

# **Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry**

## ***Draft Guidance***

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2373.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

**[Insert Month and Year]**

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# Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## I. Introduction

This guidance is intended for conventional food and dietary supplement manufacturers. It will provide questions and answers on topics related to compliance with our final rule entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (81 FR 33742 (May 27, 2016)) (to be codified at title 21 of the Code of Federal Regulations, part 101 (21 CFR part 101)). This guidance also discusses labeling of added sugars and formatting for lines (e.g. thickness of lines) and leading (e.g. space between lines) on the Nutrition Facts label.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

In this guidance, “you” (or “I”) refers to a manufacturer of conventional food or dietary supplements.

## II. Background

On May 27, 2016, we published two final rules related to the Nutrition and Supplement Facts labels, which amended our labeling regulations for foods to provide updated nutrition

information to assist consumers in maintaining healthy dietary practices. One final rule is entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (81 FR 33742, “the Nutrition Facts label final rule”) and the other final rule is entitled “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” (81 FR 34000, “the serving size final rule”).

Below is a summary of the major provisions of the Nutrition Facts label final rule and serving size final rule.

The final rules revise the Nutrition Facts and Supplement Facts labels by:

- Removing the declaration of “Calories from fat;”
- Requiring the declaration of the gram (g) amount of “added sugars” in a serving of a product, establishing a Daily Reference Value (DRV) for added sugars, and requiring the percent Daily Value (DV) declaration for added sugars;
- Changing “Sugars” to “Total Sugars” and requiring that “Includes ‘X’ g Added Sugars” be indented and declared directly below “Total Sugars;”
- Updating the list of vitamins and minerals of public health significance;
- Updating certain reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplement Facts labels;
- Revising the format of the Nutrition Facts labels to increase the prominence of the declaration of “Calories;”
- Removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets;
- Requiring the maintenance of records to support the declarations of certain nutrients under specified circumstances;
- Amending the definition of a single-serving container;
- Requiring dual-column labeling for certain packages;
- Amending several reference amounts customarily consumed that are used by manufacturers to determine their label serving size; and
- Establishing an effective date of July 26, 2016 and a compliance date of 2 years after the final rule’s effective date, except that manufacturers with less than \$10 million in annual food sales have a compliance date of 3 years after the final rule’s effective date.

### III. Questions and Answers

- 1. Must the updated Nutrition or Supplement Facts label appear on all foods sold by July 26, 2018 (or July 26, 2019 for manufacturers with less than \$10 million in annual food sales)?**

After publication of the final rule, we included a frequently asked question on our website asking “When must the label be displayed on food packages?” In our response, we stated our current thinking was for the label to be displayed on food products that are initially introduced into interstate commerce on or after the compliance date. We received a number of questions about products at various points in the distribution chain and whether the product would need to bear the new version of the Nutrition or Supplement Facts label. After further consideration, we are revising the language used to describe when products need to comply with the requirements of the final rule to avoid potential confusion.

Products that are labeled on or after July 26, 2018 (and July 26, 2019 for manufacturers with less than \$10 million in annual food sales) must bear a nutrition label that meets our new nutrition labeling requirements in 21 CFR 101.9 and 21 CFR 101.36. Products that are labeled before July 26, 2018 (and July 26, 2019 for manufacturers with less than \$10 million in annual food sales) do not need to be in compliance with the new labeling requirements, and therefore, do not need to bear the new nutrition label. To determine the compliance date for a particular food product, we would not consider the location of a food in the distribution chain. For example, the food product, whether labeled before or after the compliance date, may be at the manufacturing facility awaiting distribution, at a warehouse awaiting further distribution, in transit to the United States to be offered for import, or on the store shelf of a U.S. retail establishment. We consider the date the food product was labeled for purposes of determining the compliance date.

We do not object to the use of a sticker for providing a revised nutrition label that meets our new requirements in 21 CFR 101.9 and 21 CFR 101.36 before new packaging is printed. The sticker label should not cover any other mandatory information and should adhere to the package during normal handling.

- 2. When determining whether labels need to be in compliance with the new requirements, should the determination as to whether my company has \$10 million or more in annual food sales be based on domestic food sales or total food sales, including international sales, and how many years of sales should I consider?**

To determine whether a company has \$10 million or more in annual food sales, a firm can either take the smallest sales volume from the previous three years (i.e., 2013, 2014, and 2015), or alternately the firm can take the average of the previous three years sales volume. A firm's total (domestic plus international) food sales best reflects the firm's resources and, thus, ability to comply with the final rules. Firms with total food sales in one of the last three years (or an average of the last three years) of less than \$10 million are thought to be more resource constrained than firms with total food sales in one of the last three years (or an average of the last three years) of more than \$10 million, and therefore have an additional year to comply with the final rules.

**3. Are there certain approved companies or nutrition databases manufacturers can use to get their nutrition values for their products?**

FDA does not approve nutrition databases. However, the United States Department of Agriculture provides nutrition information for a number of foods, and there are also several commercially available nutrition databases you can use to determine nutrition values for your products.

**4. Who is responsible for the accuracy of the Nutrition Facts label on a food product's label? Who is responsible for maintaining the records needed to verify the accuracy of certain nutrient declarations?**

Under 21 CFR 101.9(g)(10), food manufacturers must make and keep records to support certain nutrient declarations on their product labels. We recognize that a manufacturer may contract with a firm to label a product that is then returned to the manufacturer for distribution, may sell a product to a firm that labels the product under the firm's own brand name for distribution (e.g., "private labeler"), or may engage in some other similar arrangement with a packager, labeler, or distributor. A firm that labels the product, whether the manufacturer or a private labeler must know, for each nutrient declared, the amount of a nutrient in a serving of food to ensure the label is truthful and accurate and does not misbrand the product. We would expect a firm that does not manufacture the product, but that is responsible for labeling the product, to have access to records that are sufficient to verify the nutrient declarations for which records are required in the final rule and make the records available during an inspection.

