

ESHA Research

ESHA Research was established in 1981 as one of the very first nutrition software solutions. Today, ESHA's suite of nutritional software products, services, and databases are recognized as the industry's top choice for food and supplement formulation, recipe development, labeling, nutritional analysis, and regulatory compliance.

ESHA Solutions

- Genesis R&D® Food Formulation
- Genesis R&D® Supplement Formulation
- Food Processor® Nutrition & Diet Analysis
- Consulting Services

Our mission is to help remove the complexity of product development and regulatory compliance for the food, beverage, and supplement industries through software, services, and nutritional databases.

Genesis R&D Food



Genesis R&D® Foods, first release in 1991, is designed to help users manage processes and industry challenges, and meet federal requirements. Industry professionals use Genesis R&D for quick and accurate nutrient evaluation, virtual product development, nutrition labeling, and government regulation compliance.

- Product Development
- Formulation Analysis
- Menu Analysis
- Reporting
- Regulatory Compliance



Upcoming Webinars



Update on Dietary Fiber | March 12, 2019

During this webinar, we will provide an update on Dietary Fiber labeling, discuss the new Dietary Fiber definition, review the list of approved dietary fibers, and cover how to use the Genesis R&D Food program for compliance with the 2016 regulations.

Working with Recipes in Genesis R&D Foods | April 24, 2019

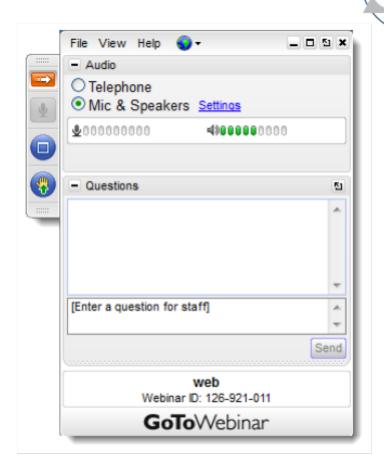
Setting up your recipe correctly in Genesis R&D is critical for ensuring you produce a regulatory compliant Nutrition Facts label. During this webinar, we will walk through the process of creating a recipe, setting the serving size, best reports for recipe auditing, and more.

To register or view archived webinars please visit: www.esha.com/news-events/webinars

Please Note!

- √ The webinar is being recorded
- ✓ All webinars available on our website
- ✓ Submit your questions in the GoToWebinar control panel





What we'll cover today

- Added Sugars Review
 - What is considered Added Sugar (and what is not)
 - Quantitative and %DV Declaration
- Guidance Documents
- Farm Bill
- User Tips for Compliance
- Best Practices for Documentation
- Q&A



Added Sugars – Brief Review

2016 FDA final rule for food labeling includes Added Sugars as a new, mandatory label nutrient

Nutrition Facts

8 servings per container 1 slice (59g)

Serving size

Calories

Amount per serving

180

_	% Daily Value*
Total Fat 6g	8%
Saturated Fat 4g	20%
Trans Fat 0g	
Cholesterol 25mg	8%
Sodium 190mg	8%
Total Carbohydrate 30g	11%
Dietary Fiber 1g	4%
Total Sugars 15g	
Includes 14g Added Su	igars 28%

