WEBINAR

2016 Nutrition Labeling Guidelines Review Presented by ESHA Research Wednesday, July 17, 2019 11:00 AM PDT | 1:00 PM CDT | 2:00 PM EDT

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 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
- Regulatory Compliance



Upcoming Webinars



Working with Proprietary Blends in Genesis R&D Supplements | July 31, 2019

Genesis R&D Supplements offers supplement formulators the ability to create proprietary blends, and then incorporate them into final formulations. During this webinar, we will demonstrate how to create a proprietary blend, add it to a final formula and review a variety of display options on the supplement facts label.

Calculating PDCAAS for %DV Protein | August 14, 2019

The PDCAAS (protein digestibility corrected amino acid score) indicates the quality of a food's protein and is commonly used to determine the %DV to show on your label. A PDCAAS either comes from lab analysis or through manual calculation. This webinar will show you how to determine a PDCAAS value and how to use that calculated value to display a %DV for protein on your nutrition facts label in Genesis R&D Foods.

Top Genesis R&D User Q&A's | September 25, 2019

Taken from user suggestions, this session covers the most common questions we receive from users about working with the software. In addition we will cover questions you ask during registration and during the live session. To ensure your question gets answered, drop your question in the registration form below.

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

Please Note!

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





What we'll cover today

- Compliance Dates
- Changes to Nutrient Requirements
- Dietary Fiber
- Added Sugars
- Servings Sizes and RACC
- Dual Column Labels
- Best Practices
- Q&A



2016 U.S. Nutrition Facts Labels

- Final rule for changes to the U.S. Nutrition Facts label went into effect May 2016.
- Since then, FDA guidance has been published to clarify and express current thinking on various pieces of the label.
- ESHA Research training provides instruction on current labeling as well as the Genesis R&D software.



Nutrition Fa	icts
8 servings per container Serving size 2/3 cu	p (55g)
Amount per serving Calories	<u>230</u>
% Da	ily Value*
Total Fat 8g	10%
Saturated Fat 1g	5%
Irans Fat Og	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
*The % Daily Value tells you how much a nu serving of food contributes to a daily diet. 2, a day is used for general nutrition advice.	trient in a)00 calories



1990 & 2016 Labels - What's the Difference?



Nutri Serving Size Servings Per	2/3 cup (Containe	Fa	cts
Amount Per Ser	ving		
Calories 230) Cal	ories fro	m Fat 70
		%Da	aily Value*
Total Fat 8g			12%
Saturated	Fat 1g		5%
Trans Fat	0g		
Cholesterol	0mg		0%
Sodium 160	mg		7%
Total Carbo	hydrate 3	37g	12%
Dietary Fit	oer 4g		16%
Sugars 12	2g		
Protein 3g			
			100/
Vitamin A 6%	• •	itamin C	10%
Calcium 25%	• In	on 45%	
*Percent Daily V calorie diet. Your lower depending	alues are ba daily values on your cale Calories:	sed on a 2, may be hig prie needs: 2,000	000 gher or 2,500
Total Fat Saturated Fat Cholesterol Sodium Total Carbohydra Dietary Fiber	Less than Less than Less than Less than te	65g 20g 300mg 2,400mg 300g 25g	80g 25g 300mg 2,400mg 375g 30g

8 servings per container Serving size 2/3	cup (55g)
Amount per serving Calories	230
%	Daily Value
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol Omg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Suga	rs 20 %
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

Note: Both formats are available in Genesis R&D as we transition through effective and compliance date timelines. Format options include the appropriate regulations for both.

Timeline for Compliance

The compliance date for the updated Nutrition Facts labels is **January 1, 2020**, for companies with \$10 million or more in annual food sales

OR

January 1, 2021, for companies with less than \$10 million in annual food sales

Manufacturers of single-ingredient sugars and certain cranberry products have until July 1, 2021 to make the changes to 2016 format labels

Serving size	1 cup (140g)
Amount per serving	160
Calones	% Daily Value
Total Fat 8g	10%
Saturated Fat 3g	15%
Trans Fat 0g	
Cholesterol Omg	0%
Sodium 60mg	3%
Total Carbohydrate 21g	8%
Dietary Fiber 3g	11%
Total Sugars 15g	
Includes 5g Added Su	ugars 10%
Protein 3g	
Vitamin D 5mcg	25%
Calcium 20mg	2%
Iron 1mg	6%
Potassium 230mg	4%

*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.



