October 13, 2015

ELECTRONIC SUBMISSION

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


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 supplemental proposed rule soliciting input on specific provisions to the revision of the Nutrition and Supplement Facts label. 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 important to update the Nutrition Facts panel to ensure that consumers get the information they need to implement healthy dietary practices and that the information presented reflects the very best nutritional science available. However, as
noted in our previous comments submitted to docket in July 2014, IDFA continues to strongly oppose the inclusion of added sugars in the Nutrition Facts label. We do not believe that the supplemental proposed changes to establish a Daily Reference Value (DRV) and require the declaration of the percent Daily Value (DV) for added sugar on the label are adequately supported by the underlying science or consumer research. We do not believe that the supplemental proposed changes will help consumers in making healthier food choices.

With a minor suggested edit IDFA does support the proposed Daily Value (DV) footnote for the Nutrition Facts label that will help educate consumers on the meaning of the abbreviated term “%DV” at the top of the Nutrition Fact label. Additionally, we agree with the Agency’s proposal that would exempt products that qualify for a simplified Nutrition Facts format, as well as small and intermediate sized packages from having to use the full footnote and allow an abbreviated version.

Each of these points is explained in further detail below:

**Dietary Guidelines Advisory Committee Report Does Not Provide an Appropriate Basis for Labeling Added Sugars**

In the supplemental proposed rule, the Agency recommended that a Daily Value for added sugars be set at 50 grams of added sugar for adults and children four years and older and a Daily Value of 25 grams for children younger than four. According to the supplemental proposed rule, the setting of a Daily Value as well as selecting the specific level was based on a recommendation in the 2015 Dietary Guidelines Advisory Committee (DGAC) report that added sugars intake should be limited to no more than 10% of calories. In examining the recommendations of the DGAC report and the studies identified as supporting these recommendations, IDFA believes that it is inappropriate for the report’s recommendation to be broadly applied to the labeling of all products that may contain added sugars.

The majority of studies cited in the DGAC report and used to support the report’s recommendation on added sugar examined sources of added sugar that are significantly different from the definition of added sugars that FDA has proposed for labeling purposes. Since FDA’s proposed definition of added sugars was not released until 2014, no study cited in the DGAC report used this exact definition for identifying sources of added sugars. There were also significant differences among the studies in regard to the products and ingredients pinpointed as added sugars for the purposes of the studies. A systematic review of added sugars and the risk for cardiovascular disease included intervention studies that tested various amounts and types of sugar, including fructose, glucose, sucrose, high fructose corn syrup, or used sugar sweetened beverages as a proxy. The observational studies in this review primarily looked at intake of sugar-sweetened beverages, such as soft drinks, colas and fruit drinks. Only two observational studies extended the categorization to include all sugars added to foods. The Nutrition Evidence Library (NEL) review of studies on a link between children’s adiposity and their intake of added sugar looked only at sugar sweetened beverages, not any other foods or beverages that contain added sugars.
The proposed definition for added sugars in the proposed rule (79 FR 11879), which would be the basis for calculating the percent Daily Value on the Nutrition Facts label, includes many more sources of sugar than the studies cited in the DGAC report. These studies did not encompass the wide variety of products that may include added sugars, such as nutrient-rich flavored milk and yogurt, but instead the studies cited relied heavily on sugar sweetened beverages as a proxy for added sugars. It is unknown whether added sugars that come along with other macro and micro-nutrients and those that are part of nutrient-rich foods may serve a different role in the diet and what their impact on the overall diet may be.

Since the majority of studies from the DGAC report did not examine sources of added sugar that are similar to the wide range of substances and ingredients that would fall under FDA’s definition of added sugars, IDFA does not believe that these studies and therefore the DGAC report form an appropriate basis for FDA’s proposed Daily Value for added sugar.