**5. How will FDA exercise enforcement discretion with respect to mandatory and dual-column nutrition labeling for bottled water products and coffee beans (whole or ground), tea leaves, plain unsweetened coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors that would have been exempt under § 101.9(j)(4) prior to the effective date of the Nutrition Facts label final rule?**

FDA will consider refraining from taking regulatory or compliance actions against only the products listed in the question above, until such time as we go through rulemaking to address issues of mandatory and dual-column nutrition labeling of these products.

## Labeling of Added Sugars

### **6. Do sugars found in fruits and vegetables that have been processed to change the form of the fruit or vegetable (e.g., concentrated fruit and vegetable purees, fruit and vegetable pastes, and fruit and vegetable powders) need to be declared as added sugars on the label?**

In the Nutrition Facts label final rule (81 FR 33742 at 33833), we excluded whole fruit, fruit pieces, dried fruit, pulps, and purees because they are nutrient rich and maintain the basic properties of a fruit when added to foods, which are not considered to contain added sugars (see response to comment 208 on p. 33835). We also excluded sugars from 100 percent fruit and vegetable juices, and sugars from certain fruit and vegetable juice concentrates used towards the total juice percentage label declaration under certain regulations, fruit juice concentrates used to formulate the fruit component of jellies, jams, and preserves under our standards of identity, and 100 percent juice concentrate sold directly to consumers (e.g. frozen orange juice concentrate).

In the preamble to the Nutrition Facts final rule (81 FR 33742 at 33833 through 33834), we explained that, while foods sweetened with concentrated fruit or vegetable juices can be a part of a healthful diet, the sugars added to the foods by the concentrated fruit or vegetable juice provide additional calories. Over the course of the day, small amounts of calories in sugar-sweetened foods and beverages can add up and make it difficult to balance the amount of calories expended. For these reasons, we consider foods sweetened with concentrated fruit or vegetable juices to be sugar-sweetened foods.

We also explained that in determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 Dietary Guidelines Advisory Committee (DGAC) report (Ref. 1) (81 FR 33742 at 33835).

We are applying these same guiding principles just discussed when determining when the sugars in an ingredient are added sugars. If the ingredient contains all of the components of a whole fruit or vegetable, but has been processed so that the plant material is physically broken down into smaller pieces or water is removed, we would not consider the sugars contributed from the portion of the fruit or vegetable that is typically eaten which is used to make such an ingredient to be added sugars. However, if a fruit or vegetable is processed in such a way that it no longer contains all of the components of the portion of a whole fruit or vegetable that is typically eaten (e.g., the pulp from the fruit has been removed) and the sugars have been concentrated, the sugars in such an ingredient are consistent with how we have considered the sugars in fruit juice concentrate because the ingredient is a concentrated source of sugars and contributes additional calories to a food when added as an ingredient without additional water. Manufacturers may use different terminology in reference to the same or similar ingredients (e.g. concentrated puree or paste) or they may use the same terminology in reference to similar ingredients (e.g. a fruit powder made by extracting and dehydrating the juice of the fruit versus a fruit powder made by pulverizing a dehydrated whole fruit). For this reason, manufacturers should consider whether the ingredient has been processed so that it no longer contains all of the components of the original portion of the

whole fruit or vegetable that is typically eaten in addition to being concentrated. If sugars are in excess of what would be expected from an ingredient made from 100 percent fruits or vegetables, those sugars must be declared as added sugars (21 CFR 101.9(c)(6)(iii)). To the extent that manufacturers are processing different ingredients made from whole fruits or vegetables, we would need to consider specific information about how an individual ingredient has been processed when determining if the sugars meet our definition of added sugars for the purpose of nutrition labeling.

**7. How should I calculate the amount of added sugars in a fruit juice blend containing the juices of multiple fruits that have not been reconstituted to 100 percent (full-strength)?**

If the juice blend is reconstituted such that the sugar concentration is less than what would be expected in the same amount of the same type of single strength juice (e.g., less than 100% juice), the added sugar declaration would be zero.

If the juice blend is reconstituted such that the sugar concentration is greater than what would be expected in the same amount of the same type of single strength juice, the amount of sugar that is in excess of what would be expected in the same amount of the same type of single strength juice must be declared as added sugars on the label. We provide two examples below of how the amount of added sugars in a serving may be calculated for a juice blend containing concentrated fruit juice.

Example 1: a manufacturer produces a fruit juice blend with apple juice concentrate, mango juice concentrate, pear juice concentrate and water (assuming a serving size of 240 g):

% formulation	% sugar in single strength juice (21 CFR 101.30) – use Brix value as estimates
10% concentrated apple juice (46% sugar)	11.5% sugar
10% concentrated mango juice (39% sugar)	13% sugar
20% concentrated pear juice (24% sugar)	12% sugar
<b>Water (60%)</b>	

There are different methods to calculate the amount of added sugar in example 1.

Method 1:

We know the final weight of the actual reconstituted juice blend (A). We then calculate the final weight of the juice blend if it were reconstituted to 100 percent juice (B). Because the juice blend has a greater sugar content than single strength juice, the weight of juice blend, A, would be less than B. Therefore, juice blend A is, in effect, concentrated even though it has water added to it, and the concentration factor is calculated as B/A. We can then use this concentration factor to calculate the amount of added sugars in a serving of the juice blend. In the example



below, we first calculate the amount of added sugars based on 100 grams and then convert the result to determine the amount of added sugars in a 240 g serving.