Font Style & Size

Nutrition Facts No smaller than 10 pt. with 1 pt. of leading.* 2 servings per container Bold, no smaller than 10 pt. Serving size 1 cup (140g) 7-pt. rule. **Bold**, no smaller than 6 pt. Amount per serving 160 **Bold**, no smaller than 22 pt. Calories Bold, no smaller than 16 pt. -3-pt. rule. % Daily Value* **Bold**, no smaller than 6 pt. No smaller than 8 pt. with 4 pt. of leading. Total Fat 8g 10% Nutrients that are not indented (Total Fat, Saturated Fat 3g 15% Cholesterol, etc.) should be **bold** and flush left. Trans Fat 0g Cholesterol Omg 0% Bold, no smaller than 8 pt. Sodium 60mg 3% **8**% Total Carbohydrate 21g 1/4-pt. rule centered between nutrients. – **Dietary Fiber 3g** 11% (2-pt. space above and below). Total Sugars 15g Shortened 1/4-pt. rule above Added Sugars. Includes 5g Added Sugars 10% Protein 3g 7-pt. rule. Vitamin D 5mcg 25% Calcium 20mg 2% No smaller than 8 pt. Iron 1mg 6% Potassium 230mg 4% (including bullets) 3-pt. rule. with 4 pt. of leading. *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. ↓ 1/2-pt. box (text inset 3 pts.) *"leading" is the amount of space No smaller than 6 pt. with 1 pt. of leading. between rows of text.

Bold, must be larger than all other text

except "Calories" numerical value.

Nutrient Listing Changes

(shown with previous requirements and, if applicable new DV) Current MANDATORY, VOLUNTARY, and NOT LISTED nutrients



Nutrient DV Changes





Daily Value Changes - Potassium

1990 Label

- DV = 3500 mg
- 1750 mg = 50% DV

Nutrition F	acts
Serving Size 1 slice (59g) Servings Per Container 8	
Amount Per Serving	Tet CO
Calories 180 Calories II	om Fal 60
<u>%</u>	6 Daily Value*
Total Fat 6g	9%
Saturated Fat 4g	20%
Trans Fat 0g	
Cholesterol 25mg	8%
Sodium 190mg	8%
Potassium 1750mg	50%
Total Carbohydrate 30g	10%
Dietary Fiber 1g	4%
Sugars 15g	
Protein 3g	
Vitamin A 4% • Vitamin	C 0%
Calcium 6% • Iron 8%	
*Percent Daily Values are based on a diet.	a 2,000 calorie

2016 Label

- DV = 4700 mg
- 1750 mg = 35% DV

Nutrition Facts

Amount per serving Calories	180
% Da	aily 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%



Nutrient DV Changes





Daily Value Changes - Carbohydrate

1990 Label

• DV = 300 g

• 30 g = 10% DV

Amount Per Serving]	
Calories 180	Calories fro	m Fat 60
	% C	aily Value*
Total Fat 6g		9 %
Saturated Fat	t 4g	20%
Trans Fat 0g		
Cholesterol 25	mg	8%
Sodium 190mg		8%
Potassium 175	0mg	50 %
Total Carbohyd	irate 30g	10%
Dietary Fiber	1g	4%
Sugars 15g		
Protein 3g		
Vitamin A 4%	• Vitamin C	0%
Calcium 6%	• Iron 8%	

2016 Label

- DV = 275 g
- 30 g = 11% DV

Nutrition Facts

Serving size 1 sl	lice (59g)
Amount per serving Calories	180
% C	aily 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 Sugar	s 28%
Protein 3g	
Vitamin D Omca	0%
Calcium 55mg	
Iron 2mg	10%
Deteccium 1750mg	250/
Polassium 1750mg	35%

