



WEBINAR



Update on Dietary Fiber

Presented by **ESHA Research**

Tuesday, March 12, 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 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



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.

Stay tuned for more 2019 webinars

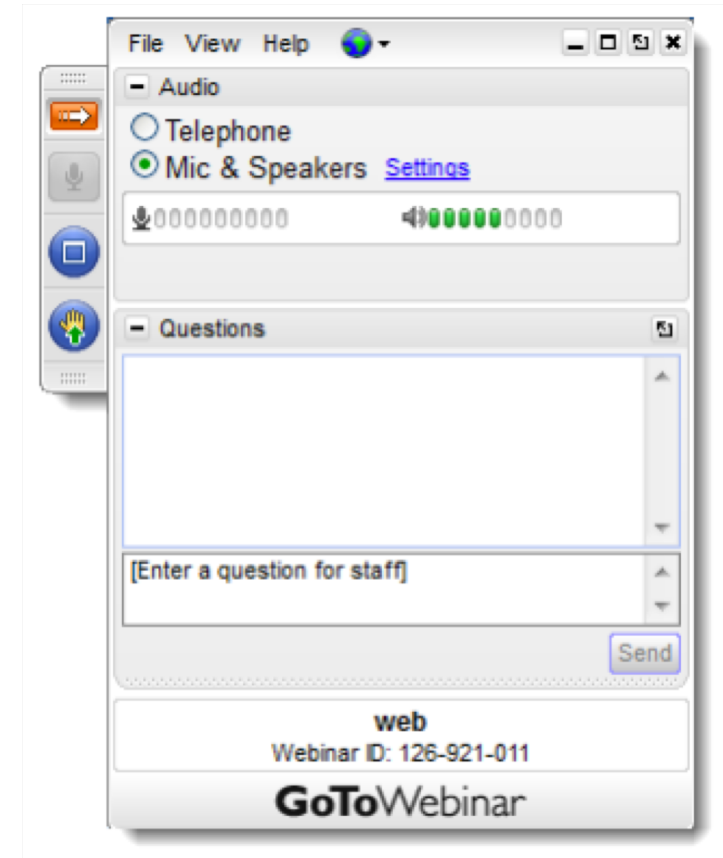
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Please Note!

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

WEBINAR





What we'll cover today

- Dietary Fiber - Review
 - What is considered Dietary Fiber for U.S. Labeling (and what is not)
- Guidance Documents
- Best Practices for Documentation
- User Tips for Compliance
- Q&A





Dietary Fiber – Brief Review

2016 FDA final rule for Nutrition Facts labeling includes an established definition for Dietary Fiber

DV = 28g

Nutrition Facts

8 servings per container

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 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 nutrient in a serving of food contributes to a daily diet.

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
- Enforcement Discretion



FDA Guidance on Dietary Fiber

- May 2016 – FDA final rule includes definition of Dietary Fiber for U.S. nutrition labeling purposes and includes list of isolated or synthetic carbohydrates that meet the definition
- November 2016 – Request for scientific data and comments and draft guidance on type of evidence to be included in citizen petitions when making a case for fiber ingredients
- FDA Q&A for Industry on Dietary Fiber listing NDCs already under review
- March 2018 – FDA final guidance on the evaluation of scientific evidence
- June 2018 – Guidance with list of additional NDCs considered beneficial Dietary Fiber





FDA Guidance - June 2018

Contains Nonbinding Recommendations

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) 240-402-1430
<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, rm. 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

Includes:

- Additional list 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

“Beneficial” Fibers (Dietary Fiber 2016)

- **Arabinoxylan***
- **Alginate***
- **Beta-Glucan**
- **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***

*Added as additional beneficial fibers on June 14, 2018





“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**



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	

cheat sheet

DIETARY FIBER

noun | di·e·tary fi·ber | \ 'dī-ə-,ter-ē 'fī-bər\

: a statement of the number of grams of dietary fiber in one serving of a food

NEW FDA FIBER DEFINITION

Naturally occurring fibers that are “intrinsic and intact” in plants (vegetables, whole grains, fruits, cereal bran, flaked cereal and flours), and added isolated or synthetic non-digestible soluble and insoluble carbohydrates that the FDA has determined to have beneficial physiological effects to human health.

