

Focus on Fiber: Taking a Closer Look at the New FDA Dietary Fiber Definition

ESHA Research

February 14, 2017



About ESHA Research

ESHA Research was established in 1981 with the goal of providing a comprehensive nutrition database with few missing values.

Our Solutions Include

- Food Formulation & Labeling Software
- Restaurant Menu Analysis & Labeling Software
- Supplement Formulation & Labeling Software
- Nutrition & Diet Analysis Software
- Consulting Services

Genesis R&D

Food Analysis & Labeling Software

- Released in 1991
- Pre & Post 2016 Label formats
- Product Development
- Menu Analysis
- Nutrient Analysis
- Nutrient Search
- Reporting Features
- Audit Trails
- Labeling & Compliance
 - Allergen Statements
 - Ingredient Statements
 - Nutrient Content Claims



Upcoming Webinars

Overview of Canada's New Nutrition Facts Table Regulations | March 28, 2017

December 14th, 2016 Health Canada released new food labeling regulations. During this 45 minute webinar, we will focus on the new features in Genesis R&D Version 11.3 including the new Health Canada Nutrition Facts tables. We will also discuss the changes to the Nutrition Facts table and ingredient statement in detail.

Restaurant Menu Labeling Regulations and Best Practices | April 4, 2017

May 2017, restaurants, supermarkets, convenience stores, and movie theaters will be required to post calories on menu items. During this 45 minute webinar, we will provide a brief overview of the FDA Menu Labeling regulations, discuss labeling best practices, and demonstrate how the Food Menu Report in Genesis R&D can help you with compliance.

Importing Supplier Ingredients with ESHA Port | May 16, 2017

The FDA finalized the new Nutrition Facts label for packaged foods and supplements to reflect new scientific information and food manufacturers have 2-3 years to update their labels with the newly required label nutrients. As a result, there is an increased pressure for Ingredient suppliers to provide updated nutrition information to their customers. During this webinar we explore how the newest version of the ESHA Port workflow utility can help you streamline data from ingredient suppliers into your Genesis R&D program database.

The Buzz on FDA's Definition of Added Sugars | May 30, 2017

As food manufacturers prepare for compliance there is still some confusion regarding the definition of Added Sugars and how to calculate this new mandatory label nutrient. On May 30th, we will discuss what is considered an Added Sugar (and what is not), best practices for documentation, and Genesis R&D user tips for achieving compliance.

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



Agenda

During this 30 minute webinar we will cover:

- Regulations Timeline
- Dietary Fiber Definition
- Approved Fibers
 - Natural vs Synthetic & Isolated
- Citizens Petition
- Documentation
- Features in Genesis R&D
- Q&A

Timeline for Compliance

- The compliance date for the updated Nutrition Facts labels will be **July 26, 2018**, for companies with more than 10 million dollars in annual food sales
- OR**
- **July 26, 2019**, for companies with less than 10 million dollars in annual food sales.

1990 NLEA & 2016 NLEA

Nutrition Facts	
Serving Size 2/3 cup (55g)	
Servings Per Container About 8	
Amount Per Serving	
Calories 230	Calories from Fat 72
% Daily Value*	
Total Fat 8g	12%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	12%
Dietary Fiber 4g	16%
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat 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

Nutrition Facts	
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 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 (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

Note: Both the preexisting and new label formats will be available in Genesis as we transition through effective and compliance date timelines. The format options will include the appropriate regulations for both. Be mindful with your labeling and remember, our Support team is on hand to help you out.

Dietary Fiber *New* Definition

1990 Regulations

- No written definition
- Level of declared dietary fiber measured by an official method of analysis

2016 Regulations

- Introduced written definition: The new definition focuses on reporting fiber (soluble and insoluble) that is considered beneficial to human health
 - *naturally occurring fibers*
 - *added fibers (isolated or synthetic) that have been determined to be beneficial*
- Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants. The fiber is still intact.
- Isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that demonstrate a physiological effect(s) that is beneficial to human health.