Column 1	Column 2	Column 3	Column 4	Column 5
Percent of each juice in the formulation (100 g)	Weight of juice concentrate <sup>1</sup>	Amount of sugar from juice concentrate <sup>2</sup>	Amount of water needed to reconstitute to single strength for juice concentrate <sup>3</sup>	Percent sugar in single strength juice <sup>4</sup>
10% concentrated apple juice (46% sugar)	$100 \times 10\% = 10 \text{ g}$	$100 \times 10\% \times 46\% = 4.6 \text{ g}$	$4.6/11.5\% - 10 = 30 \text{ g}$	11.5% sugar
10% concentrated mango juice (39% sugar)	$100 \times 10\% = 10 \text{ g}$	$100 \times 10\% \times 39\% = 3.9 \text{ g}$	$3.9 / 13\% - 10 = 20 \text{ g}$	13% sugar
20% concentrated pear juice (24% sugar)	$100 \times 20\% = 20 \text{ g}$	$100 \times 20\% \times 24\% = 4.8 \text{ g}$	$4.8/12\% - 20 = 20 \text{ g}$	12% sugar

<sup>1</sup>Weight of each ingredient =  $100 \text{ g} \times \text{percent of juice in the formulation}$

<sup>2</sup>Amount of sugar from juice concentrate =  $100 \text{ g} \times \text{percentage of juice in the formulation} \times \text{percentage sugar in the juice concentrate}$

<sup>3</sup>Amount of water needed to reconstitute to concentrated juice to single strength =  $\text{Amount of sugar from juice concentrate} / \text{percentage sugar in single strength juice} - \text{weight of initial juice concentrate}$

<sup>4</sup>Brix values in 21 CFR 101.30(h) are used as estimates.

On a 100 g basis:

- The final weight of the actual reconstituted juice blend (A) = 100 g.
- The final weight of the juice blend if it were reconstituted to 100% juice (B) = Total water needed to reconstitute to single strength (from column 4) + total weight of the concentrated juice (from column 2) =  $(30 \text{ g} + 20 \text{ g} + 20 \text{ g}) + (10 \text{ g} + 10 \text{ g} + 20 \text{ g}) = 110 \text{ g}$
- The concentration factor =  $B / A = 110 / 100 = 1.1$
- Total sugar (from column 3) =  $4.6 \text{ g} + 3.9 \text{ g} + 4.8 \text{ g} = 13.3 \text{ gm}$
- The amount of added sugar = total sugar – sugar in single strength juice blend =  $13.3 \text{ g} - 13.3 \text{ g} / 1.1 \text{ g} = 1.21 \text{ g}$

On serving size basis:

- The amount of added sugar = (serving size / 100 g) × (the amount of added sugar per 100 g) = (240 g / 100 g) × 1.21 g = **2.9 g**

## **Method 2:**

In this method, we calculate the theoretical sugar content in the single strength juice blend based on the weight percentage and the sugar percentage of the juice concentrates.

We first calculate the concentration factor for each juice used in the formulation. The concentration factor = % sugar the juice concentrate in the formulation / % sugar in single strength juice based.

For example, the concentration factor for apple juice in example 1 is 46% / 11.5 g = 4. Using similar calculation, the concentration factor for the mango juice is 3 and the concentration factor for the pear juice is 2.

The ratio of apple:mango:pear is 10% x 4 : 10% x 3 : 20% x 2 = 4:3:4, or 36.4%: 27.2%: 36.4%. The theoretical sugar content in the single strength blend is:

$$11.5\% \times 36.4\% + 13\% \times 27.2\% + 12\% \times 36.4\% = 12.09\%.$$

Single strength apple/mango/pear juice blend would have 29.02 g sugar with a serving size of 240 g (240 x 12.09% = 29.02 g).

The theoretical sugar content in the concentrate blend is (13.3 g x 240 g)/100 = 31.92 g. Therefore, the total added sugar is: 31.92-29.02 = 2.9 g.

Example 2: A manufacturer produces a fruit juice blend with single strength apple juice and passion fruit juice concentrate:

If you formulate your product with 90% single strength apple juice (at 11.5% sugar) and 10% concentrated passion fruit juice (30% sugar) to add flavor to the 100% apple juice, the serving size would be 240 g. Single strength passion fruit juice should have a minimum Brix value of 14 (21 CFR 101.30 (h)(1)) and have 14% in single strength sugar. Although the product is still labeled as “100 percentage juice,” the amount of added sugar is calculated as:

$$240 \text{ g} \times 10\% \times 30\% - 240 \text{ g} \times 10\% \times 14\% = 3.84 \text{ g}.$$

## **8. Can I use Brix values to calculate the added sugars declaration for a product containing fruit juice concentrates?**

We use Brix values to calculate the labeled percentage of juice from concentrate found in a juice or juice beverage using the minimum Brix values provided in 21 CFR 101.30. We have determined that single-strength (100 percent) juice contains at least the specified minimum Brix for each single-strength juice listed in 21 CFR 101.30.

You can calculate the added sugars declaration when a product contains concentrated fruit juice in several ways. If you know the sugar content of the single strength fruit juice before it is concentrated and added to the product, because the amount of sugar from the single strength juice has been determined through chemical analysis, you may use the known sugar content when determining the added sugars declaration. You also may choose to use the Brix values provided in 21 CFR 101.30 when determining the sugar content of a single strength fruit juice product, which is then used to calculate the added sugars contributed to the product by the concentrated fruit.

