



WEBINAR



Best Practices for Creating and Managing Nutrition Labels for Multiple Countries

Presented by ESHA Research

Wednesday, October 17, 2018

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, we provide solutions for recipe and product development, labeling, nutritional analysis, and regulatory compliance.

ESHA Services and Software 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 was released in 1991 and is designed to help users manage processes and industry challenges, and meet federal requirements.

- Product Development
- Formulation Analysis
- Menu Analysis
- Reporting
- Regulatory Compliance



Upcoming Webinars

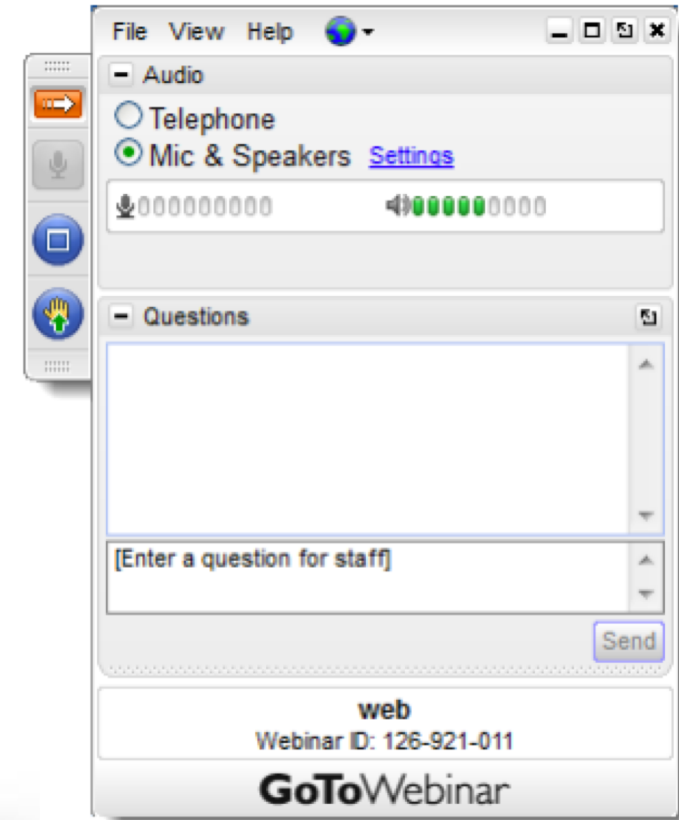


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Agenda

- General Considerations
 - Regulations and Supporting Information
 - Ingredients and Recipes
 - Naming Conventions
- Organizing
 - Data Entry
 - Groups
- Label Development
 - Label Formats and Settings
 - Ingredient Statement Naming
- Q&A



Genesis R&D Food – Labeling Modules

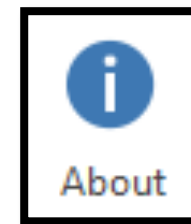
Regulation	Canada
	U.S.
	Canada
	Mexico
	European Union

Access the labeling modules in Genesis R&D Food:

Available labeling regulation modules are displayed in the Edit Label settings.

Current labels and options are available in the most recent version of the software. Click on the About button to check your version number.

Current cloud subscriptions provide the latest version automatically.





Regulatory Resources

U.S.

FDA

USDA

CFR: Code of
Federal
Regulations

Title 21, Part 101



Canada

Health Canada

CFIA: Canadian
Food Inspection
Agency

FDR: Food &
Drug Regulations



Mexico

Ministry of the
Economy

Ministry of
Health

NOM-051:
Norma Oficial
Mexicana



EU

European
Commission



Regulation EU
No. 1169/2011





General Considerations

Regulations

- In what countries are you labeling?
 - Ingredients – are they allowed or prohibited?
 - Fortification requirements – cereals, flours
 - Packaging – does size and shape affect type of label used?
- 
- 

Processing

Where does production take place?