Note: Manufacturers are required to make and keep records verifying the declared amount of dietary fiber.

beneficial dietary fibers

ADDED, NON-DIGESTIBLE ISOLATED OR SYNTHETIC FIBERS:

Beta-glucan soluble fiber

Psyllium husk

Cellulose

Guar gum

Pectin

Locust bean gum

Hydroxypropylmethylcellulose

Mixed plant cell wall fibers

Arabinoxylan

Alginate

Inulin and inulin-type fructans

High amylose starch

(resistant starch 2)

Galactooligosaccharide

Polydextrose

Resistant maltodextrin/dextrin

NEW CALCULATION

Based on the new definition, a sample bar with oats, cellulose and gum acacia would have 10g of Total Dietary Fiber. The 5g of non-digestible carbohydrates that comes from gum acacia are not used in calculating Total Dietary Fiber, but ARE used in calculating Total Carbs.

5g

BENEFICIAL Soluble Fiber (oats)

+5g

BENEFICIAL Insoluble Fiber (cellulose)

0g

NON-DIGESTIBLE Soluble Carbohydrates

+5g

NON-DIGESTIBLE Insoluble Carbohydrates (gum acacia is not 'beneficial')

10g

TOTAL DIETARY FIBER (only 'beneficial' fiber used to calculate total)

ON THE LABEL

Dietary fiber is indented and rounded to the nearest gram.

- If a serving contains less than 1 gram, declaration is not required.
- *But*, you may choose to use the statement “Contains less than 1 gram” (or “less than 1 gram”).
- If the serving contains less than 0.5 gram, the content may be expressed as zero.

Nutrition Facts

4 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	
Includes 5g Added Sugars	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.

DV CHANGE
28g up from 25g



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Best Practices for Documentation

- Make and keep records of the amount of dietary fibers included in the food
- Look for Dietary Fiber 2016 values and notes on ingredient supplier sheets
- Single ingredient foods:
 - Whole foods with intact and intrinsic fibers
 - Isolated NDCs that meet the 2016 FDA definition of dietary fiber
- Mixed food ingredients – if Dietary Fiber 2016 is not reported, contact supplier
- If the Ingredient List clearly identifies that the product contains no ingredients that are non-beneficial NDCs, 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



Pain Points for Documentation

- Unclear as to label reference – global vs. U.S.; 1990 vs. 2016
- Data sheet includes no comments about Dietary Fiber 2016
- Ingredient lists use general terms but not terms that FDA uses in guidance and industry documentation
- Suppliers cannot clarify the nature of Dietary Fiber; waiting for clarification from their suppliers
- Ingredients within ingredients within ingredients...
- Processing plays a factor for some NDCs
- Compliance date is approaching





Help from Suppliers for Documentation

- Labels provide context – U.S. vs. international; 1990 vs. 2016
- Data sheets *might* report both Total Dietary Fiber and 2016 Dietary Fiber values
- Data sheets can include footnotes or comments for clarification
- Ingredient information *might* clarify inclusion of non-beneficial NDCs
- Take advantage of the opportunity to educate customers

Fiber-Related Fields in Genesis

Ingredient: Granola Bar *

* %DV based on US Label 2016 standards.
Nutrient values based on 100.00 grams

Nutrients	Value	% DV*
Starch (g)		
Total Dietary Fiber (g)	15.00	
Total Soluble Fiber (g)	10.00	
Total Insoluble Fiber (g)	5.00	
Dietary Fiber (2016) (g)	0.00	35.71
Soluble Fiber (2016) (g)	5.00	
Insoluble Fiber (2016) (g)	5.00	
Non-digestible Carbohydrate (g)		
Soluble Non-digestible Carbohydrate (g)		
Insoluble Non-digestible Carbohydrate (g)		
Total Sugars (g)		

Show All Nutrients Alphabetize Nutrients Auto Calculations

Decimal Places: 2

All Fiber (1990 and global)

Beneficial Fiber (2016)

Non-Beneficial NDCs (2016)



Data Maintenance

Recipe Information

Recipe

Nutrients

Measures

Brix Calculation

Cost

Groups

Compare To

Preparation Method

Reference Amount

Nutrient Content Claims

Notes

HACCP

Attachments

* %DV based on US Label 2016 standards.
Nutrient values based on 0 grams

Nutrients	Value	% DV*	Override
Total Dietary Fiber (g)			
Total Soluble Fiber (g)			
Total Insoluble Fiber (g)			
Dietary Fiber (2016) (g)			
Soluble Fiber (2016) (g)			
Insoluble Fiber (2016) (g)			
Non-digestible Carbohydrate (g)			
Soluble Non-digestible Carbohydrate (g)			
Insoluble Non-digestible Carbohydrate (g)			

Show All Nutrients Alphabetize Nutrients Show Analysis Override Auto Calculations

Decimal Places: 3

Check Data Calculate Nutrients

OK Cancel



Beneficial Fiber vs. Non-Beneficial NDCs

* %DV based on US Label 2016 standards.
Nutrient values based on 100.0 grams

Nutrients	Value
Total Dietary Fiber (g)	2.71
Total Soluble Fiber (g)	
Total Insoluble Fiber (g)	
Dietary Fiber (2016) (g)	2.21
Soluble Fiber (2016) (g)	
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:

03/25/2019

4444 Broadstreet Rd. • Central City, Wyo. • 99999

PRODUCT
Blueberry Filling

INGREDIENTS

Corn syrup, sugar, water, blueberries, xanthan gum. Contains 2% or less of the following: egg whites, salt, propylene glycol, sodium, carboxymethylcellulose, tartaric acid, natural and artificial flavors, hydrochloric acid

ALLERGENS

Eggs

NUTRITIONAL INFORMATION

Serving Size	100 g	TDF as reported
Calories	303.87	
Total Fat	0	DF 2016 as reported
Sat Fat	0	
Trans Fat	0	NDCs by subtraction
Cholesterol	0	
Sodium	182.68 mg	
Total Carbohydrate	74.76 g	
Total Dietary Fiber	2.71 g	
Dietary Fiber for 2016* U.S. label	2.21 g	
Total Sugars	52.18 g	
Added Sugars	49.13 g	
Protein	1.21 g	
Vitamin D	0 mcg	
Potassium	0.46 mg	
Calcium	6.08 mg	

*As defined per U.S. FDA regulations.



Nutrient Calculator

Ingredient Information

Ingredient

Nutrients

Yields/Measures

Cost

Groups

Notes

Ingredient Statement

Allergens

Attachments

* %DV based on US Label 2016 standards.
Nutrient values based on 100.00 grams

Nutrients	Value	% DV*
Basic Components		
Gram Weight (g)	100.000	
Calories (kcal)	392.000	
Calories from Fat (kcal)		
Calories from SatFat (kcal)		
Calories from TransFat (kcal)		
Protein (g)	0	0
Carbohydrates (g)	98.000	35.636
Carbohydrate (Available) (g)		
Starch (g)		
Total Dietary Fiber (g)	98.000	
Total Soluble Fiber (g)		
Total Insoluble Fiber (g)		
Dietary Fiber (2016) (g)	0	
Soluble Fiber (2016) (g)		
Insoluble Fiber (2016) (g)		
Non-digestible Carbohydrate (g)	98.000	
Soluble Non-digestible Carbohydrate (g)		
Insoluble Non-digestible Carbohydrate (g)		

Show All Nutrients Alphabetize Nutrients Auto Calculations

Decimal Places: 3

Check Data

Indicates that the entire amount of Total Dietary Fiber is either Beneficial Dietary Fiber or (non-beneficial) Non-Digestible Carbohydrate

Calculate Nutrient

i Would you like to Calculate a Nutrient?

→ Dietary (Beneficial) Fiber (2016)
Dietary (Beneficial) Fiber (2016) = Total Dietary Fiber - Other Dietary Fiber (2016)

→ Non-digestible Carbohydrate
Other Dietary Fiber (2016) = Total Dietary Fiber - Dietary (Beneficial) Fiber (2016)

! Missing Values: Dietary Fiber (2016), Non-digestible Carbohydrate. These values will be set to 0 if used in a calculation.

Importance of Populating Data

Nutrition Facts		Nutrition Facts	
Serving Size 2/3 Cup Servings Per Container About 3		About 3 servings per container Serving size 2/3 Cup	
Amount Per Serving		Amount per serving	
Calories 190	Calories from Fat 90	Calories 190	
% Daily Value*		% 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	3%	Sodium 65mg	3%
Total Carbohydrate 25g	8%	Total Carbohydrate 25g	9%
Dietary Fiber 1g	4%	Dietary Fiber --g	--%
Sugars 22g		Total 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%
		Iron 1mg	6%
		Potassium 220mg	4%
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:		*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.	
	Calories: 2,000 2,500	Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4	
Total Fat	Less than 65g 80g		
Saturated Fat	Less than 20g 25g		
Cholesterol	Less than 300mg 300mg		
Sodium	Less than 2,400mg 2,400mg		
Total Carbohydrate	300g 375g		
Dietary Fiber	25g 30g		
Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4			

Missing Mandatory Nutrients are displayed here with a dashed line – 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	
butter, unsalted	4.8822	Gram	35.01	0.04	0.00	0	0	0.00	0	3.96	
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	
yeast, dry, instant, food service	0.6873	Gram	2.65	0.31	0.27	0.19	0.19	0	0	0.04	
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	

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?

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

Professional Genesis Training | April 10-11, 2019 | Oak Brook, IL

This training session 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, this session covers a comprehensive regulatory review.

Professional Genesis Training | May 15-16, 2019 | Oak Brook, IL

This training session 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, this session covers a comprehensive regulatory review.

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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