We require that, when sugars that do and do not meet our definition of added sugars are present in a food, manufacturers make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) (21 CFR 101.9(g)(10)(iv)). If you use Brix values provided in 21 CFR 101.30 to calculate the amount of added sugars in a product containing fruit juice concentrate, you must document this information in the records regarding the amount of added sugars added to the food during processing (21 CFR 101.9(g)(10)). If you use the amount of sugars present in a single strength juice and/or a fruit juice concentrate that is determined through chemical analysis when calculating the amount of added sugars in a product containing fruit juice concentrate, you must document the analytical information in the records that you make and keep (21 CFR 101.9(c)(6)(iii)).

**9. I add 100% fruit juice to my product, but water is removed from the product during processing. Therefore, the fruit juice is concentrated during processing of my product. How do I determine the amount of added sugars in the finished product?**

The amount of added sugars is based on the finished product composition. Therefore, you need to account for the loss of water during processing to reflect the concentration of the fruit juice ingredient.

We realize that food formulation is complex and manufacturers can use different ingredients or alternative formulas to achieve the same finished product composition. For example, you may use 100% fruit juice and dry sugar in a baking application. You also may have an alternative formulation that uses concentrated fruit juice and liquid syrup to achieve the same product composition before baking. The water in the liquid syrup can contribute towards the dilution of the fruit juice.

When water is added to a product containing concentrated fruit juice and other ingredients during processing, the amount of water that goes towards reconstituting the fruit juice or towards wetting or reconstituting other ingredients is not known. Furthermore, if the water added during formulation is divided among the ingredients when determining the amount of reconstitution or wetting that has occurred, different formulations of the same finished food could have different calculated added sugar amounts. Therefore, we considered an approach that we believe would provide a reasonable estimate of the added sugars content of a multi-ingredient product that includes concentrated fruit juice as an ingredient. When concentrated fruit juices are used in the formulation, we believe that it is practical to assume that all the water in the formulation is used to reconstitute the concentrated juice. Consequently, when

water is lost during processing, we assume that all of the water in the finished product can be used to reconstitute the juice soluble solids.

Example 1: A product is formulated as follows:

- 50% single strength orange juice (12% sugar, 88% moisture), and
- 50% other ingredients with no added sugars and 6.5% water.
- The product has about 50% moisture before baking.
- After baking, the product has a moisture content of 10% and a solids content of 90%.
- The serving size is 100 g for the finished baked product.

Calculation:

- Solids content in the finished product  $g = 100 \times 90\% = 90 \text{ g}$
- Because the solids prior to baking is 50% (moisture = 50%), the starting formulation is 180 g (90 g / 50%). Therefore, the formulation used 90 g single strength orange juice and 90 g other ingredients.
- The sugars from concentrated orange juice is  $90 \text{ g} \times 12\% = 10.8 \text{ g}$
- In the finished product, there is 10 g water per serving ( $10\% \times 100 \text{ g}$ ). This is equivalent to water from 11.5 g single strength juice ( $10/88\%$ ). The amount of sugar in 11.5 g single strength juice is 1.38 g ( $11.5 \times 12\%$ ).
- Thus, the amount of added sugars is  $10.8 \text{ g} - 1.38 \text{ g} = 9.42 \text{ g}$

Example 2: A product is formulated as follows:

- 30% single strength orange juice (12% sugar, 88% moisture),
- 5% solid cane sugar,
- 15% water, and
- 50% other ingredients with no added sugars and 8.9 % water.
- The product has about 50% moisture before baking.
- After baking, the product has a moisture content of 10%.
- The serving size is 100 g for the finished baked product.

Calculation:

- Solids content in the finished product  $= 100 \times 90\% = 90 \text{ g}$

- Because the solids prior to baking is 50% (moisture = 50%), the starting formulation is 180 g (90 g / 50%). Therefore, the formulation used 54 g (180 g x 30%) single strength orange juice, 9 g solid cane sugar, 27 g water, and 90 g other ingredients.
- The sugar from concentrated orange juice is  $54 \text{ g} \times 12\% = 6.48 \text{ g}$
- In the finished product, there is 10 g water per serving. This is equivalent to water from 11.5 g single strength juice (10 g/88%). The amount of sugar in 11.5 g single strength juice is  $1.38 \text{ g}$  ( $11.5 \text{ g} \times 12\%$ ).
- Added sugars from fruit juice concentrate =  $6.48 \text{ g} - 1.38 \text{ g} = 5.1 \text{ g}$
- Total amount of added sugars =  $5.1 \text{ g}$  (from fruit juice concentrate) +  $9 \text{ g}$  (from cane sugar added) =  $14.1 \text{ g}$ .

**10. The definition of added sugars excludes the “fruit component of fruit spreads.” What constitutes the “fruit component” of a non-standardized fruit spread?**

Please see our response to question 5 above. The fruit component of a fruit spread would include whole fruits, pieces of fruit, dried fruit, fruit purees (that have not been concentrated), fruit pulps, single strength fruit juice, or other fruit ingredients where a whole fruit has been processed so that the plant material is physically broken down into smaller pieces (e.g., chopping, dicing, grinding, pureeing, etc.) but the sugar in the ingredient has not been concentrated.

**11. Should the added sugars contribution from concentrated fruit or vegetable juices be determined on a volume basis or on a weight basis?**

The amount of added sugars declared on the label must be in grams (21 CFR 101.9(c)(6)(iii)). You may choose to arrive at the gram amount of added sugars in different ways. You may know the gram weight and concentration of sugars in an ingredient used in the production of the food.