- One facility?
 - Is product exported/imported?
- Several locations – one or more countries?
 - Are the same ingredients used at all
 - Are the same processes used at all
 - Is the same equipment used at all locations
 - Are there any incidental ingredients used – any allergen concerns across countries?
- Environmental differences
 - Humidity - moisture adjustments
 - Elevation





Organize Recipes

- Once Recipe for all countries?
- Or, multiple Recipes – one for each country

Bread Formula 10172018 US

Ingredients:

Flour, whole wheat 503 USFort
Water 971447
Sugar 101
Yeast 585OR
Wheat Bran 404MT
Soybean Oil 930-02

Bread Formula 10172018 CAN

Ingredients:

Flour, whole wheat 418 CanFort
Water 581438
Sugar 101
Yeast 514QC
Wheat Bran 404MT
Soybean Oil 930-04



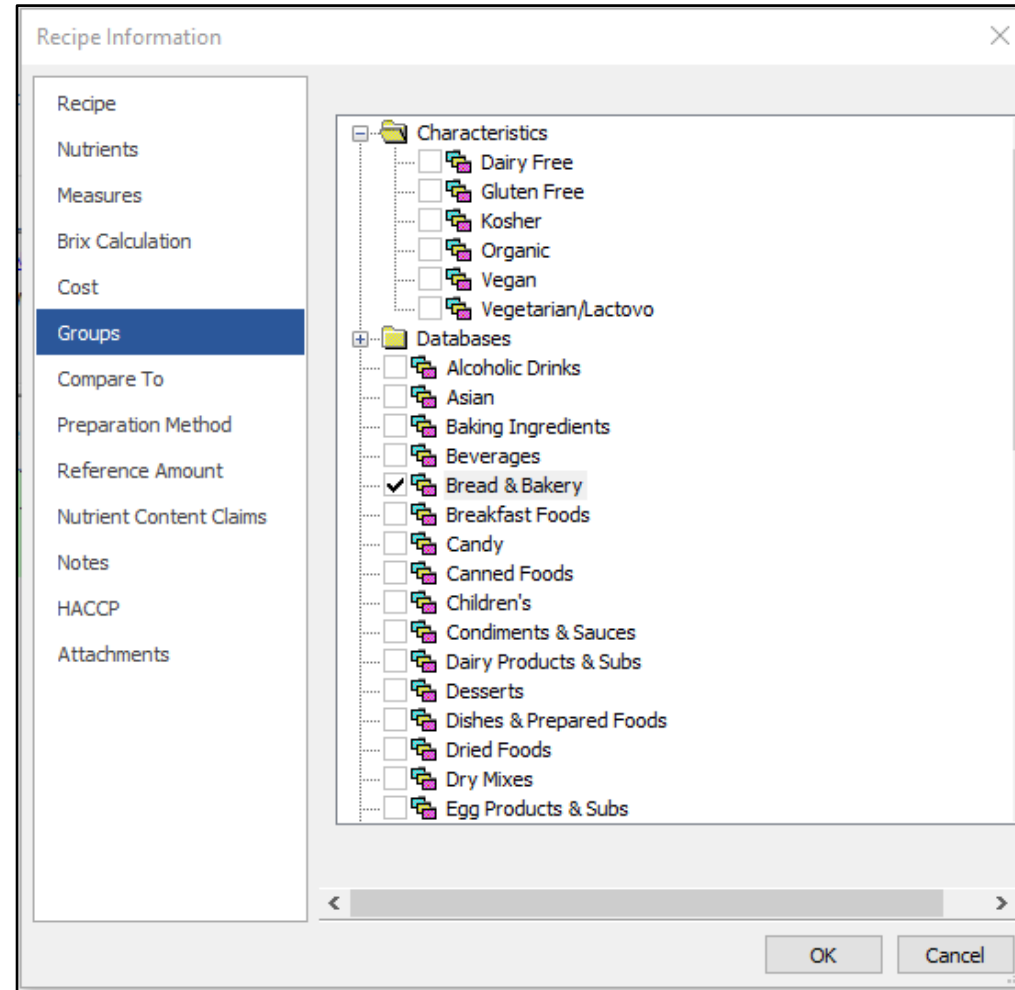
Naming Conventions

- **Naturally Ordered Elements:** from general to specific detail of importance, e.g. Latte Vanilla Nonfat Small 12oz
- **Location:** ingredients/recipes intended for a specific region, should include a region code or abbreviation in the name
- **Numbering:** use at least two-digits rather than one in order to maintain the numeric order. Include the zero for numbers 0-9 (e.g. 01, 02, 03)
- **Version Control:** differentiate between version drafts and final version of a Recipe by giving each version its own number and designation e.g. RecipeA-v01, RecipeA-v02, RecipeA-v03
- **Dates:** best practice, state dates beginning with the year: e.g. YYYYMMDD, YYYYMM, or YYYYQ1
- **User-Code:** use the User-Code field to help identify records



Groups in Genesis R&D

- Helps organize data
- Select from existing Groups or create your own
- Can assign an ingredient or a recipe to multiple Groups
- Preferences to always assign new items to Group(s)





Benefits of Using Groups

- **Searching:** You can search to include or exclude by Group
- **Exporting:** When exporting records *from* ESHA Software *to* ESHA Software or using ESHA Port, Groups can be used to filter the exported records
- **ESHA Security:** Groups are used to designate varying levels of read/write access permissions to records in the database
- **Genesis API:** Groups can be published to the Genesis API to expose formulas, analysis, and label data from Genesis R&D and send the information to external and internal interfaces such as website, point-of-sales system, inventory management system, and QC or document controls