No 4 - 1	2-
rotein	Зg

i rotom vg	
Vitamin D 0mcg	0%
Calcium 55mg	4%
Iron 2mg	10%
Potassium 1750mg	35%

^{*}The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet



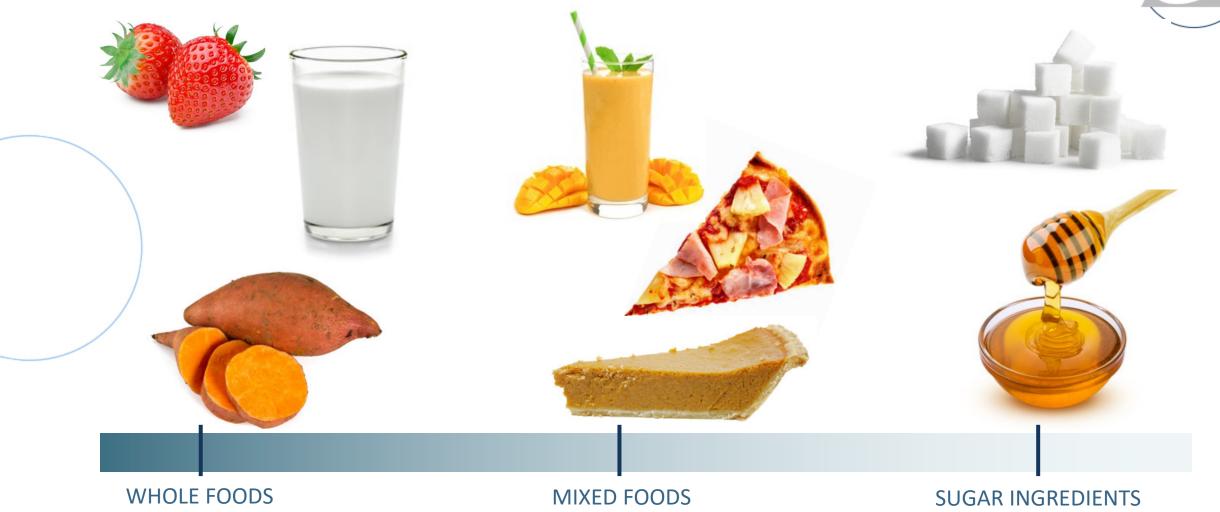
Added Sugars - DV



- Ties into Dietary Guidelines for Americans
- Recommendation of Less than 10% of Calories from Added Sugars
- 2000 Calories recommended for general labeling
- 200 Calories / 4 Calories per gram of Sugar = 50g



Nutrient Density vs. Empty Calories



Added Sugars - Definition



Sugars that are either added during the processing of foods or packaged as such and includes sugars (free, mono- and disaccharides), sugars from syrups and sugars concentrated from fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type. EXAMPLES:

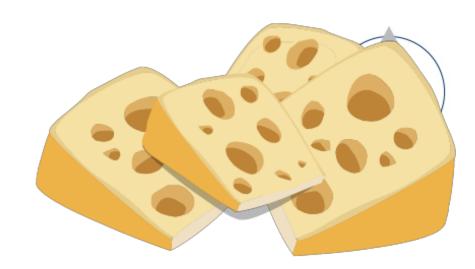
- Sugar
 - White sugar, brown sugar, beet sugar, cane sugar, invert sugar, raw sugar, turbinado sugar, dextrose, fructose, galactose, glucose, lactose, maltose, sucrose
- Honey
- Molasses
- Syrups
 - Agave syrup, high fructose corn syrup, malt syrup, maple syrup
- Juice Concentrates (in some cases)

AND MORE...

Added Sugars - Lactose

Dehydrated Milk Powder vs. Purified Lactose

- Dairy ingredients, except lactose as defined in § 168.122, are not included in the definition of added sugars.
 - Dehydrated milk powder is all of the nutrients from milk minus the water
- Lactose is defined as a sweetener under CFR 168.122
 - Lactose is the sugar from milk





FDA Guidance - November 2018



Contains Nonbinding Recommendations

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

Additional copies are available from:
Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
240-402-1450
https://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments on the guidance 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-2016-D-4414.

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

November 2018

Includes

- Clarification of Added Sugars definitions
- Concentrates
- Brix
- Examples of Added Sugars calculations
- Hydrolysis
- Fermentation

cheat sheet

ADDED SUGARS

noun | add·ed su·gars | \'a-dəd 'shu-gərs\

: a statement of the number of grams of added sugars in one serving of a food

DEFINITION

Sugars that are either added during the processing of foods or packaged as such and includes sugars (free, mono- and disaccharides), sugars from syrups and sugars concentrated from fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type.



CONSIDERED ADDED

Molasses Corn Sweetener **Pure Maple Syrup** Honey

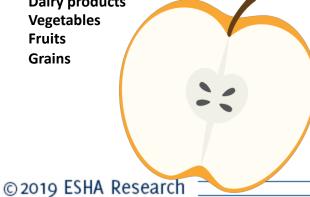
Sugar **Agave** Syrup



NOT CONSIDERED ADDED

Naturally occurring sugars in:

Dairy products Vegetables Fruits Grains



ON THE LABEL

Added Sugars are indented and listed under Total Sugars.

Rounding Rules:

- Less than 1 g: declaration not required with insignificant footnote or you can show "less than 1 g" or "< 1 g" on the label.
- Less than .5 g: may be expressed as zero

Nutrition Facts

2 servings per container 1 cup (140g) Serving size

Amount per serving Calories

160

	% Daily Value*
Total Fat 8g	10%
Saturated Fat 3g	15%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 60mg	3%
Total Carbohydrate 21g	8%
Dietary Fiber 3g	11%
Total Sugars 15g	
Includes 5g Added Su	gars 10%
Protein 3g	
Vitamin D 5mcg	25%

Iron 1ma Potassium 230mg *The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2000 calories

a day is used for general nutrition advice.

