

*Contains Nonbinding Recommendations
Draft-Not for Implementation*

The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-0075 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1450.

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

February 2018

Contains Nonbinding Recommendations

Draft-Not for Implementation

Table of Contents

I. Introduction

II. Background

III. Discussion

IV. References

The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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

The purpose of this draft guidance is to advise food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol “†” immediately after the added sugars percent Daily Value information on single ingredient packages and/or containers of pure honey or pure maple syrup and on certain dried cranberry and cranberry juice products that are sweetened with added sugars and that contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars.

With respect to the labeling of single ingredient packages of pure honey or pure maple syrup, we are taking this action in response to concerns from stakeholders that consumers might misinterpret the added sugars declaration to mean that non-endogenous sweeteners, such as corn syrup or cane sugar, have been added to the pure product.

With respect to the labeling of certain cranberry products, cranberries are a naturally tart fruit, and certain dried cranberries and cranberry juice products have added sugars added to them to bring the total sugars per serving up to levels comparable to the levels of non-cranberry competitor products that contain equivalent amounts of total sugars, but whose labels list zero “added sugars” because their fruit products are inherently sweet. Some stakeholders are concerned that consumers may think certain cranberry products are less nutritious than these competitor products because of the added sugars declaration.

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling, Nutrition Programs Staff in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Contains Nonbinding Recommendations

Draft-Not for Implementation

FDA's guidance documents, including this draft 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.

II. Background

In the *Federal Register* of May 27, 2016, we issued a final rule updating the Nutrition Facts label for packaged foods to reflect new scientific information (see 81 FR 33742, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels”) (“the final rule”). The final rule includes changes in the individual nutrients that must be declared and also changes some of the Daily Values (DVs). The science underlying the final rule, referenced above, is also reflected in the 2015-2020 *Dietary Guidelines for Americans (Dietary Guidelines)* (Ref. 1). The primary focus of the *Dietary Guidelines* is to promote overall health and prevent chronic disease in the United States. The *Dietary Guidelines* are the foundation of federal nutrition guidance and are fundamental in shaping federal policies and programs related to food, nutrition, and health.

The final rule requires that added sugars be included in the Nutrition Facts label and established a Daily Value for added sugars. The final rule defines “added sugars,” in part, to include sugars that are either added during the processing of foods, or are packaged as such. The term includes free sugars (free mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. The final rule requires added sugars to be declared on the food label by stating, “Includes ‘X’ g Added Sugars” indented directly below “Total Sugars” (see 21 CFR 101.9(c)(6)(ii)).

The final rule requires a declaration for added sugars, in part, because excess consumption of added sugars makes it difficult to meet nutrient needs within the calorie limits generally needed to maintain a healthy weight and can lead to an increase in overall caloric intake. Further, healthy dietary patterns with lower amounts of sugar-sweetened foods and beverages, as compared to less healthy dietary patterns, are associated with a reduced risk of cardiovascular disease. The science underlying the 2015-2020 *Dietary Guidelines* demonstrates that meeting nutrient needs while staying within calorie limits is difficult with more than 10 percent of total daily calories from added sugars (50 grams of added sugars based on a 2,000 calorie diet). Based on this science, the final rule establishes a Daily Value for added sugars, 50 grams based on a 2,000 calorie diet for adults and children 4 years of age and older and 25 grams based on the 1,000 calorie diet for children 1 through 3 years of age (21 CFR 101.9(c)(8)(vii)).

Pure (100%) honey, pure (100%) maple syrup, and certain cranberry products sweetened with added sugars contribute to the Daily Value of added sugars whether added by consumers to foods (e.g., maple syrup poured over pancakes; sugar added to cranberry juice to increase palatability) or consumed in isolation (e.g., a spoonful of honey). (In this guidance, we are using the terms “pure” and “100%” to distinguish the single ingredient products from similar products

Contains Nonbinding Recommendations

Draft-Not for Implementation

that cannot properly be labeled as “honey” or “maple syrup” because they contain additional ingredients such as sweeteners or flavorings.) FDA’s definition encompasses the types of added sugars that were evaluated in the science underlying the 2015-2020 *Dietary Guidelines* recommendation that no more than 10% of calories be from added sugars. These sugars were considered “empty calories” or “calories for other uses” in the USDA Food Patterns. If these products are not labeled with the amount of added sugars per serving, consumers would not be able to understand the relative significance of these sources of added sugars in the context of a total daily diet.