Groups: Country/Region

Where in the world are your labels?

Create, assign, and manage ingredients, recipes, and labels by country or region using Groups



Groups by Formulation or Characteristics



- Stages of production
- Ready for export or publication
- Claims qualifications
- Access - Security



Ingredient Data

Ingredients – time to do some investigative work

- Allowed in formulation per country's regulations?
- Naming
 - Aliases?
 - Ingredient List
 - Translations?





Ingredient Data - Nutrients

Nutrients

- What unit is used in the country you need to label?
- Do you need to convert from provided to label nutrients?
 - Populate as much information as possible
 - Use the Nutrient Calculator in Genesis R&D



Nutrient Calculator

Assists in converting nutrients from one unit to another

- Carbohydrates, Carbohydrates (Available)
- U.S. Dietary Fiber fields
- Vitamin A
- Vitamin B3/Niacin, Tryptophan
- Vitamin D
- Vitamin E
- Folate/Folic Acid
- Salt, Sodium



Calculate Nutrient

i How would you like to Calculate Vitamin A - RAE?

→ Animal Source
Vitamin A RAE (mcg) = Vitamin A IU (IU) / 3.33

→ Plant Source
Vitamin A RAE (mcg) = Vitamin A IU (IU) / 20

→ Animal Source
Vitamin A RAE (mcg) = Vitamin A RE (mcg)

→ Plant Source
Vitamin A RAE (mcg) = Vitamin A RE (mcg) / 2

Cancel



Nutrients to View

- Sets of nutrients pertinent to your reports or needed for labels
- Genesis includes several predetermined sets of nutrients
- Create as many new sets as you need
- Switch between the sets at any time when viewing Recipes





Label Nutrients

Common to U.S., Canada, Mexico, and EU:

- Energy
- Fat
- Saturated Fat
- Carbohydrates
- Sugars
- Protein

Additional:

- Energy - Calories vs kilojoules
- Trans Fat
- Carbohydrates – total vs available
- Dietary Fiber – varying definitions
- Sugars
- Mandatory/core vitamins and minerals
- Voluntary/additional nutrients



Mandatory Nutrients - U.S. 2016

- Calories
- Fat
- Saturated Fat
- Trans Fat
- Cholesterol
- Sodium
- Total Carbohydrate
- Dietary Fiber – by FDA definition



- Total Sugars
- Added Sugars
- Protein
- Vitamin D
- Calcium
- Iron
- Potassium

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.



