

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

August 24, 2022 | Integrating Genesis R&D to Improve Your Innovation Workflow

During this webinar, we will provide an overview of Genesis R&D Foods Product Formulation and Labeling Compliance Tools, discuss the capabilities of the Genesis R&D API, and highlight the benefits of using pre-built integration accelerators to connect Genesis R&D with other applications.

August 31, 2022 | Genesis R&D Foods Version 11.12 Update Overview

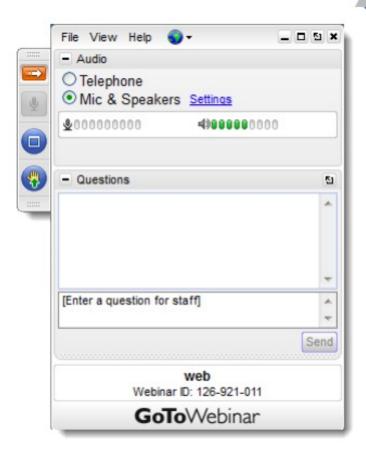
The latest update of Genesis R&D Foods, Version 11.12, is available. During this webinar we will cover the newest features and program enhancements.

To view archived webinars or sign up to receive notifications, 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
- ✓ We'll email a copy of the recording and the slides following the webinar





What We'll Cover Today

- Dietary Fiber as a U.S. Label Nutrient
- FDA Definition of Dietary Fiber
- Examples of Beneficial Dietary Fiber and Non-beneficial, Non-digestible Carbohydrates
- How to track and report Dietary Fiber in Genesis R&D
- Q&A



Dietary Fiber for U.S. Labels

- 2016 FDA final rule for Nutrition Facts labeling includes an established definition for Dietary Fiber
- Quantitative amount per serving is declared and %DV is calculated from 28g as the Daily Value



Nutrition Fac	cts
8 servings per container Serving size 1 slice	e (59g)
Amount per serving Calories	80
% Dail	y 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 Sugars	28%
Protein 3g	
Vitamin D 0mcg	0%
Calcium 55mg	4%
Iron 2mg	10%
Potassium 1750mg	35%
*The % Daily Value tells you how much a nutrie serving of food contributes to a daily diet.	ent in a

Dietary Fiber – 2016 FDA Definition



Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

21 CFR 101.9



Terms Related to Dietary Fiber



- Non-Digestible Carbohydrates (NDCs)
- Physiologically Beneficial
- Intrinsic
- Intact
- Isolated or Synthetic
- Resistant Starches



FDA Guidance on Dietary Fiber

Guidance with list of additional NDCs considered beneficial Dietary Fiber (Published June 2018*)

Includes:

- Lists of isolated and synthetic NDCs that meet the FDA 2016 definition of Dietary Fiber
- Clarification on Mixed Plant Cell Wall Fibers
- Proposed Calories of 1 kcal/g of Polydextrose
- Comments on the record keeping of foods containing a mixture of Dietary Fiber ingredients and non-beneficial NDCs

*Additional notices have been released since 2018



Contains Nonbinding Recommendation

The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels: Guidance for Industry

> Additional copies are available from: Office of Nutrition and Food Labeling Nutrition Program Staff, HFS-830 Center for Food Safety and Applied Nutrition Food and Drug Administration 5001 Campus Drive College Park, MD 20740 (Tel 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 to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, m. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-1323 listed in the notice of availability that publishes in the Federal Register.

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

June 2018

FDA Q&A on Dietary Fiber: https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-dietary-fiber

Beneficial Fibers (Dietary Fiber US 2016)

- Acacia (gum Arabic)
- Arabinoxylan
- Alginate
- Beta-Glucan
- Cellulose
- Cross linked phosphorylated RS4
- Galactooligosaccharide (GOS)
- Glucomannan
- Guar Gum
- High Amylose Starch (RS2)

- Hydroxypropylmethylcellulose
- Inulin and Inulin-type Fructans
- Locust Bean Gum
- Mixed Plant Cell Wall Fibers
- Pectin
- Polydextrose
- Psyllium Husk
- Resistant Maltodextrin/Dextrin



Non-Beneficial, Non-Digestible Carbohydrates

- CARBOXYMETHYLCELLULOSE
- KARAYA GUM
- PULLULAN
- RETROGRADED CORN STARCH (Resistant Starch 3)
- RESISTANT WHEAT AND MAIZE STARCH (Resistant Starch 4)
- XANTHAN GUM
- XYLOOLIGOSACCHARIDES

