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

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

• 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
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
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

<table>
<thead>
<tr>
<th>FIBER</th>
<th>DESCRIPTION/FUNCTION</th>
<th>COMMON NAMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inulin and Inulin-Type Fructans</td>
<td>Inulin a naturally occurring polysaccharide extracted from plants such as chicory root, and agave. Used as a bulking agent in foods.</td>
<td>Chicory Root, Chicory Root Extract, Chicory Root Fiber, Chicory Vegetable Fiber, Fructooligosaccharide Oligofructose</td>
</tr>
<tr>
<td>Locust Bean Gum</td>
<td>Locust Bean Gum is a macerated endosperm of the seed of the locust bean tree, used as a thickening and gelling agent in food.</td>
<td>Caragum, Carob Bean Gum, Carob Seed Gum, Ceratonia Siliqua Gum, LBG</td>
</tr>
<tr>
<td>Mixed Plant Cell Wall Fibers</td>
<td>Ingredients that contain two or more of the following plant cell wall fibers in varying proportions: Cellulose; Pectin, Lignin; Beta-glucan and Arabinoxylan.</td>
<td>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</td>
</tr>
<tr>
<td>Pectin</td>
<td>Pectin is present in the cell walls and intracellular tissues of fruits and vegetables primarily used as emulsifiers and stabilizers in food</td>
<td>Calcium Pectinate, Citrus Pectin, Fruit Pectin, Hydrolyzed Pectin, Methoxy Pectin, Modified Pectin, Pectinic Acid, Zinc Pectinate</td>
</tr>
</tbody>
</table>
## Resistant Starches

<table>
<thead>
<tr>
<th>RESISTANT STARCHES</th>
<th>DESCRIPTION/ FUNCTION</th>
<th>EXAMPLES FOUND IN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RS1</strong></td>
<td>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.</td>
<td>Whole Grains, Seeds</td>
</tr>
<tr>
<td><strong>RS2</strong></td>
<td>Resistant Starch 2 retains its natural granular shape yet resists digestion due to crystallinity within the granule</td>
<td>Unripe Bananas, Uncooked Potatoes, Resistant Corn Starch 260, High Amylose Starch</td>
</tr>
<tr>
<td><strong>RS3</strong></td>
<td>Resistant Starch 3 occurs if the starch granule has been broken apart and the starch chains are crystallized, cooked or heat processed.</td>
<td>Breakfast cereals</td>
</tr>
<tr>
<td><strong>RS4</strong></td>
<td>Resistant Starch 4 occurs when the starch has been chemically modified to artificially inhibit digestion</td>
<td>Hi-maize resistant starch used in baked goods</td>
</tr>
</tbody>
</table>

**BENEFICIAL FIBER**

**NON-DIGESTIBLE CARBOHYDRATES**
DIETARY FIBER

noun | di·e·tar·y fi·ber | "di·e·ter·ē fi·ber"

: 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.

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

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.

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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

- All Fiber (1990 and global)
- Beneficial Fiber (2016)
- Non-Beneficial NDCs (2016)
Data Maintenance
Benificial Fiber vs. Non-Beneficial NDCs

<table>
<thead>
<tr>
<th>Nutrients</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Dietary Fiber (g)</td>
<td>2.71</td>
</tr>
<tr>
<td>Total Soluble Fiber (g)</td>
<td></td>
</tr>
<tr>
<td>Total Insoluble Fiber (g)</td>
<td></td>
</tr>
<tr>
<td>Dietary Fiber (2016) (g)</td>
<td>2.21</td>
</tr>
<tr>
<td>Soluble Fiber (2016) (g)</td>
<td></td>
</tr>
<tr>
<td>Insoluble Fiber (2016) (g)</td>
<td></td>
</tr>
<tr>
<td>Non-digestible Carbohydrate (g)</td>
<td>0.50</td>
</tr>
<tr>
<td>Soluble Non-digestible Carbohydrate (g)</td>
<td></td>
</tr>
<tr>
<td>Insoluble Non-digestible Carbohydrate (g)</td>
<td></td>
</tr>
</tbody>
</table>

Nutrient values based on 100.0 grams.

DF 2016 as reported

TDF as reported

NDCs by subtraction
Nutrient Calculator

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

Calculate Nutrient

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

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.

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

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/
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