Natural vs Isolated & Synthetic

- Natural:
 - From whole foods
 - Produced via mechanical processes where nutrients normally found in the whole food are still present
- Isolated & Synthetic:
 - On the FDA approved list
 - Produced via chemical, enzymatic or aqueous processes
 - Can be approved via a citizens petition

New Dietary Fiber Definition Examples

Isolated or Synthetic Fibers

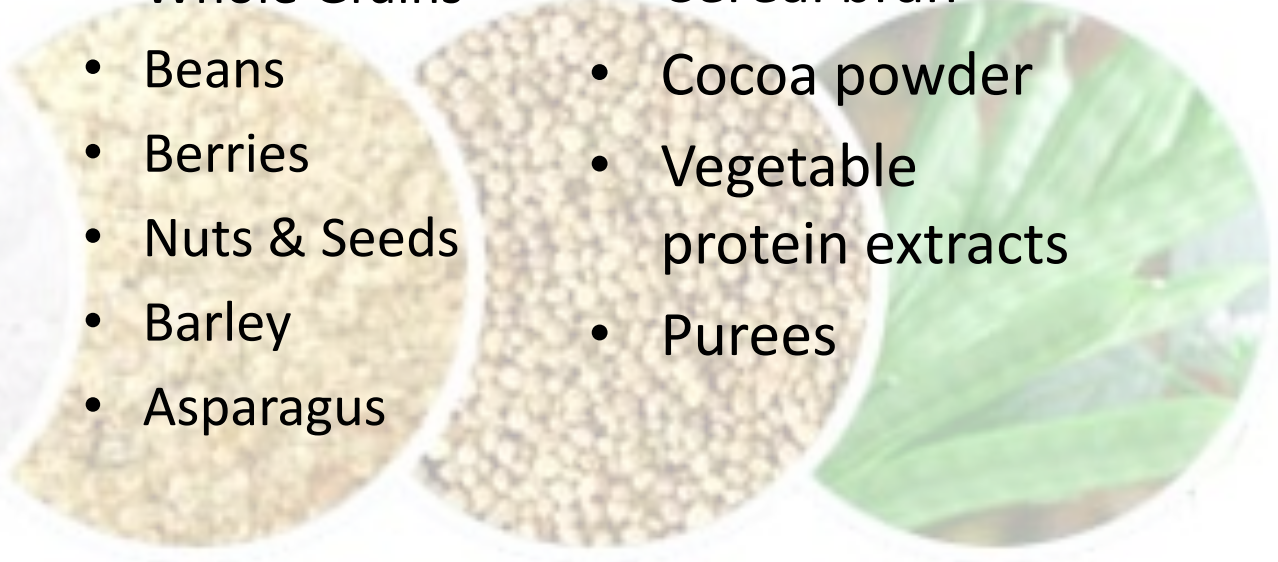
- Beta-glucan soluble fiber
- Psyllium husk
- Cellulose
- Guar gum
- Pectin
- Locust bean gum
- Hydroxypropyl methcellulose

Naturally Occurring Fibers

- Whole Grains
- Beans
- Berries
- Nuts & Seeds
- Barley
- Asparagus

Natural & Mechanically Processed

- Cereal bran
- Cocoa powder
- Vegetable protein extracts
- Purees



“Other Fibers” Under Review

The FDA published a separate notice to seek comment on the available scientific data on non-digestible carbohydrates. The comment period ended on February 13th.

- Gum Acacia
- Alginate
- Apple Fiber
- Bamboo Fiber
- Carboxymethylcellulose
- Corn Hull Fiber
- Cottonseed Fiber
- Galactooligosaccharides
- Inulin/Oligofructose/Synthetic Short Chain Fructooligosaccharides
- Karaya Gum
- Oat Hull Fiber
- Pea Fiber
- Polydextrose
- Potato Fibers
- Rice Bran Fiber
- High Amylose Corn/Maize Starch (Resistant Starch 2)
- Retrograded Corn Starch (Resistant Starch 3)
- Resistant Wheat and Maize Starch (Resistant Starch 4)
- Soluble Corn Fiber
- Soy Fiber
- Sugar Beet Fiber
- Sugar Cane Fiber
- Wheat Fiber
- Xanthan Gum
- Xylooligosaccharides
- Pullulan

Changes in RDI Values

- RDI values for Dietary Fiber under the new definition has increased from 25g to 28g.
- Still part of the total carbohydrate value.
- Carbohydrate RDI value has decreased from 300g to 275g
- Meaning, the goal is to have better more beneficial carbohydrates in your diet.

