

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.

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



Guest Speaker





Headquartered in the U.S., Thrive4Life USA offers highly tailored regulatory services to help companies ensure that their products are in compliance with country-specific labeling regulations.

Expert labeling compliance and translation services are offered for Food, Beverages, Dietary Supplements, Cosmetics, Homeopathic OTC Drugs, and OTC Drugs.

Countries served: USA, Mexico, Canada, and LATAM www.thrive4lifeusa.com



Rosemarie Sunderland President and Principal Consultant Thrive4Life

Certified Food Scientist

Rosemarie is a well regarded global regulatory expert in the Food, Cosmetic, and Drug Industry specializing in Product Labeling and Product Development.

Rosemarie is thoroughly knowledgeable in both US and international labeling and regulatory requirements

Upcoming Webinars



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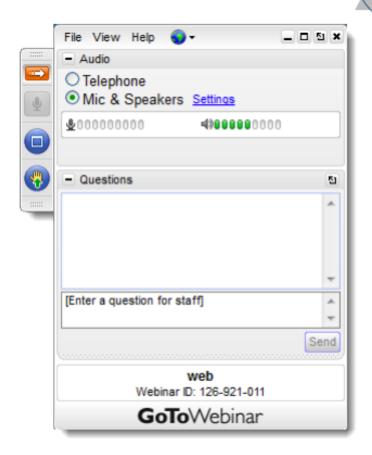
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- √ The webinar is being recorded
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What we'll cover today

- Mexico Labeling Compliance Dates
- Front-of-Package
 - Warning Seals
 - Warning Statements
- Nutrition Facts Label Changes
- Ingredient Statement
- Allergen Statement
- Changes in Genesis R&D
- Q&A



Implementation Dates



Mexico made several amendments to its food labeling regulations (Norma Oficial Mexicana NOM-051-SCFI/SSA1-2010). These regulations became final on March 27, 2020, and will be rolled out in three implementation phases:

- Phase 1 Oct. 1, 2020* Sept. 30, 2023
- Phase 2 Oct. 1, 2023 Sept. 30, 2025
- Phase 3 On and after Oct. 1, 2025

*Note: Due to the short implementation timeline for manufacturers to use existing inventory, the enforcement date has been delayed to Nov. 30, 2020.

Overview of Changes



- Updated Front-of-Package Warning Seals (replacing current icons)
- New Front-of-Package Warning Statements
- Advertising Prohibitions for Products that Bear the Warning Seals and/or Warning Statements
- Updates to the Nutrition Facts Label Format
- Updates to Mandatory Nutrients and Energy Calculation
- Changes to How Sugars Are Displayed in the Ingredient List
- Changes to the Statement of Identity Declaration for Immitation Products.
- Updated List of Allergens and Added Requirement for "May Contain" Statement

Phase 1 - Overview



Implementation Timeline for Front-of-Package Labeling

- Starting Oct. 1, 2020, manufacturers must include the new Front-of-Package (FOP) warning seals and warning statements on all product packaging (some exemptions apply).
 - The seals and statements can be *temporarily* affixed to the package as stickers until March 30, 2021.
- From Oct. 1, 2020, through March 31, 2021, packages may show existing Nutrition Facts and FOP guidelines as long as they also include the new FOP warning symbols and warning statements.

Exemptions



- Bulk food and beverage products
- Food and non-alcoholic beverages packaged at the point of sale
- Pre-packaged foods and non-alcoholic beverages subject to other labeling standards
- Other products determined by the competent authority

Phase 1 - Overview



Implementation Timeline for the Nutrition Facts Label

As of April 1, 2021, changes to Nutrition Facts labels, ingredient and allergen statements, statement of identity, and the FOP symbols and statements must be implemented on all packaging.

Additionally, advertising prohibited due to the package bearing Warning Symbols or Warning Statements must be removed. This includes the use of children, animations, animated drawings, celebrities, athletes, mascots, interactive elements such as games, digital downloads, that are meant to engage and target children.

Warning Seals



New warning seals and statements replace the current FOP icons. The original FOP (Front-of-Package) icons were designed to *inform* consumers of the amounts of selected nutrients. In contrast, the new FOP icons *warn* consumers when the amounts exceed intake recommendations for:

Una porción 100 g



EXCESO CALORÍAS

SECRETARÍA DE SALUD









OLD FOP ICONS

NEW FOP WARNING SEALS
October 1, 2020





100-gram solid products and 100-milliliter liquid products

Energy (kcal)	Sugars	Saturated Fats	Trans Fats	Sodium
 ≥ 275 kcal total (solid product) ≥ 70 kcal total or ≥ 10 kcal from free sugars (liquid product) 	≥ 10% total kcal from free sugars. Beverages with <10 kcal free sugars are exempted from warning signs	≥ 10% total kcal from saturated fats	≥ 1% total kcal from trans fats	≥ 350 mg (solid product) Calorie free beverages: ≥ 45 mg
EXCESO CALORÍAS (Excess Calories)	EXCESO AZÚCARES (Excess Sugars)	EXCESO GRASAS SATURADAS (Excess Saturated Fats)	EXCESO GRASAS TRANS (Excess Trans Fats)	EXCESO SODIO (Excess Sodium)

Phase 1 - Thresholds



Specific threshold limits are to be evaluated based on the ingredients in product formulation.