**Incorrect Basis to Establish a Daily Recommended Value for Added Sugars and to Require the Declaration of the Percent Daily Value**

IDFA questions FDA’s approach to establishing the DRV for added sugars and requiring the declaration of the Percent Daily Value for added sugars solely relying on the recommendations from the DGAC report, which is not an official government policy document, rather than relying on an Adequate Intake (AI) or Recommended Dietary Allowance (RDA). This approach is not aligned with FDA’s usual approach to setting Daily Values. According to the DGAC charter, “The 2015 DGAC is established to provide independent, science-based advice and recommendations for development of the Dietary Guidelines for Americans, 2015.” The committee was not convened with the purpose and intent of establishing reference values.

The Daily Value is developed by the FDA to help consumers determine the level of various nutrients in a standard serving of food in relation to their approximate requirement for it and is usually, although not exclusively, based on an RDA or AI. The Institute of Medicine’s (IOM) Dietary Reference Intake (DRI) framework provides an objective and scientifically rigorous process for the establishment of RDA or AI values. The DRI process undertaken by the IOM ensures and fosters transparency in decision-making and a key aspect of the DRI framework is the evaluation of the adverse effects associated with low or inadequate intakes as well as with high intakes of a nutrient. We believe that the Institute of Medicine is the appropriate body to establish DRIs upon which to base the DRV’s for total and added sugars. As the Chairman of the 2005 Dietary Guidelines Committee Janet King noted in her remarks; “In the United States, the DRIs are the science backbone of all nutrition policy. From the DRIs stems the Dietary Guidelines Advisory Committee report that translates the DRIs and additional science linking food, physical activity, and chronic disease into dietary guidelines.”

We would also like to note that the 2015 DGAC did not reevaluate IOM macronutrient report conclusions nor did they determine or resolve why their conclusions were different from IOM, as stated in their report: “An overarching premise of the DGAC is that that the Dietary Guidelines for Americans should provide food-based guidance for obtaining the nutrients needed for optimal reproductive health,

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growth and development, healthy aging, and well-being across the lifespan (ages 2 years and older). Specific nutrient intake requirements are established for each sex and life-stage group by the Food and Nutrition Board of the Institute of and as such, this DGAC report did not reevaluate IOM recommendations or make independent specific nutrient recommendations.2

In the 2005 report on Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), the Institute of Medicine Food and Nutrition Board concluded that based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there was insufficient evidence to set a daily intake for total or added sugars.3

As explained previously in our comments on the DGAC report, IDFA does not believe that the food composition data, menu modeling, or dietary survey data are suitable for determining DRVs. Furthermore, such an approach is not linked to a health outcome, which is traditionally required as a basis for determining DRVs. The Agency’s own approach dismissed the use of food modeling to set DRVs. This point was emphasized in the preamble to FDA’s proposed rule to amend the Nutrition Facts label4:

- “We do not consider the use of food composition data, menu modeling, or dietary survey data as a suitable approach to determine Dietary Reference Values (DRVs).”
- “The approach to determine DRVs using food composition data, menu modeling, or dietary surveys has a number of deficiencies. Menu modeling is an approach, based on available foods in the marketplace, to design a set of food items for meals, which will meet certain nutrient or food intake pattern recommendations. Menu modeling, by its very nature, would not permit the selection of DRVs that are based on scientific evidence related to actual public health outcomes.”
- “Based on these inherent limitations of menu modeling and the data sources used, we tentatively conclude that the menu modeling approach, as recommended in the IOM Labeling Report, is an unsuitable method for determining DRVs (or RDIs). Instead, we intend to continue using science-based recommendations to set DRVs and RDIs.”

IDFA believes that FDA has not provided sufficient scientific support to reconsider establishing a DRV for added sugars based on the lack of scientific consensus and inconclusive evidence by the most recent expert committee of the Institute of Medicine to set a daily intake recommendation for either total sugars or added sugars. As stated above there is simply not adequate intake recommendations for added sugars on which FDA can base its proposal to establish a DRV for added sugars of 50 grams (g) for children 4 year of age and older and of 25 grams (g) for children 1 through 3 years of age. Thus FDA should neither require the Nutrition Facts panel to include a declaration for added sugars nor a percent DV for added sugars on the Nutrition Facts label.