Nutrient Unit Changes

Niacin (Voluntary Nutrient)

• Change from mg of Niacin to mg of Niacin Equivalents (NE)

Vitamin A (Voluntary nutrient - previously mandatory)

Change from IU to mcg Retinol Activity Equivalents (RAE)

Vitamin E (Voluntary nutrient)

Change from IU to mg a-tocopherol

Folate (Voluntary nutrient)

• Change from mcg to mcg Dietary Folate Equivalents (DFE)

Vitamin D (Mandatory nutrient - previously voluntary)

• Change from IU to mcg







Genesis R&D[®] Nutrient Calculator

- Assists in Calculating the Following Nutrients
 - Carbohydrates
 - Dietary Fiber fields
 - Vitamin A
 - Vitamin B3
 - Niacin Equivalents
 - Tryptophan
 - Vitamin D
 - Vitamin E
 - Folate/Folic Acid
- Auto Calculation prompts as you enter Ingredient data
- Calculate Nutrients button can select after you have entered data



noun | racc | 'rak

: reference amounts customarily consumed

DEFINITION

Serving sizes of foods that can be reasonably consumed at one eating occasion. These have recently been updated to reflect real-world consumption. A RACC table can be found in the Code of Federal Regulations, 21CFR101.12.

Nutrition Fa	cts					
2 Servings Per Con	itainer					
Serving size 12 fl oz (360 mL)						
		per serving		per container		
Calories		150		300		
	% D	aily Value*	% D	aily Value*		
Total Fat	1g	1%	2g	3%		
Saturated Fat	0g	0%	0g	0%		
<i>Trans</i> Fat	0g		0g			
Cholesterol	0mg	0%	0mg	0%		
Sodium	10mg	0%	20mg	1%		
Total Carbohydrate	38g	14%	76g	28%		
Dietary Fiber	0g	0%	0g	0%		
Total Sugars	37g		73g			
Includes Added Sugars	35g	70%	70g	140%		
Protein	0g		0g			
Vitamin D	0mcg	0%	0mcg	0%		
Calcium	4mg	0%	7mg	0%		
ron	0mg	0%	0mg	0%		
Potassium	18mg	0%	37mg	0%		

2,000 calories a day is used for general nutrition advice.





8g 240 mL 170g formula MILK BEVERAGES, SUGAR YOGURT FRUIT IUICES · 85g 2 TBSP XX multiplied CANNED FISH, by 100= XX% CAKE FROSTINGS. ICINGS SHELLFISH, GAME MEAT ICE CREAM, FROZEN YOGURT

USING RACC TO DETERMINE DUAL COLUMN USAGE

With the new rules, containers that hold between 2 and 3 servings of a food may now need to show a Dual Column label to show nutrition information for a single serving and per the whole container. To determine this, check the determined serving size for your product. If your package weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, you need to use the Dual Column label.

Recipe

weight / RACC = XX

RACC Change & Claims

1990 Label: 225 g RACC & Serving Size

Nutrition Facts Serving Size 1 Container (225g)		•	RACC changes may	Nutrition Facts Serving size 1 Container (170g)		
Amount Per Serving Calories 170 Calories from Fat 10 % Daily Value*			affect Nutrient Content Claims	Amount per serving 130		
Total Fat 1g2%Saturated Fat 0g0%Trans Fat 0g		•	Be sure to evaluate your entire package	% Daily Value* Total Fat 0.5g Saturated Fat 0g O% Trans Fat 0g		
Cholesterol 10mg3%Sodium 75mg3%Total Carbobydrate 23g8%			when updating labels	Cholesterol 5mg 2% Sodium 60mg 3%		
Dietary Fiber 1g 4% Sugars 21g			with RACC changes	Total Carbohydrate 17g 6% Dietary Fiber 1g 4% Total Sugare 16g 4%		Good
Protein 19g Vitamin A 0% • Vitamin C 0%	Excellent Source of			Includes 10g Added Sugars 20% Protein 14g 14%		Source
Calcium 20% from 0% *Percent Euliy values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie paeds:	Calcium			Vitamin D. Omeg 0% Calcium 155mg 10%	5	Calciu
Calories: 2,0002,500Total FatLess than65g80gSaturated FatLess than20g25gCholesterolLess than300mg300mgSodiumLess than2,400mg2,400mg			Yogurt	Iron 0mg 0% Potassium 210mg 4% *The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2000 calories a		
Total Carbohydrate 300g 375g Dietary Fiber 25g 30g Calories per gram: Fat 9 Carbohydrate 4 Protein 4				day is used for general nutrition advice. Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4		

