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ELECTRONIC SUBMISSION

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RE: Proposed Rule for Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Docket No. FDA-2012-N-1210

Dear Sir or Madam:

The International Dairy Foods Association (IDFA), Washington, D.C, represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a \$125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's almost 200 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream, and frozen desserts produced and marketed in the United States.

We appreciate the opportunity to provide comments to the Food and Drug Administration (FDA) regarding the proposed changes to the Nutrition Facts panel. The panel is an important part of nearly every food package sold in the United States and also serves as an integral component of nutrition education and information for consumers. We agree with the agency that it is important to update the Nutrition Facts panel to ensure that consumers get the information they need and that the information presented is reflective of the very best nutritional science available. However, we have a number of concerns about the proposed changes related to the underlying science and the likely impact on consumer understanding. Each of these concerns is explained in further detail below.

At the outset, we want to underscore the impact of the proposed rule on the declared nutrient content both in the Nutrition Facts panel and with respect to nutrient content claims. The planned changes to the Nutrition Facts panel and to nutrient Daily Values have the potential to significantly change consumer's perception of the nutritional profiles of certain foods. Changes to nutrients that are required to be declared or to the daily values and corresponding percent Daily Values declared, can make a food appear to have a lower nutritive value, even if no changes have been made to the product. This may be particularly true for foods and beverages such as dairy products that are naturally nutrient-rich, or that may not be able to modify nutrient levels to accommodate newly proposed Daily Values because of specific provisions in the standards of identity.

Under FDA's proposal, many products would lose their ability to make nutrient content claims, despite no change to the product itself. For products that naturally contain these nutrients, manufacturers may not be able to add beneficial nutrients in response to the proposed rule, due to formulation concerns or additional regulatory limitations, such as federal or state standards of identity. (Note that approximately one-third of all FDA food standards are for dairy products, so this limitation adversely affects our members disproportionately). For example, based on the proposed Daily Values increase for vitamin D from DDV: 10 mcg (400 IU) to 20 mcg and potassium from 3,500 mg to 4,700, milk would no longer qualify as an excellent source of vitamin D or as a good source of potassium. Similarly, a number of dairy products, such as some natural cheeses and yogurts, could lose their eligibility for an excellent source of calcium claim with the Daily value of calcium changing from 1,000 mg to 1,300 mg. Additionally, some claims are directly tied to the name of the food, through the use of a nutrient content claim in conjunction with a standard of identity. A loss or change of such a claim would necessitate the alteration of the very nature of the product, or altering the name of the product itself. For example, a low fat or fat free ice cream could lose eligibility for those claims based on the proposed increased Reference Amount Commonly Consumed (RACC) for ice cream.

We therefore ask that FDA reconsider modifications to nutrient Daily Values, given the potential for consumer confusion or decreased availability of foods that meet nutrient content claims that could result from these changes. FDA has previously recognized the value in ensuring that nutrient content claim criteria allow a variety of foods to qualify without the need for fortification. When the agency initially defined the term "excellent source," it recognized that the criteria "should be consistent with the levels of nutrients occurring naturally in foods, and that definitions for terms should allow for a reasonable number of foods to make the claim." 56 Fed. Reg. 60421, 60443 (Nov. 27, 1991). FDA noted that the term "excellent source" would not be useful to consumers "if they can identify only very few foods or only specially formulated foods." *Id.* Based on this precedent, FDA should consider the impact of the proposed changes on the eligibility of foods with naturally occurring nutrients to qualify for nutrient content claims and the availability of such foods to consumers. FDA should also consider the potential that consumers would not understand why a food that was previously considered an "excellent source" of a nutrient no longer provides the same excellent source, when the absolute nutrient content of the food has not changed.

Nutrition Facts Panel Format

Given that the Nutrition Facts panel is updated only every 10 or 20 years, and the time and cost needed to make those changes across the entire food industry, it is important that any changes significantly help consumers understand the nutritional content of their food and make informed food choices to meet their nutritional needs. Consumer research must be conducted to ensure that consumers understand the format and content of the information presented in the proposed Nutrition Facts panel and to evaluate the likely impacts on dietary practices.

For example, there is no indication in the preamble that FDA has evaluated the proposed change to move the percent Daily Values to the left side of the panel. Moving the DV ahead of the nutrient name

could be confusing, as consumers would need to look for the nutrient name in the middle of the panel and then look at the Daily Value content on the left side and the quantitative content on the right. This runs counter to the manner in which consumers read information: left to right.

IDFA is also concerned with the additional label space that would be required to accommodate the proposed linear format, as compared to the current linear format. This is a particular concern because the linear format is specifically designed for products with small amounts of labeling space. For products with very small labels, but not small enough to qualify for a complete exemption from nutrition labeling under 21 C.F.R. § 101.9(j)(13), such as those with 13 square inches of available labeling space, an increase in the size of the linear format will be extremely problematic. We therefore ask that FDA consider (1) expanding the exemption in § 101.9(j)(3), (2) providing for a revised linear format that can fit on smaller packages that do not qualify for a complete exemption from nutrition labeling, and (3) allowing more labels to qualify for the linear and tabular formats.

FDA Should Not Adopt the Alternative Visual Format

IDFA opposes the Alternative Visual Format because it would codify dietary guidance that is regularly being updated. As nutrition science evolves, headings such as “get enough of” and “avoid too much” could become outdated faster than the regulations can be updated. For example, when the Nutrition Facts panel was originally developed, fat, saturated fat, and cholesterol were believed to be the dietary causes of many health conditions, such as obesity or heart disease. Now, updated nutritional research has resulted in a change in our understanding of the role of these nutrients in the diet. Total fat intake appears to have more neutral consequences on health, while the type of fat may be more important. See 79 Fed. Reg. 11880, 11891 (Mar. 3, 2014).

As nutrition research continues to progress, the nutrition community may find that the nutrients currently believed to have significant positive or negative effects on health are either neutral or have the opposite effect. The proposed alternate format could become outdated and present information that conflicts with nutritional recommendations or is even inaccurate or misleading for some or all of the population. In contrast, the existing Nutrition Facts panel does not pose this problem because it provides objective facts about nutrient content, rather than characterizing the nutrient content as “good” or “bad.”

Indeed, what has made the Nutrition Facts panel an American icon is that it provides consumers with “just the facts” that then allow and encourage consumers to make informed food choices that meet their dietary preferences and needs. The alternative format goes beyond the facts and provides subjective information and interpretation of the facts. This interpretation ultimately provides nutrition guidance to consumers and is not based on the specific needs of each individual. The proposed categorization of nutrients is not applicable to specific sub populations. For example, iron is not typically a nutrient of need for men and postmenopausal women, yet the alternative format lists this mineral as one of which consumers must “get enough.” For these reasons, FDA should retain an objective approach to the Nutrition Facts panel.

IDFA also opposes the alternative format because it oversimplifies complex nutrition information. By creating the “avoid too much” and “get enough” categories, the Agency is essentially designating certain nutrients and vitamins/minerals as good and bad. In order to assist consumers in maintaining a healthy diet, it is important for consumers to understand how all foods can fit within the daily diet. According to the Academy of Nutrition and Dietetics: “...the total diet or overall pattern of food eaten is the most important focus of healthy eating. All foods can fit within this pattern if consumed in moderation with appropriate portion size and combined with physical activity. The Academy strives to communicate healthy eating messages that emphasize a balance of food and beverages within energy needs, rather than any one food or meal.¹” An approach that provides subjective information about individual foods as “good” or “bad” is inconsistent with these recommendations.

We are also concerned that FDA has not conducted consumer research on the alternative visual format to assess whether consumers understand this format, and we expect that the formatting would be confusing. The separation of total carbohydrates, sugars, and added sugars could exacerbate consumer confusion about the relationship between these three declarations, including whether added sugars is part of sugars, or in addition to the amount declared as “sugars.” Similarly, total fat and saturated fat would be separated, resulting in the same potential for confusion.

The alternative format may also contribute to the confusion of consumers following a dietary regimen for the purpose of disease management. For example, it is recommended that people with kidney disease avoid or reduce potassium intake; however, the alternative format lists this mineral under “get enough”. And people with certain diseases of the bowel are referred by physicians to consume a lower fiber diet, however this nutrient is listed under “get enough.”

While it is likely obvious to many health professionals that the section under “quick facts” refers to calorie-contributing macronutrients, this understanding is not shared by the general public. Given that these “quick facts” about total fat, total carbohydrates and protein are not listed in one of the other categories, it is unknown what consumers will infer from this. Should they “get enough” or “avoid too much” total fat, total carbohydrates, and protein? The reality, which is not conveyed by the alternative visual format, is that consumers need all of those nutrients to support a healthy diet. For all of these reasons, IDFA opposes the alternative visual format.

Lastly, we recognize that FDA did not propose that companies would have the option to use either the alternative visual format or the proposed format, but we want to emphasize that the alternative visual format should not be allowed as a voluntary option. One of the strengths of the current Nutrition Facts panel is its consistency across food categories and products. With a few exceptions for the shape and size of a food package, the Nutrition Facts panel is the same on all food labels. This makes it clearly identifiable to consumers and provides the same information about nutritional content on all foods and beverages. Allowing the proposed alternate format as a voluntary option would undermine overall consistency and clarity of the Nutrition Facts panel.

¹ "Position of the Academy of Nutrition and Dietetics: Total Diet Approach to Healthy Eating." J Acad Nutr Diet. 2013;113:307-317.

Consumer Research

IDFA supports FDA’s planned consumer research to examine the proposed requirement for added sugars and to evaluate the content and format of the footnote regarding the percent daily value. FDA should also conduct consumer research on the new proposed Nutrition Facts panel format to determine whether consumers understand the proposed changes. This research is critical to determine whether the proposed changes assist consumers in maintaining healthy dietary practices. The results of any consumer research conducted in connection with this rulemaking should be made available for public review and comment prior to publication of the final rules. Only then can there be a meaningful opportunity for comment.

