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
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

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)
- Arabinosylan
- 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

<table>
<thead>
<tr>
<th>FIBER</th>
<th>DESCRIPTION/FUNCTION</th>
<th>COMMON NAMES</th>
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<tbody>
<tr>
<td><strong>Inulin and Inulin-Type</strong></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>
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<td><strong>Fructans</strong></td>
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<td><strong>Locust Bean Gum</strong></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>
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<tr>
<td><strong>Mixed Plant Cell Wall Fibers</strong></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><strong>Pectin</strong></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>
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# Resistant Starches

<table>
<thead>
<tr>
<th>Resistant Starches</th>
<th>Description/ Function</th>
<th>Examples Found In</th>
</tr>
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<tbody>
<tr>
<td>RS1</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>RS2</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>RS3</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>RS4</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>
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</tbody>
</table>
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

- **Fiber (1990 and global)**
- **Beneficial Fiber (US 2016)**
- **Non-Beneficial NDCs**
Importance of Populating & Reviewing Data

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.
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

- 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 use 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)

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 [www.esha.com](http://www.esha.com) for the full list of upcoming classes.
- Does your organization need group training? Contact training@esha.com

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<tr>
<td>Online</td>
<td>Sept 12-15, 2022</td>
<td>4-Day Genesis R&amp;D Foods Professional</td>
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<tr>
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<td>Sept 20-21, 2022</td>
<td>2-Day Genesis R&amp;D Foods Advanced</td>
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<tr>
<td>ESHA Training Center</td>
<td>Oct 18-19, 2022</td>
<td>2-Day Genesis R&amp;D Foods Professional</td>
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<tr>
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<td>Oct 20, 2022</td>
<td>1-Day Genesis R&amp;D Foods Advanced</td>
</tr>
<tr>
<td>Online</td>
<td>Nov 7-10, 2022</td>
<td>4-Day Genesis R&amp;D Foods Professional</td>
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<tr>
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<td>Nov 15-16, 2022</td>
<td>2-Day Genesis R&amp;D Foods Advanced</td>
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