guiding dietary choices.
- Consistent with the data applied from IOM dietary recommendations, along with current research, consensus reports and national survey data, the Nutrition

Facts label should continue to be designed for the general American population yet applicable to specific sub-populations and those with acute or chronic diseases.

- In order to help improve public health, changes to nutrition labeling should foster innovation, be rooted in nutritional science and encourage manufacturers to continue delivering foods with important nutrients to Americans.
- When considered in their totality, the proposed revisions represent a significant change from current nutrition labeling. Sufficient implementation time must be granted, and compliance must be based on objective, analytical measures in order to minimize challenges and costs for manufacturers and the Agency.
- Given the extensive revisions proposed in the regulations, a comprehensive educational campaign will be essential to ensure consumers' understanding and use of a new Nutrition Facts label and ultimately impact public health.

As indicated in our comments below, there are a number of proposed changes that we either support or support with minor suggested modifications. Conversely, there are a number of proposed changes with serious limitations, including inadequate scientific justification and technical challenges, which we do not support in current form and believe warrant further revision and/or removal before FDA finalizes the rules. General Mills is committed to nutrition labeling and we anticipate further work on the details and implications of these proposed rules. We look forward to submitting additional comments and research and would welcome dialogue with the Agency regarding our comments.

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Consumer Research of the Proposed Nutrition Facts Label

We believe that any change to the Nutrition Facts label must focus on the benefit to consumers and their use and understanding of the label. Pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), the proposed changes should assist consumers in maintaining healthy dietary practices. Consumer research is a critical component to understanding whether the proposed changes will assist consumers in making healthy dietary choices and provide useful and factual nutrition information. We encourage FDA to field additional consumer research to examine the many changes and different Nutrition Facts label formats prior to finalizing the rule to ensure that these goals are met.

Comprehensive and thorough consumer research on the totality of the proposed changes and the various Nutrition Facts label formats must be completed and published before issuing a final rule. This research would ensure proposed revisions would be meaningful, easy for consumers to understand and useful in guiding dietary choices. To that end, General Mills conducted a consumer research study in partnership with an external consulting service to gain insights on the proposed Nutrition Facts label to measure consumer understanding across a variety of food products and label formats. While final analyses are not complete, preliminary results indicate differences exist across label formats and product categories. We anticipate these findings will be valuable to the Agency, and would like to share them with FDA upon completion to provide further understanding of the impact of the label changes, as well as insights and direction prior to the finalization of the proposed rule.

We are aware that FDA is fielding consumer research on the added sugar declaration.^{1,2,3} General Mills requests that FDA make its research findings public and open to comment. We encourage the Agency to also conduct their proposed consumer research on the multiple formats that will appear on the shelf as a result of these complex labeling changes. FDA should conclude and publish its research studies prior to finalizing any proposed rule. At the time any consumer research report is available for comment, GMI recommends that FDA reopen the comment period on nutrition labeling simultaneously, so the Nutrition Facts label changes and consumer understanding of these changes may be considered in tandem.

¹ 78 Fed Reg 32394

² 79 Fed Reg 11887

³ 79 Fed Reg 11902

Nutrition Facts Label Format

GMI agrees with the Agency that the Nutrition Facts label should be used as a tool to help consumers make informed food choices and maintain healthy dietary practices, and we support efforts to help improve the label to better serve this goal. The Agency has proposed many changes to the Nutrition Facts label which, in totality, will dramatically change the look and content of the nutrition information provided to consumers. While individually each proposed change may not seem extensive, collectively they present a major transformation of the label. We believe that any change must focus on the benefit to the consumer, and importantly their use and understanding of the Nutrition Facts label. We are also mindful that over the past 20 years there have been significant educational campaigns focused on teaching consumers how to read the Nutrition Facts label, and an entire generation of Americans has grown up with the current label, so any changes must be carefully considered. It is imperative that the Agency conduct consumer research to thoroughly evaluate all of the proposed changes collectively and gauge the ability of consumers to comprehend the totality of the proposed Nutrition Facts label formats. We believe relevant revisions to the Nutrition Facts label should be reconsidered once FDA has conducted and analyzed the results of consumer research. We also stress the importance of consumer education to teach consumers to read and understand any updates to the label and its ultimate ability to impact public health.

I. General Mills does not support all of the proposed Nutrition Facts label changes as collectively they increase the complexity of the label and may challenge consumer use.

General Mills is concerned about the collective changes proposed for the Nutrition Facts label layout. While General Mills supports the Agency's intention to address the public health concern of obesity by giving greater prominence to calories and serving sizes, we do not support the cumulative proposed label changes. We believe that the proposed changes may diminish readability, increase the complexity of the Nutrition Facts label thereby diminishing its intended usefulness, and create space constraints for many package configurations. Appendix A details the proposed label changes and highlights the complexity of the totality of the format revisions.

As previously mentioned, General Mills has a diverse product portfolio, including products in over 20 food categories representing approximately 4500 Nutrition Facts labels. We are concerned that many of our products' Nutrition Facts labels will become more complex and the familiarity that consumers have with the label may be lost. An assessment across our product portfolio indicated that only 34% of all GMI product labels would be represented by the basic sample label (illustrating the mandatory nutrition labeling provisions) on page 11974 of the proposed rule.⁴ The remaining 66% would be arguably more complex and

⁴ 79 Fed Reg 11974

encompass different formats, lengthier labels and labels with multiple columns of nutrition information. Ultimately, packaging sizes, fortification of vitamins and minerals, multiple columns of nutrition information and voluntary declarations lead to many different presentations of the Nutrition Facts label in the marketplace. It is important that consumer research evaluate the breadth of label formats consumers will actually encounter.

On the following page, Figure 1 illustrates that the Nutrition Facts label will be significantly different as proposed and includes repositionings and additions that GMI believes may be challenging for many consumers to utilize. Although certain elements are emphasized by bold text and increased font size, the overall visual appears dense, complex and cluttered, which deviates from the consumer research themes that guided the Agency's revisions. FDA stated that research "consistently confirmed that simple formats are easier to comprehend and require less consumer effort than complex information formats. A simple format is one that minimizes clutter and best meets the NLEA requirements that nutrition information should enable the public to readily observe and comprehend such information."⁵ General Mills believes that the Agency can still abide by these principles and improve consumer understanding and utility of the Nutrition Facts label with further refinements to their proposed changes and thorough consumer research.

⁵ 79 Fed Reg 11948

Figure 1. Current versus proposed nutrition facts label

Current Label

Nutrition Facts			
Serving Size 1 cup (28g)			
Children Under 4 - ¾ cup (21g)			
Servings Per Container about 18			
Children Under 4 - about 24			
Amount Per Serving	Cheerios	with ½ cup skim milk	Cereal for Children Under 4
Calories	100	150	80
Calories from Fat	15	20	10
% Daily Value**			
Total Fat 2g*	3%	3%	1.5g
Saturated Fat 0.5g	3%	3%	0g
Trans Fat 0g			0g
Polyunsaturated Fat 0.5g			0.5g
Monounsaturated Fat 0.5g			0.5g
Cholesterol 0mg	0%	1%	0mg
Sodium 140mg	6%	8%	105mg
Potassium 180mg	5%	11%	135mg
Total Carbohydrate 20g	7%	9%	15g
Dietary Fiber 3g	11%	11%	2g
Soluble Fiber 1g			0g
Sugars 1g			1g
Other Carbohydrate 16g			12g
Protein 3g			2g
% Daily Value**			
Protein	-	-	9%
Vitamin A	10%	15%	10%
Vitamin C	10%	10%	10%
Calcium	10%	25%	8%
Iron	45%	45%	50%
Vitamin D	10%	25%	6%
Thiamin	25%	30%	35%
Riboflavin	2%	10%	2%
Niacin	25%	25%	35%
Vitamin B ₆	25%	25%	45%
Folic Acid	50%	50%	60%
Vitamin B ₁₂	25%	30%	30%
Phosphorus	10%	20%	8%
Magnesium	8%	10%	10%
Zinc	25%	30%	30%
* Amount in cereal. A serving of cereal plus skim milk provides 2g total fat, less than 5mg cholesterol, 200mg sodium, 380mg potassium, 26g total carbohydrate (7g sugars), and 8g protein.			
** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	25g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Protein		50g	65g

Proposed Label

Nutrition Facts			
About 18 servings per container			
Children Under 4 - About 24 servings per container			
Serving Size 1 cup (28g)			
Children Under 4 ¾ cup (21g)			
Amount Per Serving	Per 1 cup Cheerios	with ½ cup skim milk	Cereal for Children Under 4
Calories	100	150	80
Total Fat	3% 2g*	3% 2g*	1.5g
Saturated Fat	3% 0.5g	3% 0.5g	0g
Trans Fat	0g	0g	0g
Polyunsat. Fat	0.5g	0.5g	0.5g
Monounsatur. Fat	0.5g	0.5g	0.5g
Cholesterol	0% 0mg	1% <5mg	0g
Sodium	6% 140mg	8% 200mg	105g
Total Carbohydrate	7% 20g	9% 26g	15g
Dietary Fiber	9% 3g	9% 3g	2g
Soluble Fiber	1g	1g	0g
Sugars	1g	7g	1g
Added Sugars	XXg	XXg	XXg
Protein	3g	8g	2g
% DV*			
Protein			9%
Vitamin D	10% XXmcg	25% XXmcg	6%
Calcium	10% XXmg	25% XXmg	8%
Iron	45% XXmg	45% XXmg	50%
Potassium	5% XXmg	11% XXmg	5%
Vitamin A	10% XXmcg	15% XXmcg	10%
Vitamin C	10% XXmg	10% XXmg	10%
Thiamin	25% XXmg	30% XXmg	35%
Riboflavin	2% XXmg	10% XXmg	2%
Niacin	25% XXmg	25% XXmg	35%
Vitamin B ₆	25% XXmg	25% XXmg	45%
Folic Acid	50% XXmcg DFE	50% XXmcg DFE	60%
Vitamin B ₁₂	25% XXmcg	30% XXmcg	30%
Phosphorus	10% XXmg	20% XXmg	8%
Magnesium	8% XXmg	10% XXmg	10%
Zinc	25% XXmg	30% XXmg	30%

* Percent Daily Values are based on a 2,000 calorie diet.

II. General Mills supports the proposal to increase the prominence of calories.

General Mills commends the Agency's efforts to increase consumer attention to calories and serving size in response to public health issues related to overweight and obesity. General Mills, like the Agency and the Obesity Working Group (OWG), acknowledges that obesity rates have increased since the Nutrition Facts label was first introduced.⁶ The 2010 DGA affirmed the role of overconsumption of calories and lack of physical activity as the primary risk factors contributing to increased rates of obesity. GMI agrees with the importance of increasing consumer awareness and understanding of the caloric contents of foods, and we strongly support increasing the font size of "Calories" and the calorie value on the Nutrition Facts label. We also align with the Agency's concern about the direct readability of the caloric content of a food as part of the rationale for increasing the type size of "Calories" and its numeric amount.

III. General Mills believes duplicating serving size information is unnecessary.

General Mills supports the greater emphasis on serving size and amount per serving on the Nutrition Facts label. However, the inclusion of both "Serving size" and "Amount per serving" is duplicative information. Duplicating this information creates unnecessary clutter and imposes additional space constraints. For consistency with the current Nutrition Facts label, we recommend that the Agency continue to use "Serving size" to represent amount per serving.

IV. General Mills does not support abbreviating percent Daily Value.

General Mills does not support changing % Daily Value to "%DV" on the Nutrition Facts label. While we acknowledge that abbreviating Daily Value would save space, it will not be helpful if consumers do not understand what the abbreviation represents.

V. General Mills continues to support the declaration of percent Daily Values for vitamins and minerals and believes there are significant implementation challenges with absolute value declarations.

Reporting percentages of the Daily Values simplifies the information for consumers in a way that they can understand and apply to daily eating habits. As the Agency noted, previous research indicated that percent Daily Value information, "improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet."⁷ GMI agrees with the Agency that the percent Daily Value information continues to be useful information to consumers.

⁶ 79 Fed Reg 11880

⁷ 79 Fed Reg 11951

The Agency does not account for potential implementation challenges that may arise by labeling absolute declarations of vitamins and minerals. Specifically, we are concerned that this will add undue clutter, result in significant space constraints to the Nutrition Facts label, and give rise to labeling discrepancies (see Figures 1 and 3). The established rounding rule increments and ranges for vitamin and mineral percent Daily Value declarations allow for variability.⁸ This is important as manufacturing, ingredient sourcing and shelf-life introduce variability to many vitamin and mineral levels in foods, which is not accounted for with listing absolute values. FDA requested comments on rounding increments for the quantitative amounts; however, this highlights the additional complexity that absolute value declarations introduce. Namely, labeling discrepancies between Daily Value and absolute value declarations will likely arise.

For example, considering the proposed calcium daily value of 1300 mg, the following label values could occur:

Table 1. Potential Calcium Labeling Discrepancies

Calcium Absolute Value	Calcium % Daily Value
A. 227 mg	15%
B. 228 mg	20%
C. 228 mg (fortified)	15%

A product containing 227 mg of calcium would label at 15% Daily Value (A), whereas a product containing 228 mg of calcium would round up to 20% Daily Value (B). However, if the calcium is present due to fortification and, therefore considered a Class I nutrient, a company would likely round down to 15% Daily Value (C), versus declaring 20% of the Daily Value. The wide range within the vitamin and mineral rounding rules, while necessary due to the variability previously mentioned, results in inconsistent labeling if absolute values are also declared.

This example emphasizes not only the inconsistencies that would be present on Nutrition Facts labels, but also illustrates that requiring labeling of absolute values of these nutrients could prove confusing to consumers. Without a deep understanding of food manufacturing variability and government regulations, it is likely that many consumers will not understand discrepancies between the absolute values and percent Daily Values. Further, it is a complex topic to tackle through consumer education efforts. Continuing to declare vitamin and mineral amounts solely as a percent Daily Value prevents these challenges for implementation.

FDA relies on nutritional supplement labeling practices to support requiring reporting of absolute values of vitamins and minerals, yet food labeling is not analogous to dietary supplement labeling. The levels of nutrients in dietary supplements are often provided in

⁸ 21 CFR §101.9(c)(8)(iii)

much higher levels than in foods and beverages. Since there could be greater potential for toxicity concerns with supplements, consumers need this information. Supplements are formulated to specific nutrient levels at a controlled dosage. The formulation and processing of supplements allows for tighter rounding increments and is more applicable and necessary as a safety concern. As noted above, this does not easily translate to the manufacturing and labeling of food products.

VI. Package space will be significantly constrained by implementing all proposed Nutrition Facts label changes and various packaging layouts require greater flexibility.

a. Certain packaging configurations are space constrained by the proposed changes.

The Agency intended the proposed Nutrition Facts label changes to minimize impact to product packages; however, there are certain package configurations where layout constraints are noted. We assert that the consequential changes are inadequately accounted for by the Agency, as they will in fact necessitate significant package redesign to comply. Comparison of Figures 2 and 3 illustrates the constraint on packages that do not have the space to accommodate both the left-justified “%DV” and the inclusion of absolute nutrient amounts. Current regulation according to 21 CFR §101.9(d)(8), allows micronutrients to appear in two columns. The proposed format eliminates this space saving feature of the current standard format in order to accommodate both “%DV” and absolute nutrient amounts.

Figure 2. Current Nutrition Facts Label Example for Strawberry Yogurt (6 oz)



Figure 3. Proposed Nutrition Facts Label Example for Strawberry Yogurt (6 oz)



In addition, many product categories need to include preparation instructions. The proposed label format changes are of concern for these products because there would be limited space available for product recipe and cooking instructions. These package elements are critical to the consumers' preparation of the products and to ensure food safety (e.g., cooking time and temperature setting).

b. General Mills recommends increasing the intermediate package size criteria to ≤ 50 in².

Because the proposed format increases the space requirements for the Nutrition Facts label, steps should be taken to improve readability on packages that do not meet the small- or intermediate-sized package criteria. Therefore, we recommend increasing the intermediate size package criteria from ≤ 40 in² to ≤ 50 in². We also recommend that the Agency allow the following provisions for packages up to 50 in²:

- Option to use the linear or tabular format
- Option to omit the footnote
- Do not require quantitative values for vitamins and minerals

VII. General Mills urges the Agency to conduct comprehensive consumer research before rule finalization.

General Mills continues to emphasize the need for consumer research before the proposed Nutrition Facts label format changes are implemented. The Agency tentatively concludes that "the proposed rearrangement would assist consumers by helping them understand the nutrition information on the label in the context of a total daily diet,"⁹ yet admits there is no survey data regarding these proposed changes and consumer understanding. We urge the Agency to complete their planned consumer research¹⁰ examining the new proposed

⁹ 79 Fed Reg 11891

¹⁰ 79 Fed Reg 11882

Nutrition Facts label, publish results for comment and reopen relevant sections of this proposed rule for comment. Given the concerns noted above, it is imperative that the Agency also assess multiple label formats across multiple product categories, to thoroughly evaluate consumer understanding and application of the proposed changes. Such research will provide the Agency with a thorough understanding of consumer utility of the proposed Nutrition Facts label and ensure the modifications assist consumers in maintaining healthy dietary practices.

VIII. General Mills strongly opposes the alternate Nutrition Facts label format.

FDA should not adopt the alternate Nutrition Facts label that was included in the proposed rule on nutrition labeling. The alternate label lacks flexibility to accommodate future research and changes in dietary guidance and provides subjective information that may not be appropriate for all consumers. In addition, the alternate label would not fit on many package sizes due to the presence of 6 additional lines as compared to the proposed Nutrition Facts label.

Creating categorizations on the Nutrition Facts label does not allow for flexibility or adaptability as nutrition research and dietary guidance evolves. Dietary fat exemplifies this as intake recommendations for total fat, trans fat, polyunsaturated and monounsaturated fats have changed over time. Given that the Nutrition Facts label has not been updated since 1993, it is unlikely that significant revisions to labeling regulations will occur again for some time. Therefore, the label should remain objective to accommodate shifts in dietary guidance or nutrition research.

The intent of the Nutrition Facts label is to provide consumers with nutrition information to help them make food choices that meet their dietary preferences and needs, but the alternate label proposed by FDA may not adequately achieve this goal. First, consumers may be left wondering how much of the “quick facts” nutrients they should consume since the other nutrients are categorized as “avoid too much” and “get enough”, which are not well defined. Second, as FDA acknowledges and as noted below, there is a “lack of a physiological distinction between added and naturally occurring sugars,”¹¹ so including “added sugar” in the “avoid too much” while “sugar” is in the “quick facts” is completely arbitrary.¹² Finally, there may be individuals for whom the alternative Nutrition Facts label will be confusing or wrong. For example, some individuals with kidney disease must avoid or reduce potassium intake, but the alternative format lists this mineral under “get enough.” Similarly, individuals with hemochromatosis must avoid consuming too much iron. Individuals with these conditions may become confused by the conflicting information they receive from their doctors and health care providers when comparing to the information presented on the alternate format of the Nutrition Facts label.

¹¹ 79 Fed Reg 11905

¹² For further discussion and explanation, see sugar comments below.

The alternate Nutrition Facts label creates additional packaging space constraints by requiring 3 extra lines to accommodate the lines “quick facts,” “avoid too much,” and “get enough” and 3 additional lines for thick hairlines. On some package sizes, especially small and medium-sized packages, the 6 extra lines will not fit.

Sugars and Added Sugars

I. General Mills believes that a labeling system that declares “Sugars” is the most appropriate way to communicate the sugar content of products.

General Mills shares FDA’s commitment to improving public health by encouraging healthy dietary practices among all consumers, and we welcome opportunities to help consumers make healthy food choices. Providing information regarding the amount of sugar in a product is one way the Nutrition Facts label informs consumers, and we believe it is important to continue to declare sugars via mandatory nutrition labeling.

FDA’s definition of “sugars,” stated as “...the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose)” is consistent with the chemical definition of the term sugars, referring to a group of compounds comprised of carbon, hydrogen, and oxygen atoms $C_n(H_2O)_n$ and classified as either monosaccharides or disaccharides.^{13,14} FDA’s definition does not include oligosaccharides (e.g., some syrups) and polysaccharides which are also carbohydrates but separate from “sugars” as these terms refers to molecules containing 2-20 monosaccharide monomers or more than 20 monosaccharide monomers joined by glycosidic bonds, respectively.¹⁵

Based on this chemical characterization of sugars, General Mills supports FDA’s rationale regarding the continued declaration of sugars on the Nutrition Facts label. Given that sugars are a type of carbohydrate, “sugars” should continue to be labeled as part of “total carbohydrates”. The amount of declared sugar is possible to quantify, easy to verify using analytical methods, and is information that is easily understood by consumers, nutritionists, and health professionals.