We have, however, heard concerns regarding the declaration of added sugars on single ingredient honey or maple syrup, such as a jar of honey or a bottle of maple syrup (REF 2). In brief, the concern is that some consumers may believe that honey or maple syrup declaring “added sugars” is adulterated with other sweeteners because they may think the declaration means “sugar” is added to the pure honey or maple syrup. Both of these products have a history of economic adulteration with cheaper sweeteners.²

We received comments from the cranberry industry to the final rule and subsequent correspondence (REF 4) that the added sugars declaration would be detrimental to the cranberry industry by implying that cranberry products are less nutritious than competitive products that have similar amounts of total sugars and nutrients. These comments were similar to those we received which noted that grape juice contains 36 grams of total sugar with no added sugars while cranberry cocktail, with sugars added for palatability because cranberries are naturally tart, generally contains 28 grams of total sugars including 25 grams of added sugars and has 30 fewer calories per serving than 100% grape juice (REF 5). Likewise, comments explained that sweetened dried cranberries contain 29 grams of total sugars including 25 grams of added sugars per serving while raisins contain 29 grams of total sugars with no added sugars per serving. Both sweetened dried cranberries and raisins have the same number of calories per serving and a similar nutrient profile.³

² Under section 402(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(b)), a food is adulterated if any valuable constituent has been omitted in whole or in part or if any substance has been added so as to reduce the food’s value. Therefore, if a food is sweetened with corn syrup and labeled as “honey,” this would affect the quality of that food, and the label would make it appear to be better or of greater value than it is. We would consider such a food to be adulterated under section 402(b)(1) of the FD&C Act because a valuable constituent (honey) has been omitted in part, and under section 402(b)(2) of the FD&C Act because a substance (corn syrup) has been substituted for some of the honey so as to increase its bulk or weight or make it appear better or of greater value than it is. We have a long-standing import alert for the surveillance of honey for adulteration with cane or corn sugars (REF 3). Moreover, a food is misbranded unless the label bears: (1) the common or usual name of the food; and (2) the common or usual name of each ingredient, if the food is made from two or more ingredients (section 403(i) of the FD&C Act (21 U.S.C. 343(i))). A food consisting only of honey must be named “honey,” which is the common or usual name for honey (see section 403(i) of the FD&C Act). If the product is labeled as “honey” but also contains a sweetener (i.e., sugar or corn syrup), the product would be misbranded. With respect to maple syrup, our regulations establish a standard of identity for maple syrup. In brief, maple syrup “is the liquid food derived by concentration and heat treatment of the sap of the maple tree (*Acer*) or by solution in water of maple sugar made from such sap. It contains not less than 66 percent by weight of soluble solids derived solely from such sap” (21 CFR 168.40). The maple syrup industry expressed concern that the added sugars declaration could suggest there are additional sugars beyond the sap from which maple syrup is derived (REF 2).

³ The 2015-2020 *Dietary Guidelines* note that there is room for Americans to consume limited amounts of added sugars in their eating patterns and specifically mention that added sugars could be used to improve the palatability of nutrient dense foods such as cranberries or rhubarb (REF 1). The United States Department of Agriculture’s Food

Contains Nonbinding Recommendations

Draft-Not for Implementation

III. Discussion

The final rule defines “added sugars,” in part, to include sugars that are either added during the processing of foods, or are packaged as such. Given the concerns outlined earlier regarding the added sugars declaration on pure honey, pure maple syrup, and certain cranberry products described here (dried cranberries and cranberry juice sweetened with added sugars that provide an amount of total sugars in a serving that does not exceed the level of total sugars in a serving of a comparable product with no added sugars), we intend to exercise enforcement discretion for such products to use a “†” symbol immediately following the added sugars percent Daily Value. The “†” symbol would direct consumers to truthful and non-misleading statements on the package outside the Nutrition Facts label that would need to comply with applicable FDA statutory and regulatory requirements. Manufacturers could explain, through the use of such statements, that no sugar was added to the pure honey or pure maple syrup or that the added sugars added to dried cranberries or the cranberry juice product is meant to increase the palatability of the naturally tart fruit and that the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars.