These do not contribute to FDA defined Dietary Fiber at this time



Beneficial Dietary Fiber - Aliases

FIBER	DESCRIPTION/FUNCTION	COMMON NAMES
Inulin and Inulin-Type Fructans	Inulin a naturally occurring polysaccharide extracted from plants such as chicory root, and agave. Used as a bulking agent in foods.	Chicory Root, Chicory Root Extract, Chicory Root Fiber, Chicory Vegetable Fiber, Fructooligosaccharide Oligofructose
Locust Bean Gum	Locust Bean Gum is a macerated endosperm of the seed of the locust bean tree, used as a thickening and gelling agent in food.	Caragum, Carob Bean Gum, Carob Seed Gum, Ceratonia Siliqua Gum, LBG
Mixed Plant Cell Wall Fibers	Ingredients that contain two or more of the following plant cell wall fibers in varying proportions: Cellulose; Pectin, Lignin; Beta-glucan and Arabinoxylan.	Apple Fiber, Bamboo Fiber, Barley Fibers, Citrus Fiber, Cocoa Fibers, Corn Hull Fiber, Cottonseed Fiber, Hull Fiber, Oat Hull Fiber, Pea Fiber (Hull and Cotyledon), Potato Fiber, Rice Bran, Sugar Beet Fiber, Sugar Cane Fiber, Soy Fiber (Cotyledon and Hull), Wheat Fiber
Pectin	Pectin is present in the cell walls and intracellular tissues of fruits and vegetables primarily used as emulsifiers and stabilizers in food	Calcium Pectinate, Citrus Pectin, Fruit Pectin, Hydrolyzed Pectin, Methoxy Pectin, Modified Pectin, Pectinic Acid, Zinc Pectinate

Resistant Starches

RESISTANT STARCHES	DESCRIPTION/ FUNCTION	EXAMPLES FOUND IN		
RS1	Resistant Starch 1 delivers resistant starch because it is protected by hulls, seeds and other barriers that are not fully digested in the small intestine. They are intrinsic/intact.	Whole Grains, Seeds	BENEFICIAL FIBER	
RS2	Resistant Starch 2 retains its natural granular shape yet resists digestion due to crystallinity within the granule	Unripe Bananas, Uncooked Potatoes, Resistant Corn Starch 260, High Amylose Starch		
RS3	Resistant Starch 3 occurs if the starch granule has been broken apart and the starch chains are crystallized, cooked or heat processed.	Breakfast cereals	NON-DIGESTIBLE CARBOHYDRATES	
RS4	Resistant Starch 4 occurs when the starch has been chemically modified to artificially inhibit digestion	Hi-maize resistant starch used in baked goods		



What to Look for on Supplier Documentation

- Labels provide context U.S. vs. international; 1990 vs. 2016
- Data sheets can provide direction on the context of the Dietary Fiber. Look for U.S. label nutrients reported and for footnotes or comments for clarification.
- Supplier websites and marketing information might provide clarification, but check dates to see how recent the information was published.
- Ingredient information might identify inclusion of non-beneficial NDCs; check for ingredients within ingredients and aliases.
- Contact your suppliers with questions.

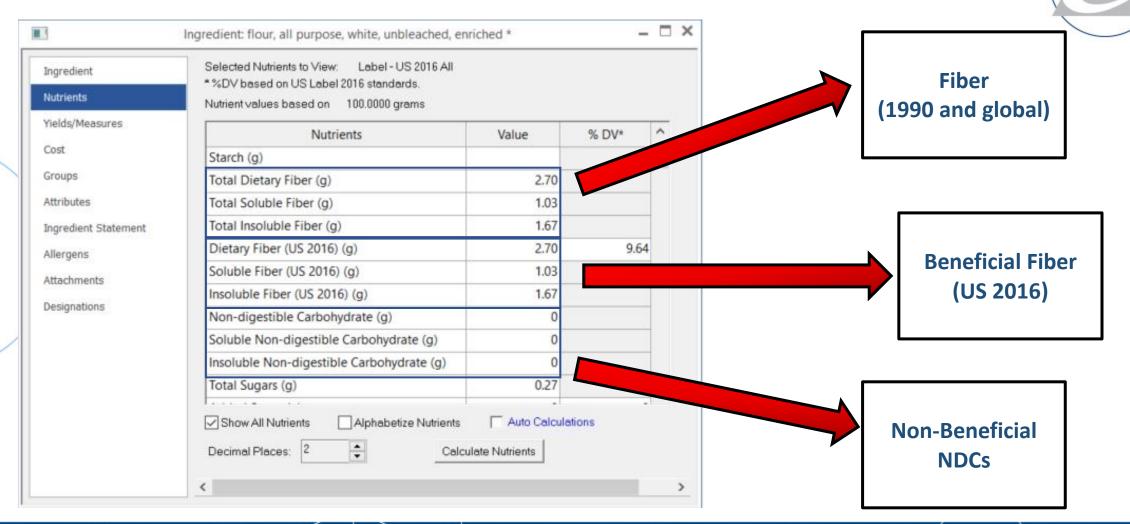


Best Practices for Documentation

- Per the regulations, manufacturers must make and keep records to verify the amount of dietary fibers included in the ingredient or food.
- Document determinations and include FDA citations when necessary and helpful.
- Document supplier clarifications and conversations as part of record-keeping.



