Genesis R&D 101
Part 4: Working with Allergens

Presented by ESHA Research

Wednesday, April 14, 2021

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.

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Genesis R&D Foods

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

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Upcoming Webinars

May 5, 2021 | Genesis R&D Foods Version 11.10 Update Overview
See what's new in the latest version of Genesis R&D Foods. During this webinar, we will cover recent UI changes and provide a review of the newly added Canadian label formats.

June 9, 2021 | Working with Serving Sizes
The FDA requires that the serving size on your Nutrition Facts label be shown as a common household measure suitable for the food and based on the amount of that food typically consumed. The FDA has defined and cataloged these amounts as RACCs (Reference Amounts Customarily Consumed). In this webinar, we will demonstrate how to enter serving size information in Genesis R&D and work with serving information on your labels.

To view archived webinars and sign up to receive notifications, visit:
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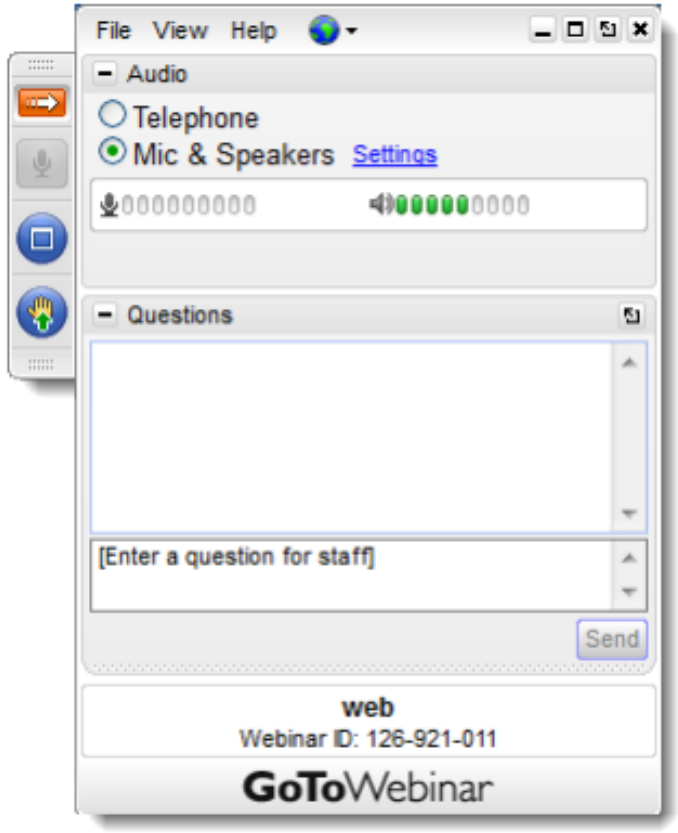
Please Note!

- ✓The webinar is being recorded
- ✓All webinars available on our website
- ✓Submit your questions in the GoToWebinar control panel
- ✓We'll email a copy of the recording and the slides following the webinar



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What We'll Cover Today

- Major Allergens that Must Be Declared
- General Rules for Allergens
- Working with Ingredient Records and Allergens
- Adding New Allergens to your Genesis R&D
- Working with the Allergen Statement Features
- Display Options
- Q&A

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Allergens

- Ingredients or protein of ingredients that have been shown to cause adverse health reactions in humans.
- Declaration of allergens required on food product packaging for consumer health and protection.

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Undeclared Allergens

- For the past three years in the U.S., undeclared food allergens have been the number one leading cause of *Class I* food recalls – where the result could be a serious adverse health consequence or death - *FDA*
  - Class I: Recalls for products which could cause serious injury or death
  - Class II: Recalls for products which might cause serious injury or temporary illness
  - Class III: Recalls for products which are unlikely to cause injury or illness, but that violate FDA regulations
- Dangerous and costly

"Voluntarily Recalls …Due to Undeclared Pecan Allergen"

"Issues Allergy Alert on Undeclared Almonds"

"Issue Voluntary Recall and Allergy Alert on Undeclared Tree Nuts"

"Issues Allergy Alert on Undeclared Milk Allergens"

"Issues Allergy Alert on Undeclared Egg"

"Issues Voluntary Allergy Alert on Undeclared Milk"

"Issues Allergy Alert on Undeclared Soy"

"Issues Allergy Alert on Undeclared Shrimp Allergen"

"Announces Limited Voluntary Recall of …Due to Undeclared Allergens"

"This recall is due to possible undeclared allergens (wheat and tree nuts)…"

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U.S. Major Allergens

Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004

Identified the major allergens that account for more than 90% of the documented food allergies at the time.