We consider it appropriate to consider our enforcement discretion for the use of this symbol on packages of pure honey and pure maple syrup to provide an opportunity for manufacturers of these products to elect to provide additional information on the label related to, for example, the fact that the sugars from honey are all from the same source and that no corn syrup or other sugar substance has been added. Additionally, we understand the cranberry industry’s interest in communicating additional information related to the declaration of added sugars on the label of cranberry juice products and dried cranberry products that have been sweetened with added sugars and that provide total sugars at a level no greater than the amount of total sugars in comparable products with endogenous sugars and no added sugars. FDA believes that permitting these factual statements to be referenced by the “†” symbol immediately following the added sugars percent Daily Value will address the concerns we heard about these products. As consumers become accustomed to the new Nutrition Facts label and educated on the added sugars declaration and the Daily Value, we may re-evaluate the placement of the “†” symbol in the Nutrition Facts label.

and Nutrition Service also provided an accommodation for dried whole fruits, or pieces, with nutritive sweeteners that are required for processing and/or palatability purposes, which included dried cranberries (REF 6), for foods sold in schools.

Contains Nonbinding Recommendations

Draft-Not for Implementation

Examples of Nutrition Facts label with “†” symbol leading to a factual statement outside the box.

| Nutrition Facts | |
|-------------------------------|----------------------|
| 8 servings per container | |
| Serving size | 1 cup (240ml) |
| Amount per serving | |
| Calories | 110 |
| <small>% Daily Value*</small> | |
| Total Fat 0g | 0% |
| Saturated Fat 0g | 0% |
| <i>Trans</i> Fat 0g | |
| Cholesterol 0mg | 0% |
| Sodium 5mg | 0% |
| Total Carbohydrate 27g | 9% |
| Dietary Fiber 0g | 0% |
| Total Sugars 25g | |
| Includes 23g Added Sugars | 54%† |
| Protein 0g | |
| Vitamin D 0mcg | 0% |
| Calcium 0mg | 0% |
| Iron 0mg | 0% |
| Potassium 45mg | 1% |

* The % Daily Value (DV) 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.

| Nutrition Facts | |
|-------------------------------|----------------------|
| 16 servings per container | |
| Serving size | 1 Tbsp. (21g) |
| Amount per serving | |
| Calories | 60 |
| <small>% Daily Value*</small> | |
| Total Fat 0g | 0% |
| Saturated Fat 0g | 0% |
| <i>Trans</i> Fat 0g | |
| Cholesterol 0mg | 0% |
| Sodium 0mg | 0% |
| Total Carbohydrate 17g | 6% |
| Dietary Fiber 0g | 0% |
| Total Sugars 17g | |
| Includes 17g Added Sugars | 34%† |
| Protein 0g | |
| Vitamin D 0mcg | 0% |
| Calcium 0mg | 0% |
| Iron 0mg | 0% |
| Potassium 0mg | 0% |

* The % Daily Value (DV) 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.

† Sugars added to improve the palatability of naturally tart cranberries. The 2015-2020 Dietary Guidelines for Americans state that there is room for limited amounts of Added Sugars in the diet, especially from nutrient dense food like naturally tart cranberries.

† All these sugars are naturally occurring in honey.

Contains Nonbinding Recommendations

Draft-Not for Implementation

Additionally, we consider our consumer education to be an important component of the implementation of the new Nutrition Facts label requirements, especially for nutrients that will be declared on the label for the first time, such as added sugars, and our education efforts will include a focus on added sugars in the context of the entire label. We intend to continue to work with other Federal Government Agencies, including other parts of the Department of Health and Human Services, the U.S. Department of Agriculture, state health departments, health professional organizations, food manufacturers, retailers, and non-profit organizations that have an interest and responsibilities in nutrition education and health promotion.

IV. References

We have placed the following references on display in the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of February 12, 2018, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this draft guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after February 12, 2018.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.
2. Letter from the International Maple Syrup Institute, dated September 7, 2016, and Letter from the National Honey Board, dated October 28, 2016.
3. Honey Import alert: http://www.accessdata.fda.gov/cms_ia/importalert_108.html
4. Letter from Ocean Spray, dated July 7, 2016.
5. Comments from Ocean Spray to Docket No. FDA-2012-N-1210, dated October 13, 2015.
6. <https://www.fns.usda.gov/sites/default/files/tn/USDASmartSnacks.pdf>
7. Comments from Ocean Spray to Proposed Rulemaking; *Food Labeling: Revision of the Nutrition and Supplement Facts Labels*; Docket No. FDA-2012-N-1210; dated August 1, 2014.