II. General Mills does not support the declaration of added sugars on the Nutrition Facts label.

FDA’s proposal to require added sugar declaration for the purposes of nutrition labeling has not met the Agency’s criteria for the mandatory declaration of non-statutory nutrients. As FDA has stated, there is no physiological distinction between added and naturally occurring

¹³ 21 CFR § 101.9(c)(6)(ii)

¹⁴ Sigman-Grant M., and J. Morita. “Defining and Interpreting Intakes of Sugars.” *The American Journal of Clinical Nutrition*. 78(4):8155-8265 (2003).

¹⁵ Fennema, O.R. Food Chemistry 3rd ed. Boca Raton, FL: Taylor & Francis, pg.108, pg. 174 (2008).

sugar, and evidence is inconclusive solely linking added sugars intake with health-related conditions.¹⁶ The 2010 Dietary Guidelines do not recommend reducing added sugar and solid fats due to any link to adverse health outcomes but to reduce *calories* and improve nutrient density.¹⁷ General Mills believes FDA is already addressing how to help consumers maintain appropriate caloric balance through increasing the prominence of calories on the Nutrition Facts label and the Dietary Guidelines are already providing consumers with recommended *food choices* to increase consumption of nutrient dense foods. In addition to statutory and scientific considerations, General Mills encourages FDA to conduct consumer research to assess comprehension of an added sugars declaration prior to any decision regarding an added sugars declaration.

a. Evidence linking added sugars intake with health outcomes does not meet FDA's criteria for the mandatory declaration of non-statutory nutrients.

FDA states that factors considered for the mandatory declaration of non-statutory nutrients include newly available scientific data, rates of certain health-related conditions have either changed or remained high, or the process for evaluating the relationship between a nutrient and health-related condition has been refined based on the use systematic, evidence based reviews.¹⁸ To assist FDA in determining the declaration of non-statutory mandatory nutrients, quantitative intake recommendations or public health significance are primary factors of consideration. We contend that FDA does not have adequate evidence regarding “added sugars” to support any of these factors.

i. FDA has not shown that a “public health significance” exists for added sugar labeling through “well-established scientific evidence.”¹⁹

FDA states that when determining public health significance, scientific evidence is “well-established” when consensus reports have determined the evidence to be “conclusive,” “documented,” or “strong”.²⁰ Consensus statements from the 2010 Dietary Guidelines Technical Report assessing the association of SSB (sugar-sweetened beverages) intake, energy intake and body weight are not of enough strength to meet FDA’s stated public health significance rationale for determining the declaration of a non-statutory nutrient to be mandatory. Furthermore, the 2010 Dietary Guidelines did not formally review the relationship between the intake of added sugar and energy intake or body weight.

¹⁶ 79 Fed Reg 11905

¹⁷ Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010. Chapter 2: Carbohydrates, pg. 7, 9, 10 (2010).

¹⁸ 79 Fed Reg 11890

¹⁹ 79 Fed Reg 11890

²⁰ 79 Fed Reg 11890

First, we agree with FDA’s conclusion that, “U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease.”²¹ The 2010 Dietary Guidelines Carbohydrates Sub-Committee initiated a systematic evidence-based review (EBR) to assess the specific question of, “In adults, what is the association between intake of SSB and energy intake and body weight?” – not the association between sugars or added sugars intake and energy intake and body weight. When added sugars was included as a search term, the sub-committee acknowledged that the number of qualifying studies identified were too few to complete a EBR specifically on added sugars and energy intake and body weight. SSBs are not a surrogate for sugar or added sugars. Ultimately, the 2010 Dietary Guidelines Carbohydrates Sub-Committee concluded that, “[a] moderate body of evidence suggests that under isocaloric controlled conditions, added sugars, including SSBs, are *no more likely* to cause weight gain than any other source of energy.”²² The committee highlighted that these conclusions resulted from randomized controlled clinical trials (RCTs) where, “...added sugars are not different from other calories in increasing energy intake or body weight.”²³

Second, the 2010 Dietary Guidelines recommendation to reduce the intake of calories from added sugars was based on outcomes using food pattern modeling, which may not be sufficient rationale for the mandatory declaration of non-statutory nutrients.^{24,25} The 2010 Dietary Guidelines Nutrient Adequacy Sub-Committee was charged with determining what nutrients and dietary components were being over-consumed, in which they identified total energy intake as well as energy intake from solid fats and added sugars (SoFAS).²⁶ Next, they utilized USDA food patterns to model the “essential calories” needed from specific food groups and oils to meet nutrient requirements.²⁷ The “discretionary calories” remaining after essential nutrient needs were met was divided equally between SoFAS.²⁸ The amount of SoFAS (e.g. tsp, grams) in the USDA food patterns is the outcome of using the remaining calories in that pattern, rather than evidence-based research. Furthermore, the committee recommended reducing total caloric intake, including calories from SoFAS.²⁹

We believe that nutrition based recommendations generated from food pattern modeling data does not provide sufficient rationale for the mandatory declaration of nutrients. The

²¹ 79 Fed Reg 11904

²² Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010. Chapter 5: Carbohydrates, pg. 25 (2010).

²³ Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010. Chapter 5: Carbohydrates, pg. 30 (2010).

²⁴ 79 Fed Reg 11889

²⁵ 79 Fed Reg 11895

²⁶ Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010. Chapter 2: Nutrient Adequacy, pg. 7 (2010).

²⁷ Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010. Chapter 2: Nutrient Adequacy, pg. 7 (2010).

²⁸ “Discretionary calories” refers to the difference between the amount of essential calories and the caloric goal for that eating pattern that could be accommodated from SoFAS within an individual’s diet. The Committee acknowledged that, “[n]either a recommendation for intake of SoFAS, nor a reasonable proportion of total energy intake as SoFAS has been determined.” Pg 10

²⁹ Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010. Chapter 2: Nutrient Adequacy, pg. 7 (2010).

same issues that prevent FDA from using food composition data, menu modeling, and dietary survey data to determine Dietary Reference Values (DRVs) are also applicable when considering the mandatory declaration of non-statutory nutrients.³⁰

Finally, implications from both 2010 Dietary Guidelines Sub-Committees in relation to the recommendation to reduce intake of added sugars ultimately translates to an appropriate maintenance of calorie balance. FDA believes that a declaration of added sugars would assist consumers to adopt and maintain healthy dietary practices by providing them with information necessary to meet the key recommendations to construct diets containing nutrient dense foods and reduce caloric intake from added sugars by reducing consumption of added sugars. However, many studies have shown that with respect to weight loss, reducing total caloric intake is more important than the source of calories and sustained overconsumption of energy, long-term imbalances between energy intake and expenditures, “excess energy in any form will promote body fat accumulation.”^{31,32,33,34,35} This has been further supported by scientific authoritative bodies recognized by FDA as U.S. consensus groups:

- The 2002 IOM DRI report concluded that “[t]here is no clear and consistent association between increased intake of added sugars and BMI.”³⁶
- The 2010 Dietary Guidelines concluded that foods containing, “...added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits.”³⁷

The 2010 Dietary Guidelines already provides guidance to help consumers meet the recommendation to reduce their intake of SoFAS, highlighting that the ingredient list is a useful tool to determine whether a food or beverage contains solid fats, added sugars, whole grains, and refined grains.³⁸

There is little to weak conclusive scientific evidence, as acknowledged by the 2010 Dietary Guidelines, relating the *intake* of added sugars in the general U.S. population to a chronic

³⁰ 79 Fed Reg 11895

³¹ Bray G.A., et al. “Effect of Dietary Protein Content on Weight Gain, Energy Expenditure, and Body Composition during Overeating: a Randomized Controlled Trial.” *The Journal of the American Medical Association*. 307(1):47-55 (2012).

³² de Souza RJ, et al. “Effects of 4 Weight-Loss Diets Differing in Fat, Protein, and Carbohydrate on Fat Mass, Lean Mass, Visceral Adipose Tissue, and Hepatic Fat: Results from the POUNDS LOST trial.” *The American Journal of Clinical Nutrition*. 95(3):614-625 (2012).

³³ Sacks F.M., et al. “Comparison of Weight Loss Diets with Different Compositions of Fat, Protein, and Carbohydrates.” *The New England Journal of Medicine*. 360:859-873 (2009).

³⁴ United Nations. Food and Agriculture Organization. “*Carbohydrates in Human Nutrition*.” Rome, Italy: Report of a Joint FAO/WHO Expert Consultation (1997).

³⁵ Hess J. et al. “The Confusing World of Dietary Sugars: Definitions, Intakes, Food Sources, and International Dietary Recommendations.” *Food & Function*. 3(5):477-486 (2012).

³⁶ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, D.C.: The National Academies Press, p313, p323 (2002).

³⁷ United States. Dept. of Agriculture and Dept. of Health and Human Services. *Dietary Guidelines for Americans, 2010*. Washington, DC: U.S. Government Printing Office, p41 (2010).

³⁸ United States. Dept. of Agriculture and Dept. of Health and Human Services. *Dietary Guidelines for Americans, 2010*. Washington, DC: U.S. Government Printing Office, p29, p42 (2010).

disease, condition, or health-related physiological endpoint beyond dental caries. If FDA's primary rationale for added sugars declaration is to assist consumers in following the 2010 Dietary Guidelines recommendation regarding added sugars and solid fats, it should be acknowledged that the 2010 Dietary Guidelines addressed *few or limited* questions related to the impact of added sugars on health due to the lack of available evidence and that the available evidence was overall inconclusive.

ii. A quantitative intake recommendation for added sugars cannot be determined due to lack of evidence.

As FDA states, there is no available scientific basis for determining a quantitative intake recommendation for sugars or added sugars. Current consensus reports, namely the 2002 IOM DRI report, state that due to conflicting and inconclusive data between increased intake of added sugars and BMI, "...[this] data cannot be used to set a UL for either added or total sugars."³⁹ Consensus reports have not been able to set a DRV for sugars or added sugars. Therefore, given this lack of scientific agreement, no Daily Value for the label can be established in regards to sugars or added sugars and a quantitative intake recommendation cannot be provided.

iii. Evidence available since the 2010 Dietary Guidelines recommendation is conflicting and inconclusive, failing to support a relationship between sugars or added sugars intake and other chronic health conditions.

General Mills supports policy based on robust available scientific evidence that is of the highest quality, reproducibility, and applicability to the population and believe that all changes to the Nutrition Facts label, and its components, must take into account the totality of credible and relevant evidence-based research.

Given FDA's acknowledgement of the science in this proposed ruling that "...foods containing solid fats and added sugars do not contribute to weight gain any more than another calorie source," it is concerning that this proposal incorrectly assumes that reduced consumption of particular ingredients, such as sugar, will reduce the problem of obesity.⁴⁰ There does not appear to be a linear relationship between Body Mass Index (BMI) and intake of added sugars for the population given that BMI is higher for individuals with low *or* high intakes of added sugars.⁴¹ Additionally, a greater proportion of individuals classified as underweight and normal weight by BMI, report higher levels of added sugars

³⁹ Institute of Medicine Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, D.C.: The National Academies Press, pg. 313, pg. 323 (2002).

⁴⁰ 79 Fed Reg 11904

⁴¹Marriott, B.P., et al. "Intake of Added Sugars and Selected Nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003-2006." *Critical Reviews in Food Science and Nutrition*. 50(3):228-258 (2010).

intakes than individuals classified as overweight or obese.⁴² Appendix B lists numerous other studies and conclusions that support controlling weight ultimately comes down to balancing calories consumed and calories expended.

Beyond obesity, FDA has highlighted the evidence between sugar consumption with an increased risk of dental caries. However, FDA presented no evidence that added sugar is more likely to cause dental carries than inherent sugar. Many factors can attribute to dental carries, including oral bacteria, salivary flow, oral hygiene behavior, and susceptibility of the tooth, and we are aware of no evidence that added sugar presents a unique risk for causing dental caries.^{43,44,45,46}

It should be noted that scientific consensus groups have found difficulty in determining any relationship between added sugars intake and health outcomes due to a variety of complex reasons. Multiple factors should be taken into consideration when evaluating the existing evidence, such as the lack of harmonization within the scientific literature of the definition and inclusion of ingredients considered to be “added sugars” and difficulties in comparing studies where the primary health outcomes measured are not consistent across studies (e.g. BMI, weight, waist circumference, adiposity measures). Additionally, systematic reviews and meta-analyses of RCTs, to which there are very few and neutral in nature in regards to added sugars and health outcomes, provide the strongest level of scientific “cause and effect”. However, drawing conclusions across multiple studies with various inclusion criteria and design (e.g. isocaloric, overfeeding studies) should be handled cautiously. When excess energy intake is not controlled for, it cannot be assumed that “added sugars” intake is linked to body weight or adiposity.

We recommend that FDA assess intervention studies specifically measuring the *effect* of added sugar intake on disease outcomes prior to a declaration on the Nutrition Facts label. We acknowledge while not showing cause and effect, epidemiological studies are important to demonstrate relationships between food and nutrient intakes and health outcomes. Although some association studies are statistically sophisticated, only so many adjustments can be accounted for when evaluating epidemiological studies with complex diseases that have no single cause and no simple solution (e.g. cardiovascular disease).⁴⁷ Intervention studies are needed to understand underlying mechanisms may support these associations.

⁴²Marriott, B.P., et al. “Intake of Added Sugars and Selected Nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003-2006.” *Critical Reviews in Food Science and Nutrition*. 50(3):228-258 (2010).

⁴³ 79 Fed Reg 11902

⁴⁴ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, D.C.: The National Academies Press, p297, (2002).

⁴⁵ Rugg-Gunn, A. “Dental Caries: Strategies to Control this Preventable Disease.” *Acta Medica Academica*. 42(2): 117-130 (2013).

⁴⁶ Gupta, P., et al. “Role of Sugar and Sugar Substitutes in Dental cCaries: A Review.” *ISRN Dentistry*. 519421 (2013).

⁴⁷ Yang Q., et al. “Added Sugar Intake and Cardiovascular Diseases Mortality among US Adults.” *The Journal of the American Medical Association - Internal Medicine*. 174(4): 516-524 (2014).

b. Mandatory labeling of added sugar may not assist consumers in “maintaining healthy dietary practices.”⁴⁸

Given the broad scope of the proposals, the collective changes, including added sugar labeling, should aim to assist consumers in “maintaining healthy dietary practices”. FDA reasons that if added sugar is included in nutrition information, consumers will be able to reduce excess calories. Although FDA is addressing increasing consumer attention to the caloric content of foods through the increased prominence of calories, FDA argues that providing information on added sugar will help consumers reduce caloric intake from added sugars. We caution against FDA’s line of reasoning that including added sugars in the Nutrition Facts label will enable consumers to reduce excess calories.

First, if consumers are to reduce the amount of excess calories they consume to address obesity risk, they need calorie information to assist them in making informed food choices. As FDA notes, “added sugars do not contribute to weight gain any more than another calorie source.” Therefore, there is reason to be concerned about adverse consequences if FDA’s proposal distracts consumer attention away from calories. For example, products with no “added sugar” may be significantly higher in calories than products with added sugar, particularly if the product is high in fat since fat contributes 9 calories per gram while sugar contributes 4 calories per gram. In some cases, it is possible consumers focusing only on added sugar would consume more calories than if they focused on calories alone. For example, consider the comparison of two separate products: one is higher in fat and lower in added sugar and the other is lower in fat but higher in added sugar. The lower fat product may be lower in calories (because sugar contains fewer calories per gram than fat). However, if a consumer only looks at added sugar, the consumer may choose the higher fat, higher calorie product. Ultimately, a singular focus on added sugar, similar to a focus on other single nutrients like fat, could parallel null results seen in sustained weight loss studies comparing low-fat diets and other weight-reducing diets. FDA cites no evidence that consumers will actually reduce caloric intake by seeing the amount of added sugar in a product.

Second, FDA’s proposal to include added sugar on the label creates both an unnecessary and unfortunate distinction between added sugars and intrinsic (or naturally occurring) sugars. As FDA acknowledges, there is a “lack of a physiological distinction between added and naturally occurring sugars.” In other words, the human body does not distinguish between added sugar and naturally occurring sugar in foods; whether a person eats 10 grams of added sugar or 10 grams of naturally occurring sugar, the body doesn’t distinguish a difference. All sugar, like all carbohydrates, contains 4 calories per gram; it makes no difference whether sugar comes from honey, agave, sugar beet, sugar cane, or fruit juice because all sugar is the same in terms of caloric content. By mandating the declaration of both added sugar and total sugar, FDA creates an arbitrary nutritional distinction between

⁴⁸ FDCA § 403(q)(2)(A)

the two types, which will not lead to any nutritional difference for consumers. For example, consumers may incorrectly conclude that the calories from one food are “worse” than calories from another food, even though the products may be identical calorically.

Third, the amount of added sugar does not educate consumers on the nutrient density of a food and may ultimately be distracting because the nutrient density of a food is driven by calories from all macronutrients, not driven solely by added sugar content. The best way for consumers to choose more nutrient dense foods is to have calorie and nutrient content information. The Nutrition Facts label already provides this information to assist consumers in making food choices and thereby meet Dietary Guideline recommendations. Although the 2002 IOM DRI report noted that it may be difficult to obtain adequate amounts of certain micronutrients if more than 25% of calories come from added sugar, a study with over 15,000 respondents determined that 12.5% of people over 4 years old consume more than 25% of their calorie intake from added sugars. Additionally, the same study indicated that even at lower levels of added sugars intake, the U.S. diets are relatively poor in nutrient intakes. A focus exclusively on reducing added sugars intake may not result in an improvement in essential nutrient intake but may also have the unintended consequence of driving consumers away from nutrient dense products because some of those products may have moderate amounts of sugars.

Fourth, labeling added sugar will not help people consume fewer calories as recommended by the Dietary Guidelines because the caloric content of many foods remains about the same even if sugar is removed. For example, a product contains 10 g of “added sugar” and 120 calories per serving. If added sugar in this product is reduced to 0 g of “added sugar,” (keeping the same serving size), the removal of sugar results in a loss of bulk, which usually needs to be compensated with another bulking agent. These bulking agents usually provide energy since many energy containing ingredients cannot be simply replaced with non-caloric nutrients. For example, when reducing sugar in a predominantly carbohydrate containing food, it is likely that another carbohydrate will replace sugar. However, carbohydrates contribute the same amount of calories as sugar (4 calories per gram). If only a few of the 10 g of sugar in the product is replaced with fat, which has 9 calories per gram, the amount of calories would actually increase.

Finally, sugar labeling currently highlights to a consumer the sugar content of a food. FDA identifies “soda, energy and sports drinks, grain based desserts, sugar-sweetened fruit drinks, dairy-based desserts and candy” as the major sources of added sugar in the diet and observes that “[m]ost of these foods are not nutrient-dense and may add calories to the diet without providing dietary fiber or essential vitamins and minerals.” As FDA is aware, the foods that it identifies as major sources of added sugar are products for which all or virtually all sugar is added and the current sugar declaration already reflects the amount of added sugar. Consumers can presently review the Nutrition Facts label to see the amount of sugar in these products as well as the nutrients.

We believe that the modifications that the Agency is making to increase the prominence of calories and serving size will help consumers manage caloric intake and maintain appropriate calorie balance. Overwhelming evidence demonstrating that increased energy intake, not added sugars intake, contributes to increased body weight. Given the multiple complex factors that can contribute to the etiology of obesity, tackling the obesity issue requires a holistic approach instead of focusing on single nutrients. Therefore, based on the evidence cited above, we maintain that mandatory labeling of added sugar may influence consumer choice in a way that does not assist consumers in “maintaining healthy dietary practices.”

c. The Federal Food, Drug, and Cosmetic Act (FDCA) does not support the idea that added sugars are “additional nutrients” that should be labeled.

To avoid consumer confusion, we believe that FDA should act within the FDCA’s authorizing language which permits mandatory labeling of “additional nutrients” if that labeling “will assist consumers in maintaining healthy dietary practices.”⁴⁹ Though the term “additional nutrients” is not defined in the FDCA, all other “nutrients” listed within the statute are substances that are chemically and structurally distinct and have different physiological effects on the body (including total fat, saturated fat, cholesterol, sodium, total carbohydrate, complex carbohydrate, sugars, dietary fiber, total protein, vitamins, and minerals.)⁵⁰ For example, although saturated fat is a type of fat, it is a chemically and structurally distinct form of fat, and different types of fat have different physiological effects in the body. “Added sugar” is not a distinct substance like those listed in the FDCA. As FDA acknowledges, “added sugar” is not chemically or structurally distinct from naturally occurring sugar and there is a no “analytical method that is capable of distinguishing between added and intrinsically occurring sugars in a food product.”^{51,52} By labeling “added sugar” as if it were a distinct additional nutrient, FDA is likely to confuse consumers and create a belief that “added sugar” is less healthful than the “sugar” already required to be declared on the Nutrition Facts label.

“Added sugar” differs from sugar only in that it is added to the product, so it is not a unique or additional nutrient for which the FDCA contemplates mandatory labeling. Congress’ list of nutrients in the FDCA does not include any substances that vary only by whether they are added or inherent in a product and remaining consistent with this legislative intent is important, especially when, as noted above, the labeling of added sugar will not assist consumers in maintaining healthy dietary practices and will likely create consumer confusion.

⁴⁹ FDCA § 403(q)(2)(A)

⁵⁰ FDCA §§ 403(q)(1)(D)-(E)

⁵¹ 79 Fed Reg 11880

⁵² 79 Fed Reg 11906

d. Food labels that declare “added sugars” in addition to “total sugars” will be confusing to consumers.

FDA should consider the lack of scientific consensus and the confusing, often conflicting, communications consumers receive regarding added sugars. Consumers’ potential misunderstanding of the role of sugars and added sugars in the diet may be further perpetuated by an emphasis on added sugar labeling. A labeling distinction may mislead consumers by suggesting that added sugars are more harmful than naturally occurring sugars, and consumers need only to monitor their “added sugars” intake while not considering their “total sugars” intake.

Based on oral comments to the Agency by the IFIC Foundation, qualitative research on changes to the Nutrition Facts label suggest that consumers have varied perceptions of what the term “Added Sugars” on the label means when presented with an example. Overall, the responses indicate consumer confusion:⁵³

- “Some believe “Added sugars” to be plain table sugar.
- Some believe that “Added sugars” are extra sugars that have been newly introduced to alter the composition of an original product.
- Others believe “Added sugars” could even encompass low-calorie sweeteners.”

Additionally, consumers “...struggled in calculating absolute amounts of sugars” when presented with the proposed new label format.⁵⁴ As mentioned in the oral comments, the IFIC Foundation’s second phase of this research includes a quantitative phase. Preliminary data from this quantitative phase furthers these insights and indicates the significant proportion of consumers that are likely to be confused over “Added Sugars” and how it relates to the “Sugars” line:⁵⁵

- 56% of consumers believe “Added sugars” are different in from “Sugars” or “Total Sugars” on the Nutrition Facts label
 - 24% of consumers do not know if “Added Sugars” contain the same number of calories as other types of “Sugars”
 - 21% of consumers believe sugars and carbohydrates are different from each other
- 45% and 34% of consumers incorrectly identified the amount declared for “Added Sugars” to the “Sugars” or “Total Sugars” line, respectively, when shown proposed label options

⁵³ International Food Information Council Foundation. “IFIC Foundation FDA NFP Public Meeting Oral Comments.” Thursday, June 26, 2014.

⁵⁴ International Food Information Council Foundation. “IFIC Foundation FDA NFP Public Meeting Oral Comments.” Thursday, June 26, 2014.

⁵⁵ International Food Information Council Foundation. “Consumer Investigation Into Nutrition Facts Panels and Sugars Labeling.” Published Aug 1st, 2014 IFIC Foundation data available at: <http://www.foodinsight.org/sugars-labeling-nutrition-panels>

- When asked, 52% and 33% of consumers believe that the number of grams of “Added Sugars” is in addition to the amount declared for “Sugars” or “Total Sugars,” respectively

It is clear from FDA’s proposed experimental study on consumer responses to an added sugars declaration on the Nutrition Facts label that the Agency is evaluating consumer choice and perceived healthfulness of products when consumers evaluate the label.⁵⁶ However, we believe that FDA has not adequately assessed consumer comprehension of an added sugars declaration within the confines of the newly proposed format. Consumer choice and perceptions of a product could be influenced by other changes observed on the Nutrition Facts label, including but not limited to the increased prominence of calories.

General Mills supports FDA conducting consumer research using the *newly proposed format* to understand how the proposed declaration of added sugars would be interpreted by consumers or used to guide healthy dietary choices. Furthermore, upon conclusion of this consumer research, FDA should reopen the commentary period on its proposed regulation for additional input from stakeholders. Comprehensive and thorough consumer research on the totality of the proposed changes and the various Nutrition Facts label formats must be completed and published before issuing a final rule.

III. FDA’s proposed definition is ambiguous and confusing.

Finally, FDA’s proposed definition of added sugar is complex and confusing, and will therefore lead to inconsistent application across the food industry, which will create confusion for manufacturers, regulators, nutritionists, and consumers. FDA has proposed to define “added sugar” as:

“...sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners.”⁵⁷

Constructing any proposed definition of added sugar while straying from an analytical based method to differentiate food components on the Nutrition Facts label will lead to inconsistent implementation across the food industry, potentially inaccurate declaration, and cannot be enforced in a non-arbitrary manner. Whereas there is concordance regarding chemical definitions for the distinction of other nutrients, no such chemical definition exists for added sugars, and currently, there are discrepancies in defining added

⁵⁶ 78 Fed Reg 32394

⁵⁷ 79 Fed Reg 11969

sugars between government agencies.⁵⁸ The result of multiple definitions for any nutrient that cannot be distinguished analytically gives rise to inconsistencies and misinterpretations by consumers, scientists, and regulators alike. Ultimately, this can have severe ramifications on dietary guidance provided and regulation of food and food ingredients. FDA's inability to clearly define "added sugars," coupled with the lack of analytical testing for enforcement, will create a challenging environment for compliance.

a. Ingredients with both naturally occurring and added sugars may lead to confusion in how to declare added sugars.

FDA's proposed added sugars definition is problematic for foods that contain both naturally occurring sugar and sugar added during processing. For example, fruit puree is often composed of both fruit and added sugar, and fruit purees are often added to foods for several purposes (i.e. fruit provides texture, flavor, nutrients, and sweetness). Given FDA's proposed definition, it is not clear how the total amount of sugar in fruit puree should be declared in the final product. For example, some companies may decide that sugar inherent in the fruit puree should be excluded from the sum of added sugars and instead only count the sugar that is added to fruit puree as added sugar. Other companies may reason that the sugar in fruit is added sugar because it is added sweetness and count both the sugar inherent to fruit and the added sugar in the puree as "added sugar." Some companies may even conclude that none of the sugar in a fruit puree is added sugar. We request FDA review Appendix C for a more detailed case study outlining these discrepancies.

Like fruit purees, sweetened condensed milk contains a mixture of both naturally occurring and added sugar. Sweetened condensed milk is milk from which the water has been removed and sugar has been added. Some of the sugar in sweetened condensed milk is from lactose, the sugar naturally found in milk, and the remaining sugar is from other sources. Companies using sweetened condensed milk as an ingredient could find several different ways to declare added sugar. Some companies might count only the amount of sugar in sweetened condensed milk, others may label the entire amount of sweetened condensed milk as added sugar, and yet others might determine a calculation for how much sugar was added to the sweetened condensed milk and how much is the naturally occurring lactose:

⁵⁸ Sigman-Grant M and J Moirta. "Defining and Interpreting Intakes of Sugars." *American Journal of Clinical Nutrition*. 78:815S-826S (2003).

Table 2. Different calculated added sugar values for sweetened condensed milk generated from various interpretations of FDA’s added sugars definition.

	<i>Company A</i>	<i>Company B</i>	<i>Company C</i>
Added sugar (g) in 1 fluid oz of sweetened condensed milk	20 g	32 g	<20 g
Ingredient(s) considered added sugar	Sucrose, other ingredients	Milk, sucrose, other ingredients	Sucrose

With so many different interpretations available to companies, the “added sugar” declaration becomes useless to consumers trying to make healthy dietary choices.

b. The proposed definition of “added sugars” is subjective when applied to fruit juice concentrate and not fruit juice.

FDA’s determination that fruit juice concentrate should be labeled as added sugar while fruit juice is not labeled as added sugar is arbitrary and will lead to confusion for manufacturers and consumers. When reconstituted, fruit juice and fruit juice concentrate have the same nutritional qualities and fruit juice concentrate is often preferred by food manufacturers for a variety of reasons, including sustainability, sourcing and logistics. FDA’s treatment of fruit juice concentrate also begs the question of how a manufacturer should treat fruit juice concentrate that has been reconstituted before being added to products. Manufacturers may reconstitute completely or partially, and in either case it is unclear how the sugar in the ingredient should be counted as well as quantified. If a manufacturer fully reconstitutes the fruit juice and then adds it to a product, arguably it is no longer “added sugar” since FDA seems to have excluded fruit juice from the definition of added sugar. However, some manufacturers may still label the reconstituted juice as added sugar because the juice started as fruit juice concentrate. Ultimately, a consumer eating a food with fruit juice or reconstituted fruit juice concentrate will be eating the same amount of sugar from the same source (fruit) but the amount of added sugar in the product will be labeled differently simply due to the water content in the ingredient.

c. The language “other caloric sweeteners” is confusing and unclear.

FDA’s proposed definition of added sugar includes “other caloric sweeteners” but does not define what is considered a “caloric sweetener.” Arguably, any substance with calories that contribute to the sweetness of a product could be considered a “caloric sweetener.” For example, applesauce, which may be sweetened or unsweetened, is sometimes used in baked dessert items as an alternative to oil. One cup of unsweetened apple sauce contains approximately 23 grams of sugar, so although the primary purpose of the applesauce is to

replace oil, it also contributes sugar and sweetness to the final product.⁵⁹ This leads to confusion as to whether the sugar in applesauce is “added sugar.” Some companies may decide to label the sugar in applesauce as added sugar while other companies may reason that the applesauce is a naturally-occurring sugar or primarily intended as a substitute to oil, and thus not label it as added sugar. Essentially identical products made with applesauce could be labeled with very different values for added sugar, and it is unclear which label would be considered compliant with FDA’s regulation.

These complexities expand if sweetened applesauce is considered. Sweetened applesauce contains approximately 36 grams of sugar, which is about 13 grams more sugar than unsweetened applesauce.⁶⁰ Three different manufacturers may come to three different declarations for added sugar content:

Table 3. Different calculated added sugar values for sweetened applesauce generated from various interpretations of FDA’s added sugars definition.

	<i>Company A</i>	<i>Company B</i>	<i>Company C</i>
Added sugar (g) in 1 cup of sweetened applesauce	36 g	13 g	0 g
Ingredient(s) considered added sugar	Applesauce, sugar	Sugar	None

One manufacturer may conclude that all 36 grams of sugar in applesauce contribute to sweetness, and therefore must all be labeled as added sugar. Another manufacturer may conclude that the 13 additional grams of sugar in sweetened applesauce are added sugar and label 13 grams of added sugar. Still another manufacturer may reason since the intent of the applesauce is to serve as an oil substitute and not a sweetener, that none of the sugar in sweetened applesauce would be considered an added sugar under FDA’s definition and label 0 grams of added sugar.

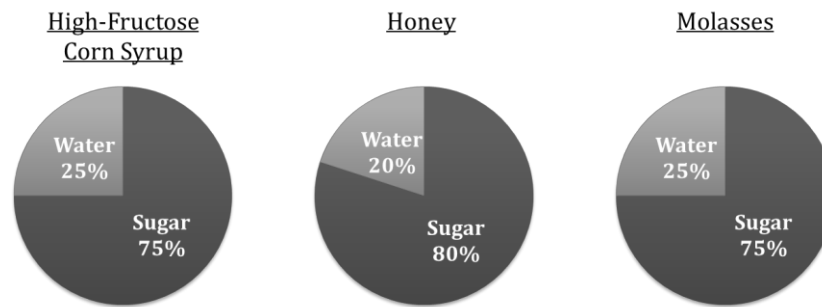
d. Some sweeteners are not 100% sugar.

Under the proposed definition, ingredients such as high fructose corn syrup, honey, and molasses are considered “added sugars,” but these ingredients are not 100% sugar:

⁵⁹ USDA nutrient database, available at <http://ndb.nal.usda.gov/ndb/foods/show/2484?fg=&man=&lfacet=&format=&count=&max=25&offset=&sort=&qlookup=applesauce>.

⁶⁰ USDA nutrient database, available at <http://ndb.nal.usda.gov/ndb/foods/show/2217?fg=&man=&lfacet=&format=&count=&max=25&offset=&sort=&qlookup=applesauce>.

Figure 4. Examples of sweeteners that are not 100% sugar.



High fructose corn syrup is approximately 75% sugar, honey 80% sugar, and molasses 75% sugar. As currently drafted, FDA's proposed definition is unclear as to how much of these ingredients should be declared as added sugar. If a manufacturer adds one tablespoon of honey to a product, the product might be labeled with 21 grams of added sugar when in fact the product only contains about 17 grams. If honey is the only source of sugar in the product, this would certainly confuse and mislead consumers as to the added sugar content of the food.

Ultimately, it is unlikely FDA will be able to correct the issues with the proposed definition of added sugar in a meaningful way for consumers because there is no nutritional difference between added sugar and naturally occurring sugar. Any proposed definition of added sugar would be arbitrary from a science and nutrition standpoint. Further, given the complexities of trying to define a substance that has no unique analytical or nutrition properties, it is unlikely FDA could propose a definition of added sugars that would not be confusing to consumers, and create significant compliance and enforcement issues for the entire food industry. Proposed changes, particularly nutrient definitions, must remain objective and grounded in analytical methods in order to yield consistent labeling practices across the food industry and ease in compliance measurements by the Agency.

Fiber

Fiber has been identified as a nutrient of public health concern by the 2010 Dietary Guidelines because intakes fall short of recommended levels.⁶¹ The 2010 Dietary Guidelines also recommend increasing fiber intake from a variety of foods to help consumers meet the recommendations. Given the 2010 Dietary Guidelines recommendations and the definitions of fiber from the IOM and Codex, FDA is proposing significant changes to fiber for nutrition labeling; namely, requiring that fibers included on the Nutrition Facts label

⁶¹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office, p33, (2010).

have a “physiological effect that is beneficial to human health”⁶² and increasing the Daily Value for fiber from 25 grams to 28 grams per day. Individually, both of these changes are substantial; the combined effect of these proposed changes is even more dramatic, and may ultimately have the unintended consequence of further decreasing intakes of this shortfall nutrient.

Another consideration that FDA must carefully weigh is the manner in which an individual’s total daily fiber intake is achieved. The 2010 Dietary Guidelines recognize that fiber comes from many sources,⁶³ and while the sources and types of fiber consumed in a day may be different, they all contribute to total daily fiber intake. This view was also expressed at the 9th Vahouny Symposium; namely that cumulative fiber intake contributes several beneficial effects and consumption of many individual fibers is important to achieve these benefits.⁶⁴

General Mills acknowledges the difficulty and complexity surrounding the fiber definition; it has been the subject of considerable discussion in numerous scientific conferences, panels and reports (e.g. the 9th Vahouny Fiber Symposium, the IOM, Health Canada, CODEX) for over a decade. Nutrition labeling must integrate this definition with other essential elements including current analytical methods and advancing food technology.

Currently, companies determine the amount of fiber to list on the Nutrition Fact label by using AOAC analytical test methods approved by FDA. These methods are specifically designed to identify carbohydrates that are resistant to digestion in the small intestine, and are, by virtue of being resistant to digestion, defined as fiber. FDA is proposing to change its approach to add a new requirement – that substances must also be “intrinsic and intact in plants” to be considered fiber. If substances are not “intrinsic and intact in plants,” they will only be considered fiber if FDA determines that they have a “physiological effect that is beneficial to human health” or are the subject of an authorized health claim. While we applaud FDA for its efforts, General Mills objects to this proposed approach for a variety of reasons. First, the proposed approach conflicts with 2010 Dietary Guidelines recommendations to increase fiber intake and to include fiber from a variety of food sources. Second, it represents a significant deviation from FDA’s long-standing enforcement policy. Third, the proposed approach is inconsistent with the Agency’s position on stearic acid. Fourth, it is not supported by the totality of the evidence. Fifth, it inappropriately imposes a pre-authorization approach similar to that required for health claims (“physiological effect that is beneficial to human health”) for fiber declaration on the Nutrition Facts label. Finally, the proposed approach does not give the food industry clear, consistent guidance that encourages innovation.

⁶² 79 Fed Reg 11909

⁶³ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office, p40, (2010).

⁶⁴ Howlett, J.F., et al. “The Definition of Dietary Fiber-Discussions at the Ninth Vahouny Fiber Symposium: Building Scientific Agreement.” *Food & Nutrition Research*. 54(1):5750 (2010).

For these reasons, General Mills supports retaining an analytical approach for the declaration of fiber on the Nutrition Facts label. For product claims about the effects or benefits of fiber, we support that the manufacturer document these effects with scientific evidence.

I. FDA’s proposal to base the Nutrition Facts label declaration of fiber on “a physiological effect that is beneficial to human health” is a significant deviation from its long-standing enforcement policy.

FDA’s proposal to base the Nutrition Facts label declaration of fiber on “a physiological effect that is beneficial to human health” is a significant deviation from its long-standing enforcement policy, inconsistent with its position on stearic acid, and not otherwise supported by the evidence. Adopting the proposed physiological definition for labeling fiber content represents an unprecedented, significant shift for nutrient declarations, moving from an analytically-based approach to a “pre-authorization” approach. It is inconsistent with FDA’s current philosophy to nutrition labeling, and introduces unnecessary complexity to the nutrition labeling process. Consideration of the physiological effects or benefits of fiber is appropriate for claims, however, and is explained later in this section.

a. FDA’s long-standing policy is to use analytical methods to ensure compliance.

For “purposes of enforcement,” Congress provided FDA with the authority to take samples of products.⁶⁵ The Agency has a long history of taking samples and using analytical methods to determine compliance with the Act. Accordingly, the final NLEA regulations included a section on compliance that set forth the sampling procedures and analytical methods it would use for enforcement purposes.⁶⁶ Proposed changes, particularly changes that affect how the quantity of a nutrient is determined for the Nutrition Facts label, must remain objective and grounded in analytical methods to ensure consistent labeling practices across the food industry and to ease in compliance measurements by the Agency.

Consistent with the above, FDA rejected a comment suggesting that it also review company records to ensure compliance. FDA explained: “To support misbranding charge for inaccurate nutrient content information, FDA must have accurate, reliable, and objective data to present in a court of law. To obtain that information, FDA relies upon the work performed by its trained employees because it does not have legal authority in most instances to inspect a food manufacturing firm’s records.”⁶⁷

⁶⁵ 21 USC 374

⁶⁶ 21 CFR §101.9(g)

⁶⁷ 58 Fed Reg 2079,2110

Under the present proposal, FDA seeks to deviate from its long-standing practice. As explained below, this aberration is not consistent with other decisions or the evidence in the record.

b. FDA's fiber proposal is inconsistent with its proposal on saturated fat.

Although FDA is proposing to base the Nutrition Facts label declaration for fiber on “a physiological effect that is beneficial to human health”, it rejected the very same proposal with regard to stearic acid and saturated fat. The agency states their position supporting a chemical versus physiological definition of nutrients for labeling when addressing saturated fats. With respect to stearic acid and saturated fat, FDA explained:

“We do not agree that stearic acid should be excluded from the definition of saturated fat. While there is evidence that there are potential differences in the physiological effects of different saturated fatty acids, including on LDL cholesterol levels, *the definitions of nutrients for food labeling purposes have traditionally been based on chemical definitions, rather than on individual physiological effects. The definition for saturated fat in § 101.9(c)(2)(i) includes all fatty acids without double bonds and the accepted analytical methods capture all of the saturated fatty acids, including stearic acid.* In adopting this definition, we addressed the issue of inclusion/exclusion of individual saturated fatty acids and determined that a chemical definition which includes all fatty acids containing no double bonds) was the appropriate approach to define saturated fat.”⁶⁸ “We further note that the 2010 DGA recommendation related to saturated fat intake is based on scientific evidence related to the intake of all saturated fatty acids combined, which includes stearic acid...”⁶⁹

c. FDA's proposal does not take into account the totality of credible and relevant evidence-based research.

The analytical methods selected by FDA for dietary fiber were developed specifically to identify those carbohydrates that are resistant to digestion in the human digestive tract and therefore are “fiber.” These methods provide definitive measurement of the dietary fibers present in foods, whether intrinsic and intact or isolated and synthetic non-digestible carbohydrates (with three or more monomeric units). Primary methods have been in place since 1985 and more inclusive methods that capture some of the more highly soluble fibers have been adopted since 2009 (Codex, AOAC). These analytical advances were not available and therefore not reflected in the 2002 IOM Macronutrient Report.⁷⁰

⁶⁸ 58 Fed Reg 2079 at 2088

⁶⁹ 79 Fed Reg 11894

⁷⁰ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, D.C: National Academy Press (2002).