2016 Label: 170 g RACC & Serving Size

19

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Dual Column Labeling

2 servings per container					
Serving size		1	cup (2	255g)	
	Per s	erving	Per con	tainer	
Calories	2	20	_4	40	
		% DV*		% DV*	
Total Fat	5g	8%	10g	15%	
Saturated Fat	2g	10%	4g	20%	
Trans Fat	0g		0g		
Cholesterol	15mg	5%	30mg	10%	
Sodium	240mg	10%	480mg	21%	
Total Carb.	35g	12%	70g	23%	
Dietary Fiber	6g	21%	12g	43%	
Total Sugars	7g		14g		
Incl. Added Sugars	4g	8%	8g	16%	
Protein	9g		18g		
Vitamin D	5mcg	25%	10mcg	50%	
Calcium	200mg	15%	400mg	30%	
Iron	1mg	6%	2mg	10%	
Potassium	470mg	10%	940mg	20%	

- Required on packages that contain 200% and up to and including 300% of the RACC
- Nutrition information presented per serving and per package

Dual Column Exemptions



- Products that meet the requirements for tabular or linear label formats
- Raw fruits, vegetables and seafood that provide voluntary labeling/advertising or when claims are made
- Products that require further preparation (e.g. pancake mix) and voluntarily provide an additional column "as prepared"
- Products that are commonly consumed in combination with another food (e.g. cereal and milk) and voluntarily provide an additional column as combined with the other food
- Products that provide information for two or more groups (e.g. infants and children less than 4 years)
- Popcorn where the second column states information for one cup popped
- Varied weight products (e.g. cheeses sold at random weights)

FDA Guidance Documents



- Between final rule, the FDA may release Draft Guidance and Guidance documents to present current thinking on specific topics
- Rules may develop and adapt as more information becomes available and as industry and public provides feedback and requests clarification
 - Compliance Dates
 - Dietary Fiber
 - Added Sugars
 - Declaration of Quantitative Amounts
 - RACC additional examples for food categories
- Enforcement Discretion the FDA does not intend to object to certain declarations or claims that fall within the framework of the guidance



Vitamin & Mineral Declarations on the Label

- FDA Guidance, November 2, 2018
- Recommendations for declaration of levels of significance for quantitative amounts of vitamins and minerals
- Example: Potassium
 - Genesis R&D Default: 31mg
 - Guidance Option: 30mg

🗄 📑 👫					
ew Edit Ingredient Allergen bel Label Stmt Stmt	Claims Barcode Front of Default Zoom Show Export Package Layout				
oel Settings		×			
General	Nutrition Facts Text	Proportional •			
Format Options	No Bolding of text in Linear Label				
Jutrient Options	Hide Trans Fat				
oluntary Nutrients					
Object Properties					
Supplement Facts Hide Vitamin D, Calcium, Iron and Potassium					
Supplement Nutrients	Use FDA Draft Guidance for nutrient rounding				
Supplement Dietary Ingredient	Hide %DV Footnote				
	Hide Quantitative Values				
	Show Insignificant Footnote				
[Show Added Sugars symbol and statement				
	Added Sugars statement text	🗸			
	Use FDA Draft Guidance for nutrient rounding Use the FDA Draft Guidance for nutrient rounding				

Added Sugars

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



Serving size 1 slic	ce (59g)
Amount per serving Calories	180
% Da	ily 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%



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...