Additionally, in finalizing the requirement for the percent daily value footnote based on the outcomes of consumer research, FDA should ensure that this change is incorporated in the final rule on the other proposed nutrition labeling changes so that there is a single final rule that includes all changes to the Nutrition Facts panel, rather than requiring a second round of label revisions to add the new footnote. This would allow for changes to food labels to be made more efficiently and at less cost. Changing every food label with a Nutrition Facts panel in America is a monumental task, and FDA should take whatever steps are necessary to make certain that these changes only have to be made once.

FDA Should Not Require Declaration of Added Sugars

FDA should not require labeling of added sugars content, because doing so will not “assist consumers in maintaining healthy dietary practices,” which is the legal standard for adding a new nutrient to the food label under the Nutrition Labeling and Education Act (NLEA). Requiring added sugars information will not be useful to consumers for the following reasons.

There is no scientific support for distinguishing between “added sugar” and “naturally occurring” sugars. All sugars have the same nutritional impact – a gram of sugar is a gram of sugar. Nor does the body distinguish between naturally occurring and added sugars. FDA recognized this principle in 1993 when it rejected mandatory labeling of added sugars:

“The agency is not persuaded that there is a need for mandatory disclosure of added sugars in place of, or in addition to, added sugars. There is no scientific evidence that the body makes any physiological distinction between added sugar molecules and those naturally occurring in a food. 58 Fed. Reg. 2079, 2098 (Jan. 6, 1993).”

There has been no change in the scientific consensus on this point. Further, federal agencies have previously concluded that foods with added sugars are no more likely to lead to weight gain or other health outcomes than foods with other calorie sources. Neither the 2010 Dietary Guidelines for Americans (DGA) nor the IOM macronutrient report concluded that added sugars consumption, in itself, increases obesity. As recognized by FDA in the preamble, “added sugars do not contribute to weight gain more than any other source of calories.” 79 Fed. Reg. at 11904. The current scientific research linking added sugar intake to health outcomes is conflicting and inconclusive. Additionally, research

does not substantiate a causal effect between including added sugars information in the Nutrition Facts panel and decreased added sugars intake.² Because there is no chemical or physiological difference between added and inherent sugars, including added sugars on the label will not impart useful information to consumers. FDA therefore does not have a sufficient scientific basis for meeting the statutory requirement under which mandatory nutrients must assist customers in maintaining healthy dietary practices. We find it inconsistent that FDA has opted to focus on the physiological effect of dietary fiber in the proposed definition for that nutrient; while ignoring the lack of physiological effect from added sugars as compared to total sugars.

Absent evidence showing a public health concern with added sugar, the proposed rationale for requiring added sugars differs from the rationale for declaring all other nutrients. In the preamble, FDA recognizes that the rationale to support other nutrients to date generally relates to the intake of a nutrient and the risk of chronic disease, a health-related condition, or a physiological endpoint. 79 Fed. Reg. at 11904. Similarly, as explained by FDA during the June 26, 2014 public meeting on updating the food label, the justification for including all other nutrients on the label is a two-fold inquiry showing that (1) there are quantitative intake recommendations for the nutrient, and (2) it is of public health significance. The one exception to this rule is trans fat, for which there is no established daily value, but the agency nonetheless concluded its declaration was warranted due to the scientific evidence showing that consumption of trans fatty acids increases blood LDL cholesterol, a primary risk factor for coronary heart disease. Based on this public health concern, FDA concluded that the declaration of trans fat “will help consumers understand that trans fat is chemically distinct from saturated fat and will assist them in maintaining healthy dietary practices.” 68 Fed. Reg. 41433, 41437 (July 11, 2003).

By contrast to trans fat, there is no scientific consensus that added sugars are any more likely to lead to adverse health outcomes than other nutrients. Also unlike trans fats, added sugars are not chemically distinct from total sugars or other nutrients declared on the label. As support for the added sugars proposal, FDA relies solely on a recommendation in the 2010 DGA that consumption of added sugars should be limited. The agency recognizes that added sugars cannot be distinguished using analytical methods, and yet, for the first time proposes to require declaration of a nutrient for which there are no valid analytical methods. There is simply no precedent for requiring nutrition labeling for a nutrient for which there is no public health concern and for which there are no test methods.

Furthermore, requiring declaration of the added sugar content is not likely to assist consumers because it does not convey nutritional information that consumers cannot already receive through the “total sugars” and “calories” disclosures. Consumers already have the information needed to make healthy dietary choices because the total sugars and calorie content, unlike the added sugar content, reflect the food’s nutritional value. The existing label also provides consumers the information needed to assess a product’s nutrient density, or the nutritional value that the food provides per the amount of calories.

²D. Weaver and M. Fink; The relationship between the use of sugar content information on nutrition labels and the consumption of added sugars. *Food policy*. 2003, 28, 213-219.

There is no evidence that consumers would understand or know how to use the added sugars declaration. FDA has not yet conducted consumer testing on the proposed added sugars line. Consumers may not understand the role of added sugars as it relates to total sugars and carbohydrates. Absent such testing, we question how the agency could reach the conclusion that an added sugars declaration will assist consumers in maintaining healthy dietary practices. In particular, consumers may not understand that added sugars is a subcomponent of total sugars and carbohydrates and is not to be added to these values. To proceed without consumer insight into whether the information would be confusing would be imprudent and inconsistent with FDA's use of consumer research in the past and for other key elements of this proposal.

Additionally, a separate declaration for added sugars could call undue attention to this nutrient as a source of calories, when it is no different than other caloric sources from a nutritional or public health standpoint. As occurred when dietary recommendations overemphasized total fat, for which we now know the type of fat may be more important than the amount, consumers would be likely to look for levels as low as possible in this one nutrient, while ignoring other declarations. This is contrary to dietary guidelines, which recommend that all nutrients be considered in the context of the total daily diet, with a focus on total calories as the most important factor for weight control. For those with restricted or controlled sugar intake, total sugars are the primary nutrient of concern, not added sugars. An over-emphasis on added sugars by requiring a separate declaration would ultimately be detrimental for consumers because it places greater importance on this nutrient than do current dietary recommendations.

Lastly, our members are concerned that requiring companies to share the amount of added sugars on the label could endanger the confidentiality of product formulations. Current FDA regulations require an ingredient listing in descending order of predominance by weight, but do not require declaration of the amount of any ingredient or component added to the food. Requiring this information to appear on the food label would give competitors unprecedented access to information about a product's formulation. For example, for flavored milks, which contain both added and naturally occurring sugars, an added sugars line would require the company to provide proprietary information on the amount of sugars added as part of the flavor system. An added sugar line would therefore provide competitors with a crucial piece of insight into a recipe, and this could compromise legitimate trade secrets.

If FDA Chooses to Require an Added Sugars Declaration, the Definition of Added Sugars Requires Significant Revision

If the agency finalizes the proposed requirement to declare added sugars, the definition for added sugars would need significant revision and clarification. FDA has proposed to define added sugars as follows:

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.

Under this definition, there are a number of naturally occurring sugars that would inappropriately be classified as added sugars. The definition should be revised to exclude any ingredients containing intrinsic sugars that are not added for the purpose of adding sweetness. A focus on the functional effect of an ingredient is needed because it more closely aligns with the “no added sugar” definition, which recognizes that ingredients that contain sugars do not preclude the use of a “no added sugar” claim unless the ingredients “functionally substitute for added sugars.” 21 C.F.R. § 101.60(c)(2).

In the preamble to the final rule defining “no added sugar,” FDA clarified that “the use of any ingredient that contains sugars, including fruit juice and modified or concentrated fruit juice, for the purpose of substituting for sugars that would normally be added to a food, precludes the use of the ‘no added sugar’ nutrient content claim.” 58 Fed. Reg. 2302, 2327 (Jan. 6, 1993) (emphasis added). Importantly, the mere presence in a food of an ingredient containing intrinsic sugars, such as fruit juice or concentrated juice would not disqualify a food from bearing an added sugars claim. Only if the ingredient were added “for the purpose of increasing the sugar content,” such as by replacing cane sugar, would its presence disallow use of the claim. *Id.* at 2327. These basic principles are well-established based on the 1993 final rules first implementing the NLEA. It is incumbent upon FDA to ensure that updating the NLEA requirements does not conflict with established treatment of added sugars.

To ensure consistency with the “added sugars” definition, FDA should revise the proposed definition to provide that an ingredient containing naturally occurring sugars is only considered an added sugar when it is added for the purpose of substituting for sugars that would otherwise be added to the food. It is critical that the definition of added sugars be consistent with the “no added sugar” claim definition. Otherwise, a product that qualifies for a “no added sugar” claim could nonetheless be required to declare an amount greater than 0 g added sugars on the label. This would be misleading and confusing to consumers.

Some examples of ingredients that should not be included in the added sugars definition because they are not added for sweetening purposes are:

- The lactose in added dairy ingredients, such as whey, nonfat dry milk, or milk protein concentrates, as well as lactose in its pure form.
- Concentrated fruit juices, such as beet juice concentrate, that are added for color rather than sweetness.
- Fruit purees or juice concentrates that retain the natural constituents of the fruit and are used to add fruit flavor, rather than simply to add sweetness or substitute for sugars.
- Concentrated fruit juice that is reconstituted in the finished product.
- Ingredients that contain sugars such as dextrose that are used as carriers.

Based on these principles, we propose the following alternative definition of added sugars:

Added sugars are all mono and disaccharides (glucose, fructose, sucrose, and maltose) in a product irrespective of their origin that are added to foods during processing or preparation. Added sugars include the mono and disaccharides present in raw materials (e.g. white sugar, brown sugar, raw sugar, corn syrup, corn-syrup solids, high-fructose corn syrup, malt syrup, maltodextrins, maple syrup, pancake syrup, fructose sweetener, liquid fructose, honey, molasses, anhydrous dextrose, and crystal dextrose, powder form of any of the mentioned syrups). Added sugars do not include the mono and disaccharides that are intrinsic sugars such as:

1. Lactose from milk;
2. Pure added lactose;
3. Lactose in other dairy ingredients; or
4. Mono & disaccharides from any pure (i.e. with no added sugars) fruit ingredient such as juices, concentrates, fruit pieces, pulps & purees, provided that these ingredients are not added for sweetening purposes.