For example:

- 20 g of apple juice concentrate is added to a food that has a concentration of 46% sugar ( $20 \text{ g} \times 0.46 = 9.2 \text{ g}$  sugar).
- 20 g of single strength apple juice has 11.5% sugar ( $20 \text{ g} \times 11.5\% = 2.3 \text{ g}$ ).
- $9.2 \text{ g}$  sugar from apple juice concentrate –  $2.3 \text{ g}$  sugar from single strength apple juice =  $6.9 \text{ g}$  added sugars per serving.

Alternatively, you may know how many grams of sugar are in the fruit juice concentrate that you are using from chemical analysis as well as the gram amount of sugars in the same single strength juice. An example of how to calculate the added sugars amount in such case is as follows:

- 9.2 g sugar in 20 g apple juice concentrate

- 2.3 g sugar in 20 g single strength apple juice
- 9.2 g - 2.3 g = 6.9 g added sugars per serving.

**12. The regulation says in 21 CFR 101.9(c)(6)(iii) that added sugars are a “statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content.” What does FDA consider to be a “sweetener?” Do sweeteners include sugar alcohols and other low-calorie sweeteners?**

We have traditionally used the term “sweetener” to refer to ingredients that provide sweetness to a food regardless of whether they provide calories (43 FR 43248, September 22, 1978; 56 FR 60437-60438, November 27, 1991; and 58 FR 2326-2327, January 6, 1993). Therefore, we consider both caloric and non-caloric sweeteners, including sugar alcohols, to be sweeteners for the purposes of this regulation.

**13. Some ingredients contain mono- and disaccharides (DP1 and DP2 (one and two degrees of polymerization)) that are created through processes such as hydrolysis. Do the mono and disaccharide portions of ingredients that are created through hydrolysis need to be declared as added sugars on the label?**

In the preamble to the final Nutrition Facts label rule (81 FR 33742 at 33831), we said that, other than sugar syrup types of products where the sugars are specifically and purposely produced via hydrolysis, we do not have information suggesting that sugars produced through incidental hydrolysis of complex carbohydrates results in significant increase in the sugar content of foods. Sugars which are produced through incidental hydrolysis would be captured in the total sugars declaration, but we did not have any comments or other information suggesting that these sugars should be captured under the added sugars declaration. Therefore, they are not included in our definition of added sugars and would not be declared as added sugars on the label. We also explained our position that if a manufacturer purposely employs a hydrolysis step as part of a food manufacturing process to increase the sugar content of a food product (e.g. enzymatic hydrolysis of corn starch to make corn syrup in the same facility as part of the cookie-making process), we would consider the sugar generated from the hydrolysis step to be added sugars, since hydrolysis was purposely used by the manufacturer to increase the sugar content of the product (81 FR 337242 at 33832).

In the preamble to the Nutrition Facts label final rule (81 FR 33742 at 33835), we also said that, in determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 DGAC Report.

Manufacturers may purposely employ methods, such as hydrolysis for a number of reasons, some of which result in an ingredient containing mono- and disaccharides with DP1 and DP2. Ingredients such as maltodextrin and corn syrup solids are hydrolyzed to achieve various degrees of dextrose equivalence (DE). The higher the DE, the lower the degree of polymerization, and the sweeter the ingredient becomes. Maltodextrins (21 CFR 184.144)

are ingredients with a DE less than 20, and corn syrup solids (21 CFR 168.121) are ingredients with a DE of 20 or higher. Depending on the manufacturing process, different maltodextrin and corn syrup solids will have different DE and different amounts of mono- and di-saccharides. Although maltodextrins are not used primarily for sweetening purposes, depending on the DE, some can contain 8-9% mono and disaccharides and can contribute to sweetness. We also understand that the hydrolysis process to manufacture maltodextrin and corn syrup solids are controlled so that the desired DE can be consistently achieved. This indicates that some maltodextrins and corn syrup solids are manufactured purposely to contain certain levels of mono- and disaccharides.

If a serving of a product contains less than 0.5 grams of added sugars from maltodextrins, corn syrup solids, or another ingredient made with a hydrolysis step, we would consider the presence of this low amount of mono- and disaccharides to be an insignificant amount towards the empty calorie contribution from the added sugars content of the diet. The added sugars content may be expressed as zero on the label at these low levels. When the mono- and disaccharides are present in such small amounts that they do not contribute to the sweetness of a product, we would anticipate that the amount of mono- and disaccharides would be so low that they would not contribute to an added sugars declaration (e.g. there would be less than 0.5 grams of mono- and disaccharides contributed by the ingredient). Such small amounts of mono- and disaccharides would also not contribute meaningful amounts of calories to the diet.

Ingredients, such as maltodextrins, are used in many food products and may contribute more than 0.5 grams per serving in some foods. When maltodextrins are intentionally created through hydrolysis in amounts of greater than 0.5 grams per serving, their contribution to the overall diet would be consistent with the concept of empty calories, and when present, must be declared as added sugars on the label. Similarly, when mono- and disaccharides with DP1 and DP2 are created through hydrolysis and are present in other ingredients in amounts of 0.5 grams or greater, those mono- and disaccharides contribute empty calories to foods and must also be declared as added sugars on the label (21 CFR 101.9(c)(9)(iii)).