Total Sugars vs. Added Sugars

Recipe Information					×
Recipe Nutrients	Selected Nutrients to View: 2016 mand + v * %DV based on US Label 2016 standards. Nutrient values based on 50.0000 grams	water			
Measures	Nutrients	Value	% DV*	Override	[
Brix Calculation	Basic Components				
Cost	Gram Weight (g)	50.000			
Groups	Water (g)	28.741			
Attributes	Calories (kcal)	86.756			
Compare To	Protein (g)	2.267	4.534		
Despective Method	Carbohydrates (g)	18.488	6.723		
Preparation Method	Total Dietary Fiber (g)	0.732			
Reference Amount	Dietary Fiber (2016) (g)	0.732	2.613		
Nutrient Content Claims	Total Sugars (g)	3.187			
Notes	Added Sugar (g)	2.352	4.703		
НАССР	Fat (g)	0.355	0.455		
	Saturated Fat (g)	0.054	0.271		
Attachments	Trans Fatty Acid (g)	0.001			
	Cholesterol (mg)	0	0		_
	Vitamins				
	Vitamin D - mcg (mcg)	0	0		
	Minerals				

Total Sugars: Includes both naturally occurring and added sugar.

Added Sugars: From empty Calorie ingredients such as: sugar, honey, high fructose corn syrup, etc. Mixed foods may contain Added Sugars.

Labeling of Single Ingredient Sugars

- Foods that *are* single ingredient sugars
- Farm Bill shall not require "Includes Xg Added Sugars"
- Latest FDA Guidance provides options:
 - Omit "Includes Xg Added Sugars" on label
 - Must list %DV
 - FDA encourage use of dagger symbol following %DV and a footnote within the label that further describes the Added Sugars content





Dagger symbol (†) used

consumers to footnote.

after %DV to refer

27

Added Sugars on the Label

Whole food with only naturally occurring sugars

acts	Nutrition F
le (182g)	6 servings per container Serving size 1 ap
90	Amount per serving Calories
aily Value*	%
0%	Total Fat Og
0%	Saturated Fat 0g
	Trans Fat 0g
0%	Cholesterol Omg
0%	Sodium Omg
9%	Total Carbohydrate 25g
14%	Dietary Fiber 4g
	Total Sugars 19g
0%	Includes 0g Added Sugars
	Protein Og
0%	Vitamin D 0mcg
0%	Calcium 11mg
0%	Iron Omg
4%	Potassium 195mg

serving of food contributes to a daily diet. 2,000 calories a

day is used for general nutrition advice.

Mixed food containing naturally occurring and added sugars

8 servings per containe Serving size 1	slice (59g)
Amount per serving Calories	180
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%
ron 2mg	10%
Potassium 1750mg	35%

Single ingredient sugar product with footnote within label

Nutrition	Facts
8 servings per contain Serving size	ner 1 tbsp (21g)
Amount per serving Calories	60
	% Daily Value*
Total Fat Og	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol Omg	0%
Sodium	0%
Total Carbohydrate 17g	6%
Dietary Fiber 0g	0%
Total Sugars 17g	
	34% †
Protein 0g	8%
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron Omg	0%
Potassium Omg	0%
*The % Daily Value tells you how m serving of food contributes to a dail day is used for general nutrition adv	uch a nutrient in a y diet . 1,000 calories a <i>v</i> ice.
†One serving adds 17g of sugar to represents 34% of the Daily Value	your diet and for Added Sugars.



Cranberry product with statement outside of label

Total Sugars 35g	
Includes 30g Added Sug	ars 60%†
Protein 0g	
Vitamin D 0mcg	0%
Calcium 18mg	2%
ron 0mg	0%
Potassium 43mg	0%
'The % Daily Value tells you how much serving of food contributes to a daily di a day is used for general nutrition advic	h a nutrient in a et. 2,000 calories ce.