With respect to reconstituted juice concentrates, FDA has previously addressed the circumstances under which such ingredients may be used in a food that bears a “no added sugars” claim. In the preamble to the “no added sugar” final rule, FDA advised that “the addition of water to a juice concentrate to produce a single strength juice would not preclude the use of a ‘no added sugar’ claim,” provided the other conditions of the claim are met. 58 Fed. Reg. at 2328. FDA should incorporate this same principle in the added sugar declaration. Otherwise, a juice made from concentrate that is reconstituted to single-strength would be declared as containing added sugars but a juice not from concentrate would not be labeled as such. These two products are nutritionally equivalent and should not bear differing added sugar declarations.

Below we provide additional detail for why lactose should not be included in the definition of added sugars. We also provide recommendations for treatment of sugars produced by, or consumed during, fermentation of foods.

Lactose Should Not be Included in the Added Sugars Definition

IDFA is especially concerned that under the FDA’s proposed definition, dairy products would be required to declare added sugars contributed by lactose-containing ingredients. Lactose contributes only a very small amount of sweetness to the product to which it is added, regardless of whether it is in its pure form or as a component of milk, whey, or other concentrated dairy ingredients. Although lactose is a disaccharide, its characteristics are distinct from other sugars listed in the proposed added sugars definition. Because of this, lactose is not used as a sweetener. It is only 20 percent as sweet as

sucrose,³ has low cariogenicity (conducive to the promotion of dental caries) relative to other sugars,⁴ and has a relatively low glycemic index of 46, which is less than half that of glucose.⁵ Because of the unique characteristics of lactose, it is not added as a sweetening ingredient and should not count as added sugars.

Lactose-containing ingredients are often added to meet the express requirements of federal and state standards of identity and not for the purpose of raising the sugars content of the food. Rather than being added for sweetness, lactose is often added to dairy products to comply with the minimum milk solids not fat (MSNF) requirements. For example, nonfat dried milk and/or concentrated nonfat milk containing lactose is added to flavored milk that is sweetened with liquid sweeteners to restore the nonfat milk solids content to the mandatory 8.25 percent minimum required by the standard. The amounts of these ingredients added will depend on the individual processor's formulation. If lactose from added dairy ingredients were required to be declared as added sugar, some milks would be declared as containing added sugars while others would not, even when the two products are nutritionally identical with respect to sugar and calorie content and both products are formulated according to the standard of identity for milk. Lactose-containing ingredients are also occasionally added for protein fortification of fluid milks. In these situations, the lactose is not intended to, nor does it, add sweetness to the product, and should therefore not be counted as added sugars.

There are also minimum MSNF content requirements for yogurts and ice creams that may require the addition of lactose-containing ingredients and would trigger added sugars labeling for some products but not others, depending on the source of the dairy ingredients used to meet the required MSNF level (i.e., fresh milk vs. milk-based ingredients). Further, under the ice cream standard of identity, the sources of milkfat or MSNF may be declared in the ingredient statement simply as "milkfat and nonfat milk" regardless of whether concentrated milk or fresh milk is used. 21 C.F.R. § 135.130(e). This provision allows manufacturers to use either concentrated milk or fresh milk without changing the label declaration. If the lactose in concentrated milk were viewed as an added sugar, the use of dried milk would result in an added sugars declaration, while the use of fresh milk would not. This would be inconsistent and misleading, particularly given that the FDA standard of identity expressly provides that no distinction between fresh milk and concentrated milk must be made in the declaration of the ingredients in an ice cream.

A similar inconsistency would exist under several of the cheese standards. The standards for cottage cheese, cream cheese, American cheese food, pasteurized process cheese food, and pasteurized process cheese spread all provide for the use of skim or low-fat milk as ingredients; or if non-fat dry milk is used, it can be declared as skim milk. Under FDA's proposal, the addition of non-fat dry milk, which contains

³ Schaafsma, G. (2002). Nutritional significance of lactose and lactose derivatives. In H. Roginsky, J. W. Fuquay, & P. F. Fox (eds.), *Encyclopedia of dairy sciences* (pp. 1529-1533). London, UK: Academic Press.

⁴ Department of Health (1989). *Dietary sugars and human disease*. Report of the panel on dietary sugars, Committee on Medical Aspects of Food Policy. Report on Health and Social Subjects No 37, Her Majesty's Stationery Office, London, UK.

⁵ Foster-Powell, K., Holt, S. H., and Brand Miller, J. C. (2002). International table of glycemic index and glycemic load values. *American Journal of Clinical Nutrition*, 76, 5-56.

lactose, would be considered as contributing added sugars, while use of fresh milk would not. This runs contrary to FDA’s determination that the use of non-fat dry milk instead of fresh milk does not need to be declared any differently on the label.

In addition, due to the higher MSNF requirements mandated by the California state standards for fluid milk, reduced and low fat milks sold in California would be required to declare added sugars while the same products sold in other states would not. The California state standards of identity, which are exempt from federal preemption, mandate a higher MSNF content than the federal standard of identity; thus requiring the addition of nonfat dried milk, condensed skim, or condensed milk. Under the federal standard of identity, milk must contain at least 8.25 percent MSNF. The national milk supply is typically 8.6 percent MSNF, which would contain 11.54 g unrounded or 12 g rounded total sugar per 8 fl oz. The California Food & Agriculture Code prescribes the following higher minimum MSNF levels, which result in added sugars declarations for reduced fat and low fat milk.

Fluid Milk	California Food & Agriculture Code Section¹	Minimum MSNF	Total Sugar Unrounded²	Total Sugar Rounded	Added Sugar
Whole	35784	8.7%	11.67 g	12 g	0 g
Fat Free/Skim	38181	9.0%	12.07 g	12 g	0 g
Reduced Fat	32211	10.0%	13.04 g	12 g	1 g
Low Fat	38191	11.0%	14.7 g	15 g	3 g

¹ California Food & Agriculture Code can be accessed at: <http://www.leginfo.ca.gov/cgi-bin/calawquery?codesection=fac>

² Calculations based on 8 fl. oz. milk = 244 grams weight and 1 gram of MSNF= 0.55 g of sugar (IDFA nutrient database).

FDA’s proposed definition would trigger declaration of added sugars for reduced fat and low fat milks sold in California, but not in reduced fat and low fat milks sold in other states without such requirements. IDFA believes consumers would be confused by the declaration of added sugars in milk sold in some states but not others. This issue illustrates that naturally occurring sugars added for reasons other than sweetening, such as to increase the MSNF content to comply with standards of identity, should not be subject to added sugars labeling.

Fermentation

In the proposed rule, the agency addresses treatment of added sugars that are partially consumed during fermentation of the food. FDA states that in general, the amount of added sugars present in foods prior to undergoing fermentation will not be significantly affected by virtue of the food having undergone fermentation. In fact, in some cultured dairy products, the amount of sugars will be meaningfully reduced during the fermentation process. IDFA recommends that added sugars that are consumed by the microorganisms during fermentation should be subtracted from the added sugar declaration, and any sugars produced during fermentation should be omitted from declaration as added sugars. This is based on the following rationale:

- a) Sugars broken down or converted through the process to form compounds other than sugars should not need to be declared. For example, lactose in an ingredient added to a product where

the lactose is converted to lactic acid should not be declared as added sugars as it no longer exists when consumed.

- b) Sugars produced during the fermentation process should not be counted because they are not added to the product as such, but rather are formed during the manufacturing process. For example, where polysaccharides are processed through a fermentation step resulting in the formation of mono and disaccharides, the mono and disaccharides are not added in that form but rather are produced via fermentation.

As explained above, IDFA does not believe that lactose-containing dairy ingredients should count as added sugars because they are not added for sweetening purposes. Should FDA nonetheless include lactose as an added sugar in the final rule, the amount of added lactose that is consumed during the fermentation process (i.e., converted to lactic acid) should be subtracted from the added sugars declaration, as this amount is not present as sugars in the finished product, and any sugars produced during fermentation should be omitted from declaration as added sugars.

Recordkeeping Requirements for Added Sugars and Other Nutrients

IDFA opposes the proposed recordkeeping requirements for added sugars and other nutrients for which there is no reliable analytical method. The Federal Food, Drug, and Cosmetic Act (FFDCA) provides no express authority for FDA to impose requirements for recordkeeping, records access, or copying of records related to nutrition labeling. Moreover, there is no need for FDA to have records access for enforcement of the added sugars labeling requirement. Companies are already required to ensure that their nutrition declarations are not false or misleading under section 403 of the FFDCA, 21 U.S.C. 343(a)(1) and 21 C.F.R. § 101.9(g). This could be accomplished using a variety of approaches depending on the company and the product, and does not require that FDA have access to food manufacturing records. For example, a processor could explain the procedure used to determine the declared amounts or provide the values from a database where applicable, without providing the underlying records such as recipes or product formulations.

The agency has already recognized that it does not have authority to access food manufacturing records as part of its enforcement of the nutrition labeling requirements. FDA stated in the 1993 preambles to the final rules that it “does not have legal authority in most instances to inspect a food manufacturing firm’s records,” including in instances where FDA is seeking to “support a misbranding charge for inaccurate nutrient content information.” 58 Fed. Reg. 2066, 2110 (Jan. 6, 1993).

More specifically, FDA does not have authority to access highly proprietary records such as recipes and formulations. The Bioterrorism Act of 2002 expressly carves out “recipes” as a type of record that FDA cannot access, even in food safety emergency situations when the agency is granted access to other records. 21 U.S.C. § 350c(a). If Congress specifically protected recipes when food safety is involved, it follows that FDA does not have authority to access recipes in order to assess routine compliance with food labeling requirements. This statutory exemption also demonstrates that Congress did not consider the procedural protections of the Freedom of Information Act (FOIA) to be sufficient to protect records

as sensitive as recipes. FDA should clarify that it is not requiring companies to provide access to recipes or product formulations as part of the proposed recordkeeping requirements.