Mandatory Nutrients - Canada

- Calories
- Fat
- Saturated Fat
- Trans Fat
- Total Carbohydrates
- Dietary Fiber
- Sugars
- Protein
- Cholesterol
- Sodium
- Potassium
- Calcium
- Iron



Nutrition Facts	
Valeur nutritive	
Per 2 slices (79 g) pour 2 tranches (79 g)	
Per Container 8 par contenant 8	
Calories 130	% Daily Value*
	% valeur quotidienne*
Fat / Lipides 0.4 g	1 %
Saturated / saturés 0.1 g + Trans / trans 0 g	1 %
Carbohydrate / Glucides 28 g	
Fibre / Fibres 1 g	4 %
Sugars / Sucres 4 g	4 %
Protein / Protéines 4 g	
Cholesterol / Cholestérol 0 mg	
Sodium 1 mg	1 %
Potassium 1750 mg	37 %
Calcium 10 mg	1 %
Iron / Fer 1.5 mg	8 %
*5% or less is a little , 15% or more is a lot	
*5% ou moins c'est peu , 15% ou plus c'est beaucoup	



Mandatory Nutrients - Mexico

- Energy – kJ and kcal
- Fat
- Saturated Fat
- Carbohydrates - Available
- Sugars
- Dietary Fiber
- Sodium

Información Nutrimental / Nutrition Facts	
Tamaño de la Porción 1 rodaja 59g / Serving Size 1 slice 59g Raciones por Envase 8 / Servings Per Container 8	
Contenido Energético / Energy content	750 kJ (180 kcal)
Proteínas / Proteins	3 g
Grasas / Fats	6 g
Grasa Saturada / Saturated Fat	4 g
Carbohidratos / Carbohydrates	28 g
Azúcares / Sugars	15 g
Fibra Dietética / Dietary Fiber	1 g
Sodio / Sodium	190 mg





Mandatory Nutrients - EU

- Energy – kJ and kcal
- Fat
- Saturates
- Carbohydrates - Available
- Sugars
- Protein
- Salt

Nutrition Information			
	Per 100 g	Per portion of 2 slices (79 g) %Reference Intake RI	
Energy	588 kJ / 138 kcal	470 kJ / 111 kcal	6% RI
Fat	0 g	0 g	0% RI
Of which Saturates	0 g	0 g	0% RI
Carbohydrate	30 g	24 g	9% RI
Of which Sugars	4.1 g	3.2 g	4% RI
Protein	4 g	3.2 g	6% RI
Salt	0 g	0 g	0% RI

Reference intake of an average adult (8,400 kJ / 2,000 kcal)





Energy

- U.S. – Calories; kJ is optional
 - Six acceptable methods to determine for labeling purposes
- Canada – Calories; kJ is optional
 - Atwater Factors, 4-4-9-7, and adjustments
- Mexico – kJ and kcal reported – variety of ways to display
 - 4-4-9 is used to calculate
- EU – kJ and kcal reported
 - Specific factors are used to calculate

Nutrition Labels



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Carbohydrate / Glucides 28 g			
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Ingredient Lists

Naming Ingredients

- Refer to supplier spec sheets 
- Refer to Standards of Identity
- Use common and usual names
- Translate accurately
- Be aware of provisions that allow you to omit incidental ingredients

United States

Meets FCC (Food Chemical Codes) requirements

Standard of Identity 21 CFR 168.121

GRAS Affirmation 21 CFR 184.1865

Labeling:

Corn Syrup Solids or Dried Corn Syrup or
Glucose Syrup Solids or **Dried Glucose Syrup**