Fiber-Related Fields in Genesis R&D



Importance of Populating & Reviewing Data



Nutrition Facts

Serving Size 2/3 Cup (130g) Servings Per Container 4

Amount Per Serving	
Calories 280 Calories	from Fat 130
	% Daily Value*
Total Fat 14g	22%
Saturated Fat 9g	45%
Trans Fat 0g	
Cholesterol 45mg	15%
Sodium 100mg	4%
Total Carbohydrate 37g	12%
Dietary Fiber 2g	8%
Sugars 33g	
Protein 5g	

Vitamin C 2%

Iron 6%

Vitamin A 10%

Calcium 15%

	Nutrition Fa	cts
	4 servings per container Serving size 2/3 Cup	(130g)
	Amount per serving Calories	<u> 280</u>
		y Value*
	Total Fat 14g	18%
	Saturated Fat 9g	45%
	Trans Fat 0g	
	Cholesterol 45mg	15%
	Sodium 100mg	4%
	Total Carbohydrate 37g	13%
(Dietary Fiberg	%
	Total Sugars 33g	
	Includes 30g Added Sugars	60%
	Protein 5g	
	Vitamin D 0.3mcg	2%
	Calcium 140mg	10%
	Iron 1.2mg	6%
	Potassium 320mg	6%
	*The % Daily Value tells you how much a nutri serving of food contributes to a daily diet. 2,00 day is used for general nutrition advice.	

Missing Mandatory Nutrients are displayed here with a dashed line – NOT COMPLIANT

NOTE: All ingredients need to report Dietary Fiber properly. If only one of your ingredients reports Dietary Fiber 2016 information, the label will show a value but that may be understated for the actual fiber content.

^{*}Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

Review the Spreadsheet Report



	Item Name	Quantity	Measure	Cals (kcal)	Fat (g)	Prot (g)	Carb (g)	TotFib (g)	Fib(16) (g)	Sugar (g)	SugAdd (g) Sa
1	√ Webinar Gluten Free Bread	1	Serving	270.3171	7.7004	6.0867	45.0814	1.9586	0.2403	5.2020	3.7924
10	a flour, baking, gluten free	48.2	Gram	163.8800	0	2.6028	39.0420	1.3014	<u> </u>	> 0	0
Ţ	water, distilled	19.4	Gram	0	0	0	0	0	0	0	0
	egg, raw	16.5	Gram	23.5950	1.5692	2.0724	0.1188	0	0	0.0611	0
	butter, unsalted	6.35	Gram	45.5295	5.1505	0.0540	0.0038	0	0	0.0038	0
	sugar, white, granulated	3.8	Gram	14.7060	0	0	3.7992	0	0	3.7924	3.7924
	powdered milk, whole	3.5	Gram	17.3600	0.9348	0.9212	1.3447	0	0	1.3447	0
	yeast, dry, instant web	0.89	Gram	3.4354	0.0454	0.4005	0.3560	0.2403	0.2403	0	0
	a salt, table	0.82	Gram	0	0	0	0	0	0	0	0
	a gum, xanthan, web	0.54	Gram	1.8112	0.0005	0.0359	0.4169	0.4169		0	0
	📸 Total	-1	Serving	270.3171	7.7004	6.0867	45.0814	1.9586	0.2403	5.2020	3.7924

Identify missing values (indicated by dashes) and populate **Ingredient records** to fill in the blanks. Can you determine the Dietary Fiber value from the ingredient list or by the nature of the ingredient? Do you need supplier clarification to fill in the blanks?

Fill in Blanks at the Ingredient Record



Ingredient: gum, xanthan, web			_	
Selected Nutrients to View: Label 2016 + Total Dietary Fiber *%DV based on US Label 2016 standards. Nutrient values based on 100.0000 grams				
Nutrients	Value	% DV*	7	
Total Dietary Fiber (g)	77.20		1	
Total Soluble Fiber (g)	75.00		ľ	
Total Insoluble Fiber (g)	2.20			
Dietary Fiber (US 2016) (g)	þ		0	
Soluble Fiber (US 2016) (g)	0			
Insoluble Fiber (US 2016) (g)	0			
Non-digestible Carbohydrate (g)	77.20			
Soluble Non-digestible Carbohydrate (g)	75.00			
Insoluble Non-digestible Carbohydrate (g)	2.20			
Total Sugars (g)	0			
Added Sugar (g)	0		0	

- Open the Ingredient record
- Fill in the missing nutrient field(s)
- Save the record
- Changes that you make to an Ingredient will be reflected in the Recipes that you the Ingredient and the labels for the Recipes using that Ingredient
- Note: For ESHA Database items, nutrient fields cannot be edited; if you need to fill in missing nutrients for an ESHA Database item, you will need to make a copy of the Ingredient record, "Save As", make changes, and substitute the newly created Ingredient for the one missing values

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	Sept 12-15, 2022 Sept 20-21, 2022	4-Day Genesis R&D Foods Professional 2-Day Genesis R&D Foods Advanced		
ESHA Training Center	Oct 18-19, 2022 Oct 20, 2022	2-Day Genesis R&D Foods Professional 1-Day Genesis R&D Foods Advanced		
Online	Nov 7-10, 2022 Nov 15-16, 2022	4-Day Genesis R&D Foods Professional 2-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 training@esha.com

QUESTIONS?



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