Moreover, even if FDA had authority to access to review these records during an inspection, the agency lacks authority to copy food manufacturing records. This is because copying the records is not needed for the “efficient enforcement of the Act,” which is the legal standard when FDA issues rules under its residual rulemaking authority. FDA inspectors can review the documentation and verify the nutrient declarations on-site rather than copying the records. Additionally, once a company’s records are copied by FDA and become part of the agency’s records, they are subject to potential release in the event of a data breach or inadvertent FOIA disclosure. IDFA is concerned that the proposed authority to copy records both exceeds the agency’s authority under the statute because it is not necessary to verify the nutrient declarations, and also is detrimental to industry given the possibility of an inadvertent release. This concern is heightened here due to the highly proprietary nature of the records at issue and the ability of FDA to require verification of added sugars without access to product formulation information.

If FDA does finalize the provision on copying records, the agency must ensure the security of its data systems. Records submitted to FDA for enforcement purposes should not be available to the public through FOIA. We request that the agency explicitly clarify this in the preamble to the final rule to ensure protection for this sensitive business information. FDA should also take steps to ensure the security of other forms and correspondence associated with enforcement of added sugars declarations, such as 483 forms coming from inspections. If an inspection that includes a review of the added sugars documentation results in a 483 form (or other paperwork), currently this form is releasable under FOIA and could contain sensitive information. The agency should develop and implement procedures to ensure that no confidential information is inadvertently disclosed.

The agency should also clarify that records may be kept at corporate headquarters and should specify the timeframe by which companies would need to provide these records upon request by FDA. The typical 24-48 hour period to provide records is likely not long enough for these types of records. Since substantiation for nutrition labeling declarations is not a food safety issue, we request a longer timeframe of 15 days (similar to the time required for a response to an FDA Warning Letter) to respond to a request for these records.

Trans Fat Declaration

In November 2013, FDA published a tentative determination that would remove the Generally Recognized as Safe (GRAS) regulatory status for partially hydrogenated oils (PHOs). In comments to the docket on this tentative determination, IDFA explained its concerns about the potential unintended consequences of such a regulatory change and the impact on companies.

If FDA’s tentative determination to remove the GRAS status for PHOs is finalized, “trans fat” should no longer be a mandatory nutrient to declare on the NFP. If finalized, the tentative determination would effectively remove industrially-produced trans fats from the U.S. food supply, leaving only naturally-occurring trans fats from animal products. In the tentative determination, FDA cites the 2005 Institute

of Medicine (IOM) recommendations to limit consumption of trans fats while consuming a nutritionally adequate diet, recognizing that naturally occurring trans fats are unavoidable in ordinary, non-vegan diets without significant dietary adjustments that may introduce undesirable effects. Because dietary guidelines do not recommend limiting naturally occurring trans fats in the diet, it would be logical to discontinue mandatory declaration of trans fat if the tentative determination is finalized. If trans fat labeling is still required, the declaration of trans fat at a minimum level of 0.5 grams should be retained.

Lastly, it is imperative that FDA coordinates its actions around changes to the NFP and any changes to the GRAS status of PHOs. This will allow manufacturers to make any changes required by these two rulemakings in the most efficient, timely manner.

Sodium Declaration

IDFA agrees with FDA that there is insufficient evidence to support setting the Daily Value for sodium at 1500 mg. In proposing the revised DV for sodium, FDA appropriately sought to take into account “its essentiality in relatively small amounts as well as its association with increased blood pressure at greater but varying levels of intake.” 79 Fed. Reg. at 11915.

While the DGA recommend a lower level of sodium for a number of subgroups in the American population, the 2013 IOM report on Sodium Intake in Populations found there is “no evidence on health outcomes to support treating population subgroups differently from the general U.S. population.” Moreover, it is unnecessary for the general US population to lower their sodium intake below the 2300 mg level. As the IOM concluded in its 2013 report, there is insufficient evidence to conclude that lowering sodium intakes below 2300 mg will increase or decrease the risk of cardiovascular disease outcomes or all-cause mortality in the general U.S. population. In fact, recent research suggests that low sodium intakes may increase health risks for some individuals. In particular, some recent research has pointed to the effects of sodium consumption on morbidity and mortality,⁶ as well as the possible negative consequences of a low sodium diet for certain subpopulations.⁷ This research should be understood as part of the total body of scientific evidence regarding sodium and health. Based on these considerations, IDFA supports FDA’s proposal to reject a Daily Value of 1500 mg for sodium.

As a next step, IDFA recommends that a credible scientific panel re-evaluate the sodium intake range that is compatible with optimal health and considers data on biomarkers (such as blood pressure) as well as data on health outcomes and mortality, considering all recent studies.

The Institute of Medicine’s (IOM) most recent evaluation of the science linking sodium intake to cardiovascular disease outcomes did not define an intake range associated with optimal health or reduced risk of disease and suggested the need for additional research. In addition to the IOM report, a recent study has further supported safe consumption of sodium at levels above 2300 mg. This meta-

⁶ Alderman, MH. “The Cochrane review of sodium and health.” *Am J Hypertens*. 24(8): 2011.

⁷ Waikar, SS et al. “Mortality associated with low serum sodium concentration in maintenance hemodialysis.” *Am J Med*, 124(1): 2011.

analysis identified a specific range of sodium intake (2,645-4,945 mg) associated with the most favorable health outcomes, within which variation in sodium intake is not associated with variation in mortality.⁸ Therefore, we recommend that FDA convene a credible scientific panel to consider all recent research concerning sodium and health, and in particular, to recommend a new Dietary Reference Value for sodium.

Dietary Fiber Definition

IDFA is concerned that FDA's proposal to establish a definition for dietary fiber and require pre-approval for isolated fibers would treat one nutrient differently than all others without legal authority or justification to do so. FDA does not cite any legal authority for its proposal to define dietary fiber in a way that would require a fiber to have a physiological effect that is beneficial to health, as established through a mandatory petition process. Nor does the NLEA provide legal authority for FDA to allow declaration of a nutrient only if it has a beneficial effect. Rather, the existing approach under the statute for all other nutrients is that label declaration is based on the chemical definition of the nutrient, as determined by analytical methods. As stated by FDA in the preamble, "the definitions of nutrients for food labeling purposes have traditionally been based on chemical definitions, rather than on individual physiological effects." 79 Fed. Reg. at 11894-95. Applying this traditional practice, FDA rejected an approach that would exclude stearic acid from the definition of saturated fat. It would be arbitrary and capricious for FDA to take a different approach for dietary fiber than for saturated fat and all other nutrients. Therefore, FDA should retain the existing requirements for dietary fiber declaration without restricting the types of fibers that may be counted as dietary fiber.

Even if such an approach were authorized, isolated fibers have beneficial health effects and should therefore be included in the definition of dietary fiber for labeling purposes. There are many fibers or soluble carbohydrates that pass through the small intestine and progress to the colon where they may be used by beneficial bacteria as a source of energy. Such carbohydrates are typically of the soluble type and include inulin, lactulose, calcium lactobionate, galacto-oligosaccharides, and others. An evidence review of the composition, source of inulin and oligofructose, their characteristic and physiological effects of support their inclusion as dietary fibers. Inulin and oligofructose are not digested in the upper part of the gastrointestinal tract, or are they absorbed or metabolized in the glycolic path way, or directly stored as glycogen like sugar or starches. These materials reach the colon where they are fermented leading to selective stimulation of bifidobacteria population⁹. Further both inulin and oligofructose have most of the characteristics of a dietary fiber's physical effects such as gastric emptying and small intestinal transit time resulting in improved glucose tolerance and decreased

⁸ Graudal N, G Jurgens, B Baslund, and MH Alderman. Compared with usual sodium intake, low-and excessive-sodium diets are associated with increased mortality: a meta-analysis. *American J. Hypertens.* 2014; 1-9.

⁹ Flamm G., et al., "Inulin and oligofructose as dietary fiber: a review of the evidence", *Cit Rev Food Sci Nutr*, 2001: July;41(5) 353-62

digestion of starch, and also increase colonic transit time and fecal mass.¹⁰ These soluble fibers, as well as others not listed, commonly provide benefits such as improved mineral absorption and digestive function.

In the alternative, should FDA decide to finalize the proposed definition of dietary fiber, we request that the agency use a voluntary pre-notification process instead of a mandatory pre-approval process, similar to the existing procedures for FDA Modernization Act (FDAMA) health claims.¹¹ Use of a voluntary pre-notification process would reduce the regulatory burden on the agency and provide more consistency and certainty with respect to the timing of the process. Companies could choose whether to avail themselves of this voluntary process, based on the facts at hand and the extent to which they may desire regulatory certainty before making a claim. In this way, companies would be able to declare isolated fibers as dietary fiber if they have scientific documentation of the beneficial effects of the fiber.

To the extent that FDA continues to believe an emphasis on physiological benefit of fibers is warranted, the appropriate way to address the issue would be to clarify that where a company makes a structure-function claim for dietary fiber, such as “fiber helps maintain healthy digestive function,” the substantiation for that claim would need to be based on a physiological effect. Companies are already required to substantiate all claims appearing on the food label, and this clarification could be done through guidance rather than by amending the definition of dietary fiber. The chemical definition should continue to serve as the relevant definition for purposes of declaration of dietary fiber as part of the Nutrition Facts panel.

Declaration of Other Nutrients

In the comments that follow, IDFA offers its perspective on several of the proposed provisions on declaration of other nutrients, including on analytical methods, the units for declaration, and the mandatory or voluntary declaration of nutrients.

Absolute Amounts for Vitamins and Minerals

FDA should not require the listing of all vitamins and minerals by their absolute amounts on the Nutrition Facts panels of conventional foods. Unlike for dietary supplements, the conventional food industry cannot accurately identify the precise quantitative amounts of vitamins and minerals in conventional foods. The vitamins and minerals in conventional foods such as dairy products are often naturally occurring in the various ingredients such as milk or fruit, and are subject to far more variability.

¹⁰ Roberfroid M, Dietary Fiber, inulin and oligofructose: a review on comparing their physiological effect, *Cit Rev Food Sci Nutr*, 1993;33(2) 103-48

¹¹ Although quite different in authority and scope, there is precedent for seeking consultation from the agency short of formal rulemaking, such as the GRAS or FDAMA health claim notification processes, or the biotechnology consultation process.