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4 79 Federal Register 11880 at 11895, March 3, 2014
Consumer Research Indicates Confusion Regarding Added Sugars

The FDA released its findings from their study “Experimental Study on Consumer Responses to Nutrition Facts Labels with Declaration of Amount of Added Sugars” (OMB No. 0910-0764). This research indicates that consumers are unable to understand added sugars information in the context of the overall nutritional profile of a dairy product, specifically. The survey presented respondents with Nutrition Facts labels from two hypothetical pairs of yogurt, cereal and meal products. One product from each pair was “more nutritious” (defined as fewer calories, less fat, and more fiber, vitamins and minerals) but had a higher amount of added sugars than the comparison product. The study found that, when the more nutritious product had more added sugars, the percentage of respondents identifying the product as healthier decreased. Respondents who saw either of the added sugars formats (vs. the control format) were less likely to choose the more nutritious product when that product had more added sugars. Their ability to correctly identify the product with less added sugar also decreased when the more nutritious product had the same amount or more added sugars than the less nutritious product.

Dairy products, including flavored milk and yogurts, that contain sweeteners contribute essential nutrients to the American diet. Dietary guidance statements and positions from leading health professional organizations acknowledge the role of small amounts of added sugars in increasing the palatability and consumer liking of nutrient dense foods. FDA’s consumer research clearly found that some of respondents misinterpreted the added sugars declaration despite the product’s overall healthier nutrition profile.

Furthermore, while the addition of the %DV was never tested with the “Added Sugars” declaration by the Agency, IDFA believes that the presentation of a DRV for added sugars could exacerbate consumer confusion as to the overall healthfulness of a nutrient-dense product. Consumer confusion may easily lead to the unintended consequence of discouraging consumption of nutrient-dense dairy products that provide valuable nutrients to the American diet. The declaration of added sugars and a percent Daily Value for added sugars in the Nutrition Facts label will not help consumers maintain healthy dietary practices, the main objective cited by FDA for proposing the Nutrition Facts label changes.

Reanalysis of FDA’s Consumer Research Shows Differences with Understanding of Added Sugars with At-risk Segments of the Population

IDFA along with six other food trade associations commissioned Dr. Jeremy Keyes, Associate Professor of Marketing, Villanova School of Business, to undertake a reanalysis of FDA’s study data, using similar methodologies as summarized in the FDA memo. A summary of the key observations are listed below and a copy of the full report will be filed with the docket by the author.

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In addition to a replication of the FDA findings among the aggregate sample, this report outlines additional findings pertaining to important at-risk segments of the population. There is an abundance of research that suggests that at-risk segments, such as low-education and ethnic minority consumers, are especially important to consider whenever a label change as significant as modifications to the Nutrition Facts label is contemplated.

The reanalysis of the data confirms some of the major findings from the FDA memo such as the provision of added sugars information on the Nutrition Facts label can both increase consumers’ accuracy of the amount of added sugars in food products and decrease consumers’ accuracy of the amount of total sugars in food products relative to a label without added sugars information. The reanalysis findings suggest that at-risk consumers seem to be especially prone to misinterpret the amount of total sugars in products when added sugars are displayed on the label. These findings suggest that the provision of added sugars on the label can have the intended effects of increasing consumers’ accuracy of the amount of added sugars contained in the product, but also have the unintended effect of decreasing consumers’ accuracy of the amount of total sugars contained in the product, especially for at-risk segments of the population.

The reanalysis of the data confirms the finding in the FDA memo that that the provision of added sugars information on the label can reduce consumers’ overall healthfulness perceptions of food products relative to a label without added sugars information. However, the reanalysis findings suggest that this effect was not consistent across race and education level. When examining at-risk segments of the population, the provision of added sugars on the label is sometimes found to have no effect or unintended effects. For some segments, the provision of added sugars resulted in decreased healthfulness perceptions for healthy foods or increased healthfulness perceptions for unhealthy foods.