**14. If sugars are added to a food that already contains inherent sugars (e.g. to cranberries, tart cherries, or yogurt), does that make “added sugars” a Class I nutrient for purposes of compliance under 21 CFR 101.9(g)? If so, does that mean that the composite must be formulated to be at least equal to the value for the added nutrient (added sugars) declared on the label per 21 CFR 101.9(g)(4)(i), or is 21 CFR 101.9(g)(5) allowing up to 20% in excess of the value declared applicable?**

Under 21 CFR 101.9(g)(3)(i), added sugars would be a nutrient in a fortified or fabricated food. Added sugars is not a nutrient listed in 21 CFR 101.9(g)(4)(i). The nutrients listed in this regulation include: vitamins, minerals, protein, and dietary fiber.

When a food contains sugars that are indigenous and not exogenous sugars, the nutrient content of the composite for “Total Sugars” and “Added Sugars” would be subject to 21 CFR 101.9(g)(5). Section 101.9(g)(5) requires that the nutrient content of the composite be no greater than 20 percent in excess of the value for that nutrient declared on the label and states that no regulatory action will be based on a determination of a nutrient value that falls above

this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

However, because there are no generally recognized analytical methods available to quantify added sugars in a food when the food contains sugars that do and do not meet our definition of added sugars, the parenthetical after “added sugars” in § 101.9(g)(5) states that, “when the only source of sugars in the food is added sugars.” The parenthetical is intended to clarify that the requirement in § 101.9(g)(5) for the added sugars declaration would only apply when there is an analytical method available to quantify the added sugars. When a food contains a combination of sugars that do and do not meet our definition of added sugars, we would verify the declaration of added sugars in a food using the records required by § 101.9(g)(10) and (11).

With respect to the total sugars declaration, § 101.9(g)(5) would apply whether the food contains only added sugars, only sugars that do not meet our definition of added sugars, or a combination of these sugars in a food because there would be an analytical method to quantify “Total Sugars” under these circumstances.

A food that already contains some indigenous sugar and additional added sugars, either directly or as a component in an ingredient, such as sweetened fruit added to yogurt, would be misbranded if the actual “Total Sugars” amount is greater than 20 percent in excess of the value for that nutrient declared on the label, or the records requirements for “Added Sugars” are not met (see § 101.9(g)(11)).

**15. Do sugars present in a sweet fermented beverage after fermentation need to be declared as total or added sugars on the label?**

If the fermented beverage contains only sugars that meet our definition of added sugars (e.g. table sugar), then the amount of sugars present in a serving of the product after fermentation must be declared as both total and added sugars (21 CFR 101.9(c)(6)(iii)).

If the fermented beverage contains both sugars that do and do not meet our definition of added sugars, you can determine the amount of total sugars in the finished food analytically. You have the following options related to the added sugars declaration:

- Determine a reasonable approximation of the amount of added sugars in the finished product and make and keep records of all relevant scientific data and information you relied upon that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation; or
- Declare the amount of added sugars added prior to fermentation and make and keep records to verify the amount. The amount of added sugars declared should not exceed the amount of total sugars on the label; or



- If you have no way to determine a reasonable approximation of the amount of added sugars in the finished food, but have reason to believe that a significant reduction of added sugars took place during fermentation, you may submit a petition, under 21 CFR 10.30, to request an alternative means of compliance. The petition should provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to fermentation. A significant reduction would be where reduction in added sugars after fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within good manufacturing practice under § 101.9(g)(6). In addition, the scientific data or other information should include the reason why you are unable to determine a reasonable approximation of the amount of added sugars in a serving of the finished product and a description of the process that you used to come to that conclusion.

**16. Ingredients made primarily from sugar and created through non-enzymatic browning are added to some products for coloring and flavoring purposes. After non-enzymatic browning occurs, the sugar is reduced in the ingredient. In such a case, how much sugar must be declared as added sugars on the label?**

If only a portion of the sugar contributed by an ingredient that undergoes non-enzymatic browning is detectable by testing in the finished product, you may declare the amount of sugar that is detectable by analytical testing in the finished product as added sugars. When such an ingredient is added to a product that contains other sugars that do not meet the definition of added sugars, you must make and keep records of the results of their analytical testing that is used to demonstrate the amount of added sugars contributed by the ingredient in the finished product after non-enzymatic browning occurs and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation (21 CFR 101.9(g)(10)(v)(A)).

**17. If sugar is added for fermentation during the leavening process of a baked good and some of the sugars are consumed by yeast, should the reduction in the amount of sugars be accounted for the declaration of added sugars?**

As described in our response to question 15, you may declare the amount of added sugars in the food after fermentation. If you do so, you must make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation (21 CFR 101.9(g)(10)(v)(A)).

**18. There is a chance that added sugars content prior to non-enzymatic browning and/or fermentation may be higher than the total sugars content of the finished food determined through chemical analysis. How do I approximate the added sugars value in this case?**

The added sugars declaration should not exceed the total sugars declaration. In a case where sugars added prior to or during processing are reduced through non-enzymatic browning and/or fermentation, and the manufacturer chooses to declare the amount of sugars added prior to non-enzymatic browning and/or fermentation, the added sugars declaration could conceivably exceed the amount of total sugars determined through chemical analysis. In such a case, you should declare the same amount for added sugars as the amount of total sugars obtained through analytical testing for a serving of the food.

## **Format Issues**

### **19. What are the specifications for thickness of lines and leading (e.g. space between lines) on the Nutrition Facts label?**

We have provided graphic illustrations on the new Nutrition Facts label depicting line thickness and leading elements that have not changed, such as line thickness, font styles, and leading specifications that were previously shown in Appendix B to 21 CFR Part 101. This and more information can be assessed at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm513734.htm>.