Additionally, FDA has not established rounding rules for most vitamins and minerals, as it has for other nutrients and for the percent DVs for vitamins and minerals. Absent this type of flexibility, a requirement to declare absolute amounts of vitamins and minerals would make ensuring compliance with the declared value unrealistic given the inherent variability of naturally occurring vitamins and minerals.

Protein

IDFA agrees with the Agency's current approach regarding labeling and the proposed Daily Value for protein. However, we would also like to provide information on a new approach for calculating protein quality, the digestible indispensable amino acid score (DIAAS). We would ask for future consideration of the DIAAS for labeling purposes once the method is fully evaluated.

The percent DV for protein must be declared on the Nutrition Facts label whenever a protein claim is made and be based on the "corrected amount of protein (gram) per serving" (21 CFR 101.9). The current method required by regulations for determining the protein digestibility-corrected amino acid score (PDCAAS) is based on the "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, as published by the Food and Agriculture Organization (FAO) of the United Nations/World Health Organization.

More recently, in 2011, another FAO Expert Consultation on Protein Quality Evaluation in Human Nutrition was held. The FAO recognized that the PDCAAS method had now been in use for over 20 years and had proved to be of considerable value in practice. However, limitations of PDCAAS method have been debated, and new research findings had evolved. Thus, it had become timely to review the adequacy of PDCAAS and its application vis-à-vis other methods of estimating dietary protein quality. Amongst other specific objectives, the Consultation reviewed the effectiveness and use of the PDCAAS method for evaluating protein quality, assessed current concerns and limitations of the PDCAAS method as reported in the literature, and considered the need for revisions or modifications based on knowledge and experience of the previous two decades.

The report from the Expert Consultation, *Dietary protein quality evaluation in human nutrition*, was published in 2013.¹² The report provides an objective assessment of the current state of scientific knowledge in the area of dietary protein quality and advice for current best practice. A key recommendation by the Consultation was to replace PDCAAS with a new protein quality measure known as digestible indispensable amino acid score (DIAAS). DIAAS is defined as: $\text{DIAAS \%} = 100 \times [(\text{mg of digestible dietary indispensable amino acid in 1 g of the dietary protein}) / (\text{mg of the same dietary indispensable amino acid in 1g of the reference protein})]$. The report concluded that DIAAS more

¹² Food and Agriculture Organization Expert Consultation. "Dietary protein quality evaluation in human nutrition." <http://www.fao.org/ag/humannutrition/35978-02317b979a686a57aa4593304ffc17f06.pdf>. Accessed July 28, 2014.

accurately reflects protein digestion and amino acid absorption compared to the values used as part of the PDCAAS calculation.

The FAO report states that for regulatory purposes DIAAS is the recommended method for dietary protein quality assessment. Two scoring patterns are recommended: the amino acid composition of human milk for infant formula, and for all other foods and population groups the amino acid pattern for young children (6 months to 3 years). The report also recognizes that more research is needed to fully adopt the DIAAS method for protein quality and provide best practice guidelines.

Niacin

IDFA supports FDA's proposal to change the units for niacin content to niacin equivalents (NE). We are pleased that this change would include both niacin and tryptophan in the declaration of niacin content in the Nutrition Facts panel. Dairy foods contain both preformed niacin and tryptophan, so we are pleased to be able to highlight the full nutritional content of these products.

Vitamin D

IDFA agrees with FDA's proposal to require mandatory declaration of both vitamin D and potassium. We believe that since these nutrients are designated as nutrients of concern, with intakes among the US population consistently below recommended levels, it is important for consumers to be able to identify foods that are good or excellent sources of these nutrients.

Many dairy products are excellent sources of vitamin D through fortification. The levels of vitamin D that may be added to dairy products are strictly regulated through the requirements of product standards of identity and food additive and GRAS regulations. Many of these restrictions were first put into place due to concerns about over-consumption of vitamin D. There are fewer concerns today about consumption of excessive amounts of vitamin D, as illustrated by the proposed 200 percent increase in the Daily Value of vitamin D.

With an increase in the Daily Value for vitamin D, but with no corresponding increase in the level of vitamin D fortification allowed in dairy foods, the percent Daily Value for vitamin D declared for these products will decrease, although no change has been made to the product. As compared to other products, for which the food additive or GRAS regulations permit higher levels of vitamin D fortification or that are not subject to standards of identity, nutrient-rich dairy products could appear to be a less desirable choice when, in fact, they are a valuable source of vitamin D.

Therefore, we request that, in conjunction with changes to the Nutrition Facts panel declarations, work be undertaken to amend—at the same time—the applicable standards of identity and the food additive or GRAS regulations to allow for higher levels of fortification of vitamin D in dairy products and allowing many dairy products to continue to provide good or excellent sources of vitamin D. This would ensure consistency between the Daily Values and the restrictions on fortification.

Calcium

We are pleased that calcium will continue to be a mandatory nutrient for declaration on the Nutrition Facts panel. As recognized by FDA in the proposed rule, the vast majority of Americans do not consume adequate amounts of calcium. Dairy foods continue to be the class of foods that provides most Americans with their calcium intake.

With the proposed change in the Daily Value for calcium, many dairy products will be able to continue making claims about their high levels of calcium. However, the natural levels of calcium in many cheeses will fall just below the level required for an “excellent source” claim. Additionally, under the proposed smaller RACC for yogurts, many yogurts will no longer qualify for an “excellent source” claim. We are concerned that shoppers will notice these lower levels of calcium, or the loss of the “excellent source of calcium” claim, and be confused that calcium is being reduced or removed from the cheese. As noted above, we ask that FDA consider the potential for consumer confusion or detriment to consumers resulting from decreased availability of foods with naturally occurring sources of nutrients that qualify for “excellent source” claims.

Compliance Date

Implementation of the planned changes in the two proposed rules would require a significant investment of time and resources. These changes would require reformulation, updating labels and new packaging. An implementation date should allow for a sufficient amount of time for companies to make labeling and product changes.

The cost of labeling changes estimated by FDA in the proposed rule was significantly understated. We understand that FDA is in the process of developing and circulating a survey to learn about the costs involved with label changes. We support this effort to allow a clear understanding of the resources needed for companies to alter their labels.

These costs include:

- Time and resources to reformulate products. With the changes in definitions of nutrients and in the Daily Value levels, many products may lose the ability to make nutrient content claims, including those included in the product names. If manufacturers want to continue using these nutrient content claims that consumers recognize, then they will need to reformulate the products (where authorized under the regulations) in order to ensure that they meet the new requirements.
- The resources needed for packaging and labeling design, both within companies and possibly with outside labeling companies. Many dairy processors work with specialized label design companies to make the labels for their products. With a mandate to change the label of every food product sold with a Nutrition Facts panel, these labeling companies will experience a huge

demand and could develop a significant backlog, further extending the time needed to make updated labels available.

- Time and cost to update nutrition labeling software. Many dairy companies utilize computer software to calculate the nutrient values that will be placed in the Nutrition Facts panels of their products. The multitude of changes that would be required, including changes to Daily Value levels, new nutrients to declare, changes in definitions of nutrients, and changes in the units used to declare nutrient levels, will require significant updates to the labeling software.
- The value of discarded labeling that does not meet the new requirements. Although companies do work to efficiently plan the number of labels or printed packages they need over a given period of time, a compliance date that does not provide sufficient time would disrupt this planning, and may require large amounts of labeling and packaging inventory to be discarded. For companies that have many different products with many different labels, such as ice cream or yogurt manufacturers with many flavors, the cost of discarded labels could be even higher. A longer timeframe for implementation of the new labeling requirements will help lower the number of labels that must be discarded, therefore lowering the cost of coming into compliance with the new regulations.

Further, the time and cost required to implement the proposed changes would be significantly greater than that required for initial implementation of the nutrition labeling rules in 1993. The number of products has greatly increased since 1993, each of which will need a revised label. Additionally, today's labeling and packaging materials are frequently more complex and costly to revise than in 1993. For example, rather than a simple yogurt cup with a printed wrap-around label, companies may use printed film labels, for which new plates for printing would be required. Additionally, packaging for dairy products may be in the form of grab-and-go or multi-component packages that are more complicated and costly to revise and reprint. Lastly, food labels now include more nutrition and health-related information on-pack, in response to consumer preferences for such information. All claims will need to be evaluated to determine whether products remain eligible for the claims under the new requirements. These factors all result in the need for additional time and resources to make the changes.

Based on these considerations, we ask FDA to set a compliance date for all proposed changes to the Nutrition Facts panel of four (4) years following the publication of a final rule. Providing a longer compliance period would also significantly reduce the financial burden of implementing the new requirements. It would allow for a more efficient transition and would require fewer packages and labels to be disposed of because manufacturers would have additional time to use up inventory.

Conclusion

In conclusion, IDFA asks FDA to carefully revisit the proposed rule with special consideration given to: (1) the agency's legal authority for the proposed revisions, and (2) consistency with the best available scientific evidence, including dietary recommendations and consumer research. We also urge the agency to set a compliance date of four (4) years after the effective date.

IDFA appreciates the opportunity to provide the foregoing comments and believes with the modifications requested above, the planned changes will provide consumers with more accurate and useful information to help facilitate informed dietary choices. We look forward to continuing to work collaboratively with the agency to provide a variety of nutrient-rich foods to Americans and to effectively communicate nutrition information using the food label.

Respectfully submitted,



Connie Tipton,
President and CEO



Cary Frye
Vice President,
Regulatory and Scientific Affairs

July 31, 2014

ELECTRONIC SUBMISSION

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Re: Proposed Rule for Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments, Docket No. FDA-2004-N-0258

Dear Sir or Madam:

The International Dairy Foods Association (IDFA), Washington, D.C, represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a \$125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's nearly 200 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream, and frozen desserts produced and marketed in the United States.

We appreciate the opportunity to provide comments to the Food and Drug Administration (FDA) regarding proposed changes to serving sizes of foods that can be consumed in one-eating occasion, modifications to reference amount customarily consumed (RACCs), and the new approach to require dual-column labeling. The Nutrition Facts panel is an important part of nearly every food package sold in the United States and also serves as an integral component of nutrition education and information for consumers. We agree with the agency that it is essential to update the Nutrition Facts panel serving sizes to ensure that consumers get accurate information on the amount of food they are consuming and that the information presented is reflective of the very best nutritional science available. However, we have a number of concerns about some of these proposed changes, and their potential impacts on the way that consumers understand the information available on the label relative to the portions of food they eat. Additionally, our comments below provide detailed information on FDA's proposed modifications to the RACCs for ice cream and yogurt.