The reanalysis of the data confirms the finding in the FDA memo that the provision of added sugars on the label can result in consumers perceiving higher levels of added sugars in products. The reanalysis findings show that the provision of added sugars information on the label can also result in consumers perceiving higher levels of total sugars in the product. In particular, the presence of added sugars information on the label of healthy foods that are low in sugars can result in consumers perceiving higher levels of total sugars in those foods.

In sum, the incremental findings from the reanalysis suggest that the provision of added sugars on the label may not be helpful to at-risk segments of the population, and in some cases, may have negative outcomes. The findings from the reanalysis have a number of implications for interpreting the initial findings reported in the FDA memo:

- Findings from both the FDA report and the reanalysis suggest that the provision of added sugars on the Nutrition Facts label can result in misperceptions and confusion among the general population.
- Both the FDA memo and reanalysis also show that the provision of added sugars on the label will likely adversely impact consumers’ perceptions of other information on the label (e.g., total sugars). The provision of added sugars on the label should impact only perceptions of added sugars and should not result in misperceptions of other nutrition information on the label.
While the FDA memo does not address effects on at-risk segments, the reanalysis results suggest that low-education consumers and ethnic minorities (e.g., Hispanics and African Americans) seem to be especially prone to unintended consequences when added sugar is displayed on the label.

The FDA study did not have a sample size large enough to fully address the impact of the provision of added sugars on low-education and ethnic minorities, thus more research is needed to understand how the provision of added sugars on the Nutrition Facts label can impact at-risk segments of the population.

The combined observations from FDA’s initial memo and this reanalysis point to a number of issues associated with the presence of added sugar information on the label. The misperceptions among the broad population and at-risk segments resulting from the provision of added sugars on the label demonstrate a clear need for more research to fully understand the impact of the provision of added sugars to the Nutrition Facts label before making any labeling policy changes.

In developing the March 2014 proposed rule to update the Nutrition Facts label, the Agency considered changes that would assist consumers in maintaining healthy dietary practices and recognized that it is important for the updated Nutrition Facts label to be useful and relevant to the American population.

However, FDA should realize that its own research has confirmed a lack of understanding by consumers about the term “added sugar,” which will not be improved with the addition of a percent DV for added sugars. Since this proposed change will not foster the consumers’ ability to choose healthier foods or improve their dietary practices, it should not be pursued as an update to the Nutrition Facts label.

**FDA Should Not Require Declaration of Added Sugars**

As stated in IDFA’s previous comments we continue to assert that 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. 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 nutrient labeling must assist customers in maintaining healthy dietary practices.

Furthermore, requiring a 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 “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. The current label information is also helpful for diabetic consumers. The American Diabetic Association provides this guidance for diabetics when reading labels “It is more helpful to check the total carbohydrate because it includes both sugar and starch. If you only look at the sugar content, you are not accounting for the starch in a food.”

Additionally, a separate declaration for added sugars could call undue attention to this nutrient as a source of calories, when it is not calorically different than other carbohydrate sources from a nutrition 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.

The Proposed Definition of Added Sugars Requires Significant Revision and is Unclear for Dairy Based Ingredients

IDFA contends that it is important for FDA to resolve its conflicting definition of “added sugar.” 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.*

*Names for added sugars include: Brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high-fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado, sugar, trehalose, and sucrose."

The proposed definition as it applies to use of dairy based ingredients in foods is unclear, particularly the phrase, “naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component.” A number of dairy based ingredients are isolated from milk and concentrated such that lactose, the naturally occurring sugar in milk, is the primary component. Examples include non-fat dry milk, dry whole milk, some forms of concentrated whey and dried whey, and milk and whey permeate. None of these ingredients are added to foods for the purpose of increasing sweetness. Lactose has only one-sixth the sweetness factor of sucrose.

Dairy ingredients are added to foods for a variety of other purposes. Dry milk ingredients (e.g., nonfat dry milk, dry whole milk), for example, provide functional properties to baked goods, sausages, soups,
sauces, beverages, salad dressings, cheese and yogurt. These include water binding, which helps enhance texture, flavor and product shelf-life; foaming properties beneficial for cakes and frozen desserts; and emulsification in production of sausages, soups, sauces, beverages and salad dressings. Milk and whey protein concentrates, some of which contain lactose as the primary component, are typically used to increase the protein content of foods. Milk and whey permeates⁸, most of which have lactose as the primary component, are often used as salt replacers to reduce the amount of sodium in a broad range of food applications because of their unique salt enhancement characteristics.