The label of a food that contains an ingredient that *is* or contains protein from a "major food allergen" shall declare the presence of the allergen.

- Crustacean shellfish* (crab, lobster, shrimp, etc.)
- Eggs
- Fish*
- Milk
- Peanuts
- Soybeans
- Tree Nuts*
- Wheat

*Specific species or variety is to be declared

Sesame – likely to become 9th allergen; FASTER Act in progress

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Allergens by Country

Fish: U.S. and Canada, specific species (bass, flounder, salmon, etc.) must be declared.

Gluten: Canada, EU, and Mexico, cereals containing gluten are defined as wheat, rye, barley, triticale, and/or hybridized strains and products of these. EU and Mexico also include spelt. Canada, gluten must be declared with its source.

Milk: EU and Mexico include lactose.

Sesame: U.S., sesame is under review as a major allergen. Manufacturers can voluntarily declare.

Shellfish (Crustacean): U.S. and Canada, specific species (crab, lobster, shrimp, etc.) must be declared.

Shellfish (Molluscan): Canada, specific species (oysters, clams, mussels, scallops) must be declared.

Soy: U.S., Canada, EU, and Mexico, single-ingredient products, or products containing soybeans or soybean protein, must include "soybean" (or an approved synonym) in the Contains statement or in the ingredient statement.

Tree Nuts: U.S., Canada, and EU, specific type of tree nut (almonds, pecans, walnuts, etc.) must be declared.

Sulphites: U.S., Canada, EU, and Mexico the presence of sulphites ("sulfites" in the U.S.) must be declared if directly added and the amount is 10 ppm (10 mg/kg) or more. If added, the specific sulfiting agent must be declared.

Wheat: Neither EU nor Mexico considers "wheat" an allergen, but both list wheat as a gluten source. If a product contains wheat, gluten must be declared.

	U.S.	CANADA	EU	MEXICO
Celery			x	
Egg	x	x	x	x
Fish	x	x	x	x
Gluten/ Cereals Containing Gluten*		x	x	x
Lupin			x	
Milk/Dairy*	x	x	x	x
Mustard/Mustard Seed		x	x	
Peanut	x	x	x	x
Sesame/Sesame Seed*	voluntary	x	x	
Shellfish (Crustacean)*	x	x	x	x
Shellfish (Molluscan/Mollusc)*		x	x	x
Soy/Soybean*	x	x	x	x
Tree Nuts*	x	x	x	x
Wheat*	x	x		
Sulphites/Sulfites*	x	x	x	x

Allergens listed for U.S., Canada, EU, & Mexico. These are the labeling modules currently available for Genesis R&D.

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Allergen Declaration for U.S.

Allergens Can Be Declared in One of Two Ways:

Option 1 - Clearly stated in the Ingredient List:

> ***Ingredients****: Enriched flour (****wheat*** *flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, soybean oil, high fructose corn syrup, whey (****milk****),* ***eggs****, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (****soy****), mono and diglycerides (emulsifier)*

Option 2 - Using a "Contains" statement (Allergen Statement):

> *Contains Wheat, Milk, Egg, and Soy*

May Contains:

- Advisory statements, like "May Contains" is not required.
- Some manufacturers use "may contains" or processing statements to help identify potential trace content or cross contamination.

Incidental ingredients:

- If the individual ingredient is not required to be listed in the Ingredient List (per allowed exemptions) but contains an allergen, the *allergen* must clearly be stated.