Additional Changes

- Calorie Calculation Method (C) in CFR 101.9c1
- 4-4-9 per gram of protein, total carbohydrate (minus non-digestible carbohydrates and sugar alcohols), and total fat.
 - “Insoluble” non-digestible carbs still contribute zero kcal/gram
 - “Soluble” non-digestible carbs contribute 2 kcal/gram (replaces previous level of 4)

So What Does That REALLY Mean?

5g Total Soluble Fiber
(oats)
+10g Total Insoluble Fiber
(inulin + cellulose)

15g Total Dietary Fiber
(as calculated and what
will appear on the label)

Previous Calculation

Based on the previous Dietary Fiber definition my bar would have 15g of Total Dietary Fiber.

5g BENEFICIAL Soluble Fiber
(oats)
+5g BENEFICIAL Insoluble Fiber
(cellulose)
0g OTHER Soluble Fiber
+5g OTHER Insoluble Fiber
(inulin is not 'beneficial')

10g Total Dietary Fiber
(only 'beneficial' fiber totals
now appear on the label)

New Calculation

Based on the new Dietary Fiber definition my bar would have 10g of Total Dietary Fiber. The 5g of fiber that comes from inulin are not calculated in the Total Dietary Fiber, but they ARE calculated in the Total Carbohydrates.

Implications for the label

Nutrition Facts			
Serving Size 2/3 cup (55g)			
Servings Per Container About 8			
Amount Per Serving			
Calories 230	Calories from Fat 72		
		% Daily Value*	
Total Fat 8g			12%
Saturated Fat 1g			5%
Trans Fat 0g			
Cholesterol 0mg			0%
Sodium 160mg			7%
Total Carbohydrate 37g			12%
Dietary Fiber 4g			16%
Sugars 1g			
Protein 3g			
Vitamin A			10%
Vitamin C			8%
Calcium			20%
Iron			45%

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

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat 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

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
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Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



- Change in %DV
- Nutrient Content Claims may need to be evaluated
- Lacking data – check spreadsheet report!

Checking Ingredient Statements

- It is important to scan your ingredient statements for “trigger ingredients”
- Ingredients on the review list
- Ingredients that make you go hmm...

Ingredient Statement

INGREDIENTS: ALMOND FLOUR (ALMONDS, SALT), COCOA POWDER, ALMOND MILK (WATER, ALMONDS, CITRIC ACID), BANANA, BUTTER, SALTED, SUGAR, GUM ARABIC, EGG, RAW, SALT, TABLE, BAKING SODA.



- Gum Arabic is also known as Acacia Gum which is on the list up for review

Citizens Petition

- Manufacturers can submit either electronically or via snail mail
- Petition Format:
 - A) Action requested
 - B) **Statement of grounds**
 - C) Environmental Impact
 - D) Economic Impact
 - E) Certification
- In order for an isolated or synthetic fiber to be added the list it must of course meet all of the definitions we have discussed
- Be prepared to have ample research to make your case