## **Declaration of Quantitative Amounts of Vitamins and Minerals**

### **20. What are the requirements (e.g. for rounding) for the declaration of quantitative amounts of vitamins and minerals declared on the Nutrition and Supplement Facts labels? What does “levels of significance” mean in this context?**

We require, under 21 CFR 101.9(c)(8)(iii), that the quantitative amounts of vitamins and minerals, excluding sodium, be the amount of the vitamin or mineral included in a serving of the product using the units of measurement and the levels of significance given in 21 CFR 101.9(c)(8)(iv) (which refers to the Reference Daily Intakes (RDI) table). However, zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram). This is consistent with the requirements for the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label (see 21 CFR 101.36(b)(2)(ii)(B)).

In addition, regarding conventional foods, quantitative amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared on the Nutrition Facts label. However, they may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table that is followed by the statement “Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)” or “Contains <2 percent of the Daily Value of this (these) nutrient (nutrients).” Alternatively, if vitamin D, calcium, iron or potassium is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement “Not a significant source of \_\_\_ (listing the vitamins or minerals omitted)” is placed at the bottom of the table of nutrient values (21 CFR 101.9(c)(8)(iii)).

Regarding dietary supplements, the quantitative amounts of vitamins and minerals with an RDI must be declared on the Supplement Facts label when they are present in a dietary supplement in quantitative amounts by weight that equal 2 percent or more of the RDI in accordance with § 101.9(c). Any other vitamins and minerals listed in § 101.9(c)(8)(iv) or (c)(9) may be declared, but they must be declared when they are added to the product for the purposes of supplementation, or when a claim is made about them. Vitamins and minerals that have an RDI must not be declared on the Supplement Facts label if they are present in amounts corresponding to less than 2 percent of the RDI for vitamins and minerals (21 CFR 101.36(b)(2)(i)).

As for the phrase “levels of significance,” as used in §§ 101.9 (c)(8)(iii) and 101.36(b)(2)(ii)(B) and whether the phrase refers to statistical testing of hypotheses or mathematical concepts related to the degree of accuracy starting with the first nonzero digit, the phrase “levels of significance” refers to the degree of accuracy when rounding nutrients for purposes of declaring quantitative amounts of vitamins and minerals on the label.

Our regulations, at 21 CFR § 101.9(c), provide specific rounding requirements for nutrients such as sodium. Before we issued the Nutrition Facts label final rule, sodium and potassium content was to be expressed as zero when the serving contained less than 5 milligrams (mg), to the nearest 5 mg increment when the serving contained less than or equal to 140 mg, and to the nearest 10 mg increment when the serving contained more than 140 mg. The Nutrition Facts label final rule amended 21 CFR 101.9(c)(5) to replace the requirements for the labeling of potassium with those of fluoride and amended 21 CFR 101.9(c)(8)(iv) to establish an RDI for potassium and add it to the list of vitamins and minerals with RDIs. The requirements for declaring the quantitative amount of potassium are now the same as those for other vitamins and minerals with RDIs.

Although the requirements for the declaration of quantitative amounts of vitamins and minerals that are present at less than 2 percent of the RDI differ between the Nutrition and Supplement Facts labels (i.e. quantitative amounts may be declared on the Nutrition Facts label when present in quantities of less than 2 percent of the RDI per serving whereas they must not be declared on the Supplement Facts label when present in such small amounts), we recommend that you use the same principles for the declaration of quantitative amounts of vitamins and minerals on both the Nutrition and Supplement Facts labels for consistency. The principles are driven largely by the requirement that vitamins and minerals present in amounts of less than 2 percent of the RDI per serving must not be declared on the Supplement Facts label. However, we considered how our recommendations impact both conventional foods and dietary supplements. The following recommendations apply to quantitative amounts of vitamins and minerals declared on both the Nutrition Facts and Supplement Facts labels.

The RDIs for some vitamins and minerals are small numerical values (e.g., thiamin 1.2 mg, pantothenic acid 5 mg, and copper 0.9 mg). Manufacturers also may wish to declare additional digits after the decimal point when nutrients are present in such small amounts. Furthermore, nutrients with an RDI of less than 25 would not be able to be declared on the

Supplement Facts label if they contain less than 2 percent of the RDI (e.g. 2 percent of the RDI for copper is 0.018 mg) and the amount is declared to the nearest mg or microgram (mcg) (e.g. if the amount of copper in a serving of the product is 0.017, but is rounded to zero). Therefore, the quantitative amount of vitamins and minerals with an RDI of less than 25 mg or mcg (i.e. iron, vitamin D, vitamin E, thiamin, riboflavin, niacin, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, pantothenic acid, zinc, copper, and manganese) should be declared to the nearest tenth of a mg or mcg per serving. However, the quantitative amount may be declared to the nearest hundredth or thousandth of a mg or mcg when that level of specificity is necessary to attain a value that is at least 2 percent of the RDI in a serving of the food, and therefore, sufficient to declare the quantitative amount of the nutrient on the Supplement Facts label. If a manufacturer determines that rounding to the nearest hundredth or thousandth of a mg or mcg would not be accurate given the variation of the nutrient in the food supply, the manufacturer should provide a nutrient declaration that is accurate and does not suggest a greater level of precision in the amount of the nutrient present than is practical.

A vitamin or mineral with an RDI of at least 25 mg or mcg, but less than 250 mg or mcg, would not be declared on the Supplement Facts label if it contains less than 2 percent of the RDI unless the quantitative amount is declared to the nearest mg or mcg. However, for conventional foods, declaring the quantitative amounts of such nutrients to the nearest tenth or hundredth of a mg or mcg could indicate that there is greater precision in the amount of the nutrients present in a serving of the product than is practical, given the variation in the food supply. Therefore, the quantitative amount of vitamins or minerals with an RDI of at least 25 mg or mcg but less than 250 mg or mcg (i.e. vitamin C, vitamin K, biotin, iodine, selenium, chromium, and molybdenum) should be declared to the nearest mg or mcg per serving.