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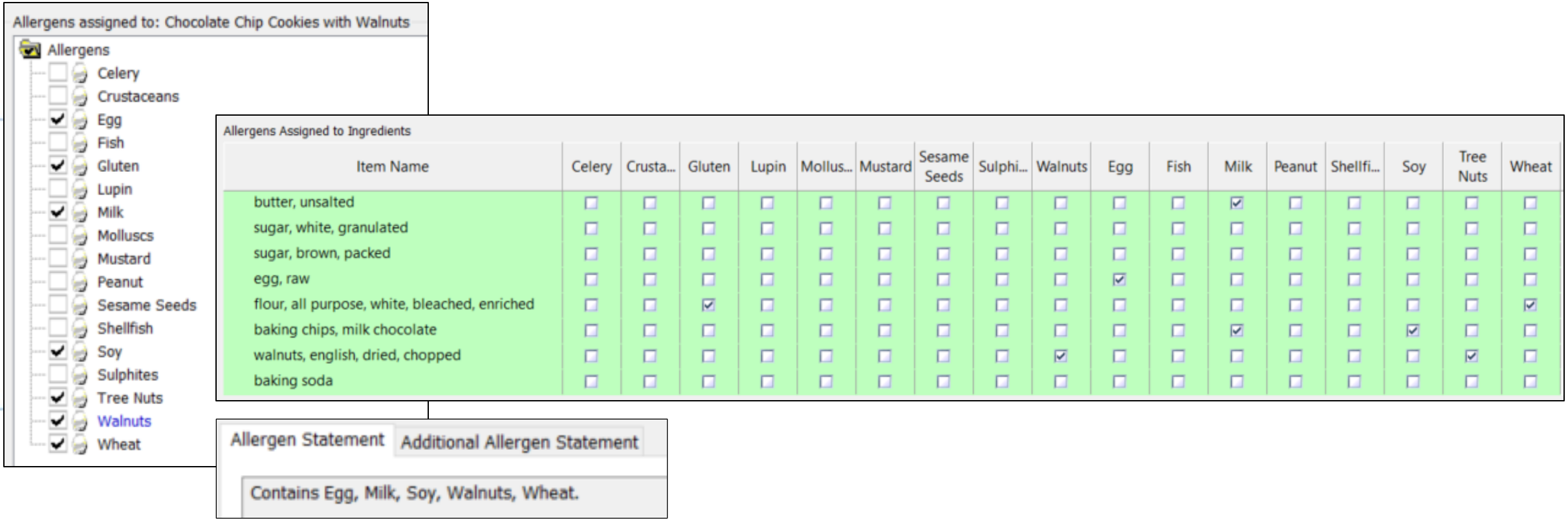
Allergen Statement in Genesis R&D



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Best Practices in Working with Allergens

When working with Genesis R&D:

- Best practice: assign the correct allergens when adding and entering Ingredient information in the Ingredient record
- Allergens are marked in the Ingredient record and pull forward to Recipes
- Documentation: use the Attachments feature to include allergen-related documents for ingredients
- Review the Allergen Statement in the Recipe record

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Genesis R&D Training

Genesis R&D Foods Professional + USDA Regulations

This 2-day training session covers the fundamentals of the Genesis R&D Food program with a primary focus on USDA 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 USDA regulatory review.

Genesis R&D Foods Professional + FDA Regulations

This 2-day 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 FDA regulatory review.

Genesis R&D Foods Advanced Training

The 1-day 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.

Session Options:

- 3-day Combined Professional + Advanced Training
- 2-day Professional Training
- 1-day Advanced Training (Prerequisite: Professional Training)

Date	Training Session Title
April 20-21, 2021	Genesis R&D Foods Professional + USDA
May 11-13, 2021	Genesis R&D Foods Professional and/or Advanced
June 22-24, 2021	Genesis R&D Foods Professional and/or Advanced

https://esha.com/news-events/training-schedule/ training@esha.com

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QUESTIONS?

CONTACT US

Phone: 503-585-6242

Sales: sales@esha.com

Support: support@esha.com

Consulting Services: cs@esha.com

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