Revisions to the Definition of a Single Serving Container

IDFA generally supports FDA proposed revisions to the definition of a single serving container such that a product that is packaged and sold individually and contains less than 200 percent of the RACC would be considered as a single serving container and the entire content of the product would need to be labeled as one serving regardless of the size of the RACC. We believe this change will provide consistency across all food products on the amount that constitutes a single serving. We agree that the definition of a single serving should not include containers with 200 percent or more of the RACC as this amount would represent two or more servings, rather than a single serving, based on the updated consumption data. An approach that deemed containers with 200 percent of the RACC as a single serving container would also be a significant departure from the existing approach, whereby the RACC is the amount customarily consumed in a single eating occasion, and would be confusing to consumers.

Dual-column Labeling May Be Confusing to Consumers

We are concerned about the newly proposed requirement for containers with 200 percent up to and including 400 percent of the RACC to bear a second column of nutrient values based on the entire container. We believe that the second column of nutrient values would be confusing to consumers. Consumers could interpret a dual-column label as indicating that it is appropriate (or intended by the manufacturer) to consume the entire container in one sitting. Additionally, the proposed dual-column label format provides significantly more information than the existing voluntary dual-column label format. It includes both absolute values and percent DVs for all nutrients, vitamins, and minerals. We expect that this would be too much information for most consumers to digest, and could result in information-overload, thereby undermining the value of the Nutrition Facts panel.

The potential for consumer confusion has not been fully evaluated because FDA did not conduct consumer testing on the proposed dual-column format, which includes significantly more information, but rather only tested the existing, simpler dual-column format. FDA does not explain on what basis it believes the results from that study may be assumed to apply to the proposed format. The proposed change is significant and its impact should be more fully studied.

Dual-column Labeling May Not Be Appropriate for All Products with 200 to 400 percent of the RACC

As noted above, we believe dual-column labeling is likely to be confusing to consumers. In the event FDA conducts further consumer research and decides to finalize the proposed requirements, a number of exemptions are warranted.

First, IDFA agrees with the agency that products that qualify for the tabular or linear format should not be required to provide a second column of nutrition information. It will be challenging to incorporate dual column labeling on certain packages based on the limitation of space especially for these small size packages with 200 to 400 percent of the RACC. We would like to point out that dairy products, such as cottage cheese, which has a ½ cup RACC and is packaged in an 8 ounce container, may not have

sufficient label space to accommodate dual-column nutrition information. Additionally, natural cheese may be packaged in 3.5 ounce packages which would be less than 400 percent of the RACC and would require dual-column labeling, which would be especially difficult on a package of this small size. Therefore, we support FDA's exemption for dual-column labeling on packages with limitations in labeling space that use the tabular or liner format of the Nutrition Facts panel. The exemption is practical and necessary.

IDFA also agrees that a product used primarily as an ingredient, rather than consumed on its own, should be exempt from dual-column labeling and should only be required to declare nutrient information on a "per serving" basis. We agree with the agency that labeling these products with nutrition information on a "per container" basis would not be consistent with how these products are typically consumed. We realize that many dairy products can be used both for direct consumption and as an ingredient in baking or cooking other foods. IDFA requests that FDA consider the following milk and dairy products as multiuse products that should be exempted from dual-labeling requirements: milk (unflavored), acidified milk, cultured milk, concentrated milk, sweetened condensed milk, nonfat dry milk, evaporated milk, dry whole milk, dry cream, heavy cream, light cream, light whipping cream, sour cream, acidified sour cream, and half-and-half. We understand that milk and dairy products such as flavored milk, eggnog, and yogurt that are mostly directly consumed will be required to bear dual-column labeling. There are also cheeses that are either consumed directly, or that may also be primarily used as an ingredient in other foods, depending on the form of the cheese, such as shredded or grated, or the type of the cheese, such as ricotta cheese, mascarpone, cream cheese, and Neufchatel. We ask that FDA provide additional clarification in the final rule that cheeses that are primarily used as an ingredient in other foods will be exempt from dual-column labeling.

IDFA also recommends that FDA consider expanding the exemptions from dual column labeling to products for which a consumer would not reasonably consume an entire container with 200 - 400 percent of the RACC in one eating occasion. We understand the intent of dual-column labeling is to provide consumers with information about the calories and nutrients they would consume if they eat or drink the entire container in one sitting. Therefore, it is important to recognize that some foods like fluid milk are rarely consumed at the level of 200 to 400 percent of the RACC. There is no danger of over consumption of milk leading to excess calories. Throughout the last three decades fluid milk consumption has been on a consistent downward trend from 30.14 gallons per capita in 1970 to 19.79 gallons in 2012 (from about 1.32 to 0.87 servings per day).¹ This decrease in milk consumption is attributed in large part to displacement of milk by beverages such as carbonated soft drinks, bottled water, fruit juices, fruit drinks, flavored teas, and in more recent years, non-dairy alternative milk beverages. Based on this information, IDFA believes it is not appropriate for certain products like a quart of fluid milk (400 percent RACC) to be labeled with dual-column nutrition information as there is little likelihood that four servings of milk would be consumed in an entire sitting. We request that fluid milk

¹ IDFA, Dairy Facts 2013, US Per Capita Sales of fluid milk products, 1955-2012.

be exempt from dual-column labeling based on the level of consumption, in addition to its use, noted above, as an ingredient in other foods.

IDFA also asks FDA to confirm that packages that contain multiple individually packaged units are exempt from the proposed dual-column labeling requirements unless the individual units contain between 200 and 400 percent of the RACC. The proposed regulations would require dual column labeling if “a unit” contains between 200 and 400 percent of the RACC (proposed § 101.9(b)(2)(i)(D)). Further, the requirements would apply to products that are “packaged and sold individually” and contains between 200 and 400 percent of the applicable RACC (proposed § 101.9(b)(12)(i)). Based on the proposed codified language, it does not appear that the criteria for mandatory dual-column labeling would apply to a multi-pack product as a whole. Rather, it would only apply where the individually packaged unit contains between 200 and 400 percent of the RACC. This makes sense because where products are sold as multi-packs of discrete, individually packaged units, consumers typically consume only one unit per eating occasion. Additionally, the dual-column label would likely not fit on the outer label for many multi-pack products, such as multi-packs of yogurt that contain 4 - 6 ounce cups together in one package. We therefore ask FDA to clarify that the dual-column labeling requirements would not apply to multi-unit packages and that the 200-400 percent of the RACC criterion applies to individually packaged units.

The Proposed RACC for Frozen Desserts Ice Cream and Novelties

Ice Cream Consumption Did Not Change Significantly from 1993 and the RACC Should Remain at ½ cup

IDFA strongly objects to the newly proposed RACC of 1 cup for “Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk,” which would be a twofold increase from the current RACC of ½ cup. FDA’s own calculations from data on the current consumption of ice cream from the median intake estimates from the NHANES 2003-2008 confirmed that consumption data on the original product category, which included both bulk and novelty ice creams, “generally did not change by at least 25 percent.” 79 Fed. Reg. at 12012. It is only by proposing to separate the ice cream product category into separate RACCs for bulk ice cream and novelties, that FDA was able to determine that consumption of one of those categories (i.e., “bulk ice cream) had increased by more than 25 percent since 1993.

FDA has stated there were two factors used to evaluate whether to consider updating the current 1993 RACC. *Id.* at 12008. The first consideration would be to determine if there is an adequate sample size of consumption data for the product in the NHANES 2003-2008 data set. The second factor was to assure that the median estimate of intake from the NHANES 2003-2008 consumption data significantly differed from the 1993 RACC for the product. FDA stated that a significant difference would be an increase or decrease of at least 25 percent. The agency chose the 25 percent approach based on its analysis of the data and after evaluating other values for percent differences (e.g., 5%, 10%), when applied to the data. FDA stated, “For a product which there was not at least a 25 percent difference in consumption, we did not consider updating the 1993 RACC.” *Id.*

IDFA is concerned that FDA made an arbitrary decision to depart from these principles when considering consumption data for the original product category for all ice creams. If we examine the two factors for evaluating a change to the 1993 RACC, it is clear that the NHANES 2003-2008 data set had an adequate number of samples to evaluate, as there were 9372 samples for bulk ice cream and novelties. However, with respect to the second factor, FDA found that the consumption data for the original ice cream product category did not change. It is only by splitting the ice cream category into two separate categories that the agency could determine that the 25 percent threshold was met for one of the categories. IDFA believes that based on the lack of a significant change for ice cream FDA should retain the current 1993 serving size of 1993 RACC of ½ cup for both bulk and novelty ice cream, rather than splitting the category into two groups for the apparent purpose of allowing the RACC for one of these categories to qualify for an increase.

Moreover, the separation of the ice cream category into two sub-categories raises an issue of consistency that counsels in favor of retaining the existing ½ cup RACC for all ice cream. Often, the exact type of ice cream sold in a ½ cup individual serving container (referred to as “novelties—cups” by FDA) can be packaged in a larger bulk container such as a pint or ½ gallon. Although the products will have identical formulations, the differing RACC between bulk and novelties package size would result in different criteria for the nutrient content claims such as “low fat” or “fat free.” This would mean the same ice cream will meet the criteria for “low fat” when packaged in a small novelty-sized cup, but not when it is packaged in a larger container. FDA should rectify this and ensure consistency between the two RACCs for ice cream by retaining a RACC of ½ cup for all ice cream.

It is crucial for FDA to adopt a consistent approach for establishing RACCs for all foods and to apply that approach uniformly. Otherwise, the labeled serving size could mean different things for different food categories and would not permit consistent comparisons of nutrition information across foods.

A Half Cup Measure for Ice Cream is a Practical and Realistic Reference Amount

IDFA understands that in response to the Advanced Notice of Proposed Rule Making (ANPRM) the agency received a number of comments stating that the RACC for ice cream was “unrealistic” and “misleading” and that a ½ cup of ice cream is smaller than a household ice cream scoop. We disagree with these comments, as the common household scoop is traditionally what is considered as a # 8 size portioning scoop, meaning that it dispenses 8 servings of ice cream per quart, or exactly a one ½ cup (4.0 ounces) of ice cream. We acknowledge that, as with many foods, consumers who enjoy ice cream may choose to serve themselves multiple scoops, but the ½ cup measure is a simple common reference point that consumers clearly understand. With ongoing concerns about obesity in America, it is important to have simple tools to help consumers manage their weight. Portion control and accurately determining the amount of food that one consumes is vital to manage calorie intakes for healthy eating and body weight management. Consumers often use the serving size stated on the label of a multi-serving package as a reference to determine what is an appropriate portion of food to consume. Just as the Nutrition Facts panel provides references on the proper amounts of nutrients, vitamins and minerals by stating the amount of nutrients as a percentage of the recommended daily values, it should also be a guide to determine reasonable portion sizes. If FDA sets the serving size of ice cream at a whole cup,

this would be viewed by consumers as an indication that two scoops of ice cream is an appropriate portion. IDFA strongly believes that the RACC serving size of bulk ice cream and frozen dessert should remain at ½ cup to provide a practical and easily understood guide for reasonable portion sizes.

If FDA Determines the RACC for Ice Cream Should be Separated into Two Product Categories, a 3/4 cup Household Measure for Bulk Ice Cream Reflects Current Consumption Data and Product Composition

FDA used incorrect density measurements to determine household measure for ice cream

The ice cream industry believes that FDA used incorrect and outdated density measurements for ice cream when converting from the amount of ice cream consumed, as reported in NHANES, data to the common household measure based on cups in order to determine the RACC for bulk ice cream.

By way of brief background, the federal standard of identity for ice cream and frozen custard (21 C.F.R. §135.110) prescribes that the product is “produced by freezing while stirring, a pasteurized mix consisting of optional dairy ingredients...” The incorporation of air into the ice cream mix while freezing is a critical step to create the creamy texture of the final frozen product. The standard for ice cream also includes a minimum weight per gallon for ice cream and frozen custard, which is not less than 4.5 pounds per gallon, so there is a de facto threshold for the amount of air that can be incorporated. A typical ice cream mix made up of cream, milk, nonfat milk solids, sweetener, and stabilizers weighs approximately 9.0 pounds per gallon. Therefore, ice cream must not have more than 50 percent air incorporated during freezing. So as a general rule of thumb, 1 ounce of ice cream on a weight basis would result in 1.5 fluid ounces or less on a volumetric basis. This is the basis for the conversion factor between weight and volume, which is discussed further below.

Packaged ice cream that is sold to consumers at the retail store from the freezer case is often referred to as hard ice cream. Soft serve ice cream is typically dispensed from the ice cream freezer for immediate consumption by the consumer on cones or shakes at food service establishments. Both hard ice cream and soft serve ice cream are made from ice cream mixes with similar ingredients of cream, milk, milk solids, sweeteners, and small amounts of stabilizers, but packaged hard ice cream includes an additional deep freezing or “hardening” step after packaging. Since soft ice cream is immediately consumed in cones and dishes it must be dispensed from the freezer in a semi-firm state, which is achieved by freezing at a higher temperature, but with less air so that the product remains creamy but stiff.

Production of packaged ice cream that includes the hardening step requires incorporation of greater amounts of air during freezing. When formulating and freezing ice cream there are a number of factors that must be considered and balanced to produce the desired creamy textured ice cream such as fat content, milk solids level, sweeteners used that may affect the freezing point, flavorings, and amount of air incorporation during freezing. Typically higher fat ice premium creams have less air incorporated, while lower fat and economy ice creams have higher amounts of air. However, advances in ice cream

processing technology over the past decades introduced “low temperature extrusion” also known as “slow churned” freezing resulting in superior low fat ice cream with creamy texture with less air incorporation.

In summary, IDFA would like to point out that determining an average density for ice cream to apply when converting a weight to volume is not a simple matter. As explained in further detail below, we believe that FDA used incorrect density data to convert the 2003-2008 NHANES median serving size in grams to the household measure units for determining the household measure of ice cream and frozen desserts.

We reviewed the information in FDA Table 6 “Mean and median consumption amounts per eating occasion of the general food supply (individual 4 years of age and older)” for Desserts from the NHANES 2003-2008 data (in grams and in household measures), the 1993 RACCs, and the proposed changes to the RACCs.² We noted that footnote 4 in Table 6 states the household units were calculated using the following conversion factors: 1 oz. of ice cream or frozen yogurt = 1.5 fl. oz; 1 cup= 8 fl. oz (citing 21 C.F.R. § 101.9(b)(5)(viii)). As described above, we agree with this conversion factor based on the air typically incorporated into ice cream. However, we do not believe FDA has appropriately applied the conversion factor. The median weight for “Ice cream, bulk, and regular” from 2003-2008 NHANES is 116 grams. In the proposed rule FDA states that “current consumption increased to 0.875 cup which is close to 1 cup as compared to the current RACC of ½ cup.” But if the footnote conversion factor were applied to the median serving size of ice cream expressed by weight, it would result in a lower value of 6.108 fl. ounces or 0.767 cups, which would round in household measures to ¾ of a cup. (116 grams/28.35 grams per oz. = 4.09 oz. x 1.5 = 6.138 fl. oz.). This corresponds to a density value of 151 g per cup for ice cream and frozen yogurt; i.e. (1 oz./1.5 fl. oz.)(8 fl. oz./1 cup)(28.35 g/oz.) = 151 g/cup.

FDA provides no explanation for departing from the conversion factor in the NHANES data.

FDA should use the most current NHANES data from 2003-2010 and updated food codes for portions of ice cream

IDFA reviewed information on additional analysis of USDA’s What We Eat in America (WWEIA) NHANES database to better understand the portion weights and volumes for ice cream, frozen desserts that was prepared by an expert consultant Victor Fulgoni, III of Nutrition Impact LLC. Based on this assessment, we recommend that FDA use the most current density measurement for ice cream of 148 g per cup, based on NHANES data from 2003-2010, which will result in a RACC of ¾ cup for bulk ice cream.

Participants in the NHANES Survey provide information to interviewers on the amount of food consumed using a variety of measurement descriptors such as scoop, cup or piece size. The information is then converted to weight using USDA’s Food and Nutrition Database for Dietary Studies (FNDDS),

² Juan, W. Memorandum to file: “Consumption estimates for foods for infants and children 1 through 3 years of age and for the general food supply for individuals ages 4 years and older in the United States by general category and product category using data from the National Health and Nutrition Examination Survey, 2003-2008 compared to the 1993 RACCs and Proposed Changes to RACCs” February 2014.

which is associated with USDA’s National Nutrient Database for Standard Reference. In the proposed rule FDA stated that “1 cup of ice cream generally weighs about 133 g.” 79 Fed. Reg. at 12012. The value of 133 grams per cup for ice cream that FDA cited is from FNDDS 3.0. Nutrient values for FNDDS 3.0 are based on values in USDA National Nutrient Database for Standard Reference, Release 20 (SR20). In fact, FNDDS 3.0 lists the weight of a one cup measure to be 133 grams, but in the newer version FNDDS 4.1, the weight of a one cup was revised to 148 grams. Nutrient values for FNDDS 4.1 are based on values in USDA’s database (SR22). This higher value of 148 grams per cup is maintained in the NHANES for 2009-2010 that utilizes food composition data from the USDA National Nutrient Database for Standard Reference 24. Based on this information, IDFA strongly suggests that FDA utilize the most current density measurement for ice cream of 148 grams per cup.

Food Code	Food Description	Measure Description	Measure Weight
13110100	Ice cream, regular, flavors other than chocolate	1 cup	148 grams

Reference: **What’s in the Foods You Eat Search Tool 4.1**

<http://www.ars.usda.gov/Services/docs.htm?docid=20511>

We understand that FDA’s proposed RACC for ice cream is based on the 133 gram measurement that resulted in 0.875 cup serving which rounded to a one cup household measure. However, when the 148 gram per cup density measurement for ice cream (FNDDS 4.1 to 5.0) is applied to the 2003-2008 NHANES median amount consumption per eating occasion (116 g), the household measure is calculated at 0.783 cups (6.26 fl. oz. or ¾ cup).

IDFA and Nutrition Impact, LLC also undertook additional analysis to combine ice cream and frozen consumption data from the most recent NHANES 2009-2010 with the older data FDA used from NHANES 2003-2008 (see Tables below). We found the median amount for ice cream per eating occasion did increase slightly to 120 grams, compared to the median amount from NHANES 2003-2008 data of 116 grams. However, when the updated density measurement for ice cream (148 grams per cup) is applied to the median serving of bulk, regular, ice cream (120 grams) the household measure is ¾ of a cup. (120 g median serving NHANES 2003-2010/148 grams per cup = 0.811 cups (6.48 fl. oz. or ¾ cup)).