A vitamin or mineral with an RDI of at least 250 mg or mcg, but less than 500 mg or mcg, would not be declared on the Supplement Facts label if it contains less than 2 percent of the RDI unless the quantitative amount is declared to the nearest 5 mg or mcg. However, for conventional foods, declaring the quantitative amounts of such nutrients to the nearest mg or mcg, or even to the nearest tenth of a mg or mcg, could indicate that there is greater precision in the amount of the nutrient present in a serving of the product than is practical given the variation in the food supply. Therefore, the quantitative amount of vitamins and minerals with an RDI of at least 250 mg or mcg, but less than 500 mg or mcg (i.e. folate and magnesium), should be rounded to the nearest 5 mg or mcg per serving.

A vitamin or mineral with an RDI of 500 mg or mcg or greater would not be declared on the Supplement Facts label if it contains less than 2 percent of the RDI unless the quantitative amount is declared to the nearest 10 mg or mcg. However, for conventional foods, declaring the quantitative amounts of such nutrients to the nearest 5 mg or mcg or smaller increment could indicate that there is greater precision in the amount of the nutrient present in a serving of the product than is practical given the variation in the food supply. Therefore, the quantitative amount of vitamins or minerals with an RDI of 500 mg or mcg or greater (i.e. vitamin A, calcium, phosphorous, chloride, potassium, and choline) should be rounded to the nearest 10 mg or mcg per serving.

Manufacturers may calculate the percent DV for all nutrients other than protein by dividing either the amount of the nutrient declared on the label or the actual amount of the nutrient (i.e., before rounding) to provide for the greatest amount of consistency on the food label (21 CFR 101.9(d)(7)(ii)).

**Recommendations for declaration of quantitative amounts of vitamins and minerals on the Nutrition and Supplement Facts labels using RDIs for adults and children  $\geq$  4 years**

Nutrient	Unit of Measure	RDI for Adults and Children $\geq$ 4 years	Recommended increment
<b>Vitamin A</b>	Micrograms RAE (mcg)	900	Nearest 10 mcg
<b>Vitamin C</b>	Milligrams (mg)	90	Nearest mg
<b>Calcium</b>	Milligrams (mg)	1,300	Nearest 10 mg
<b>Iron</b>	Milligrams (mg)	18	Nearest .1 mg
<b>Vitamin D</b>	Micrograms (mcg)	20	Nearest .1 mcg
<b>Vitamin E</b>	Milligrams (mg)	15	Nearest .1 mg
<b>Vitamin K</b>	Micrograms (mcg)	120	Nearest mcg
<b>Thiamin</b>	Milligrams (mg)	1.2	Nearest .1 mg
<b>Riboflavin</b>	Milligrams (mg)	1.3	Nearest .1 mg
<b>Niacin</b>	Milligrams NE (mg)	16	Nearest .1 mg
<b>Vitamin B<sub>6</sub></b>	Milligrams (mg)	1.7	Nearest .1 mg
<b>Folate</b>	Micrograms DFE (mcg)	400	Nearest 5 mcg
<b>Vitamin B<sub>12</sub></b>	Micrograms (mcg)	2.4	Nearest .1 mcg
<b>Biotin</b>	Micrograms (mcg)	30	Nearest mcg
<b>Pantothenic acid</b>	Milligrams (mg)	5	Nearest .1 mg
<b>Phosphorous</b>	Milligrams (mg)	1,250	Nearest 10 mg
<b>Iodine</b>	Micrograms (mcg)	150	Nearest mcg
<b>Magnesium</b>	Milligrams (mg)	420	Nearest 5 mg
<b>Zinc</b>	Milligrams (mg)	11	Nearest .1 mg
<b>Selenium</b>	Micrograms (mcg)	55	Nearest mcg
<b>Copper</b>	Milligrams (mg)	0.9	Nearest .1 mg
<b>Manganese</b>	Milligrams (mg)	2.3	Nearest .1 mg
<b>Chromium</b>	Micrograms (mcg)	35	Nearest mcg
<b>Molybdenum</b>	Micrograms (mcg)	45	Nearest mcg
<b>Chloride</b>	Milligrams (mg)	2,300	Nearest 10 mg
<b>Potassium</b>	Milligrams (mg)	4,700	Nearest 10 mg
<b>Choline</b>	Milligrams (mg)	550	Nearest 10 mg

<sup>1</sup> The quantitative amount may be declared to the nearest hundredth or thousandth of a mg or mcg when that level of specificity is necessary to attain a value that is at least 2 percent of the RDI in a serving of the food, and therefore, sufficient to declare the quantitative amount of the nutrient on the Supplement Facts label.

<sup>2</sup> This table provides recommendations for the declaration of quantitative amounts of vitamins and minerals using only the RDIs that have been established for adults and children 4 years of

age and older. Our regulations, at 21 CFR 101.9(c)(8)(iv), provide RDIs for infants through 12 months, children 1 through 3 years, and pregnant and lactating women. The declaration recommendations provided in this guidance can also be applied to the RDIs for these subpopulations.

#### **IV. References**

U.S. Department of Agriculture and U.S. Department of Health and Human Services. “Scientific Report of the 2015 Dietary Guidelines Advisory Committee”, Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, D.C., 2015. Retrieved from: <https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf>