

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
- REX® Regulations Expert Document Search Portal
- 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 Software



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

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



Upcoming Webinars

Tune in to the 2022 webinar schedule.

New Regulatory
Focused webinars
and topics continue
to be added.

ESHA Webinar Notification Signup Page

https://esha.com/news-events/webinar-notice-signup

First Name*	
Last Name*	
Company	
Job Title	
Email [♠]	
Webinar Topics [★]	☐ Genesis R&D Food Software
	☐ Genesis R&D Supplements Software
	☐ Food Processor Software
	☐ Food Labeling Regulatory Compliance
	☐ Supplement Labeling Regulatory Compliance
	☐ Menu Labeling Regulatory Compliance
	Sign Up

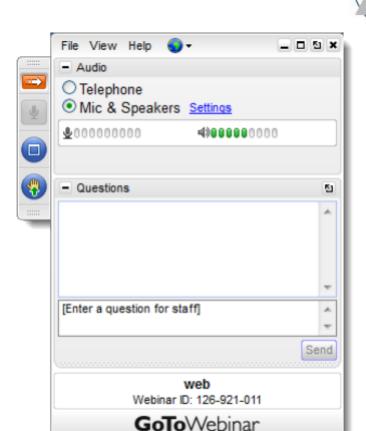
To view archived webinars: www.esha.com/news-events/webinars



Please Note!

- √ The webinar is being recorded
- ✓ All webinars available on our website
- ✓ Submit your questions in the GoToWebinar control panel
- ✓ We'll email a copy of the recording and the slides following the webinar





What We'll Cover Today

- Added Sugars FDA Definition
- Regulations and Guidance Documents
- Recording Added Sugars in Genesis R&D
- Best Practices for Data Checks and Documentation
- Q&A



Added Sugars in U.S. Foods and Labeling

• Contribute excess Calories and excess sugars when compared to whole food sources

 Identification and declaration of Added Sugars has led some manufacturers to reformulate products









Added Sugars – Overview

- 2016 FDA final rule for food labeling includes Added Sugars as a mandatory label nutrient
- Quantitative amount (for most products) and a percent Daily Value is reported for Added Sugars

Nutrition Facts

8 servings per container

Serving size

1 slice (59g)

Amount per serving

Calories

180

100
aily Value*
8%
20%
8%
8%
11%
4%
28%
0%
4%
10%
35%

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



Added Sugars – Daily Value

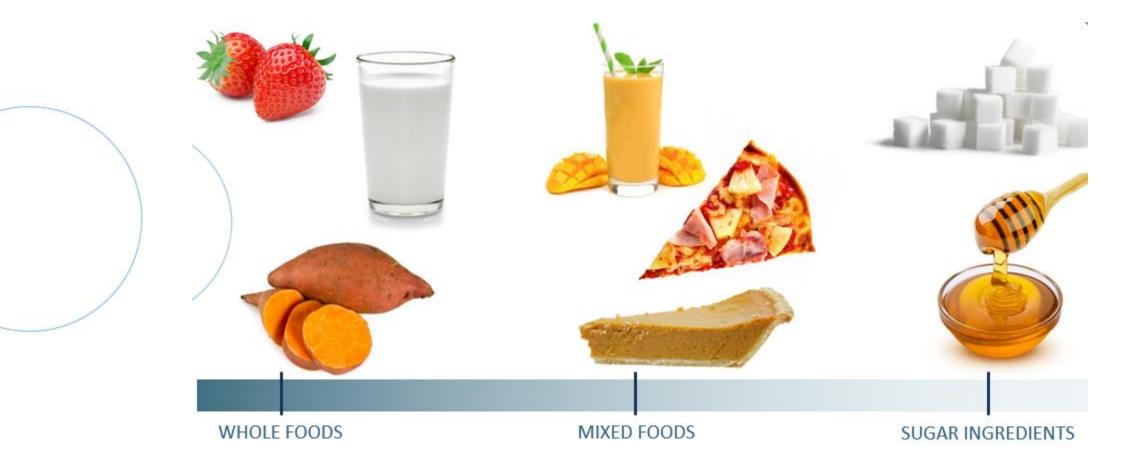


- Ties into Dietary Guidelines for Americans
- Recommendation of Less than 10% of Calories from Added Sugars
- 2000 Calories general Calories value used for adult labels
- 200 Calories / 4 Calories per gram of Sugar = 50g



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...





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 contains 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

Added Sugars from Juice Concentrates



- 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
- Does your product contain juice concentrate?
- Does the moisture content of the finished product include enough moisture that the juice concentrate would be fully reconstituted (no longer concentrated)?
- Purees and puree concentrates that contain the whole fruit or vegetable are not considered contributing to Added Sugars.







FDA Guidance – December 2019



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

> Issued November 2018 Revised December 2019

Includes:

- Clarification of Added Sugars definitions
- Use of enforcement discretion regarding labeling of Added Sugars
- Concentrates
- Brix
- Examples of Added Sugars calculations
- Hydrolysis
- Fermentation

cheat sheet

ADDED SUGARS

add ed su gars | \'a-ded 'shu-gers\

: 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

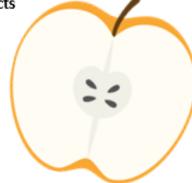
Molasses Corn Sweetener Pure Maple Syrup Honey

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 Serving size 1 cup (140g)

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	
noudes 5g Added Sugar	s 10%
Protein 3g	
Vitamin D 5mcg	25%
Calcium 20mg	2%
Iron 1mg	6%
Potassium 230mg	4%

"The % Baily Value tells you have reach a natricet in a serving of food contributes to a daily diet. 2000 calories a day is used for general natrition advice.

MANDATORY NUTRIENT

DV: 50g.

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



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.

...if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(21 CFR 101.9)

Nutritio	า Facts
12 servings per conserving 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	28g 10 %
Dietary Fiber 1g	4%
Total Sugars 4g	
Protein 4g	
Vitamin D 0mcg	0%
Calcium 5mg	0%
Iron 1mg	6%
Potassium 43mg	0%
Not a significant source trans fat and added su	

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

*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.

Labeling of Single Ingredient Sugars



- Foods that are single ingredient sugars
- Agriculture Improvement Act of 2018 aka the Farm Bill
 - The food labeling requirements under section 403...of the Federal Food, Drug, and Cosmetic Act...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 singleingredient food bear the declaration "Includes X g Added Sugars."
- Latest FDA Guidance provides options:
 - Omit "Includes Xg Added Sugars" on label
 - Must list %DV
 - FDA encourages use of dagger symbol following %DV and a footnote within the label that further describes the Added Sugars content

Nutrition Facts 8 servings per container Serving size 1 tbsp (21g) Amount per serving 60 Calories "Added Sugars" text removed. % Daily Value Total Fat 0g %DV remains as is. Saturated Fat 0g Trans Fat 0g Cholesterol Oma 0% Sodium Total Carbohydrate 170 6% 0% Dietary Fiber 0g Total Sugars 17g 34%[†] **Added Sugars footnote** (with dagger) set inside Vitamin D 0mcg **Nutrition Facts panel.** Calcium 0mg Iron Omg The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories One serving adds 17g of sugar to your diet and resents 34% of the Daily Value for Added Sugars.

Dagger symbol (†) used after %DV to refer consumers to footnote.

Added Sugars on the Label

Whole food with only naturally occurring sugars

6 servings per containe Serving size 1 a	er <mark>pple (182g</mark>
Amount per serving Calories	90
	% Daily Value
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 25g	9%
Dietary Fiber 4g	14%
Total Sugars 19g	
Includes 0g Added Suga	ars 0 %
Pretein 0g	
Vitamin D 0mcg	0%
Calcium 11mg	0%
Iron 0mg	0%
Potassium 195mg	4%

Mixed food containing naturally occurring and added sugars

Nutrition F	ac	cts
8 servings per containe Serving size 1		(59g)
Amount per serving Calories	1	80
9	⋴ 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 Sug	jars	28%
Protein 3g		
Vitamin D 0mcg		0%
Calcium 55mg		4%
Iron 2mg		10%
Potassium 1750mg		35%

Single ingredient sugar product with footnote within label

Nutrition	Facts
8 servings per contail Serving size	ner 1 tbsp (21g)
Amount per serving Calories	60
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium	0%
Total Carbohydrate 17g	6%
Dietary Fiber 0g	0%
Total Sugars 17g	
	34%†
Protein 0g	9%
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron Omg	0%
Potassium 0mg	0%
*The % Daily Value tells you how m serving of food centributes to a dail day is used for general nutrition adv	ly diet. 1,000 calories a
†One serving adds 17g of sugar to represents 34% of the Daily Value	



Cranberry product with statement outside of label

Includes 30a Added Sugare	
Includes 30g Added Sugars	60%†
Protein 0g	
Vitamin D 0mcg	0%
Calcium 18mg	2%
Iron 0mg	0%
Potassium 43mg	0%

†Sugars added to improve the palatability of naturally tart cranberries.

Genesis R&D - Total vs. Added Sugar Fields



٠.				
~	-	~	m	-
п	6	L.	IJ	6

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

Genesis R&D - Spreadsheet Report



Complete and correct entry of Ingredients contributes to accurate and compliant recipe analysis and labels. Review the Spreadsheet report for ALL *Recipes* to ensure that required information is reported. Identify missing values (indicated by dashes) and populate the **Ingredient record** to fill in the blanks.

	Item Name	Quantity	Measure	Cals (kcal)	Prot (g)	Carb (g)	Fib(16) (g)	Sugar (g)	SugAdd (g)	Fat (g)
E	∃ 🞳 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
	cranberries, dried, sweetened	0.883637	Gram	2.72	0.00	0.73	0.05	0.64		0.0
	- syrup, 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	
	starch, corn	0.017579	Gram	0.07	0.00	0.02	0.00	0	0	0.0
	Moisture Adjustment: Loss	0.03	Pound							
	ĕ Total	1	Serving	137.08	3.58	29.21	1.16	5.04	3.72	0.5

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
 - Might not be labeled by suppliers, but when used as an ingredient, the sugars are considered Added Sugars
- 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.

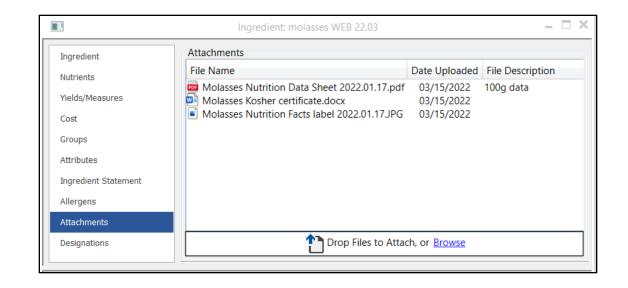
21 CFR 101.9(c)(6)(iii) When a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation and/or non-enzymatic browning, the manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of added sugars in the label and labeling of food.

Genesis - Record-Keeping



Use the tools available in Genesis R&D for consistent record-keeping:

- Notes Fields
- Audit Trail
- Attachments
 - Attach files to Ingredient records, Recipes, and Advanced Labels for documentation purposes
 - Various file types can be attached PDF, JPG, CSV, MP4, and more



Genesis R&D Training

Location Options:

- ESHA Training Center (Oak Brook, IL)
- Online

Session Options:

- Professional (12 CPE Credits)
- Advanced* (6 CPE Credits)
- Combined Professional and Advanced

*(**Prerequisite**: Professional Training)

Location	Dates	Course
Online	Apr. 11-14, 2022 Apr. 19-20, 2022	4-Day Genesis R&D Foods Professional 2-Day Genesis R&D Foods Advanced
Online	May 16-19, 2022 May 24-25, 2022	4-Day Genesis R&D Foods Professional 2-Day Genesis R&D Foods Advanced
Online	June 13-16, 2022 June 21-22, 2022	4-Day Genesis R&D Foods Professional 2-Day Genesis R&D Foods Advanced
ESHA Training Center Oak Brook, IL	July 19-20, 2022 July 21, 2022	2-Day Genesis R&D Foods Professional 1-Day Genesis R&D Foods Advanced



Course Overview

Genesis R&D Foods Professional - This training session covers the fundamentals of the Genesis R&D Food program with a primary focus on FDA regulations: creating ingredients and composite ingredients, building recipes/formulas, nutrition analysis, moisture loss, reporting, labeling, best practices, and much more. In addition, this session covers a comprehensive regulatory review.

Genesis R&D Foods Advanced Training - The Advanced session builds upon the skills learned in the Professional training and offers deeper learning on topics including PDCAAS, International Food Labeling, Advanced Label Settings, and more.

Learn More:

- Visit <u>www.esha.com</u> for the full list of upcoming classes.
- Does your organization need group training?
 Contact <u>training@esha.com</u>

QUESTIONS?



CONTACT US

Phone: 503-585-6242

Sales: sales@esha.com

Support: support@esha.com

Consulting Services: cs@esha.com

Training: training@esha.com



HELPFUL RESOURCES

LinkedIn: linkedIn: linkedin.com/company/esha-research/

eLearning Center: esha-elearning-center/

Blog: esha.com/blog

eNewsletter: https://esha.com/esha-enewsletter/