21 CFR 10.3

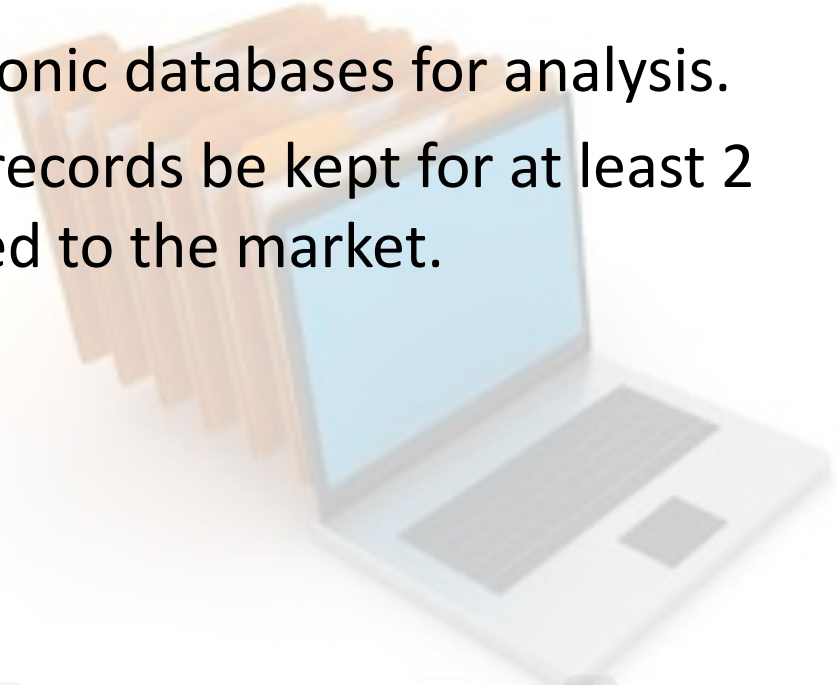
Statement of Grounds

- Provide all available & appropriate studies – good or bad
- Certain parameters must be followed in research
 - Healthy populations
 - Length & number of studies sufficient
 - Sample population representative of US
- Positive provable effects:
 - Lowering blood glucose
 - Lowering blood cholesterol
 - Lowering blood pressure
 - Increased mineral absorption

Documentation

Because there are not analytical methods that can distinguish the required nutrient definitions, the new labeling regulations require maintenance records to support the amount of dietary fiber on the label:

- The FDA allows for use of electronic databases for analysis.
- The final rule requires that the records be kept for at least 2 years after the food is introduced to the market.



How have the fiber fields changed in Genesis?

3 OLD Fiber fields

Dietary Fiber
Soluble Fiber
Insoluble Fiber

(have been converted)



Newly Named Fiber Fields

1) Total Dietary Fiber
2) Total Soluble Fiber
3) Total Insoluble Fiber

We've also added 6 more for a total of 9 fiber fields:

- 4) Dietary Fiber (2016)
- 5) Soluble Fiber (2016)
- 6) Insoluble Fiber (2016)
- 7) Other Fiber (2016)
- 8) Other Soluble Fiber (2016)
- 9) Other Insoluble Fiber (2016)

Dietary Fiber in Genesis

Ingredient: apple, fresh, small, 2 3/4" ×

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

Nutrients	Value
Total Dietary Fiber (g)	2.40
Total Soluble Fiber (g)	0.24
Total Insoluble Fiber (g)	2.16
Dietary Fiber (2016) (g)	2.40
Soluble Fiber (2016) (g)	0.24
Insoluble Fiber (2016) (g)	2.16
Other Fiber (2016) (g)	
Other Soluble Fiber (2016) (g)	
Other Insoluble Fiber (2016) (g)	
Total Sugars (g)	10.39
Added Sugar (g)	0

Show All Nutrients
Decimal Places: 2

Old 1990
Label Fields

New 2016
Label Fields

Dietary Fiber in Genesis

Ingredient: apple, fresh, small, 2 3/4" ×

Ingredient

Nutrients

Yields/Measures

Cost

Groups

Ingredient Statement

Allergens

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

Nutrients	Value
Total Dietary Fiber (g)	2.40
Total Soluble Fiber (g)	0.24
Total Insoluble Fiber (g)	2.16
Dietary Fiber (2016) (g)	2.40
Soluble Fiber (2016) (g)	0.24
Insoluble Fiber (2016) (g)	2.16
Other Fiber (2016) (g)	
Other Soluble Fiber (2016) (g)	
Other Insoluble Fiber (2016) (g)	
Total Sugars (g)	10.39
Added Sugar (g)	0