Table 1. Nutrition Impact Analysis of Ice Cream and Frozen Dessert Consumption Amounts per Eating Occasion from USDA's WWEIA National Health and Nutrition Examination Survey (NHANES) – June 2014

	FDA ³		Nutrition Impact Analysis (June 2014)		
	Median	N	Median	SE	N
2003-2008					
Ice cream, bulk, regular	116	4507	116	± 2	4506
Ice cream, bulk, soft serve	174	418	189	± 15	418
Ice cream, bars, sandwiches, etc.	68	2381	74	± 1	2382
Frozen yogurt	145	277	144	± 8	277
Sherbet	144	258	139	± 9	258
Frozen yogurt cones	78	23	105	± 35	23
Popsicles, snow cones, slurps, fruit juice bar	74	1508	104	± 6	1508
2003-2010					
Ice cream, bulk, regular	-	-	120	± 2	5907
Ice cream, bulk, soft serve	-	-	189	± 17	530
Ice cream, bars, sandwiches, etc.	-	-	73	± 1	3101
Frozen yogurt	-	-	146	± 9	387
Sherbet	-	-	128	± 7	330
Frozen yogurt cones	-	-	102	± 9	34
Popsicles, snow cones, slurps, fruit juice bar	-	-	103	± 5	1995

³ From Table 6, Ref. 46 in FDA Proposed Rule – Serving Size RACC

Market basket survey of the top 20 selling ice cream confirms the industry practices and consumer preferences have changed

The ¾ cup household serving size is also supported by examining a market basket survey of the top 20 selling ice creams compared with online nutrition information for weight per ½ cup serving. This survey found the average weight per cup to be 163.5 grams (81.75 g per ½ cup) (Table 4). The top 20 selling ice creams vary in density from 60 -106 grams per ½ cup (or 120 to 212 g per cup), demonstrating that many ice creams in the market have a higher density due to lower air incorporation. This market basket survey confirms that consumers now favor more dense ice creams and the ice cream industry has evolve processing and formulations to meet consumer expectations. If the 163.5 gram density was applied to the 120 gram serving size (2003-2010 NHANES) the household measure would also round to ¾ cup (120 gram median serving NHANES 2003-2010/163.5 grams per cup = 0.736 cups (5.89 fl. oz. or ¾ cup).

Table 4: Market Basket Survey of Weight per Serving of Top 20 Ice Creams by Sales Dollars

Ranking	Product Description	\$ Volume Last 4 weeks ending 5/25/14	YTD Ending 5/24/14 \$ Volume	Weight (g) per 1/2 cu
1	BLUE BL GLD REG IC SAME UPC ALL FLAVORS 64 FLD OZ	\$14,792,937	\$67,621,639	88
2	BLUE BL BRW REG IC SAME UPC ALL FLAVORS 64 FLD OZ	\$5,880,799	\$28,075,681	74
3	BRYR REG IC NTRL VAN 48 FLD OZ	\$3,546,573	\$16,415,333	66
4	BRYR REG IC CHOC 48 FLD OZ	\$1,917,275	\$8,257,832	66
5	BRYR REG IC FRN VAN 48 FLD OZ	\$1,898,551	\$8,117,403	66
6	BEN JRY REG IC CHRY GARCIA 16 FLD OZ	\$1,589,654	\$7,655,162	106
7	HGND REG IC VAN 14 FLD OZ	\$1,511,020	\$7,315,717	102
8	BEN JRY 2 REG IC HF BAKED 16 FLD OZ	\$1,582,774	\$7,259,114	106
9	BRYR REG IC VAN CHOC STRBER 48 FLD OZ	\$1,729,157	\$6,899,648	66
10	DREYER'S/EDY'S SLOW CHURNED LT LT VAN 48 FLD OZ	\$1,374,888	\$6,857,785	60
11	HGND REG IC COF 14 FLD OZ	\$1,361,278	\$6,591,069	102
12	BRYR REG IC MNT CHOC CHP 48 FLD OZ	\$1,457,535	\$6,119,282	66
13	DREYER'S/EDY'S GRAND REG IC VAN 48 FLD OZ	\$1,155,086	\$6,038,433	65
14	BRYR REG IC BTR PCN 48 FLD OZ	\$1,557,361	\$5,957,179	63
15	BEN JRY REG IC CHOC FDG BRWNIE 16 FLD OZ	\$1,257,613	\$5,791,437	105
16	BREYERS BLASTS! REG IC CKIES N CREM 48 FLD OZ	\$1,455,996	\$5,775,613	64
17	BEN JRY REG IC CHOC CHP CKIE DGH 16 FLD OZ	\$1,255,104	\$5,759,275	106
18	DREYER'S/EDY'S SLOW CHURNED LT LT VAN BN 48 FLD OZ	\$1,106,539	\$5,554,855	60
19	HGND REG IC CHOC 14 FLD OZ	\$1,147,731	\$5,487,903	102
20	HGND REG IC BTR PCN 14 FLD OZ	\$1,122,280	\$5,366,509	102
			Average	81.75

Note: Weight per serving accessed from nutrition information found on companies web sites

Source: AC Nielsen market data

In summary, IDFA was surprised to see that FDA proposed changing the RACC for bulk ice cream to one cup when consumption trend data for the original product category for ice cream had not significantly changed more than the 25 percent criteria the Agency set forth. We strongly believe that the 1993 RACC

of ½ cup should be retained for all types of ice cream and that the category should not be split into two subcategories. However, if FDA moves forward with separating the RACCs for bulk ice cream and novelties, and revising the RACC for bulk ice cream, we feel it is imperative to reconsider the serving size using the most current density measurements, which results in a RACC of ¾ cup.

RACC and Product Name for Ice Cream Novelties

As discussed above, IDFA opposes the proposed separation of the ice cream RACC into two separate categories for (1) all types of bulk ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, and frozen fruit juices and (2) all types of novelties of the same products that are packaged in bars, sandwiches, cones, etc. However, if FDA finalizes a separate category for novelty ice cream, we support the proposed change in the RACC for ice cream and frozen dessert novelties from a weight measurement in grams (85 g) to a volume measurement of ½ cup. We also strongly agree with the agency that the data for ice cream novelties do not support an increase in the RACC for this category.

Additionally, in the event FDA proceeds with this change, we would like to suggest that FDA consider removing the term “ice milk” from the category name as the standard for Ice Milk was abolished in 1994 when FDA acted on a citizen petition from the International Ice Cream Association “Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream” (59 Fed. Reg. 47072, Sept. 14, 1994).

Proposed RACC for Yogurt

IDFA applauds FDA’s decision to propose a change to the existing RACC for yogurt from 225 g (approximately 8 oz.) to 170 g (approximately 6 oz.), which is in line with current consumption levels as demonstrated in the National Yogurt Association’s citizen petition submitted to FDA on June 2, 2011, requesting such a change, and other data the agency evaluated in arriving at this decision. An accurate yogurt RACC is important to consumers and the yogurt industry because the RACC is used to determine whether products qualify for nutrient content claims (such as “high” or “good source”) and health claims. The revised RACC will make it easier for consumers to compare the benefits of yogurt against other food options and make well-informed nutritional choices. IDFA fully supports this change.

However, as noted in our comments on the Nutrition Facts panel proposed rule, if FDA adopts the proposed increase in the DV for vitamin D in the final rule, it is imperative that the agency allow for increased fortification with vitamin D in the yogurt standards of identity – at the same time as finalizing these rules – so that products could continue to qualify for an “excellent source of vitamin D” claim on the basis of the new RACC.

Compliance Date

Implementation of the planned changes in the two proposed rules would require a significant investment of time and resources. These changes would require reformulation, updating labels and new packaging. An implementation date should allow for a sufficient amount of time for companies to make labeling and product changes.

The cost of labeling changes estimated by FDA in the proposed rule was significantly understated. We understand that FDA is in the process of developing and circulating a survey to learn about the costs involved with label changes. We support this effort to allow a clear understanding of the resources needed for companies to alter their labels.

These costs include:

- Time and resources to reformulate products. With the changes in definitions of nutrients and in the Daily Value levels, many products may lose the ability to make nutrient content claims, including those included in the product names. If manufacturers want to continue using these nutrient content claims that consumers recognize, then they will need to reformulate the products (where authorized under the regulations) in order to ensure that they meet the new requirements.
- The resources needed for packaging and labeling design, both within companies and possibly with outside labeling companies. Many dairy processors work with specialized label design companies to make the labels for their products. With a mandate to change the label of every food product sold with a Nutrition Facts panel, these labeling companies will experience a huge demand and could develop a significant backlog, further extending the time needed to make updated labels available.
- Time and cost to update nutrition labeling software. Many dairy companies utilize computer software to calculate the nutrient values that will be placed in the Nutrition Facts panels of their products. The multitude of changes that would be required, including changes to Daily Value levels, new nutrients to declare, changes in definitions of nutrients, and changes in the units used to declare nutrient levels, will require significant updates to the labeling software.
- The value of discarded labeling that does not meet the new requirements. Although companies do work to efficiently plan the number of labels or printed packages they need over a given period of time, a compliance date that does not provide sufficient time would disrupt this planning, and may require large amounts of labeling and packaging inventory to be discarded. For companies that have many different products with many different labels, such as ice cream or yogurt manufacturers with many flavors, the cost of discarded labels could be even higher. A longer timeframe for implementation of the new labeling requirements will help lower the number of labels that must be discarded, therefore lowering the cost of coming into compliance with the new regulations.

Further, the time and cost required to implement the proposed changes would be significantly greater than that required for initial implementation of the nutrition labeling rules in 1993. The number of

products has greatly increased since 1993, each of which will need a revised label. Additionally, today's labeling and packaging materials are frequently more complex and costly to revise than in 1993. For example, rather than a simple yogurt cup with a printed wrap-around label, companies may use printed film labels, for which new plates for printing would be required. Additionally, packaging for dairy products may be in the form of grab-and-go or multi-component packages that are more complicated and costly to revise and reprint. Lastly, food labels now include more nutrition and health-related information on-pack, in response to consumer preferences for such information. All claims will need to be evaluated to determine whether products remain eligible for the claims under the new requirements. These factors all result in the need for additional time and resources to make the changes.

Based on these considerations, we ask FDA to set a compliance date for all proposed changes to the Nutrition Facts panel of four (4) years following the publication of a final rule. Providing a longer compliance period would also significantly reduce the financial burden of implementing the new requirements. It would allow for a more efficient transition and would require fewer packages and labels to be disposed of because manufacturers would have additional time to use up inventory.

Conclusion

In conclusion, IDFA asks FDA to carefully revisit the proposed rule with special consideration given to consistency with the best available scientific evidence, including the most current consumption data, dietary recommendations, and consumer research. IDFA asks the agency to incorporate our comments above with regard to the exemptions needed for dual-column labeling and the RACC for ice cream. We also urge the agency to set a compliance date of four (4) years after the effective date.

IDFA appreciates the opportunity to provide the foregoing comments and believes with the modifications requested above, the planned changes will provide consumers with more accurate and useful information to help facilitate informed dietary choices. We look forward to continuing to work collaboratively with the agency to provide a variety of nutrient-rich foods to Americans and to effectively communicate nutrition information using the food label.

Respectfully submitted,



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