Dietary Fiber 2016

- FDA adopted specific definition
- Increase in DV from 25g to 28g
- Evolving since the 2016 introduction with several Guidance documents to clarify
- Non-digestible Carbohydrates
 - All dietary fiber is non-digestible carbohydrate

but

- Not all non-digestible carbohydrate is dietary fiber
- "Beneficial" is the key

Serving size	1 slice (59g)
Amount per serving Calories	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 S	Sugars 28%
Protein 3g	
Vitamin D 0mcg	0%
Calcium 55mg	4%
Iron 2mg	10%
Potassium 1750mg	35%

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 nondigestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

21 CFR 101.9

Dietary Fiber – List of Beneficial Isolated



- Arabinoxylan
- Alginate
- Beta-Glucan Soluble Fiber
- Cellulose
- Galactooligosaccharide (GOS)
- Guar Gum
- High Amylose Starch (Resistant Starch 2)
- Hydroxypropylmethylcellulose
- Inulin and Inulin-type Fructans
- Locust Bean Gum

- Mixed Plant Cell Wall Fibers
- Pectin
- Polydextrose
- Psyllium Husk
- Resistant Maltodextrin/Dextrin
- Cross linked phosphorylated RS4



"Non-Beneficial", Non-Digestible Carbohydrates

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





Fiber-Related Fields in Genesis R&D



Working with Supplier Data



Ingredient	× %D)/ based on LIC Label 2010 standards					
Mutricate	Nutrient values based on 100 0 grams					
Nutrients						
Yields/Measures	Nutrients	Value				
Cost	Total Dietary Fiber (g)	2.71				
Croups	Total Soluble Fiber (g)					
Groups	Total Insoluble Fiber (g)					
Ingredient Statement	Dietary Fiber (2016) (g)	2.21				
Allergens	Soluble Fiber (2016) (g)					
Attachments	Insoluble Fiber (2016) (g)					
	Non-digestible Carbohydrate (g)	0.50				
	Soluble Non-digestible Carbohydrate (g)					
	Insoluble Non-digestible Carbohydrate (g)					
	Show All Nutrients Alphabetize Nutrients Auto Calculations					
	Decimal Places: 2 📮 Check Data 4	Calculate N	lutrie			



Importance of Populating Data

Nutrition Fact Serving Size 2/3 Cup Servings Per Container About 3	S Nutrition Facts About 3 servings per container Serving size 2/3 Cup
Amount Per Serving	Amount per serving
Calories 190 Calories from Fat	👳 Calories 👘 190
% Daily Val	ue* % Daily Value
Total Fat 10g 15	Total Fat 10g 13%
Saturated Fat 6g 30	Saturated Fat 6g 30%
Cholesterol 30mg 10	Cholesterol 30mg 10%
Sodium 65mg	Sodium 65mg 3%
Total Carbabydrate 25g	Total Carbohydrate 25g 9%
	Dietary Fiberg%
Dietary Fiber 1g	Total Sugars 22g
Sugars 22g	Includes 15g Added Sugars 30%
Protein 3g	Protein 3g
Vitamin A 8% • Vitamin C 2%	Vitamin D 0mcg 0%
Calcium 10% • Iron 4%	Calcium 96mg 8%
*Percent Daily Values are based on a 2 000 cal	Tiron 1mg 6%
diet. Your daily values may be higher or lower	Potassium 220mg 4%
Calories: 2,000 2,500	*The % Daily Value tells you how much a nutrient in a
Total Fat Less than 65g 80g Saturated Fat Less than 20g 25g	serving of food contributes to a daily diet. 2000 calories a day is used for general nutrition advice.
CholesterolLess than300mg300mgSodiumLess than2,400mg2,400Total Carbohydrate300g375gDietary Fiber25g30g	Calories per gram: The second secon
Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4	_

Serving size	2/3 Cu
Amount per serving Calories	190
%	Daily Valu
Total Fat 10g	13
Saturated Fat 6g	30
Cholesterol 30mg	10
Sodium 65mg	3
Total Carbohydrate 25g	9
Dietary Fiberg	
Total Sugars 22g	
Includes 15g Added Suga	ars 30
Protein 3g	
Vitamin D 0mcg	0
Calcium 96mg	8
	6

Missing Dietary Fiber 2016 displayed here with dashes **NOT COMPLIANT**

NOTE: If only one of your ingredients reports the required dietary fiber information, only that one ingredient's dietary fiber will appear on the label. This can result in understated label values.