MANDATORY NUTRIENT

DV: 50g.

Calcium 20mg

The FDA recommends that your added sugar intake Not to exceed 10% of total calories.



THESE ITEMS **REQUIRE SPECIAL CONSIDERATION**

Juice concentrates -Example: if juice concentrate is added to a product, and the sugar content exceeds that contributed by whole foods and 100% juices, some of the sugars may be considered added sugars.

Purees/Pastes, Sugars after fermenting, Corn syrup solids

Rounding and Consistency of Declarations



(iii) "Added Sugars": 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. Except as provided for in paragraph (f) of this section, if a statement of the added sugars content is not required and, as a result, not declared, the statement "Not a significant source of added sugars" shall be placed at the bottom of the table of nutrient values in the same type size.

21 CFR 101.9

Nutrition	า Facts
12 servings per co Serving size	ontainer 2 slices (79g)
Amount per serving Calories	130
	% Daily Value*
Total Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 2	8g 10 %
Dietary Fiber 1g	4%
Total Sugars 4g	
Protein 4g	
Vitamin D 0mcg	0%
Calcium 5mg	0%
Iron 1mg	6%
Potassium 43mg	0%
lot a significant sourc	e of saturated fat,

Ingredients: Flour, Water, Sugar, Yeast, Soybean Oil, Salt, Wheat Gluten, Corn Starch.

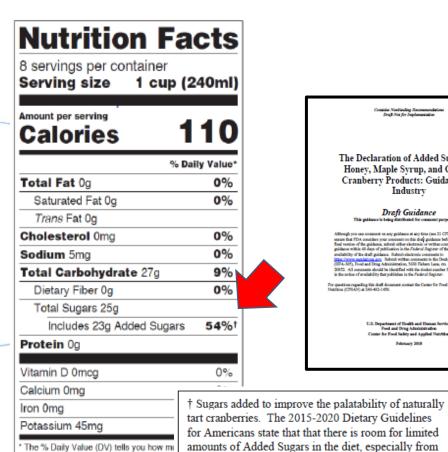
trans fat and added sugars.

*The % Daily Value tells you how much a putrient in a

*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.

FDA Draft Nonbinding Recommendations

Published February 2018



The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry Draft Guidance Amongly 90 Case continent on any gratients at any fines (far 21 CVF to 11 TgG(25)) to cause the TDA contains your constants to the still galaxies which was buglet work on the same that TDA contains your constants to the still galaxies which was buglet work on the galaxies within 60 days of publication in the Federal Requirer of the notion associating the subshillify of the day galaxies. Subshill actervatic comments to the Deckum Management fleaff 1074-MSD, Food and Dong Administration, 5000 Federal Laws, m. DOL (Rockvill, MDD 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.

nutrient dense food like naturally tart cranberries.

"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"

Nutrition Fa	cts
16 servings per container Serving size 1 Tbsp	. (21g)
Amount por sorving Calories	60
% D.	ally Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 17g	6%
Dietary Fiber 0g	0%
Total Sugars 17g	
Includes 17g Added Sugars	34%1
Protein 0g	
Vitamin D 0mog	0%

Calcium 0mg

Iron 0mg

All these sugars are naturally occurring in honev.

0%

The % Daily Value (DV) tells you how mu

a serving of food contributes to a daily die

a day is used for general nutrition advice

2018 Evolution of Declaration of Single Ingredient Sugars



- Single Ingredient Sugars that Meet FDA definition of Added Sugars for 2016 Nutrition Facts label
 - White sugar, brown sugar, agave syrup, corn syrup, honey, maple syrup, etc.
- Honey, Pure Maple Syrup, and Some Cranberry Products
 - Symbol and factual statement allowed on packages
- FDA continues review of the approach to single ingredient sugars
- Agriculture Improvement Act of 2018



"Is this a dagger which I see before me..."