The common or usual name of each ingredient used in a food must be listed in the ingredient statement in order of predominance by weight⁹. The common and usual names for dairy based ingredients are descriptive of the dairy ingredients, not as sweetening agents for foods. Particularly when a food contains no obvious sweetener, consumer confusion about the source of added sugar in the food could occur. For example, if a food with a dairy based ingredient such as nonfat dry milk or whey protein concentrate would be required to declare the inherent lactose as added sugars on the Nutrition Facts label and the food contained no identifiable source of added sugars, consumers reading the ingredient list likely would not expect or recognize dairy ingredients as sources of “added sugars.”

As we suggested in our previous comments if FDA unfortunately still decided to proceed with requiring an added sugars declaration 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.

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⁸ Permeate covers a family of products with a minimum of 59% lactose and a maximum of 10% protein and 27% ash. Permeate (also called dairy product solids, deproteinized whey or modified whey) are co-products of the production of whey protein concentrate, whey protein isolate, ultrafiltered milk, milk protein concentrate or milk protein isolate. Composition varies depending on the original material used; sweet whey and milk are the most common starting materials for permeate production in the U.S.

⁹ 21 CFR 101.4 Food; designation of ingredients
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 which are necessary for dispersion or as a standardizing compound for a stabilizer which due to the raw material variation requires additives to ensure uniform consistency for its functional application. 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 for sweetening purposes. 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.

**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,\(^\text{10}\) has low cariogenicity (conducive to the promotion of dental caries) relative to other sugars,\(^\text{11}\) and has a relatively low glycemic index of 46, which is less than half that of glucose.\(^\text{12}\) 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 forms of milk were viewed as an added sugar, the use of concentrated or 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 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.13

As stated in IDFA’s previous comments about the proposed rule, the Agency should also consider that added sugars declaration for fermented dairy products will pose a significant challenge. It will be difficult to calculate the amount of added sugars remaining in a fermented product that contains both milk and added milk-derived ingredient containing lactose. This is due to the fact that the lactose from both sources will be consumed during fermentation, but there is no way to determine what percentage of the final lactose content is from which source, thereby making it impossible to declare how much “added sugar” remains after fermentation.

**Use of the Term “Total Sugars” instead of “Sugars”**

As stated previously IDFA continues to oppose the declaration of added sugars in the Nutrition Fact label due to consumer confusion with the proposed label. The International Food Information Council (IFIC) conducted a national survey to investigate consumer understanding of the “added sugars” declaration on the proposed Nutrition Facts label. Consumers were shown 3 versions of Nutrition Facts labels for the same food product. Version (S) was in the proposed Nutrition Facts label showing only a “Sugars”

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13 21 CFR 101.4 Food; designation of ingredients
IFIC’s research findings which were submitted to the FDA docket are as follows:

The ability for consumers to accurately identify the total amount of sugars in a product is significantly higher when an “Added Sugars” line is not presented on the NFP.

Our initial results illustrate significant differences in comprehension between NFP versions with and without an “Added Sugars” declaration. Accurate determination of total sugars content in a product was:

- Highest (92%) when shown an NFP with only a “Sugars” line (S). *This was significant versus the other two NFP versions (S+A and TS+A).
- Lowest (55%) when shown an NFP with a “Sugars” line and an “Added Sugars” line (S+A).
- 66% when shown an NFP version with a “Total Sugars” line and an “Added Sugars” line (TS+A). *This was significant versus the S+A version.

Consumer understanding that the sugars in an “Added Sugars” line would be included in a “Sugars” line or “Total Sugars” line was significantly higher on NFPs with a “Total Sugars” line, but still demonstrates confusion around total sugar content in the presence of an “added sugars” declaration.