Review the Spreadsheet Report

Item Name	Quantity	Measure	Cals (kcal)	Prot (g)	Carb (g)	TotFib (g)	Fib(16) (g)	Sugar (g)	SugAdd (g)	Fat (g)	Sa
🖃 🤠 Gluten Free Bread	1	Serving	217.88	4.79	35.96	1.55	0.19	4.35	3.24	5.96	;
💧 flour, baking, gluten free	38.1807	Gram	134.15	2.06	30.96	1.03		0	0	0)
💧 water, distilled	15.2865	Gram	0	0	0	0	0	0	0	0	
💧 egg, raw	12.8928	Gram	18.44	1.62	0.09	0	0	0.05	0	1.23	ļ.
💧 butter, unsalted	4.8822	Gram	35.01	0.04	0.00	0	0	0.00	0	3.96	i
💧 sugar, white, granulated	3.2469	Gram	12.57	0	3.25	0	0	3.24	3.24	0	
powdered milk, whole	2.7492	Gram	13.64	0.72	1.06	0	0	1.06	0	0.73	ļ.
à yeast, dry, instant, food service	0.6873	Gram	2.65	0.31	0.27	0.19	0.19	0	0	0.04	ļ.
💧 salt, table	0.6478	Gram	0	0	0	0	0	0	0	0	
gum, xanthan, Novaxan, 200 granular	0.4266	Gram	1.43	0.03	0.33	0.33	-	0	0	0.00	
📷 Total	1	Serving	217.88	4.79	35.96	1.55	0.19	4.35	3.24	5.96	i

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

Nutrients to View

- Label sets already available
- Label U.S. 2016
 - Mandatory
 - All
- Add your own custom sets as needed

Tutorial: <u>https://www.esha.com/tutorials/using-nutrients-to-view-effectively/</u>





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Documentation

- Document how you arrived at your nutritional information
- Attach document files to your recipes and ingredients in Genesis R&D
- Documentation examples:
 - Ingredient spec sheets
 - Recipes or formulations
 - Batch records
 - Lab analyses
 - Analyses from nutrient databases
 - Adjustments and calculations
 - FDA Guidance references or communication
 - Any other records that provide supporting information





Checklist for Transition to 2016 Label



- Did formulas or ingredients change?
- Did the RACC change?
- Does your package require a dual column based on 200% 300% RACC?
- Are your nutrient content claims supported by your 2016 labels?
- Use Spreadsheet report find and populate missing nutrient values
- Contact suppliers for updated information that supports 2016 labels
- Review Dietary Fiber information and document sources
- Calculate and document Added Sugars value in ingredients and/or finished products

ESHA Database



ESHA continues to update the foods and ingredients included in Genesis R&D – this is an on-going process



Use the Spreadsheet for all Recipes to review completeness of data



Extra attention may be needed *especially* for:

Dietary Fiber Added Sugars Vitamin D

Potassium

Genesis R&D Training

Genesis R&D Training | August 20-22, 2019 | Oak Brook, IL

Professional *and/or* Advanced training session. The first two days cover the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, you can attend a third day of Advanced instruction, or just attend the Advanced session as a single day. Advanced training presents more complex scenarios and more comprehensive regulatory issues.

Genesis R&D Training | October 8-10, 2019 | Oak Brook, IL

Professional, and/or Advanced training session. See description above.

Genesis R&D Training | November 5-7, 2019 | Oak Brook, IL Professional, *and/or* Advanced training session. See description above.

Genesis R&D Training: Professional + Menu Label | December 4-5, 2019 | MicroTek, Miami, FL

Instruction covers the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, the class includes direction and discussion on the 2018 Menu Labeling requirements and Menu Label features in Genesis R&D.

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

41

Q U E S T I O N S ?



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