Macbeth (II, i, 33)

Agriculture Improvement Act of 2018



H.R.2 a.k.a. 2018 Farm Bill

Sec. 12516 Labeling Exemption for Single Ingredient Foods and Products:

The food labeling requirements under section 403(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)) shall not require that the nutrition facts label of any single-ingredient sugar, honey, agave, or syrup, including maple syrup, that is packaged and offered for sale as a single-ingredient food bear the declaration "Includes X g Added Sugars."



https://www.congress.gov/bill/115th-congress/house-bill/2/text

Best Practices for Documentation



- Make and keep records of the amount of added sugars included in the food and added during processing
- Look for Added Sugars on ingredient supplier sheets
- Added Sugars can be equal to or less than Total Sugars
- Added Sugars should not be greater than Total Sugars
- Single ingredient sugars: Total Sugars = Added Sugars
 - As per Farm Bill, Added Sugars is not required to be declared for single-ingredient sugars, then the nature of the ingredient itself (it meets the FDA definition of Added Sugars) will be a factor in your documentation.
- Mixed food ingredients if Added Sugars are not reported, contact supplier
- If the Ingredient List identifies that the product contains no Added Sugars ingredients, then a value *might* be determined.
- You want to be accurate in the values you record and confident that your documentation supports the values you report.

Total vs. Added Sugar Fields in Genesis

Recipe

Nutrients

Measures

Brix Calculation

Cost

Groups

Compare To

Preparation Method

Reference Amount

Nutrient Content Claims

Notes

HACCP

Attachments

Audits

* %DV based on US Label 2016 standards.

Nutrient values based on 100,000000 grams

Nutrients	Value	% DV*		
Insoluble Fiber (2016) (g)	0			
Non-digestible Carbohydrate (g)	0			
Soluble Non-digestible Carbohydrate (g)	0			
Insoluble Non-digestible Carbohydrate (g)	0			
Total Sugars (g)	12.09792			
Added Sugar (g)	3.45000	6.90000		
Monosaccharides (g)	2.18064			
Galactose (g)	0.01799			
Glucose (g)	2.85280			
Fructose (g)	4.86984			
Disaccharides (g)	3.19929			
Lactose (g)	0			
Sucrose (g)	4.00531			
Maltose (g)	0.02397			
Other Carbs (g)	0.56100			

Total Sugar: Contains both naturally occurring and added sugar.



Added Sugar: Empty
Calorie ingredients
such as: sugar, honey,
high fructose corn
syrup, etc.
Mixed food may
contain Added Sugars



Review the Spreadsheet Report

Item Name	Quantity	Measure	Cals (kcal)	Prot (g)	Carb (g)	Fib(16) (g)	Sugar (g)	SugAdd (g)	Fat (g)
⊡ 🖶 Bread	1	Serving	137.08	3.58	29.21	1.16	5.04	3.72	0.5
flour, all purpose, white, unbleached, enriched	0.068126	Pound	112.48	3.19	23.58	0.83	0.08	0	0.3
a water, distilled	0.116788	Pound	0	0	0	0	0	0	
a sugar, white, granulated	0.00781	Pound	13.71	0	3.54	0	3.54	3.54	
yeast, bakers, active, dry	0.001946	Pound	2.87	0.36	0.36	0.24	0	0	0.0
araisins, seedless	1.00669	Gram	3.01	0.03	0.80	0.04	0.60	0	0.0
a cranberries, dried, sweetened	0.883637	Gram	2.72	0.00	0.73	0.05	0.64	-	0.0
ayrup, corn, light	0.234387	Gram	0.66	0	0.18	0	0.18	0.18	0.0
a oil, soybean, salad or cooking	0.17579	Gram	1.55	0	0	0	0	0	0.1
alt, table	0.023439	Gram	0	0	0	0	0	0	
atarch, corn	0.017579	Gram	0.07	0.00	0.02	0.00	0	0	0.0
Moisture Adjustment: Loss	0.03	Pound							
₹ Total	1	Serving	137.08	3.58	29.21	1.16	5.04	3.72	0.5

Identify missing values (indicated by dashes) and populate the Ingredient record to fill in the blanks.



FDA Resources and Contacting the FDA

FDA Industry Resources page:

- Links to Guidance
- Access the Inquiry form to submit questions to the FDA

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm513734.htm





Genesis R&D Training

Advanced Genesis Workshop | March 13-14, 2019 | Oak Brook, IL

This workshop session covers advanced topics in detail such as new FDA labeling regulations, due diligence and documentation for transitioning to the new labels, new program features, PDCAAS (protein digestibility score), range formulas, advanced labels, and more.

Professional Genesis + Menu Label Training | June 19-20, 2019 | Oak Brook, IL This training session covers ingredient creation and recipe/menu building, best practices, and analysis reporting specific to restaurants, grocery stores, and those who have to comply with the FDA's Menu Labeling regulations. Additionally, we will discuss how Genesis R&D helps you comply with the Menu Labeling regulations.

See the Full Schedule: https://www.esha.com/news-events/training-schedule/

QUESTIONS?



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