Show All Nutrients

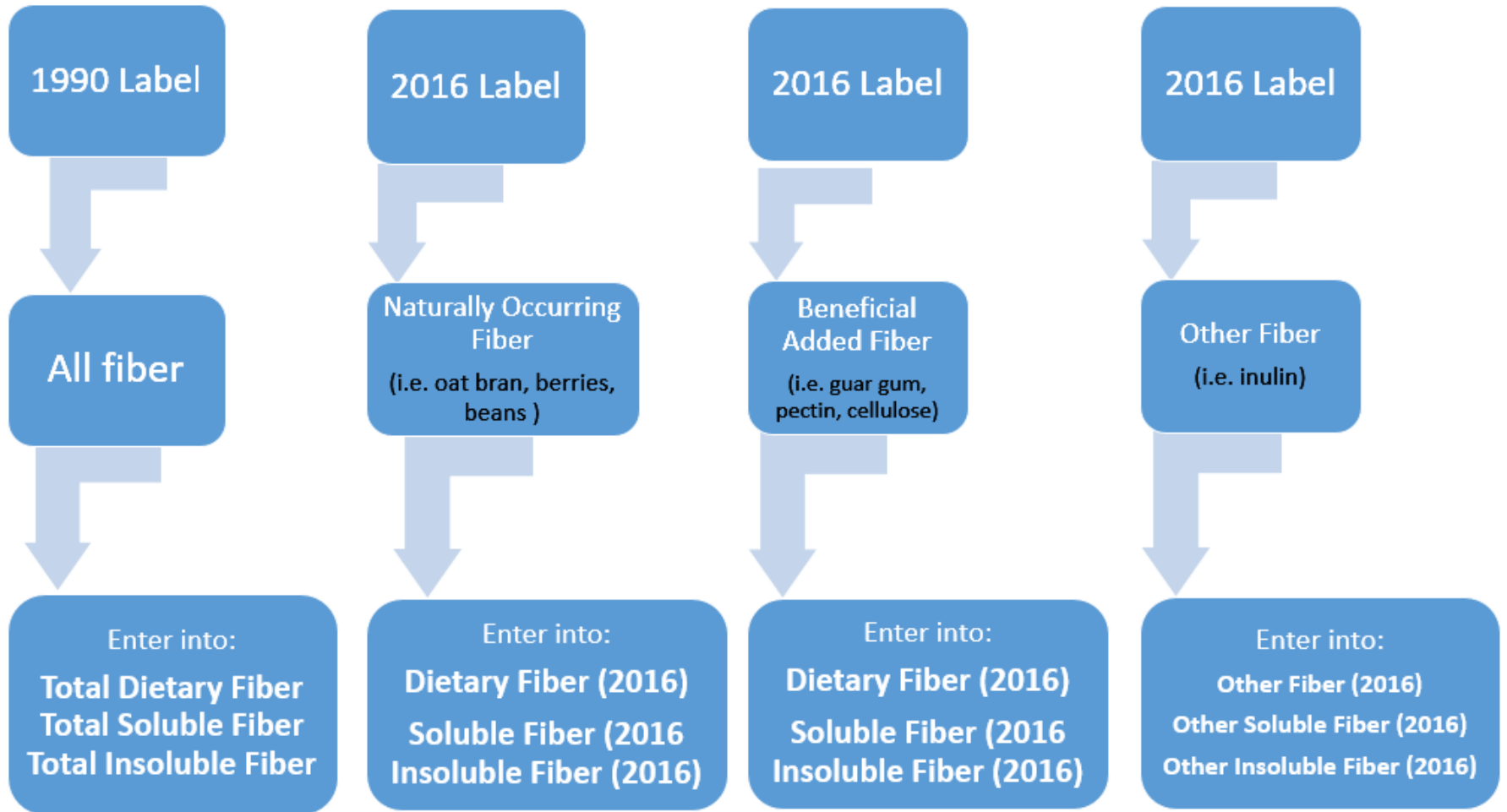
Decimal Places: 2

Old 1990
Label Fields

New 2016
Label Fields

Not seeing the new Fiber fields?
Change your Nutrients to View or
check "Show All Nutrients"

Dietary Fiber in Genesis



Genesis R&D Training

Genesis Professional Training | March 23-24, 2017 | Washington, DC

This training session will cover the essentials of Genesis R&D including creating ingredients and recipes/formulas, reporting, best practices, and basic labeling features.

Genesis Professional Training for Restaurants | March 27-28, 2017 | Lombard, IL

This training session covers ingredient creation and recipe/menu building, best practices, and analysis reporting specific to the restaurant industry. Additionally, we will discuss how Genesis R&D helps you comply with the Restaurant Menu Labeling regulations.

Advanced Genesis Workshop | April 25-26, 2017 | Washington, DC

This workshop covers advanced topics in detail such as new FDA labeling regulations, due diligence and documentation for transitioning to the new labels, new program features, PDCAAS (protein digestibility score), range formulas, advanced labels, and more

Genesis Professional Training (*Canadian Specific*) | April 27-28, 2017 | Toronto, ON

This training session will cover the essentials of Genesis R&D including creating ingredients and recipes/formulas, reporting, best practices, and basic labeling features.

For more information including cost and availability, please contact our training coordinator by phone at 503-585-6242 or by email at training@esha.com.



Questions?

Contact Us!

Phone: 503-585-6242

Email: sales@esha.com

Helpful Resources

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