All changes to the Nutrition Facts label must be based on credible and relevant evidence-based research, yet in this proposal, FDA's consideration of fiber's physiological effects is arbitrarily limited to three.⁷¹ In addition to the three effects named by FDA in their proposal (attenuation of postprandial blood glucose concentrations, attenuation of blood cholesterol concentrations, and improved laxation), Health Canada also recognizes as a physiological effect the production of energy-yielding metabolites through colonic fermentation.⁷² The 2005 IOM Report discusses numerous additional effects⁷³ and the 9th Vahouny Symposium provides a more complete list of physiological effects:⁷⁴

1. Reduced blood total and/or LDL cholesterol levels
2. Attenuation of postprandial glycemia/insulinemia
3. Reduced blood pressure
4. Increased fecal bulk/laxation
5. Decreased transit time
6. Increased colonic fermentation/short chain fatty acid production
7. Positive modulation of colonic microflora
8. Weight loss/reduction in adiposity
9. Increased satiety

We believe that FDA should adopt this more specific and comprehensive list (from the 9th Vahouny Symposium) of physiological effects within FDA's fiber definition framework. Additionally, research advances may expand this list as the science evolves.

Expanding the list of fiber's physiological effects and requiring food manufacturers to have adequate scientific substantiation supporting specific claims about fiber eliminates the need for FDA's proposed petition process, retains consistency with current practices and ensures continuity and clarity for the food industry, the Agency and most importantly, consumers.

II. General Mills supports a more globally accepted fiber definition that retains the analytical approach FDA utilizes for all other nutrients.

We support FDA adopting a single definition for dietary fiber rather than IOM's separate definitions of "dietary fiber" and "functional fiber. To enhance global harmonization, GMI urges FDA to expand their proposed definition of dietary fiber (21 CFR §101.9(c)(6)(i)(1)). FDA's proposed definition is consistent with the IOM, but it could be enhanced by including other minor substances that are an intrinsic part of plant fibers. Including the associated

⁷¹ 79 Fed Reg 11910

⁷² Health Canada. Bureau of Nutritional Science. Food Directorate. Health Products and Food Branch. *Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products*. (2012).

⁷³ Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington DC. National Academies Press; 2005.

⁷⁴ Howlett, J.F., et al. "The Definition of Dietary Fiber-Discussions at the Ninth Vahouny Fiber Symposium: Building Scientific Agreement." *Food & Nutrition Research*. 54(1):5750 (2010).

substances would make the proposed fiber definition congruent with a variety of other recognized definitions (e.g. CODEX, AACCI).^{75,76,77}

GMI proposes changing the proposed definition to include many fiber sources in current use, such as bran, β -glucans and inulin; we suggest changing 21 CFR §101.9(c)(6)(i)(1) to read as follows:

Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin or other compounds associated with polysaccharides in the plant cell walls, such as waxes, cutin, and suberin, that are intrinsic and intact in plants, or that are isolated and synthetic.

III. General Mills recommends a minor change in the proposed analytical methods section to address future advancements.

General Mills supports FDA's proposed fiber analytical methods with a minor change to allow for future flexibility and advancements in methodology. GMI proposes eliminating a reference to a specific edition (19th edition) of the "Official Methods of Analysis of the AOAC International" from the proposed rule. This would allow future editions of this reference to be in compliance. The new, suggested wording would be:

101.9(c)(6)(1) ...dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber (in proposed Sec. 101.9(c)(6)(i)) from the value obtained using AOAC 2009.01, AOAC 2011.25 or an equivalent AOAC method of analysis as given in the "Official Methods of Analysis of the AOAC International."

IV. General Mills believes that when making a product claim about fiber's physiological effect or benefit, adequate scientific substantiation is necessary, and rests with the manufacturer.

We acknowledge that fibers have varying physiological effects and agree that claims made regarding such effects must be substantiated with credible scientific evidence. When making claims about the physiological effects or health benefits of fiber, regulations require that the fiber provide the stated effect or benefit. However, the onus should continue to be on companies to provide the appropriate substantiation to support the statement or claim. This is consistent with FDA's current process for substantiating claims about the effects or benefits of a nutrient and its process for health claims. As stated previously, for purposes of

⁷⁵ Joint FAO/WHO Food Standards Programme, Secretariat of the CODEX Alimentarius Commission. *CODEX Alimentarius (CODEX) Guidelines on Nutrition Labeling CAC/GL 2-1985 as Last Amended 2010*, Rome: FAO (2010).

⁷⁶ AACC Dietary Fiber Definition Committee. "Definition of Dietary Fiber: Report of the Dietary Fiber Definition Committee to the Board of Directors of the American Association of Cereal Chemists," *Cereal Foods World*, 46(3):112-126 (2001).

⁷⁷ United States. National Academy of Sciences. Institute of Medicine *Dietary Reference Intakes: Proposed Definition of Dietary Fiber*. Washington, D.C: National Academy Press (2001).

labeling the quantity of dietary fiber on the Nutrition Facts label and the percent Daily Value, analytical verification should continue to be sufficient.

a. FDA’s proposal for premarket approval creates significant challenges and complexity, and may have the unintended consequence of decreasing fiber consumption.

FDA’s proposal for premarket approval creates numerous and substantial challenges. First, FDA lacks the authority for its proposed premarket approval process for fiber. Unlike food additives, FDA does not have preapproval authority for nutrients under NLEA (see 21 USC 343). Moreover, the proposal fails to explain how FDA plans to decide what substances are considered “fiber” and which are not. Also, the timing of FDA’s conclusions is uncertain on whether a substance is a “fiber” or not. We encourage the Agency to have further dialogue with stakeholders and provide the opportunity to comment before finalizing.

The Agency’s lack of clarity creates unprecedented challenges and unnecessary complexity for the food industry. Under FDA’s current proposal, products currently using “isolated or synthetic” fiber ingredients that analyze as fiber (unless the subject of an authorized health claim) may need to make significant product changes to maintain current fiber label values and claims and/or make significant labeling changes. In effect, a product that is currently a significant source of fiber may no longer be a significant source. The manufacturer would need to either reformulate the product to include an “approved” source of fiber, or change the label to reflect the lower fiber content. In addition, FDA’s approach does not help foster innovation and encourage the food industry to develop fiber-rich products, and may result in continued inadequate fiber intakes in the U.S. population. To help improve public health, changes to nutrition labeling should be rooted in nutritional science and encourage manufacturers to continue delivering foods with important nutrients.

Furthermore, the Agency’s proposed definition is problematic as it lacks clarity needed to indicate which fibers would require premarket approval. “Intrinsic and intact in plants” and “isolated and synthetic” are not nutrition definitions or measurable quantities and these terms are not sufficient to delineate fiber types. This will lead to inconsistent application of dietary fiber labeling across food products and the industry.

b. There is scientific support for differentiating between the label value for fiber and claims about fibers' effects.

More specifically, the 9th Vahouny conference provided the following conclusion in their Symposium Report: ⁷⁸

“...in considering beneficial effects in the context of a definition for dietary fiber and resultant nutrient content claims, it is important to keep in mind the consumption of fibers of all types. The total fiber content of the diet contributes several different effects simultaneously and the overall benefit, however achieved mechanistically, derives primarily from the fact that fiber is not digested in the small intestine and passes to the colon intact. The beneficial outcomes of individual fiber types in individual foods should be seen in terms of their contribution to the overall benefit achieved through their contribution to total dietary fiber intake as reflected in nutrient content claims. This is in contrast to health claims made in relation to individual components where the claim is product specific and required substantiation on a case-by-case basis in relation to the individual food ingredient.”

In summary, to ensure consistent labeling practices across the food industry and to ease compliance measurements by the Agency, General Mills' recommended approach retains appropriate analytical methodology as the basis for declaring fiber on the Nutrition Facts label and for nutrient content claims based on the label (e.g. “good source” and “excellent source” claims). FDA would ensure compliance of the label fiber value and nutrient content claims based on appropriate analytical methodology. For statements or claims about fiber's health effects or benefits, the manufacturer would be responsible for substantiating those claims. This approach eliminates the need for the Agency to maintain an approved list of fibers, creates less confusion for consumers and would continue to encourage innovation in the food industry.

V. General Mills supports FDA's proposed approach to caloric contributions of fibers.

GMI supports FDA's proposal to recognize 2 calories per gram for soluble fiber and continue to recognize 0 calories per gram for insoluble fiber, as reflected in 21 CFR §101.9(c)(1)(i)(C). To support future advancements in food science and analytical assessment, we also support the provision of other calorie values for specific fibers supported by appropriate scientific documentation. This approach maintains the Agency's current analytical approach used for nutrient values, and allows for continued advances in fiber science.

⁷⁸ Howlett, J.F., et al. “The Definition of Dietary Fiber-Discussions at the Ninth Vahouny Fiber Symposium: Building Scientific Agreement.” *Food & Nutrition Research*. 54(1):5750 (2010).

VI. General Mills believes the Daily Value for fiber should remain at 25 g and opposes the proposed increase to 28 g.

As described below, General Mills outlines our opposition to using Adequate Intakes (AI) for establishing Daily Values. We do not support FDA's proposed increase in the Daily Value for fiber from 25 g to 28 g per day. While this increase reflects the 2002 DRI's that set an AI for fiber at 14 g per 1000 kcals,⁷⁹ there are global recommendations and practical considerations that support the retention of the current 25 g fiber Daily Value.

From a nutrition perspective, the IOM based the recommended intake of fiber on an AI versus EAR, as fiber is not a required nutrient, and there was not sufficient clinical evidence to establish an EAR. Thus, the IOM set the AI for fiber at 14 g per 1000 kcal based on recommended energy intake and the relationship of fiber consumption and coronary heart disease. Because the fiber recommendation is tied to calorie requirements, those with lower calorie needs have lower fiber needs than those with higher calorie requirements. Finally, from a global perspective, both the WHO/FAO and EFSA recommend 25 g of fiber per day as the amount needed for healthy laxation.^{80,81}

From a consumer standpoint, raising the fiber Daily Value from 25 g to 28 g means some foods that are currently a "good source" of fiber will no longer qualify for this nutrient content claim. Examples of foods that would potentially fall into this category are whole wheat bread, a small apple, a small orange, some whole grain cereals and some mixed dishes.

Finally, raising the fiber Daily Value to 28 g could act as a deterrent for industry to develop products that help consumers close the fiber gap. To close the large fiber intake gap, fiber in food products will likely need to come from a variety of sources, including "intrinsic and intact" and "isolated and synthetic." Consumers are clearly not meeting fiber recommendations now; it is not practical to think that they will be able to meet (or even approach) these more robust fiber recommendations in a calorie neutral manner. Filling the fiber gap through a combination of fibers is a more feasible way to achieve fiber recommendations while maintaining appropriate calorie levels and choosing realistic, practical dietary consumption patterns.

⁷⁹ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, D.C: National Academy Press (2002).

⁸⁰ Nishida, C.R., et al. "The Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases: Process, Product and Policy Implications." *Public Health Nutrition*. 7(1A):245-50 (2004).

⁸¹ European Food Safety Authority. "Outcome of the Public Consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) on establishing Food-Based Dietary Guidelines." *EFSA Journal*. 8(5):1506 (2010).

Labeling of Vitamins and Minerals

General Mills supports revisions to the reference values used in nutrition labeling as a way to help translate current scientific knowledge to the public. IOM DRI committees have issued new reports^{82, 83, 84, 85, 86, 87} and revised many of the previously set RDAs for vitamins and minerals. We believe these reports to be the most thorough review of the science available for establishing the RDAs. Therefore, we support FDA's conclusion that the existing RDIs for vitamins and minerals should be revised and based on the DRIs set by the IOM to reflect the most current science regarding nutrient requirements. Specifically, for reasons cited below, we support using the highest RDA as the most appropriate basis for establishing an RDI, yet in the absence of scientific evidence for an RDA, we oppose the use of an AI.

I. General Mills supports FDA's conclusion that the population-coverage approach using the highest RDA is the most appropriate basis for establishing RDIs.

As stated by the Agency, RDIs are intended as general food labeling reference values and are not intended to represent dietary allowances for individuals.⁸⁸ Furthermore, they function as an overall population reference to help consumers judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and compare nutrient contributions of different foods.⁸⁹ There has been much debate in the scientific community regarding the best method for establishing nutrient Daily Values, specifically whether the EAR or RDA should be used and whether the population-coverage or population-weighted approach should be applied. Recent research from Murphy et al examined this debate in the context of how these approaches would affect food fortification and US population nutrient intakes. For most nutrients, estimates of the percentage of the population with intakes below the EAR were similar regardless of whether the Daily Value corresponded to the population-weighted EAR or the population-coverage RDA.⁹⁰ In earlier

⁸² United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline*. Washington, DC: The National Academies Press (2000).

⁸³ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids*. Washington, DC: The National Academies Press (2000).

⁸⁴ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc*. Washington, DC: The National Academies Press (2001).

⁸⁵ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, DC: The National Academies Press (2002).

⁸⁶ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride, and Sulfate*. Washington, DC: The National Academies Press (2004).

⁸⁷ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Vitamin D, and Calcium*. Washington, DC: The National Academies Press (2011).

⁸⁸ 55 Fed Reg 29476, 29478

⁸⁹ 55 Fed Reg 29476

⁹⁰ Murphy, M.M., et al. "Revising the Daily Values May Affect Food Fortification and in Turn Nutrient Intake Adequacy." *The Journal of Nutrition*. 143:1999-2006 (2013).

comments to the Agency,⁹¹ we previously voiced our support of establishing Daily Values based on population-weighted EARs, in accordance with the 2003 IOM Labeling Committee report and recommendation. However, when considering this recent research, along with FDA's approach and rationale cited in the proposed regulation,⁹² including their interpretation of the IOM Dietary Planning Report discussion, and importantly the prior history of established use, we support FDA's tentative conclusion that the population-coverage approach using the highest RDA is the most appropriate basis for establishing RDIs.

II. In the absence of an RDA, General Mills opposes the use of an AI to establish an RDI for individual nutrients.

An AI is defined as a recommended average daily nutrient intake level, based on experimentally derived intake levels or approximations of observed mean nutrient intake by a group of apparently healthy people that are assumed to be adequate.⁹³ The AI value is established at a level *assumed* to ensure nutritional adequacy in all members of a healthy population when there is insufficient scientific evidence to develop an RDA. As noted by the Agency,⁹⁴ the RDIs are intended as general food labeling reference values to help consumers judge foods' usefulness in meeting overall daily recommendations. Using a reference value that is based on inadequate quantity or quality of science would be providing inconclusive information to consumers, especially for nutrients to encourage. Therefore, given the lack of scientific evidence to establish an RDA, we oppose the use of an AI for updating the RDIs for potassium, fiber, and sodium. In lieu of using an AI to establish an RDI, we advocate maintaining current values for potassium and fiber and using the UL to establish a 2300 mg Daily Value for sodium (see additional comments in Fiber, Sodium and Potassium sections).

III. Labeling of Sodium

Sodium intake and its relationship to hypertension and cardiovascular disease (CVD) continue to be an active area of research and of public health interest. Consumers are interested in the amount of sodium in our products, and consumer research indicates that sodium is one of the top three food components Americans consider when making decisions about buying packaged foods or beverages.⁹⁵ For these reasons, General Mills agrees with FDA that it is important to continue to label sodium on all food products. National nutrition policy and regulations should reflect the totality of robust, scientifically sound evidence, including the most current research. We support the Agency's rationale and approach in proposing a new Daily Value of 2300 mg. Furthermore, we oppose alternative approaches

⁹¹ General Mills' public comments submitted to FDA Docket ID: FDA-2007-0566 [April 30, 2008]

⁹² 79 Fed Reg 11927

⁹³ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes: Applications in Dietary Assessment*. Washington, DC: The National Academies Press (2000).

⁹⁴ 79 Fed Reg 11925

⁹⁵ International Food Information Council Foundation. *"2014 Food & Health Survey - The Pulse of America's Diet: From Beliefs to Behaviors."* Washington, DC: U.S (2014).

or recommendations to lower the sodium Daily Value below 2300 mg, given the lack of available science to show a benefit of sodium intakes below 2300 mg for the general population and the potential adverse effects in specific sub-populations.

a. General Mills supports FDA’s approach in establishing a new sodium Daily Value of 2300 mg.

General Mills supports FDA’s proposal to reduce the Daily Value of sodium to the DRV of 2300 mg. This new Daily Value aligns with the 2013 IOM Report “Sodium Intake in Populations: Assessment of Evidence” (“The 2013 IOM Report”), which concluded that the studies on health outcomes are inconsistent in quality and insufficient in quantity to determine that sodium intakes <2300 mg per day either increase or decrease the risk of heart disease, stroke, or all-cause mortality.⁹⁶ As FDA notes, the 2013 IOM Report “concluded that the evidence was insufficient and inconsistent to recommend sodium intake levels below 2300 mg per day for the general U.S. population.”⁹⁷ This 2300 mg Daily Value also aligns with the 2010 Dietary Guidelines goal of reducing dietary sodium intake to <2300 mg per day for the general population.⁹⁸ FDA also acknowledges the proposed DRV of 2300 mg would reflect the UL applicable to 88% of the U.S. population, including those who are susceptible to high blood pressure.⁹⁹

b. General Mills supports the Agency’s decision to not establish a sodium Reference Daily Intake of 1500 mg or pursue alternative approaches to lower the Daily Value below 2300 mg.

i. There is no direct scientific evidence to support that a reduction of sodium intake to 1500 mg per day will successfully result in lower CVD and stroke risks.

While reducing sodium intakes may help lower blood pressure levels, General Mills does not support establishing a Daily Value of 1500 mg for sodium as the scientific evidence available from both short term intervention and observation studies for sodium restriction and CVD and stroke risk is conflicting and inconclusive. While research indicates that blood pressure, on average, rises with increased sodium intake, there is well recognized heterogeneity in the blood pressure response to changes in sodium intake. The 2013 IOM Report acknowledged: “Use of statistical modeling with a set of linked assumptions, namely that sodium reduction lowers blood pressure; lower blood pressure reduces the risk of stroke and coronary heart disease. Statistical modeling can give us some insights, but are no means a replacement for randomized controlled trials to study a cause-effect

⁹⁶ United States. National Academy of Sciences. Institute of Medicine. *Sodium Intake in Populations: Assessment of Evidence*. Washington, DC: The National Academies Press (2013).

⁹⁷ 79 Fed Reg 11916

⁹⁸ United States. Dept. of Agriculture and Dept. of Health and Human Services. *Dietary Guidelines for Americans 2010*. Washington, DC: U.S. Government Printing Office (2010).

⁹⁹ 79 Fed Reg 11915

relationship.”¹⁰⁰ As FDA notes, the 2013 IOM Report “concluded that the evidence was insufficient and inconsistent to recommend sodium intake levels below 2300 mg per day for the general U.S. population.”¹⁰¹ Despite the relationship between sodium intakes and blood pressure, a surrogate marker for CVD, there is no direct scientific evidence to suggest that a reduction in daily intake of sodium to 1500 mg per day will successfully result in lower CVD and stroke risks.

ii. Some evidence suggests lower sodium intakes for certain population sub-groups may have adverse health effects.

The recent 2013 IOM Report has indicated that for some population sub-groups (e.g. those with diabetes, kidney disease or CVD), low sodium intakes in ranges of 1500-2300 mg per day may lead to a greater risk of adverse health effects, with no evidence for benefit.¹⁰² The committee concluded that the evidence for either benefit or harm imparted to these subgroups based on this range of sodium intake is not strong enough to indicate that these subgroups should be treated differently than the general population.

iii. Implementing a tiered approach or a sodium Daily Value based on an AI would be scientifically unfounded and inconsistent.

As previously noted, there is lacking scientific rationale for establishing a sodium Daily Value <2300 mg per day, including no global data to show that population-wide sodium reductions in intake to 1500 mg per day are beneficial in lowering risk of CVD. As such, we agree with FDA’s conclusion that there is, “inadequate justification in consensus reports or arguments presented by comments to propose a tiered option.”¹⁰³ Additionally, a tiered approach to further lower the sodium Daily Value would be an unprecedented process compared to other nutrients to limit in the diet including saturated fat and cholesterol.

Furthermore, establishing a RDI based on an AI would be inconsistent with FDA’s current and proposed approach for other nutrients that should be limited in the diet. Similar to sodium, the current and proposed DRVs for saturated fat and cholesterol, two other nutrients to limit in the diet, are based on quantitative intake recommendations and underlying science that links the excess intake of these nutrients to specific adverse health effects, which is acknowledged by FDA.¹⁰⁴ General Mills strongly encourages FDA to consistently apply this long-standing approach for nutrients to limit in the diet to sodium rather than make an exception given the current state of the science.

¹⁰⁰ United States. National Academy of Sciences. Institute of Medicine. *Sodium Intake in Populations: Assessment of Evidence*. Washington, DC: The National Academies Press (2013).

¹⁰¹ 79 Fed Reg 11916

¹⁰² United States. National Academy of Sciences. Institute of Medicine. *Sodium Intake in Populations: Assessment of Evidence*. Washington, DC: The National Academies Press(2013).

¹⁰³ 79 Fed Reg 11917

¹⁰⁴ 79 Fed Reg 11915-11916

iv. Given recent scientific developments, a re-evaluation of the sodium DRI may be warranted.

Although it is unlikely that results could be available for this iteration of nutrition label changes, we urge FDA to request the IOM to establish a credible independent panel through the IOM to re-evaluate the DRI for sodium considering all the evidence on biomarkers, human physiology, cardiovascular disease, and mortality. This panel should include a range of expertise related to the science of sodium including nutritionists, epidemiologists, clinicians, nephrologists, and renal physiologists. Interestingly, a more recent meta-analysis by Graudal and colleagues, which included 25 separate studies encompassing over 250,000 participants further shows that there is a U-shaped relationship between sodium intake and health outcomes.¹⁰⁵ This U-shaped relationship could enable a more precise determination of intake levels to be achieved rather than relying on the existing dietary modeling data and a somewhat arbitrary cutoff on a continuous scale.

c. Other dietary approaches and lifestyle modifications can assist in blood pressure reduction.

While limiting sodium may help lower blood pressure levels, not addressing a holistic diet and lifestyle change will inappropriately misdirect consumers to a “one-size fits all” mentality which may have unintended dietary consequences. Research has shown that other dietary modifications, such as a diet high in potassium, low in fat, and rich in minerals, can blunt the effects of sodium on blood pressure.^{106, 107} Encouraging a holistic approach to reducing sodium intake, such as promoting an overall dietary pattern consistent with the Dietary Approaches to Stop Hypertension (DASH) diet, should be reinforced and promoted to help shift dietary patterns.

Separately, research demonstrates that weight management may also have a significant benefit on blood pressure reductions. For example, data has shown lifestyle modifications that result in weight reduction, such as reducing calories and increasing physical activity, should be a major component in the treatment of hypertension.¹⁰⁸ Research shows that physical activity, and more so physical fitness, has a dose-dependent blood pressure benefit, and even modest physical activity can have a meaningful impact on blood pressure.¹⁰⁹

¹⁰⁵ Graudal, N., et al. “Compared with Usual Sodium Intake, Low- and Excessive-Sodium Diets are associated with increased Mortality: A Meta-Analysis.” *American Journal of Hypertension* (2014).

¹⁰⁶ Schmidlin, O., et al. “NaCl-Induced Renal Vasoconstriction in Salt-Sensitive African Americans: Antipressor and Hemodynamic Effects of Potassium Bicarbonate.” *Hypertension*. 33(2):633-639 (1999).

¹⁰⁷ Appel, L.J., et al. “A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure.” *New England Journal of Medicine*. 336(16):1117-1124 (1997).

¹⁰⁸ Neter, J.E., et al. “Influence of Weight Reduction on Blood Pressure: A Meta-Analysis of Randomized Controlled Trials.” *Hypertension*, 42(5):878-884 (2003).

¹⁰⁹ Frisoli, T.M., et al. “Beyond Salt: Lifestyle Modifications and Blood Pressure.” *European Heart Journal*. 32(24): 3081-3087 (2011).

Restricting and focusing attention on a single ingredient, such as sodium, may not be successful in improving consumers' overall eating behaviors and health.

d. General Mills agrees with the Agency that revising the DRV to 2300 mg would yield less consumer confusion than changing to an RDI of 1500 mg.

General Mills agrees with the Agency that a DRV of 2300 mg is the most appropriate Daily Value to assist consumers in maintaining healthy dietary practices and in understanding the relative significance of the sodium content within the context of a total daily diet. Specifically, we agree that consumers are generally aware that sodium intakes should be managed, and therefore the current consumer education messaging is consistent with a DRV of 2300 mg. For example, consumer data from the IFIC 2014 Food and Health Survey shows that 62% of respondents consider sodium when making food purchasing decisions, second only to calories (70% of respondents), and 53% of consumers make an effort to limit or avoid sodium when making food or beverage decisions.¹¹⁰ Further, we believe that an unrealistic and restrictive goal, such as a Daily Value change to 1500 mg, is more likely to alienate consumers and de-motivate them from making dietary changes to a seemingly unachievable goal.

e. General Mills agrees with FDA's views and recommends that the current qualifying sodium level for claims be retained.

GMI supports retaining the qualifying level of sodium for claims of 480 mg.¹¹¹ If the proposed Daily Value of 2300 mg is finalized, a proportional decrease of 20-30 mg in the sodium qualifying level would not significantly change the labeled percent Daily Value and will not be impactful in the context of consumers' overall diets. As the Agency previously noted, technological barriers and consumer product acceptance issues may result from a more restrictive sodium qualifying level.¹¹²

¹¹⁰ International Food Information Council Foundation. "2014 Food & Health Survey: Consumer Attitudes toward Food Safety, Nutrition & Health." Washington, DC: U.S. (2014).

¹¹¹ Per 21 CFR 101.65, the disqualifying level of sodium for a health claim is 480 mg per reference amount and per labeled serving size for products with a reference amount of 30 g or less or 2 tablespoons or less, per 50 g for a non-meal product or 600 mg sodium per serving for main dish products. 480 mg is currently 20% of the 2400 mg DV for sodium (or 600 mg/25% DV for main dish/meal products)

¹¹² 79 Fed Reg 11916

IV. Labeling of Potassium

- a. General Mills does not support FDA's tentative conclusion to replace the existing DRV for potassium until there is sufficient science to establish an RDA.**

While General Mills supports FDA's efforts to update and align the RDIs with newer research and specifically the DRIs set by the IOM, we do not support an update without sufficient scientific support. As referenced by FDA,¹¹³ the IOM has established specific AIs for potassium due to its health effects of lowering blood pressure, blunting adverse effects of sodium intake on blood pressure, reducing the risk of kidney stones and decreasing the risk of bone loss.¹¹⁴ Additionally, the 2010 Dietary Guidelines has concluded that potassium is a nutrient of concern for the general American population.¹¹⁵ As cited by FDA,¹¹⁶ usual mean intakes of potassium from the diet is 2644 mg per day (NHANES 2003-06) and are well below the current population-weighted AI of 4622 mg per day (and the current DRV of 3500 mg per day) indicating that potassium is a shortfall nutrient.

While General Mills recognizes the importance of potassium in the diet for overall health, we are not supportive of increasing the DRV based on the AI, because there is insufficient evidence to support this significant increase. The numerical Daily Value proposed for potassium is based on an intake that is *assumed to be adequate* because an IOM Committee (2005) concluded that there was insufficient data to determine an EAR, and hence an RDA. There is now additional evidence^{117, 118} that is more reflective of the current state of the science and recognizes the importance of the sodium-to-potassium ratio. General Mills encourages the IOM to re-assess the DRI for potassium in light of new data to determine if the current AI is truly reflective of actual requirements. Until such time, General Mills proposes maintaining the current DRV for potassium as we believe this value is most reflective of the science and the best representation of dietary needs to consumers.

- b. General Mills recommends the declaration of potassium should continue to immediately follow the declaration of sodium.**

Based on public health and scientific and regulatory rationale, we question the separation of potassium from sodium on the Nutrition Facts label. A dietary interrelationship exists between these two nutrients, which has been recognized by scientists and policy makers

¹¹³ 79 Fed Reg 11930

¹¹⁴ United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*. Washington, DC: The National Academies Press (2005).

¹¹⁵ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office (2010).

¹¹⁶ 79 Fed Reg 11922

¹¹⁷ Weaver, C.M. "Potassium and Health." *Advances in Nutrition*. (4):368S-377S (2013).

¹¹⁸ Aburto, N.J., et al. "Effects of Increased Potassium Intake on Cardiovascular Risk Factors and Disease: Systematic Review and Meta-Analyses." *BMJ*. 346:f1378 (2013).

alike. For example, the 2010 Dietary Guidelines recommend that Americans simultaneously reduce sodium intakes while increasing potassium intakes.¹¹⁹

Scientific rationale for these public health recommendations is in part based on the interrelationship that has been demonstrated between sodium and potassium intakes, in that the sodium-to-potassium ratio is an important risk factor for cardiovascular disease. Research shows that higher intakes of sodium are related to increased prevalence of high blood pressure, whereas dietary potassium can blunt the adverse effects of sodium.¹²⁰ Specifically, it has been shown that urinary sodium-to-potassium ratio is directly related to systolic blood pressure,¹²¹ a risk factor for cardiovascular disease. Additionally, in recent analyses of NHANES III data (1988–1994), higher sodium-to-potassium ratios were associated with a higher risk of all-cause and cardiovascular disease mortality.¹²²

FDA has previously recognized the importance of potassium and its relationship to sodium in the risk reduction of chronic diseases. Specifically, in 2000, a FDAMA notification for a health claim about potassium, blood pressure and stroke was submitted to FDA. No objection was made by the Agency and as such, food companies can make the following claim “*Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke.*” For the large portion of the population who are managing blood pressure and CVD, sodium and potassium are generally a key focus and are often highlighted together. Therefore, it would be helpful for both consumer understanding and food formulation practices to continue to place the declaration of sodium and potassium in proximity to each other so balance could be observed.

V. Labeling of Vitamins A, C, D, Calcium, Iron and Potassium

General Mills continues to support the mandatory labeling of Vitamins A and C, supports the mandatory labeling of potassium, and questions the practicality of mandatory Vitamin D labeling. Vitamins A, C and D, calcium, iron, and potassium are all important nutrients of need. As further explained below, vitamins A and C continue to be nutrients of need that FDA should continue to encourage through labeling. Consumers will continue to seek products with vitamins A and C, which are markers for and promote fruit and vegetable intake. Although Vitamin D is also an important nutrient of need, mandatory labeling of Vitamin D poses questions for its practicality and implementation.

¹¹⁹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office (2010).

¹²⁰ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office (2010).

¹²¹ Tzoulaki, I., et al. “A Nutrient-Wide association Study on Blood Pressure.” *Circulation*. (21):2456-64 (2012).

¹²² Yang Q., et al. “Sodium and Potassium Intake and Mortality among US Adults: Prospective Data from the Third National Health and Nutrition Examination Survey.” *Archives of Internal Medicine*. (13):1183-91(2011).

a. Vitamins A, C and D, calcium, iron, and potassium are all important nutrients of need.

Vitamin D, calcium, iron, and potassium are nutrients of need and should be encouraged, but, as FDA has acknowledged and data supports, intakes of vitamins A and C are not at the recommended levels and remain important nutrients of need for several groups of individuals. Based on 2009-10 NHANES data and shown in Table 4, significant portions of the population fall short of recommended vitamin A and C intakes. For vitamin A, 46% of 13–18 year olds had intakes below the EAR and nearly 48% of 19-50 year olds had intakes below the EAR. For vitamin C, nearly 33% of 13-18 year olds had intakes below the EAR and almost 43% of 19-50 year old had intakes below the EAR. Interestingly, nearly 40% and 36% of those surveyed from the general population (2+ years old) had Vitamin A and C intakes below the EAR, respectively. Research from this dataset emphasizes that some individuals are not meeting the recommended intake levels of vitamins A and C. In addition, FDA has acknowledged the importance of Vitamin C by proposing to raise the Daily Value.¹²³

Table 4: Intakes of vitamins A and C based on 2009-2010 NHANES

	<i>2+ years, percent below EAR</i>	<i>6-12 year olds, percent below EAR</i>	<i>13-18 year olds, percent below EAR</i>	<i>19-50 year olds, percent below the EAR</i>
<i>Vitamin A</i>	39.2	12.8	46.1	47.7
<i>Vitamin C</i>	35.7	14.1	32.6	42.7

b. Consumers continue to seek Vitamins A and C in food products.

In addition, consumers are looking for vitamins A & C and, in fact, are trying to purchase more products containing these vitamins. A study done by NPD reveals that 50% of shoppers are trying to get more vitamin C and 40% are trying to get more vitamin A.¹²⁴ Additionally, The 2013 HealthFocus® Trend Report, A National Study of Public Attitudes and Actions, found that the importance of numerous label claims remains relatively steady with more than 40% of shoppers looking for “good source claims.” Specifically, 40% are looking for food products that are a “good source of antioxidants” (e.g., Vitamin C).

c. Vitamins A and C are markers of fruit and vegetable intake.

Vitamins A and C are generally abundant in fruits and vegetables, which are foods that are generally under-consumed and should continue to be encouraged.¹²⁵ Because most vegetables and fruits are major contributors of a number of nutrients that are under-

¹²³ 79 Fed Reg 11931

¹²⁴ NPD Group, Inc. *NPD Group Dieting Monitor* (2014).

¹²⁵ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office (2010).

consumed in the United States, encouraging consumers to look for foods with vitamins A and C may encourage the consumption of fruits and vegetables. In fact people with higher vegetable consumption better meet their recommendations for Vitamins A and C.¹²⁶

d. Database and regulatory challenges exist for Vitamin D.

It is important for FDA to know that there is limited data available on the vitamin D content in many foods and ingredients, thus making it difficult for companies to provide this information on the label. An analysis of 7,819 foods in the USDA nutrient database reveals that ~1/3 of those foods are missing values for Vitamin D. This does not take into account the thousands of food ingredients that are also missing Vitamin D values. If labeling vitamin D becomes mandatory, it will take time and resources for all companies to populate these values so they can be included on product Nutrition Facts labels.

Additionally, fortification with vitamin D presents challenges from a regulatory perspective. As provided in 21 C.F.R. 172.379 and 172.380, there are limited levels permitted for vitamin D fortification. Specifically, the amount of vitamin D that may be added to dairy products is tightly controlled through the requirements of product standards of identity and through food additive regulations. Currently, many dairy products are good or excellent sources of vitamin D through fortification of these products. Given the proposed 200% increase in the Daily Value of vitamin D, these products may no longer meet these good or excellent source levels. The food additive regulations and standards of identity for dairy foods would need to be revised to allow for higher levels of fortification to permit dairy products to continue to be good or excellent sources of vitamin D.

VI. Daily Value revisions and implications for fortification

a. General Mills agrees with FDA that using the RDAs as the basis for the RDIs will not lead to widespread overconsumption due to discretionary fortification.

FDA requested comment on their analysis and for additional information regarding the basis of the Daily Value (EAR or RDA) has in consumption of the nutrients above the UL in discretionary fortification of foods. General Mills appreciates the due diligence of FDA's analysis¹²⁷ to better understand the potential risk for excessive intakes of vitamins and minerals from both foods and dietary supplements. We support the Agency's conclusions

¹²⁶ Gugger, C., S. Bidwai, N. Joshi, N. Holschuh, and A. Albertson. "Vegetable Consumption and Associated Nutrient Intakes in the United States: Results from NHANES 2009-10 and the New USDA Food Patterns Equivalents Database" *Journal of the Federation of American Societies for Experimental Biology*, (28):S1023.5 (2014).

¹²⁷ Department of Health and Human Services. *Documentation for the methodology used to determine total usual intakes of vitamins and minerals compared to Tolerable Upper Levels (UL) and results of analysis*. Memorandum dated February 14, 2014.

and believe additional data^{128, 129} also supports FDA's analysis and conclusions, as provided in Appendix D.

b. General Mills agrees with the Agency that using either the EARs or RDAs for the RDIs will not increase the risk for overconsumption of vitamins and minerals.

Research supports the value of fortification which is generally accepted by consumers, policy makers and regulatory agencies in the United States. Judicious fortification has helped both correct and prevent nutrition inadequacies and in some cases deficiencies, and recent research has pointed out the valuable role fortified foods have in the modern food supply. Appendix D further describes the numerous benefits of fortification. General Mills supports the Agency's current fortification policy¹³⁰ and agrees with the conclusions of FDA's thorough analysis comparing total dietary intakes of vitamins and minerals to ULs, such that regardless of whether the basis of the RDIs is the EAR or RDA, it is unlikely that widespread overconsumption of certain vitamins and minerals is a risk if manufacturers continue to follow judicious fortification practices.¹³¹

While FDA gives food manufacturers some discretion in determining how much and when to fortify food products, general guidance offered by FDA and the IOM ensure thoughtful and practical fortification decisions to minimize overexposure of certain fortificants to the population overall and to specific subpopulations. The decision-modeling approach as proposed by the IOM provides a clear process for evaluating the scientific rationale for fortification of a particular food and ingredients.¹³² Adoption of this decision tree approach within FDA fortification policy would enhance the objectivity used in making fortification decisions.

c. General Mills supports lowering the RDI for vitamin B12 from 6 mcg to 2.4 mcg.

We support reducing the vitamin B12 RDI to 2.4 mcg, as it is in line with the RDA established by the IOM in 2000. As noted by FDA, NHANES data indicates that ready-to-eat cereal is a primary source of crystalline B12 added to food. As noted by the Agency in the proposed rule, if the proposed RDI for vitamin B12 is adopted, manufacturers of fortified ready-to-eat cereals and other products may adjust fortification levels of vitamin B12 to

¹²⁸ Fulgoni III, V.L., et al. "Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?," *The Journal of Nutrition*. (141):1847-1854 (2011).

¹²⁹ Berner, L.A., et al. "Fortified Foods Are Major Contributors to Nutrient Intakes in Diets of US Children and Adolescents." *Journal of the Academy of Nutrition and Dietetics*. (114):1009-1022 (2014).

¹³⁰ §104.20

¹³¹ Department of Health and Human Services. *Documentation for the methodology used to determine total usual intakes of vitamins and minerals compared to Tolerable Upper Levels (UL) and results of analysis*. Memorandum dated February 14, 2014.

¹³² United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes Guiding Principles for Nutrition Labeling and Fortification*. Washington, D.C.: The National Academies Press (2003).

maintain their current Daily Value claim levels, thereby creating an overall reduction in the amount of crystalline vitamin B12 in the food supply. Based on current research by Murphy et al, it is unlikely that this change will lead to a significant increase in the proportion of the population with inadequate dietary intakes of vitamin B12. Researchers examined this same scenario by conducting a modeling exercise to better understand the implications of Daily Value revisions assuming that manufacturers would choose to maintain current label claims for fortified micronutrients.¹³³ Two different potential Daily Value scenarios were examined: the population-weighted EAR and the population coverage RDA. Results indicated that the difference in the proportion of the total population (≥ 4 years) with usual intakes of vitamin B12 less than the EAR would be about 3% regardless of whether the revised Daily Value was based on the population-weighted EARs or the highest RDAs. This is within two percentage points of the percentage calculated by using the current Daily Value. With regards to specific subpopulations, results for older adults and teenage girls are a little higher, but similar regardless of the approach. Vitamin B12 would continue to be a nutrient to promote to at-risk subpopulation groups. General Mills recommends continued monitoring of population intake and science to determine if at-risk subpopulations are meeting recommendations.

VII. Units of measure revisions for folic acid and vitamin E

In previous comments to the Agency, General Mills supported the unit conversion to μg RAE (retinol activity equivalents), μg , mg α -tocopherol and μg DFE (dietary folate equivalents) for the Daily Values for vitamins A, D, E, and folic acid, respectively.¹³⁴ We agree these conversions would allow for harmonization with more recent DRI reports and the 2010 Dietary Guidelines. However, certain complexities arise, particularly for folic acid and vitamin E, and warrant additional consideration. These complications are also commented on in the Records Requirements and Compliance section below.

a. Folate and Folic Acid

i. General Mills does not support the replacement of units of measure for folic acid.

Whereas we agree that the conversion to Dietary Folate Equivalent (DFE) would allow for harmonization with the DRIs, we oppose the replacement of units of measure for folic acid for the purposes of food labeling. As noted by the Agency,¹³⁵ there are no analytical methods that differentiate between the naturally occurring and synthetic forms, and thus the unit conversion of folic acid to DFEs would necessitate additional record keeping to measure compliance for this nutrient labeling. General Mills is opposed to this framework

¹³³ Murphy, M.M., et al. "Revising the Daily Values May Affect Food Fortification and in Turn Nutrient Intake Adequacy." *The Journal of Nutrition*. 143:1999-2006 (2013).

¹³⁴ General Mills' public comments submitted to FDA Docket ID: FDA-2007-0566 [April 30, 2008]

¹³⁵ 79 Fed Reg 11933

for compliance and Agency enforcement, as outlined in the Records Requirements and Compliance section below.

ii. General Mills believes that the term “folic acid” should continue to be allowed in the labeling of conventional foods.

We oppose removing the provision for the optional declaration of “folic acid” in conventional foods. While FDA acknowledges that education efforts would need to be provided to assist with consumer understanding of the new “equivalent” units of measure for folic acid, the Agency does not recognize updating the labeling term to “folate” versus “folic acid” would also affect consumer recognition of this labeling change.¹³⁶ The enrichment of grain-based foods with folic acid was mandated by FDA in 1996 in order to reduce the risk of neural tube defects. Since that time, women of child-bearing age, especially those who are pregnant or planning to be, have been encouraged to consume the recommended amounts of “folic acid”. While this affects a subset of the population, campaigns and education efforts (by healthcare providers, WIC, March of Dimes, dietitians, etc.) are clear and directly targeted to encourage foods, such as ready-to-eat cereals, that contain “folic acid.” The change to the word “folate” would have little benefit to consumers or public health but would require significant re-education efforts by the government (e.g. Women, Infants, and Children Program), health care providers, non-profits (e.g. March of Dimes) and industry. Furthermore, the majority of folic acid consumed by individuals is in the form of synthetic “folic acid” from enriched/fortified foods and dietary supplements.¹³⁷ Given these concerns, it would make practical sense that the Nutrition Facts label would continue to allow the declaration of “folic acid.”

With regards to the approach cited by FDA allowing for the declaration of folic acid quantity in parentheses similar to that permitted for the percent of vitamin A as beta carotene, General Mills does not see this as a feasible or practical alternative to folic acid labeling due to space availability on the label and font size requirements.¹³⁸

b. Vitamin E

i. General Mills does not support the record requirements for vitamin E.

General Mills recognizes the need to update the unit of measure for vitamin E. With this update comes the analytical challenge of distinguishing between *all* rac- α tocopherol acetate and RRR- α tocopherol in order to provide an accurate value. Because no analytical

¹³⁶ 79 Fed Reg 11932

¹³⁷ Fulgoni III, V.L., et al. “Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?,” *The Journal of Nutrition*. (141):1847-1854 (2011).

¹³⁸ 79 Fed Reg 11932; FDA cited the following example: “For example, for a conventional food that contains both folic acid and folate, the total mcg DFE could be declared and in parenthesis indicate how much is from folic acid.”

methods exist which distinguish between these two stereoisomers, manufacturers would be required to maintain records to support the declared value of vitamin E on products. As outlined below, GMI opposes the proposed records requirements for compliance and Agency enforcement.

Labeling of Calories, Fat, Other Carbohydrates and Protein

I. General Mills supports FDA's proposal to remove the declaration of calories from fat and to not establish a DRV or percent Daily Value for calories.

General Mills supports FDA's proposal to remove the declaration of calories from fat from the Nutrition Facts label. Original nutrition labeling regulations placed an emphasis on reducing risk of heart disease, and at that time it was believed that calories from fat (and percent calories from fat) were critical in modulating risk. More recent recommendations^{139, 140} (e.g. IOM and 2010 Dietary Guidelines), however, support more flexibility in the daily allowance for total fat (20-35% of calories, rather than <30% of calories) and emphasize that the type versus the quantity of fat is important. Furthermore, scientific evidence concludes that overall caloric intake rather than a strict proportion of macronutrient intakes are important for weight management.

Additionally, General Mills supports FDA's rationale and decision not to establish a DRV for calories or percent Daily Value for the declaration of calories. As noted by the Agency, there is a lack of an appropriate quantitative intake recommendation to establish a DRV for calories.¹⁴¹ The estimated energy requirements (EERs) from the IOM macronutrient report does not provide an appropriate basis for the derivation of a reference calorie intake level for the purpose of nutrition labeling, as noted by the IOM Labeling Report.^{142, 143} Additionally, daily calorie needs vary greatly by individual, and a Daily Value for calories could be interpreted by consumers that 2,000 calories is what everyone needs

¹³⁹ United States. National Academy of Sciences. Institute of Medicine *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, D.C: National Academy Press (2002).

¹⁴⁰ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th Edition, Washington, DC: U.S. Government Printing Office (2010).

¹⁴¹ 79 Fed Reg 11893

¹⁴² United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, D.C: National Academy Press (2002).

¹⁴³¹⁴³United States. National Academy of Sciences. Institute of Medicine. *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*. Washington, D.C: National Academy Press (2003).

II. General Mills supports the continued mandatory declaration and DRVs for total fat and saturated fat.

General Mills agrees with FDA's rationale and proposal in regards to total fat and saturated fat. For total fat, we are in support of keeping the current definition, requirement for mandatory declaration, and DRV of 30% of calories. For saturated fat, General Mills supports FDA's proposal to continue the required declaration of the percent Daily Value for saturated fat and the DRV of 20 g.

III. General Mills supports the continued declaration of trans fat and urges FDA to consider <0.2 grams for the declaration of 0 grams trans fat.

GMI is aware of the published tentative determination citing that partially hydrogenated oils, the source of industrially produced trans fat, may not be generally recognized as safe.¹⁴⁴ GMI submitted comments to the Agency on this notification and request that the Agency reference those remarks.¹⁴⁵ FDA is requesting comments on whether mandatory labeling of trans fat would still be necessary if this determination is finalized. In General Mills' comments regarding the tentative determination, we urged the Agency to not move forward with the revocation of the GRAS status of partially hydrogenated oils. However, if this determination is finalized, General Mills still supports the continued declaration of trans fat and also urges the Agency to consider an alternative declaration of 0 g. It is important that trans fat continue to be labeled because consumers may not be aware of natural sources of trans fat if it is not labeled; this is information consumers need in order to make informed dietary choices.

General Mills urges FDA to consider revising nutrition labeling regulations to permit a declaration of 0 g of trans fat only if the product contains less than 0.2 g of trans fat per serving, versus the current 0.5 g per serving. It should be noted that this is the same approach taken in Canada in regards to labeling trans fat. This approach offers an effective regulatory alternative to encourage continued progress towards FDA's goal of significantly reducing consumption of industrial produced trans fat.

In 2003, FDA added trans fat as a mandatory nutrient on the Nutrition Facts label providing consumers with the information needed to reduce their intake of trans fat. Responding to consumers' desire to lower their trans fat intake, the food industry has diligently worked over the past decade to reduce trans fat in food products, often with a goal of labeling foods as 0 g trans fat per serving. This resulted in a 78% decrease in trans fat intakes from PHOs since that time. Thus, revising the nutrition labeling regulation and lowering the maximum

¹⁴⁴ 78 Fed Reg 67169

¹⁴⁵ General Mills' public comments submitted to FDA Docket ID: FDA-2013-N-1317. Comments ID: FDA-2013-N-1317-0156 and posted on FDA website 03/21/2014.

amount permitted for a declaration of 0 g to less than 0.2 g per serving would be an incentive to drive further reductions of trans fat intakes in the U.S.

We recognize that the proposed rule stated that FDA is not aware of “[v]alidated analytical methodologies that provide sensitive and reliable estimates of trans fatty acids in all foods at levels below 0.5 g per serving are currently not available.” However, validated analytical methodology exists to detect trans fat below 0.5 g per serving, and GMI believes such methods could successfully be implemented for compliance.¹⁴⁶

IV. General Mills supports retaining the provision for voluntary labeling of “Other Carbohydrates”.

General Mills supports retaining the provision for voluntary labeling of “Other Carbohydrates” on the Nutrition Facts label. This declaration allows interested, knowledgeable consumers to better understand the “Total Carbohydrates” portion of the Nutrition Facts label, as the various components that make up Total Carbohydrates come closer to adding up with “Other Carbohydrates” included. In addition, “Other Carbohydrates” is currently commonly labeled voluntarily within certain product categories (e.g., ready-to-eat cereals) and removing this line could cause consumer confusion for those interested in that information.

V. General Mills supports maintaining the declaration of protein and the current DRV.

General Mills supports FDA’s proposal to maintain the requirement for declaring protein, and the voluntary declaration of the percent Daily Value, except for when a claim is made. We also support maintaining the DRV for protein of 50 g.

Single-Serving Containers, Dual-Column Labeling and RACCs

General Mills supports changes to the Nutrition Facts label and serving size information to help increase consumer awareness and utility of the information presented. We support efforts to provide consumers with more accurate and up-to-date information on serving sizes, and we support the majority of the Agency’s conclusions regarding changes to Reference Amounts Customarily Consumed (RACC). As the Agency acknowledges, a body of research indicates that package and portion size can impact overall consumption^{147,148,149,150}; however, General Mills is concerned that this research does not

¹⁴⁶ AOAC 996.06

¹⁴⁷ Rolls, B.J. et al. “Portion Size of Food Affects Energy Intake in Normal-Weight and Overweight Men and Women.” *The American Journal of Clinical Nutrition*. 76:1207-13 (2002).

¹⁴⁸ Wansink, B., and J. Kim. “Bad Popcorn in Big Buckets: Portion Size Can Influence Intake as Much as Taste.” *Journal of Nutrition Education and Behavior*, 37(5):242-5 (2005).

provide sufficient evidence to support the proposed serving size modifications (single-serving containers and dual-column labeling) and their broad application for all food categories and the general population.

I. General Mills does not fully support the proposed changes to the single-serving container definition.

General Mills supports FDA's decision not to change existing regulations that use a cutoff of less than 200% of the applicable RACC as the criterion for labeling a product as a single-serving container. General Mills agrees that, by definition, a product that contains more than 200% of the RACC would not be a "single" serving. General Mills also notes that increasing the cutoff above 200% may lead to unintended consequences by encouraging manufacturers to increase package sizes to avoid single-serving labeling and less favorable nutrition information.

However, we disagree with FDA's proposal to eliminate the current 21 C.F.R. §§ 101.9(b)(6) and 101.9(b)(2)(i)(D)-(E), which give manufactures flexibility to label products with a RACC of over 100 g (or 100 mL) that provide 150-200% of the RACC as 1 or 2 servings.¹⁵¹ FDA supported its decision to eliminate this regulation based on an analysis of the correlation between consumption variation and the RACCs for all products containing less than 200% of the applicable RACC. FDA asserts this analysis demonstrated that a consumer is not less likely to consume approximately twice the reference amount of a food with a large RACC as a food with a smaller RACC.¹⁵² We believe the Agency's analysis is flawed.

Average variability in the analysis was defined by the Agency as the standard deviation as a percent of the mean, and represents the standard deviation of individual intakes from one person to the next. However, the standard deviations of the medians in all tables in the Agency's analysis are actually the standard errors of the medians and not the standard deviations of individual intakes as previously described.¹⁵³ Therefore, it does not appear that the Agency has actually conducted the appropriate analysis, and no conclusion should be drawn from these reported summaries. We urge the Agency to reconsider the removal of this exemption without appropriate data to support this modification.

¹⁴⁹ Rolls, B.J. et al. "Increasing the Portion Size of a Sandwich Increases Energy Intake." *Journal of the American Dietetic Association*. 104:367-752 (2004).

¹⁵⁰ Schwartz, J., and C. Byrd-Bredbenner. "Portion Distortion: Typical Portion Sizes Selected by Young Adults." *Journal of the American Dietetic Association*. 106:1412-8 (2006).

¹⁵¹ 79 Fed. Reg. 12001.

¹⁵² 79 Fed Reg 12001.

¹⁵³ Juan, W., Memorandum to file: "Technical Support for Documentation on Examining the Association between the Foods Consumed in the United States from NHANES 2003-2008 at the 90th percentile and Reference Amounts Customarily Consumed (RACCs) per Eating Occasion by General Category and Product Category." February 11, 2014.

II. General Mills does not support the proposed requirement for mandatory dual-column labeling.

FDA should not require dual-column labeling for food packages that contain between 200% and 400% of the RACC. First, making such a broad mandatory requirement may actually decrease the utility of the Nutrition Facts label by cluttering the label and making it difficult for consumers to read. Second, FDA's decision to establish 400% of the RACC as the cutoff for dual-column labeling is arbitrary. Finally, applying dual-column labeling for all products is impractical and will likely lead to consumer confusion.

Mandatory dual-column labeling will needlessly clutter many food labels. The comparison of Figures 5 & 6 on the following page illustrates the added density of nutrient information with the proposed dual-column label. The dual column adds significant complexity to the existing Nutrition Facts label.

Figure 5. Current Nutrition Facts Label Example for Soup



Figure 6. Proposed Nutrition Facts Label Example for Soup



Further, FDA's decision to use a cutoff of 400% of the RACC is unreasonable. FDA established the 400% of the RACC cutoff based on the 90th percentile of consumption, but

the 90th percentile, by definition, well-exceeds the amount most consumers eat. In fact, even at the 90th percentile, consumers eat significantly less than 400% of the RACC. We reviewed FDA's data used to support the decision to use 400% of the RACC and found that in 84% of the food categories reviewed, average consumption was 299% or less of the RACC and in 68% of categories, average consumption was 250% or less of the RACC¹⁵⁴. Only a small number of product categories had consumption greater than 300% of the RACC, and those categories, which included wine coolers, fluid cream, lemon and lime juice, horseradish and mustard, are not commonly consumed categories that should drive labeling changes.

Finally, mandatory dual-column label format requirements would also lead to impractical labeling of products that are rarely consumed at 400% of the RACC. For example, a 16 ounce container of cottage cheese and a quart of juice contain 400% of their respective RACCs, and under the Agency's proposal, would require dual-column labeling. However, consumers rarely eat or drink these large amounts. Similarly, with the proposed increase in RACC for "bagels, toaster pastries, muffins (excluding English muffins)," a package of 6 toaster pastries would fall within 200%-400% of the RACC, triggering the requirement for a dual-column label. However, consumption data indicates that less than 4% of consumers across all age categories consume more than 2 pastries at one time, and almost no consumers would eat an entire box of 6 toaster pastries.¹⁵⁵ Requiring labeling of the entire box of toaster pastries would be impractical since the majority of consumers would never eat an entire box in one sitting, and it may even lead to over-consumption if consumers think the label suggests they should consume the entire package.

Although General Mills does not support mandatory dual-column labeling, if the Agency moves forward with these requirements, General Mills recommends the use of a label format that includes only calorie information per serving and per container following the serving size information in the Nutrition Facts label. In order to help meet public health goals of reducing obesity and improving health, Nutrition Facts label changes should focus and emphasize the necessary information of calories and serving sizes. A label that follows this approach would provide consumers with information they need to accurately identify the number of calories in a product, but would also save space and avoid cluttering the Nutrition Facts label. In the Lando Study,¹⁵⁶ it was noted that "a label format with dual listings for calories only had the next highest level of accuracy (total correct) on the broad index of the nutrient content questions posed to study participants compared to the accuracy of the one serving, single-column format and two serving, dual-column formats."

¹⁵⁴ Juan, W., Memorandum to file: "Comparison between the foods consumed in the United States from NHANES 2003-2008 at the 90th percentile and Reference Amounts Customarily Consumed (RACCs) per eating occasion by general category and product category," February 11, 2014

¹⁵⁵ Research conducted by General Mills internal Consumer Research Services (2005)

¹⁵⁶ Lando, A.M., and S.C. Lo. "Single-larger-Portion Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Food Choices." *Journal of the Academy of Nutrition and Dietetics*, 113:241-50 (2013).

If FDA proceeds with dual-column labeling, we also recommend that FDA create exemptions for certain products. GMI supports FDA's tentative conclusion that products that require further preparation should be exempt from dual-column labeling. Similarly, FDA should exempt products that voluntarily include an additional column of nutrition information, such as products labeled for children under 4 years and over 4 years, products that are most often consumed with other foods (e.g., cereal with milk) and products in discrete units that provide an additional column of nutrition information per unit. These labels all provide additional information that represent the product "as consumed" and provide helpful information to consumers. Finally, General Mills supports the Agency's conclusion that products using a tabular or linear Nutrition Facts label should be exempt from dual-column labeling requirements. For all of these types of labels, adding additional nutrition information will make the Nutrition Facts label more difficult for consumers to read and interpret.

III. General Mills is concerned that the proposed changes to the single-serving container definition and dual-column labeling, when considered in combination with other serving size proposed changes, could foster confusion for consumers in the marketplace.

Inconsistencies in serving sizes at the point where consumers are comparing and selecting products will introduce unnecessary challenges. The Agency has also highlighted this consideration and the importance of consistency in order to "allow consumers to view the same type of label and make an easy comparison."¹⁵⁷ When the proposed changes to the single-serving container definition, dual-column labels and RACCs are considered in combination, products within the same category would have competing label formats and serving sizes in the marketplace. At a minimum, consumers would see three label formats, with different serving sizes, when comparing products. This confusing scenario is exemplified in Appendix E, which summarizes a market analysis of the soup and frozen vegetable categories. It is likely that consumers may not recognize and understand these different serving sizes, particularly when presented across multiple label formats, and therefore be challenged to appropriately compare similar products to inform their dietary selections. We urge FDA to consider these proposed changes collectively and reconsider their utility given these potential unintended consequences and likely consumer confusion.

IV. Evidence is lacking to demonstrate that single-serving container and dual-column labeling would be effective for all product categories and the general population.

Although research indicates package and portion size can impact intake during an individual eating occasion, evidence supports this for products within certain categories,

¹⁵⁷ 79 Fed Reg 12003

namely snack foods;^{158, 159, 160} however, many other food categories have not been examined. Therefore, General Mills cautions the agency to generalize these findings across all food categories.

The Agency highlighted several studies as rationale for the proposed single-serving container and dual-column labeling requirements.^{161,162} Results from the Antonuk study suggest that dual-column labeling would lead consumers who are not dieting to reduce their consumption.¹⁶³ However, the investigators caution that consumers who are not dieting are less likely to pay attention to nutrition information on labels. They further suggest that additional research is needed to understand the impact of dual-column labeling in less artificial environments to address the large population of consumers who are not actively dieting. Results from the Lando study suggest that single serving per container labels and dual-column labels resulted in more participants correctly identified the number of calories and other nutrients per container and per serving compared to two serving, single-column labels.¹⁶⁴

It should also be noted that the research cited was not conducted using the proposed new Nutrition Facts label format, which more clearly emphasizes both calories and serving size. The Obesity Working Group final report emphasized the importance of calorie balance in weight control and recommended an emphasis on calories. General Mills agrees that increasing consumer awareness of calorie information is important, and feels that the Agency's increased prominence of calories on the Nutrition Facts label will support enhanced consumer understanding. Comprehensive and thorough consumer research on the totality of the proposed changes and the various Nutrition Facts label formats must be completed and published before issuing a final rule. This research would ensure proposed revisions would be easy for consumers to understand, meaningful and useful in guiding dietary choices. Further, General Mills does not believe that the evidence from existing research on the single-serving container and dual-column labeling formats is sufficient to support a mandatory requirement for these label formats across all product categories.

¹⁵⁸ Rolls, B.J., L.S. Roe, T.V. Kral, J.S. Meengs, and D.E. Wall. "Increasing the Portion Size of a Packaged Snack Increases Energy Intake in Men and Women." *Appetite*, 42(1):63-9 (2004).

¹⁵⁹ Wansink, B., and J. Kim. "Bad Popcorn in Big Buckets: Portion Size Can Influence Intake as Much as Taste." *Journal of Nutrition Education and Behavior*, 37(5):242-5 (2005).

¹⁶⁰ Wansink, B., and M.M. Cheney. "Super Bowls: Serving Bowl Size and Food Consumption." *Journal of the American Medical Association*, 13(14):1727-8 (2005).

¹⁶¹ Lando, A.M., and S.C. Lo. "Single-larger-Portion Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Food Choices." *Journal of the Academy of Nutrition and Dietetics*, 113:241-50 (2013).

¹⁶² Antonuk, B., and L. Block. "The Effect of Single Serving Versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food Intake." *Journal of Nutrition Education and Behavior*, 38:365-70 (2006).

¹⁶³ Antonuk, B., and L. Block. "The Effect of Single Serving Versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food Intake." *Journal of Nutrition Education and Behavior*, 38:365-70 (2006).

¹⁶⁴ Lando, A.M., and S.C. Lo. "Single-larger-Portion Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Food Choices." *Journal of the Academy of Nutrition and Dietetics*, 113:241-50 (2013).

V. General Mills supports updating RACC's to align with current dietary intake data.

We support FDA updating established RACCs to more closely align with current dietary intake data as compiled by the NHANES survey. The NHANES survey is internationally recognized for development and use of the Automated Multi-Pass technique for the accurate collection of individual food intake data in large dietary surveys.

General Mills supports the methodological approach to apply median intake estimates, rather than means, to provide a more accurate representation of the central tendency for the amount typically consumed per eating occasion. In addition, General Mills supports the establishment of a 25% change above or below the RACCs established in 1993 as the standardized criteria to define a significant difference in the amount customarily consumed per eating occasion. General Mills encourages the Agency to maintain a standardized approach and criteria to determining a significant change in amounts customarily consumed for all food categories, and feel that the Agency should be judicious about deviating from these criteria for changing RACCs.

We acknowledge that the Agency's analysis of NHANES 03-08 consumption data was completed prior to the release of the most recent data available, NHANES 09-10. As a means of extending the approach of the Agency to assess current food consumption quantities per eating occasion, GMI performed an analysis combining NHANES 03-08 with the 09-10 release of the NHANES dietary survey to determine median intake estimates of participants ages 4+ for specific food product categories as described in Appendices F and G. Inclusion of the 09-10 NHANES sample to the NHANES 03-08 analysis represents the most current U.S. consumption data available. Overall our extended analyses of NHANES 03-10 data corroborated the Agency's findings and support the proposed retention of, or modifications to, RACC categories.

a. General Mills supports the maintenance of the current RACCs for ready-to-eat breakfast cereals.

General Mills supports maintaining the RACCs established in 1993 of 30 g and 55 g for ready-to-eat breakfast cereals under the product category "cereals and other grain products". As described in Appendix F, results from NHANES 03-10 show median intake estimates of ready-to-eat breakfast cereals with a 30 g RACC or 55 g RACC were not 25% different compared to the current RACCs. Overall, these results support the Agency's indication to maintain current RACCs for ready-to-eat breakfast cereals.

b. General Mills supports the establishment of a new product category "Appetizers".

General Mills supports the proposal to establish a new product category of "Appetizers" for foods such as: hors d'oeuvres, mini mixed dishes, e.g., "mini bagel pizzas, breaded mozzarella

sticks, eggs rolls, dumplings, potstickers, wontons, mini quesadillas, mini quiches, mini sandwiches, mini pizza rolls, potato skins” with a RACC of 85 g, add 35 g for products with gravy or sauce topping. This will harmonize with USDA labeling requirements for similar products.

c. General Mills supports the maintenance of the RACC for the product category “Mixed Dishes, not measurable with cup”.

General Mills supports the proposal to maintain the product category “Not measurable with cup”, under the general category “Mixed Dish” at the current RACC of 140 g, add 55 g for products with gravy or sauce topping. This category includes food such as: “burritos, enchiladas, pizza, pizza rolls, quiche, sandwiches.” The Agency acknowledged the higher frequency of consumption of burritos, pizza and sandwiches compared to other foods in the same product category. However, the methodology used by the Agency indicated that amounts customarily consumed for those items were not significantly different from the 1993 RACC of 140 g. Similarly, GMI internal analyses of NHANES 03-10 incorporating the most current diet survey observed the median estimated intake for pizza (all crust types) is 169 g or 21% of the current RACC, which is within the 25% threshold (Appendix F). This further supports the Agency’s assessment that maintaining the current RACC is still an appropriate representation of amounts customarily consumed for this product category.

d. Other categories that should maintain current RACCs

The Agency requested comment on specific product categories that were highlighted in consumer comments to the ANPRM stating the serving size should be increased. GMI supports the Agency’s assessment that the RACC for specific product categories such as crackers, cookies and salty snacks should remain at the amounts of the current 1993 RACC amounts. GMI analysis of NHANES 03-10 also demonstrated the median estimated intake of the amount customarily consumed per eating occasion for cookies, crackers and fruit snacks was slightly lower than the current 30 g RACC, and median estimated intakes per eating occasion for salty snacks including chips, pretzels and popcorn was 30 g, an exact reflection of the 1993 RACC (Appendix F).

e. General Mills supports the proposed change for the RACC of the product category “yogurt” to 170 g.

General Mills agrees with the proposed change to update the RACC of the product category “yogurt” from 225 g to 170 g. Although consumption data showing the estimated median for the amount customarily consumed did not meet the 25% change level compared to the RACCs established in 1993, this amount more appropriately reflects both current population consumption practices and current container sizes in the marketplace. As

referenced in the National Yogurt Association citizen petition¹⁶⁵, 2010 Nielson Company sales and marketing data indicate that 84% of yogurt found in retail outlets is sold in 6 oz containers and only 1% of yogurt was sold in an 8 oz container.

VI. Proposed nutrition labeling updates have significant implications for claims.

The proposed nutrition labeling and serving size rules will have an impact on current regulations for nutrient content and health claims. If FDA intends to amend regulations related to nutrient content and health claims and does so after finalizing the proposed nutrition labeling and serving size rules, manufacturers may have to change their labels and labeling multiple times over the course of only a few years. General Mills urges FDA to clarify whether it intends to amend the regulations related to claims prior to finalizing these proposed rules and, if so, General Mills requests that FDA propose the amendments prior to finalizing nutrition labeling and serving size rules. The Agency should also reopen comments on nutrition labeling at that time to give industry and stakeholders critical time to evaluate both proposals concurrently.

Records Requirements and Compliance

I. General Mills opposes the proposed records requirements for compliance and Agency enforcement.

The Agency has proposed several aspects of nutrition labeling compliance that would require maintenance of records by manufacturers and access to these records by FDA. General Mills does not support the proposed records requirements as we believe compliance should be based on objective, analytical measures; the Agency has inadequately considered the complexity and cost; and GMI believes that FDA lacks the authority to issue the records access provision.

As previously stated, GMI does not support the proposed changes to added sugars, dietary fiber, vitamin E and folate that incorporate these new proposed compliance measures. GMI strongly believes that proposed changes to nutrition labeling and compliance must be based on objective, analytical measures, in order to yield consistent labeling practices across the food industry and ease in compliance measurements by the Agency.

FDA has not adequately considered the complexity and cost of compliance for food manufacturers. Although manufacturers currently maintain detailed records of all product recipes, the proposed nutrient declarations that would necessitate records would also require additional measures and impose significant costs. Indeed, FDA has estimated the

¹⁶⁵ 79 Fed Reg 11995

total annual cost of compliance with these requirements to be between \$1.8 million and \$2.3 million across the entire industry. In reality, the costs to *each manufacturer* could approach these estimates. In an effort to better understand these costs, we have attempted to identify the numerous additional processes that our company would need to execute in order to comply with the proposed recordkeeping requirements. Some of these are identified below.

As is generally well known, manufacturers must rely upon specifications from ingredient suppliers and, in the case of the proposed areas requiring records maintenance, the manufacturer would have no ability to verify the information analytically. Thus, at the outset, our company would need to send to each ingredient supplier a request for documentation of relevant ingredient specifications. In almost every case, the information is not currently provided to us by the supplier because the supplier views the information as highly proprietary. We expect that some or all suppliers would request that additional contract terms addressing our use, storage, and disclosure of this information be executed before the information is provided. This would result in significant legal work and back-and-forth communication that would vary according to the size, resources, and relationship with each of several thousand suppliers. We would need to input the additional analytical data we receive from the suppliers into our data management systems. This would require additional personnel and other overhead (e.g. information technology).

In total, we anticipate that compliance with the proposed regulations would result in numerous categories of cost including and without limitation: testing and analysis of new and existing ingredients; reviewing and updating record systems (with corresponding incremental personnel costs); record system modification and updates (with hardware and software costs); reformulation of products; packaging changes (and corresponding packaging inventory management costs); updating nutrition labels; maintaining nutrient data in records systems; and ongoing reporting and records maintenance (with additional hardware, software, and personnel costs).

We also note that the proposed regulations also require that, when a food manufacturer maintains records electronically, the records would be subject to 21 CFR Part 11. The costs associated with the creation and maintenance of an electronic records database for FDA's access under the proposed regulations would result in additional significant capital expenditure and ongoing personnel and maintenance costs.

In short, the cost to each manufacturer would be significant (very possibly millions of dollars). FDA has not adequately considered these costs nor sought to establish that the benefits for the portions of the proposed regulations (e.g., added sugar labeling) that drive these recordkeeping costs are sufficient to justify these significant costs.

It also bears noting that, for a number of reasons, FDA lacks the authority to issue the above records access provision. First, the language of the statute indicates that FDA does not have the authority for purposes of enforcing the NLEA provisions. Congress has been careful to provide FDA with records authority only in those specific instances where Congress

deemed it to be justified. Section 301(e) of the Act lists the specific sections where Congress had granted FDA records authority. It specifically prohibits companies from “refus[ing] to permit [FDA] access or copying of any record as required by section 412, 414, 417(j), 416 . . .” It does not include § 403(q), the NLEA provision.

Second, consistent with the above, FDA has previously conceded that it lacks the records authority for purposes of enforcing the NLEA provisions.¹⁶⁶ Third, although FDA has suggested that, under § 701(a), it can expand its authority by the issuance of a regulation, that is simply not the case. Courts have made clear that “no order or regulation issued by an administrative agency can confer on it any greater authority than it has under statute.”¹⁶⁷

Fourth, FDA’s reliance on the *National Confectioners* case is misplaced. The case was decided twelve years before Congress enacted NLEA, and (as noted above) FDA subsequently conceded that it does not have records authority for NLEA purposes. Moreover, in the years since the case was decided, Congress has granted FDA records access authority on a number of occasions, but not for NLEA purposes.¹⁶⁸ Those enactments make clear that Congress intends to limit records access to specific instances. This post-1978 information was not before the court.

Finally, FDA’s statement of need for the authority is not sufficient—a grant of authority must still come from Congress. However, before granting any records access authority, Congress carefully weighs the needs of the FDA against the burdens on companies to determine whether the authority is justified. Congress has addressed this issue on many occasions, including at a hearing 1991,¹⁶⁹ just a year after the enactment of NLEA, and has declined to provide FDA with the authority except in the instances noted above in § 301(e).

If FDA pursues records maintenance and access, we recommend that manufacturers should be permitted to demonstrate the validity of their nutrition label declarations using the records they believe best accomplish this. Moreover, we believe the final rule should not mandate the creation or retention of any particular type of records. Demonstrating the validity of nutrition label declarations is a performance standard and there is more than one

¹⁶⁶ In 1993 when FDA issued its NLEA regulations, FDA admitted that it lacked the authority to access company records for purposes of ensuring compliance with NLEA regulations. In response to a comment urging FDA to review company records to ensure compliance with the NLEA regulations, FDA explained: “To support misbranding charge for inaccurate nutrient content information, FDA must have accurate, reliable, and objective data to present in a court of law. To obtain that information, FDA relies upon the work performed by its trained employees because it does not have legal authority in most instances to inspect a food manufacturing firm’s records.” 58 Fed. Reg. 2079, 2110 (Jan. 6, 1993).

¹⁶⁷ *Assoc. of American Physicians & Surgeons v. FDA*, 226 F. Supp. 2d 204, 215 (DDC 2002). See also *id* at 212 (“Section 371 [701(a)] does not constitute an independent grant of authority that permits FDA to issue any regulation the agency determines would advance the public health. Rather, 371 permits the FDA to use rules as a means of administering authorities otherwise delegated to it by the Congress.”).

¹⁶⁸ For example, since that case was decided in 1978, Congress has granted FDA records access authority in several cases, but not for NLEA. See e.g., FDCA § 414 (Bioterrorism Act, 2002); § 417 (Reportable Food Registry, 2007); and § 418 (FSMA, 2011).

¹⁶⁹ At the hearing, in response to Commissioner Kessler’s request, Rep. Hastert made his concerns clear: “What would prevent somebody from your Agency from coming in, learning the [Coca-Cola] formula, or a formula like that, for instance, that is proprietary information and then several years later, once he has that information and is not in your employ any more, going out and exploiting it?” Food, Drug, Cosmetic, and Device Enforcement Amendments,” *Hearing Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives*, 102d Cong., 1st Sess. at 87 (1991).

way to meet the standard besides disclosing proprietary information such as product formulations. Manufacturers should be able to decide how they will meet this performance standard taking into account the realities of their business and existing records systems.

II. General Mills requests that FDA provide more than 2 years for compliance with the final rules.

When considered in totality, changes to the Nutrition Facts label proposed by FDA are extensive. Companies will likely need more than the proposed 2 years to achieve a smooth transition to the new format. This will also allow sufficient time for the development of comprehensive consumer education campaigns to accompany finalized label changes.

As a corollary, the Facts up Front campaign took approximately three years to implement within GMI. GMA found through a poll commissioned through Harris Poll that 93% of people who use Facts Up Front said it was easy to find information and 92% said it was easy to understand.¹⁷⁰ The proposed changes are significantly more complex than the Facts up Front campaign which has served consumers well in quickly understanding total calories, fat and key nutrients in foods. Adherence and timely compliance to these proposed rules will require resources beyond what FDA estimated. Specifically, General Mills would like to highlight how implementation spans across the entire production process from the supply chain to the finalized product at retail, with a multitude of impediments at each stage:

- 1) Challenges with the ingredient acquisition process include obtaining data from suppliers for added sugars, folate/folic acid, potassium, and vitamins D and E.
- 2) New business practices will need to be implemented to ensure fiber substantiation from suppliers, and to comply with the proposed definition of dietary fiber. The fiber premarket approval process may also represent further timing challenges, as the citizen petition for fiber approval, and the time required for the FDA review process, is currently not clearly articulated.
- 3) Quantitative label declarations for vitamin and minerals require additional analysis and, when paired with proposed increases in RACCs and Daily Values, require a re-evaluation of nutrient content claims.
- 4) The necessary changes to maintain adherence with nutrient content claims and fortification policies further embody the need for time to conduct research to overcome the associated technical challenges with reformulation.
- 5) The redesign of the label format presents a challenge for smaller packages, and the physical process of printing and distributing to manufacture locations is a time costly process.

Given the multitude of changes, we respectfully request that FDA provide more than 2 years for compliance with the final rule regarding the conversion of labels and packages.

¹⁷⁰ FactsUpFront.org. (2014, March 3). Press Release: Facts Up Front Launches Consumer Education Campaign to Drive Awareness and Increase Nutrition Knowledge. Retrieved from <http://factsupfront.org/Newsroom/8>

Conclusion

GMI is committed to Nourishing Lives- making lives healthier, easier, and richer. We applaud the Agency's efforts to update nutrition labeling to help consumers make informed food choices and maintain healthy dietary practices. We believe changes should focus on benefits to the consumer supported by comprehensive and thorough consumer research, and all changes should be reinforced through consumer education. We appreciate the opportunity to provide FDA with these comments.

Respectfully submitted,

A handwritten signature in black ink that reads "Kathryn L. Wiemer MS, RD". The signature is fluid and cursive, with the initials "MS, RD" written in a slightly more formal, blocky style at the end.

Kathryn L. Wiemer, MS, RD
Senior Fellow
General Mills Bell Institute of Health and Nutrition

APPENDIX A: Collective proposed format changes to the Nutrition Facts label

Nutrition Facts Label Elements	Proposed Changes for Nutrition Facts Label Elements
CALORIES	<ul style="list-style-type: none"> • Increase the type size for “Calories” and numeric value for calories • Bold/extra bold numeric value for calories and “Calories”
CALORIES FROM FAT	<ul style="list-style-type: none"> • Eliminate “Calories from Fat”
SERVING SIZE	<ul style="list-style-type: none"> • New placement below “Servings per Container” • Capitalize only the first “S” in “Serving size”
SERVINGS PER CONTAINER	<ul style="list-style-type: none"> • New placement immediately below “Nutrition Facts” and above “Serving Size” • Numeric number of servings appears first in “__servings per container” <ul style="list-style-type: none"> ○ Bold/extra bold lower case text; ○ Increase type size to ≥ 11 point, except tabular & linear labels ≥ 8 point type size
AMOUNT PER SERVING	<ul style="list-style-type: none"> • Add numeric serving size amount in household units to read “Amount per serving __” • Increase font size to no smaller than 8 point <ul style="list-style-type: none"> ○ Exception - linear display for small packages • Change text to semi-bold font
% DAILY VALUE	<ul style="list-style-type: none"> • Switch term from “% Daily Value” to “%DV” • Add vertical hairline rule after the numeric % Daily Value • Reposition % Daily Value to left of nutrient names, except for dual column Nutrition Facts labels
DUAL COLUMN	<ul style="list-style-type: none"> • Add vertical hairline rule after nutrient listing • Nutrient values appear immediate after % Daily Values • Nutrition Facts label presented as dual column for products between 200-400% of applicable RACC <ul style="list-style-type: none"> ○ Option 1 – Include Calories only per serving & per container ○ Option 2 – Include Calories, Sat Fat, Sodium per serving & per container
NUTRITION FACTS LABEL FOOTNOTE	<ul style="list-style-type: none"> • Replace footnote • Increase type size • Change to bolded font • Replace horizontal hairline with horizontal bar
NUTRIENTS	<ul style="list-style-type: none"> • Add quantitative amount of vitamins & minerals for mandatory and voluntary nutrients <ul style="list-style-type: none"> ○ Exception for tabular and linear labels on small packages ≤ 40 inches²
TOTAL CARBOHYDRATES	<ul style="list-style-type: none"> • Change to “Total Carbs”
ADDED SUGARS	<ul style="list-style-type: none"> • Nutrition Facts labels to include “Added Sugars” as double indent
NUTRITION FACTS HEADING	<ul style="list-style-type: none"> • Add new hairline rule [0.25 point] under “Nutrition Facts” <ul style="list-style-type: none"> ○ Exception – linear labels for small packages

APPENDIX B: Weight management and calorie balance research

CITATION	STUDY TYPE	OUTCOME
Van Buul V.J., L. Tappy, and F.J. Brouns. "Misconceptions about Fructose-Containing Sugars and their Role in the Obesity Epidemic." <i>Nutrition Research Reviews</i> . 27(1):119-130 (2014).	Review	<ul style="list-style-type: none"> Recommendations and policies to reduce intake of fructose for weight management purposes are ineffective, as fructose is not consumed in isolation in the diet and is not accountable for metabolic effects that result in increased body weight.
Ervin R.B., B.K. Kit, M.D. Carroll MD, and C.L. Ogden. "Consumption of Added Sugar among U.S. Children and Adolescents, 2005–2008." <i>NCHS Data Brief</i> . 87 (2012).	Intake Data	<ul style="list-style-type: none"> The National Center for Health Statistics determined the percent of daily kilocalories derived from added sugars declined between 1999–2000 and 2007–2008. In children, regarding sugar intake as a percent of daily kilocalories, differences prevail regarding sex, age group, race and ethnicity, but not regarding poverty income ratio. More kilocalories were consumed from food (not beverages) and consumed at home rather than away from the home.
Ervin R.B., and C.L. Ogden. "Consumption of Added Sugars among U.S. Adults, 2005–2010." <i>NCHS Data Brief</i> . 122 (2012).	Intake Data	<ul style="list-style-type: none"> In adults, regarding sugar intake as a percent of daily kilocalories, differences prevail regarding sex, age group, race, ethnicity, and poverty income ratio. More kilocalories were consumed from food (not beverages) and consumed at home rather than away from the home.
Nicklas T.A., C.E. O'Neil, and Y. Liu. "Intake of Added Sugars (AS) is not Associated with Weight Measures in Children 6 to 18 Years: National Health and Nutrition Examination Surveys 2003-2006." <i>Nutrition Research</i> . 31(5):338-346 (2011).	Cross-sectional	<ul style="list-style-type: none"> In an analysis of NHANES 2003-2006 data, while added sugar represented 17% of total energy intake, there was no significant association between added sugar intake and several measures of weight/adiposity in children.

Song W.O., Y. Wang, C.E. Chung, B. Song, W. Lee, and O.K. Chun OK. "Is Obesity Development Associated with Dietary Sugar Intake in the US?" <i>Nutrition</i> . 28(11-12):1137-1141 (2012).	Cross-sectional	<ul style="list-style-type: none"> • In an analysis of NHANES 1971-1975 and 1988-1994 data, total caloric intake (not total sugar intake) was determined the most important regarding BMI for both adults and children. • While carbohydrates were a predictor of energy intake, there was no relationship between carbohydrate consumption and obesity in both children and adults.
Murphy, M.M., L.M. Barraj, X. Bi, and N. Stettler. "Body Weight Status and Cardiovascular Risk Factors in Adults by Frequency of Candy Consumption." <i>Nutrition Journal</i> . 12(53):1-11 (2013).	Cross-sectional	<ul style="list-style-type: none"> • In an analysis of NHANES 2003-2006 data, despite having higher energy intake and higher intakes of total sugars, added sugars, and total fat, frequent candy consumers did not have an increased risk of overweight/obesity or an increase in other cardiovascular risk factors.
Zheng M., A. Rangan, N.J. Olsen, L.B. Andersen, N. Wedderkapp, P. Kristensen, A. Grontved, M. Ried-Larsen, S.M. Lempert, M. Allman-Farinelli, and B.L. Heitmann. "Sugar-Sweetened Beverages Consumption in Relation to Changes in Body Fatness over 6 and 12 Years among 9-year Old Children: The European Youth Heart Study." <i>European Journal of Clinical Nutrition</i> . 38(1):77-83 (2014).	Cohort	<ul style="list-style-type: none"> • In a longitudinal study with a 6 and 12 year follow-up, consumption of more than one daily serving of SSB at age 15 resulted in larger increases in BMI and waist circumference over the subsequent 6 years compared to non-SSB consumers.
Rippe J.M. "The Metabolic and Endocrine Response and Health Implications of Consuming Sugar-Sweetened Beverages: Findings from Recent Randomized Controlled Trials." <i>Advances in Nutrition</i> . 4(6):677-686 (2013).	Review	<ul style="list-style-type: none"> • In a review of recently conducted RCTs examining intake of fructose, HFCS, and sucrose, it was determined that caution should be exerted in attributing adverse health consequences to fructose consumption and added sugar when consumed at a normal level in the diet (at a level of 25% of calories). • No causal relationship was found between HFCS consumption and obesity.