Canada

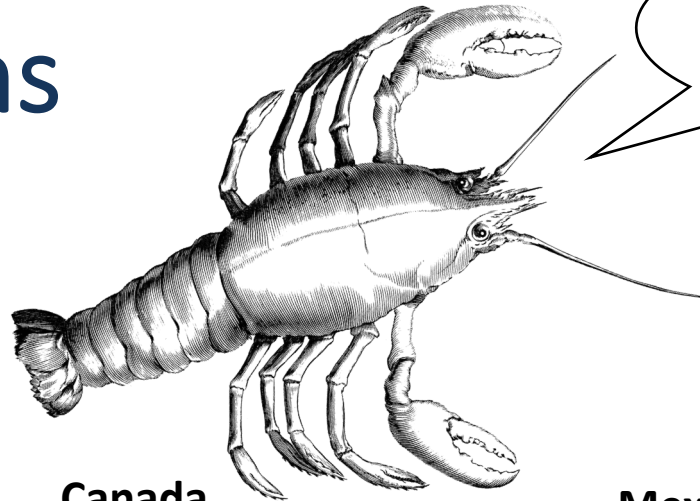
Standard Food CFDA Regulation

Standard of Identity B.18.017

Labeling:

Glucose Solids or **Dried Glucose Syrup**

Allergens



Wait!! Am I allergic to you?

It depends on where you are.



U.S.

Crustacean shellfish
Eggs
Fish
Milk
Tree Nuts
Peanuts
Soybeans
Wheat

Canada

Crustacean and molluscs
Eggs
Fish
Gluten
Milk
Mustard
Peanuts
Sesame
Soy
Sulphites
Tree Nuts
Wheat and Triticale

Mexico

Cereals containing gluten*
Crustaceans*
Eggs*
Fish*
Milk*
Peanut*
Soy*
Sulfite
Tree Nuts*

*and their products or derivatives

EU

Celery
Cereals containing gluten
Crustaceans
Eggs
Fish
Lupin
Milk
Molluscs
Mustard
Nuts
Peanuts
Sesame
Soybeans
Sulphur Dioxide/Sulphites



Allergens – Across the Board

Allergen	U.S.	Canada	Mexico	EU
Celery				X
Crustaceans	X	X	X	X
Eggs	X	X	X	X
Fish	X	X	X	X
Gluten		X	X	X
Lupin				X
Milk	X	X	X	X
Molluscs		X		X
Mustard		X		X
Nuts/Tree Nuts	X	X	X	X
Peanuts	X	X	X	X
Sesame		X		X
Soy	X	X	X	X
Sulphur/Sulphites		X	X	X
Triticale		X		
Wheat	X	X		

Countries may have a specific requirement for stating the allergen.

Fish: sardine, salmon

Nuts: almonds, hazelnuts

Gluten: the source ingredient, e.g. wheat, rye, etc.

Derived products: allergen guidelines may encompass the allergen and all products derived from the allergen



Nutrient Content Claims

Genesis identifies the claims that can be made for your products

Show	Description	Selected Claim	Claims are Available?	Nutrient Amounts
<input type="checkbox"/>	Cholesterol		⊘	0 mg
<input type="checkbox"/>	Sodium (Salt)	Low sodium	✓	5 mg
<input type="checkbox"/>	Potassium		⊘	175 mg
<input type="checkbox"/>	Carbohydrate and sugars		⊘	12 g
<input type="checkbox"/>	Dietary fibre	Contains fibre	✓	2 g
<input type="checkbox"/>	Vitamin A		⊘	%DV
<input type="checkbox"/>	Vitamin D		⊘	0 %DV
<input type="checkbox"/>	Vitamin E		⊘	2 %DV
<input type="checkbox"/>	Vitamin C	Rich in vitamin C	✓	26 %DV
<input type="checkbox"/>	Vitamin B1		⊘	3 %DV
<input type="checkbox"/>	Vitamin B2		⊘	3 %DV
<input type="checkbox"/>	Niacin	Contains niacin	✓	5 %DV

Claims Based On: Canada

OK Cancel





Genesis R&D Training

Genesis Professional Training | Nov 7-8, 2018 | Oak Brook, IL

This training session covers the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, obtaining nutrition analysis, analysis reporting, best practices, and basic labeling features.

Advanced Genesis Workshop | Dec 6-7, 2018 | El Segundo, CA

This workshop session 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.

Learn more: <https://www.esha.com/news-events/training-schedule/>

QUESTIONS?



CONTACT US

Phone: 503-585-6242

Sales: sales@esha.com

Support: support@esha.com

Consulting Services: cs@esha.com



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