To confirm how consumers interpret an “Added Sugars” declaration when determining the total amount of sugars in a product, the IFIC survey asked directly if the sugars in the “Added Sugars” line were added to, or included in the “Sugars” line or “Total Sugars” line for those two NFP versions (S+A and TS+A). These answers are consistent with the inability of consumers to make the correct determination of total sugars content:

- Over half (52%) believe that the amount in the “Added Sugars” line is added to the amount in the “Sugars” line. *This was significant versus the TS+A NFP version.
- 37% believe the amount in the “Added Sugars” line is included in the amount in the “Sugars” line.
- One third (33%) believe that the amount in the “Added Sugars” line is added to the amount in the “Total Sugars” line.
- Over half (52%) believe the amount in the “Added Sugars” line is included in the amount in the “Total Sugars” line. *This was significant versus the S+A version.

IFIC’s findings are consistent with FDA’s in that the provisions for added sugars on the Nutrition Facts label will result in significant consumer misperceptions of the amounts of total sugars in the food products.

IDFA believes that if FDA proceeds with requiring added sugars to be declared, the use of the term “Total Sugars” instead of “Sugars” would slightly decrease the confusion and may provide some additional information to help consumers understand that added sugars are included in the total sugars declaration. Additionally, should FDA proceed with requiring added sugars and a declaration of the
percent DV to be declared, it will be critical for FDA to develop a very robust communication and education plan to address consumer confusion.

**Change to Footnote to be used on the Nutrition Facts Label**

IDFA supports the suggested footnote for the Nutrition Facts label “*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice*” to help consumers understand the meaning of the abbreviated term “%DV” at the top of the nutrition Fact Label. However, we suggest a slight modification to the wording of the footnote to change the term “food” to “food or beverage.” We recognize that FDA’s definition for the term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. However, the label is used to inform consumers who are unfamiliar with FDA’s definitions. It is important to help educate consumers with this simple footnote that both foods and beverages they consume contribute to their daily nutrient intake. We suggest the footnote read as follows: “*The % Daily Value tells you how much a nutrient in a serving of food or beverage contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.*”

**Exemptions from the Proposed Footnote Requirement**

IDFA fully supports the Agency’s proposal that would exempt products that qualify for a simplified Nutrition Facts format, as well as small and intermediate packages, provided that the following abbreviated statement is used in the NFP: “%DV = % Daily Value.” We also agree with the change that an exception for foods that qualify to use the terms “calorie free,” “free of calories,” “no calories,” “zero calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietary insignificant source of calories” as defined in 21 CFR § 101.60(b). The proposed exemption for the footnote would provide a practical solution for smaller packages that have less space for labeling thus allowing for more space on the label to be allotted for the required nutrient declarations.

**Conclusion**

IDFA makes the following recommendations on nutrition labeling of foods and beverages:

- IDFA continues to strongly oppose the inclusion of added sugars in the Nutrition Facts label, and the addition of a percent Daily Value on labeling will not aid consumers in making healthier choices.
- The majority of studies cited in the DGAC report and used to support the report’s recommendation on added sugar examined sources of added sugar that are significantly different from the definition of added sugars that FDA has proposed for labeling purposes.
- The DGA was not convened for the purpose of setting Dietary Reference Values. The DGAC report is not an appropriate source for the Daily Value to be used for labeling of added sugars.
- The declaration of added sugars and a percent Daily Value for added sugars in the Nutrition Facts label will not help consumers maintain healthy dietary practices, since FDA’s research indicates that consumers are unable to understand added sugars information in the context of the overall nutritional profile of a dairy product.
• Additionally, at-risk consumers seem to be especially prone to misinterpret the amount of total sugars in products when added sugars are displayed on the label.
• If the agency finalizes the proposed requirement to declare added sugars, the definition for added sugars would need significant revision and clarification.
• IDFA supports the suggested footnote for the Nutrition Facts label. However, we suggest a slight modification to the wording of the footnote to change the term “food” to “food or beverage.”

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 that 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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