Emond J.A., R.E. Patterson, P.M. Jardack, and L. Arab. "Using Doubly Labeled Water to Validate Associations between Sugar-Sweetened Beverage Intake and Body Mass among White and African-American Adults." <i>International Journal of Obesity</i> . 38:603-609 (2014).	Clinical Trial	<ul style="list-style-type: none"> • Underreporting of SSB intake by overweight/obese individuals may misrepresent associations between SSB intake and the risk of being overweight/obese. • In an analysis of true reporters, SSB intake increased the risk of overweight/obesity by fourfold.
Lowndes J., S. Sinnett, S. Pardo, V.T. Nguyen, K.J. Melanson, Z. Yu, B.E. Lowther, and J.M. Rippe. "The Effect of Normally Consumed Amounts of Sucrose or High Fructose Corn Syrup on Lipid Profiles, Body Composition and Related Parameters in Overweight-Obese Subjects." <i>Nutrients</i> 6(3):1128-1144 (2014).	RCT	<ul style="list-style-type: none"> • Fructose and glucose consumed as part of a eucaloric diet does not influence body weight, body composition, blood lipids, or blood pressure, even when consumed at four times the levels recommended by the AHA. • Sucrose and HFCS do not exhibit any metabolic differences under normal dietary consumption patterns.
Reid M., R. Hammersley, M. Duffy, and C. Ballantyne. "Effects of Obese Women of the Sugar Sucrose Added to the Diet Over 28 d: A Quasi-Randomised, Single-Blind, Controlled Trial." <i>British Journal of Nutrition</i> . 111(3):563-570 (2014).	RCT	<ul style="list-style-type: none"> • Obese women randomly assigned to consume sucrose containing drinks, compared to an aspartame control, over the course of 4 weeks, did not gain weight. • Daily energy intake did not increase significantly indicating that sucrose is partially compensated for by obese women.
Te Morenga L., and J. Mann. "Dietary Sugars and Body Weight: Systematic Review and Meta-Analyses of Randomized Controlled Trials and Cohort Studies." <i>British Medical Journal</i> . 346:e7492 (2013).	Review	<ul style="list-style-type: none"> • Exchanging sugars for other carbohydrates has no statistically significant effect on body weight. • Body fatness associated with modified intake is mediated by energy intake, not sugar substitution for alternative carbohydrates.
Welsh J.A., et al. "Consumption of Added Sugars is Decreasing in the United States." <i>The American Journal of Clinical Nutrition</i> . 94(3): 726-734 (2011).	Intake Data	<ul style="list-style-type: none"> • Sugar intake has decreased on average over the past 15 years from ~18% of energy to ~15% of energy.

APPENDIX C: Fruit flavored yogurt case study

The following is a case study highlighting the complexities in calculating added sugars using a fruit preparation purchased from a vendor to be used in a fruit flavored yogurt;

A typical ingredient declaration for a fruit flavored yogurt may contain the following ingredients. Some of the ingredients underlined below could be or could not be considered added sugars based on differing interpretations of FDA's proposed definition:

Cultured Pasteurized Grade A Low Fat Milk, Sugar, Fruit, Modified Corn Starch, Nonfat Milk, Kosher Gelatin, Citric Acid, Tricalcium Phosphate, Colored with Carmine, Natural Flavor, Pectin, Vitamin A Acetate, Vitamin D3.

	<i>Interpretation 1</i>	<i>Interpretation 2</i>	<i>Interpretation 3</i>	<i>Interpretation 4</i>
Ingredient(s) considered added sugar	Sugar, Fruit, Milk, Natural flavor	Sugar, Fruit, Natural flavor	Sugar, Natural flavor	Sugar
Ingredient(s) excluded from added sugar calculation	-	Milk	Fruit, Milk	Fruit, Milk, Natural flavor

There are several ingredients that analyze for trace levels of sugar but do not function as a sweetener by the manufacturer, such as some natural flavors. However, based on the proposed definition of added sugar, it is unclear if the sugar from these ingredients are included as added sugar.

In this example, the processing of yogurt provides additional challenges when calculating added sugar values. Per extensive analytical testing, the significant and consistent consumption of sugar due to fermentation has been observed and well documented. Analytically determined total sugar content in a finished product is significantly lower when comparing the total sugar calculated from the product formula. Without an analytical test to distinguish added sugar from those naturally occurring in the milk, manufacturers will not be able discern where the loss is occurring to provide an accurate added sugar value on the label. This may force manufacturers to inaccurately assume the loss of sugar due to fermentation from naturally occurring and over declare added sugars.

These different interpretations can result in varying interpretations not only among manufacturers but also suppliers, such that even minor differences in calculations, compounded by rounding, could result in widely different declared values of added sugars.

APPENDIX D: Daily Value revisions and implications for fortification

The following appendix includes 1) additional data supporting FDA's analysis and conclusions emphasizing that using the RDAs as the basis for the RDIs will not lead to widespread overconsumption due to fortification; and 2) research supporting the benefits of fortified foods.

I. Using the RDAs as the basis for the RDIs will not lead to widespread overconsumption due to discretionary fortification.

In response to FDA's request for comment on their analysis and additional information regarding the basis of the Daily Value (EAR or RDA) has in consumption of the nutrients above the UL in discretionary fortification of foods, General Mills appreciates the due diligence of FDA's analysis¹⁷¹ to better understand the potential risk for excessive intakes of vitamins and minerals from both foods and dietary supplements. We support the Agency's conclusions, and additional data supports FDA's analysis and overall conclusions.

A similar analysis conducted by Fulgoni et al¹⁷² examined the contribution of micronutrients from all dietary sources (naturally occurring, fortified/enriched, and dietary supplements) to usual intakes. They found that while enriched and/or fortified foods contribute a large proportion of the intakes of vitamins A, C, and D, thiamin, iron, and folate, intakes are still below the EAR for a significant portion of the population. The percentage of the total population with total dietary intakes greater than the tolerable upper intake level (UL) was low for most nutrients (including calcium, iron, vitamins D, C, and E). More recent research by Berner et al¹⁷³ also concluded that fortification reduced the percent of people with intakes below the EAR for many micronutrients and did not lead to intakes above the UL for most nutrients.

While some research suggests specific subgroups of the population may have dietary intakes above the ULs for certain micronutrients, it should be noted there are questions around how best to apply ULs and interpret their value. By definition, the UL is based on a risk assessment approach, and its value is not meant to be used as a rigid cutoff point, rather it provides a value at which there may be an increased risk for an adverse health outcome if intake is consistently exceeded over time.

ULs offer some guidance; however there are limitations to their utility:

¹⁷¹ Department of Health and Human Services. *Documentation for the methodology used to determine total usual intakes of vitamins and minerals compared to Tolerable Upper Levels (UL) and results of analysis.* Memorandum dated February 14, 2014.

¹⁷² Fulgoni III, V.L., et al. "Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?," *The Journal of Nutrition*. (141):1847-1854 (2011).

¹⁷³ Berner, L.A., et al. "Fortified Foods Are Major Contributors to Nutrient Intakes in Diets of US Children and Adolescents." *Journal of the Academy of Nutrition and Dietetics*. (114):1009-1022 (2014).

- Given extrapolation methods and approximations to account for uncertainty factors (e.g. variability among populations including ethnicity, age, and sex), ULs may be set too low thereby creating conservative decisions regarding fortification levels.
- Most of the ULs for children are extrapolated from adult values based on limited available data and are not determined experimentally.
- As UL values assess risk related to chronic intake, there is no clear data on whether potential adverse health effects occur when the UL for individual nutrients is exceeded intermittently.

Similar to the Agency's analysis, other dietary intake research indicates that a percentage of the population within certain subgroups have intakes above the UL for a few nutrients. Sacco et al examined the risk of exceeding intakes above the UL for micronutrients due to discretionary fortification practices.¹⁷⁴ They found that children, ages 1-8 years old, who were more likely to consume zinc, retinol, folic acid, selenium, and copper from fortified foods were also more likely to have a greater risk of intakes above the UL for those nutrients. They also found that, for some age/gender groups in adults, higher intakes of calcium and iron from fortified foods were associated with greater risk of intakes above the UL. An analysis by Fulgoni et al also reported that, in children ages 2-18 years old, the percentages of the population with total dietary intakes above the UL were observed for a few nutrients (zinc (24%), niacin (16%), vitamin A (15%) and folate (15%))¹⁷⁵. Recent research from Berner et al¹⁷⁶ also noted dietary intakes above the UL for zinc, niacin, vitamin A and folic acid in children ages 2-8 years old. While research confirms that some children within this subset of the younger population may have intakes above the UL for several micronutrients, it's not clear what, if any, result this has on health.

Further research and better methods to understand implications of dietary intakes of nutrients above the UL are certainly needed. At present, it's important to recognize that limitations exist and to understand that ULs can best serve as a guide rather than an absolute threshold that cannot be crossed.

II. General Mills believes that using either the EARs or RDAs for the RDIs will not increase the risk for overconsumption of vitamins and minerals.

Research supports the tremendous value of fortification which is broad and generally accepted by consumers, policy makers and regulatory agencies in the United States. Judicious fortification has helped both correct and prevent nutrition inadequacies and in some cases deficiencies, and recent research has pointed out the valuable role fortified foods have in the modern food supply.

¹⁷⁴ Sacco, J.E., et al. "Voluntary Food Fortification in the United States: Potential for Excessive Intakes." *European Journal of Clinical Nutrition*, 67, 592-597 (2013).

¹⁷⁵ Fulgoni III, V.L., et al. "Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?," *The Journal of Nutrition*. (141):1847-1854 (2011).

¹⁷⁶ Berner, L.A., et al. "Fortified Foods Are Major Contributors to Nutrient Intakes in Diets of US Children and Adolescents." *Journal of the Academy of Nutrition and Dietetics*. (114):1009-1022 (2014).

- The public health success of enriching refined grains with B vitamins and iron has been well proven with the virtual elimination of pellagra and beriberi in the US. A more recent, but equally notable, enrichment success was the addition of folic acid to enriched grains/grain foods. Since this regulation was fully implemented in 1998, the CDC reported a 36% reduction in neural tube defects from 1996 to 2006.^{177,178,179}
- The 2010 Dietary Guidelines encourages consumers to make nutrient dense choices within their calorie needs. Fortified foods can increase the nutrient density of many common food sources, like many ready-to-eat cereals and dairy products fortified with calcium and vitamin D, and help consumers close the gap on many important nutrients.
- Consumers' wide acceptance and the value they place on fortified foods are revealed by products they look for and purchase. The IFIC Food and Health Survey reports that many Americans choose foods and/or beverages specifically because of fortification.¹⁸⁰
- The analysis conducted by Fulgoni et al indicates that many Americans would not have achieved the recommended intake levels for micronutrients without fortified foods, enriched foods, dietary supplements or a combination of these sources.¹⁸¹
- Analysis by Berner et al¹⁸² of NHANES data demonstrated the significant value fortified foods have on the nutrient intakes of children and adolescents. Fortification was a significant contributor of many micronutrients, assuring that adequate intakes were achieved without resulting in excessive intakes for most nutrients.

¹⁷⁷ Centers for Disease Control and Prevention. "Ten Great Public Health Achievements – United States, 2001-2010." *Morbidity and Mortality Weekly Report*. 60:619-623 (2011).

¹⁷⁸ Centers for Disease Control and Prevention. "Spina Bifida and Anencephaly Before and After Folic Acid Mandate – United States, 1995-1996 and 1999- 2000." *Morbidity and Mortality Weekly Report*. 53:362-5 (2004).

¹⁷⁹ Centers for Disease Control and Prevention. "CDC Grand Rounds: Additional Opportunities to Prevent Neural Tube Defects with Folic Acid Fortification." *Morbidity and Mortality Weekly Report*, 59:980-4 (2010).

¹⁸⁰ International Food Information Council Foundation. "Functional Foods Consumer Survey." Washington, DC: U.S (2013).

¹⁸¹ Fulgoni III, V.L., et al. "Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?," *The Journal of Nutrition*. (141):1847-1854 (2011).

¹⁸² Berner, L.A., et al. "Fortified Foods Are Major Contributors to Nutrient Intakes in Diets of US Children and Adolescents." *Journal of the Academy of Nutrition and Dietetics*. (114):1009-1022 (2014).

APPENDIX E: Market analysis of the soup and frozen vegetable categories depicting competing label formats and serving sizes

	Maintain Current Serving Size and Label ($<150\%$ of RACC)	Move to Single Serving Size Declaration ($150\text{--}<200\%$ of RACC)	Move to Dual Column Format ($200\text{--}400\%$ of RACC)
Soup Category (all packaging formats)*	8%	38%	54%
Soup Category (canned soups only)*	1%	31%	68%
Frozen Vegetable Category**	19%	9%	72%

*Based on the top 95% of the soup category

**Based on assessment across 3 name brand frozen vegetable lines representing 66% of the frozen vegetable category

APPENDIX F:

Mean and median consumption amounts per eating occasion for specific product categories from NHANES 03-10 ¹						
Current Product Category	Product	N (Number of Eating Occasions)	NHANES 03-10 Mean (grams)	NHANES 03-10 Median (grams)	1993 RACC (grams)	Difference Between Median intake and 1993 RACC
Breakfast cereals, ready-to-eat	Breakfast Cereals, ready-to-eat, weighing <20g per cup	62	20	19	15	27%
	Breakfast Cereals, ready-to-eat, weighing >20g but <43g per cup	6790	41	37	30	24%
	Breakfast Cereals, ready-to-eat, weighing ≥43g per cup	1413	62	56	55	2%
Mixed Dishes, not measurable with cup	Pizza	3137	216	169	140, add 55 grams for sauce	21%
Cookies	Cookies	6643	31	26	30	-13%
Crackers	Crackers eaten as a snack	3310	28	24	30	-20%
All varieties, chips,	Chips, pretzels, multigrain	7979	37	30	30	0%

pretzels, popcorns, extruded snacks, fruit-based snacks, grain-based snack mixes	mixes, popcorn					
	Fruit snacks	588	27	28	30	-13%

¹ NHANES 03-10: The combined National Health and Nutrition Examination Survey, 2003-2004, 2005-2006, 2007-2008 and 2009-2010. Data include complete intake responses from day 1 from the general food supply consumed by individuals' ages 4 years and older.

APPENDIX G:

List of Product Categories, Products, and USDA 8-digit Food Codes Used to Estimate Amounts Customarily Consumed per Eating Occasion, NHANES 2003-2010 ¹		
<i>Current Product Category</i>	<i>Product</i>	<i>USDA 8-digit Food Codes</i>
Breakfast cereals, ready-to-eat	Breakfast Cereals, ready-to-eat, weighing <20g per cup	57416000, 57307500, 57340000, 57301500
	Breakfast Cereals, ready-to-eat, weighing >20g but <43g per cup	57103050, 57123000, 57124000, 57132000, 57134000, 57134090, 57135000 57148000, 57148500, 57151000, 57231000, 57303100, 57304100, 57325000 57336000, 57337000, 57339000, 57401100, 57403100, 57404100, 57406100 57410000, 57418000, 57103000, 57103100, 57104000, 57106250, 57107000, 57117000, 57119000, 57120000, 57124200, 57124300, 57125000, 57126000, 57127000, 57128000, 57130000, 57137000, 57139000, 57144000, 57201900 57211000, 57212100, 57213000, 57213850, 57216000, 57218000, 57221700 57221800, 57221810, 57223000, 57224000, 57355000, 57238000, 57240100 57241000, 57243000, 57301530, 57302100, 57305100, 57305150, 57305170 57305180, 57305200, 57305210, 57305300, 57305500, 57305600, 57306500 57306800, 57307150, 57308400, 57316710, 57328000, 57335550, 57339500

		57342010, 57344000, 57347000, 57348000, 57349000, 57349020, 57404200 57407100, 57409100, 57416010, 57419000, 57237100, 57237300, 57344005 57344010, 57344015, 57344020, 57344025, 57101000, 57101020, 57110000 57111000, 57128880, 57131000, 57206700, 57207000, 57208000, 57209000 57219000, 57221000, 57318000
	Breakfast Cereals, ready-to-eat, weighing ≥ 43 g per cup	57230000, 57308300, 57316300, 57327500, 57341000, 57411000, 57417000 57214000, 57214100, 57241200, 57301505, 57301510, 57301511, 57413000 57106100, 57106530, 57125900, 57143500, 57206000, 57231200, 57231250 57237200, 57244000, 57245000, 57301512, 57301520, 57307010, 57308150 57308190, 57316450, 57316500, 57321700, 57321800, 57329000, 57330000 57330010, 57331000, 57332050, 57332100, 57341200, 57346500, 57320500, 57143000, 57227000, 57228000, 57229000, 57229500, 57327450, 57408100 57319500
Mixed Dishes, not measurable with cup	Pizza	58106205, 58106230, 58106260, 58106305, 58106330, 58106350, 58106360 58106413, 58106443, 58106463, 58106505, 58106560, 58106630, 58106660 58106705, 58106730, 58106734, 58106737, 58106760, 58106830, 58106920 58107100, 58106200, 58106210, 58106220, 58106225, 58106240, 58106250

		58106255, 58106300, 58106310, 58106320, 58106325, 58106340, 58106345 58106347, 58106357, 58106358, 58106359, 58106410, 58106411, 58106412, 58106440, 58106441, 58106442, 58106460, 58106461, 58106462, 58106500 58106540, 58106550, 58106555, 58106610, 58106620, 58106625, 58106640 58106650, 58106655, 58106700, 58106710, 58106720, 58106725, 58106733 58106735, 58106736, 58106738, 58106740, 58106750, 58106755, 58106780 58106810, 58106820, 58106825, 58106900, 58106910, 58106915, 58107030, 58107050, 58107060
Cookies	Cookies	53201000, 53202000, 53203000, 53203500, 53205250, 53205500, 53205600 53205750, 53205760, 53206000, 53206010, 53206020, 53206030, 53206050 53206100, 53206500, 53206550, 53207000, 53207050, 53208000, 53208200 53209000, 53209010, 53209020, 53209050, 53209100, 53209500, 53210000 53210900, 53210910, 53215500, 53216000, 53222010, 53222020, 53222100 53223000, 53223100, 53224000, 53225000, 53226000, 53226500, 53226550 53226600, 53227000, 53228000, 53230000, 53231000, 53231400, 53233000 53233010, 53233020, 53233030, 53233040, 53233050, 53233060, 53233080 53233100, 53233500, 53234000, 53234010, 53234100, 53234250, 53235000

		53235500, 53235600, 53236000, 53236100, 53237000, 53237010, 53237500 53238000, 53239000, 53239010, 53239050, 53241500, 53241600, 53242000 53243000, 53243050, 53243100, 53244010, 53244020, 53245000, 53246000 53247000, 53247050, 53247500, 53248000, 53251100, 53260030, 53260150, 53260200, 53260300, 53260400, 53270100
Crackers	Crackers eaten as a snack	54001000, 54204010, 54205010, 54205030, 54205100, 54210010, 54301000, 54301100, 54301200, 54304000, 54304100, 54304500, 54309000, 54327950, 54337000, 54337050, 54337100, 54338000, 54338100, 54339000, 54328000, 54328100, 54328110, 54328200, 54101010, 54102010, 54102020, 54102050, 54102060, 54102100, 54102110, 54102200, 54308000
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks, grain-based snack mixes	Chips, pretzels, multigrain mixes, popcorn	54402200, 54402300, 54402500, 54402600, 54402700, 54403000, 54403010 54403020, 54403040, 54403050, 54403060, 54403070, 54403090, 54403110 54403120, 54403150, 54406010, 54406200, 54408000, 54408010, 54408020 54408030, 54408040, 54408050, 54408070, 54408100, 54408200, 54408250 54408300, 54412110
	Fruit snacks	91708030, 91708040, 91708100

¹ NHANES 03-10: The combined National Health and Nutrition Examination Survey, 2003-2004, 2005-2006, 2007-2008 and 2009-2010. Data include complete intake responses from day 1 from the general food supply consumed by individuals' ages 4 years and older