- For products with Added Sugars, evaluate only Energy and Sugars threshold requirements.
- For products with Added Fats, evaluate only Energy, Saturate Fat, and Trans Fat threshold requirements.
- For Products with Added Sodium, evaluate only Sodium threshold requirements.

Definitions for Sugar



Azucares añadidos (Added Sugars) are defined as "Sugars added during the industrial process"

Azucares (*Free* Sugars), defined as "available mono and disaccharides added to the product plus naturally occurring sugars in honey, syrups, and fruit and vegetables juices.

Phase 2 & 3



- Phase 2 Oct. 1, 2023 Sept. 30, 2025: Specific threshold limits are to be evaluated based on the ingredients in product formulation.
 - For products with Added Sugars, evaluate only Energy and Sugars threshold requirements.
 - For products with Added Fats, evaluate only Energy, Saturate Fat, and Trans Fat threshold requirements.
 - For Products with Added Sodium, evaluate only Sodium threshold requirements.
- Phase 3 On and after Oct. 1, 2025: Products with Added Sugars, Added Fat, or Added Sodium must bare seals for any nutrients that exceed ANY of the threshold requirements.

Phase 2 & 3 Thresholds



100-gram solid products and 100-milliliter liquid products

Energy (kcal)	Sugars	Saturated Fats	Trans Fats	Sodium
 ≥ 275 kcal total (solid product) ≥ 70 kcal total or ≥ 8 kcal free sugars (liquid product) 	≥ 10% total kcal from free sugars.	≥ 10% total kcal from saturated fats	≥ 1% total kcal from trans fats	 ≥ 1 mg of sodium per kcal or ≥ 300 mg (solid products). Calorie free beverages: ≥ 45 mg of sodium
EXCESO CALORÍAS (Excess Calories)	EXCESO AZÚCARES (Excess Sugars)	EXCESO GRASAS SATURADAS (Excess Saturated Fats)	EXCESO GRASAS TRANS (Excess Trans Fats)	EXCESO SODIO (Excess Sodium)

Warning Seal Layouts

The layout and order of the seals are predetermined by the regulations

and cannot be modified. Here are some examples:













Small Packages



Products with a primary display area of ≤ 5 cm² must include one sign with a number that indicates how many nutrients exceed the recommended threshold.















Cautionary warnings/legends to discourage the consumption of caffeine by children.

Caffeine

A warning statement "Contiene cafeína evitar en niños" (Contains caffeine, avoid giving to children) is required if the product contains any caffeine at all.



CONTIENE CAFEINA EVÍTAR EN NIÑOS

Caffeine Defined

Caffeine: For purposes of a
 Warning Statement requirement,
 Caffeine is defined as any caffeine
 ingredient that is ADDED to a
 product formulation.



Sweeteners Warning Statement



Cautionary warnings/legends to discourage the consumption of sweeteners by children.

Sweeteners

A warning statement "Contiene edulcorantes, no recomendable en niños" (Contains sweeteners, not recommended for children), is required on products containing excess sugar.

CONTIENE EDULCORANTES, NO RECOMENDABLE EN NIÑOS

CONTIENE EDULCORANTES, NO RECOMENDABLE EN NIÑOS

Sweeteners Defined

"Sweeteners" are defined in the NOM as substances different from mono and disacharides that impart sweetness to products. These may be considered "Natural" or "artificial".

These include: Acesulfame Potassium, Alitame, Aspartame, Aspartame- Acesulfame, Cyclamate, Sodium Cyclamate, Calcium Cyclamate, Cyclamic Acid, Steviol Glycosides, Stevia, Reb A, Neotame, Potassium Nitrate, Neohesperidin dihydrochalcone, Saccharin, Sucralose, Thaumatin, Sugar Alcohols: Polyglycitol Syrup, Erythritol, Isomaltol, Isomalt, Isomaltose, Lactitol, Maltitol, Manitol, Sorbitol, Xylitol.



Warning Statements Layout Specs



- Shape: Regular octagon
- Background color: Black with white outline
- Font: Arial Bold in white, to contrast with the background.
- Placement: Primary Display Panel (almost always the front)
- Top right corner
- Warning Statement must appear below warning seals

In addition, products with one or more warning seals or those that include the Sweetener Warning Statement, **should not** include any elements directed towards children to promote consumption. This includes characters, cartoons, pictures of celebrities or athletes, games or interactive elements or digital downloads.



Changes to the Nutrition Facts Label

Cobre

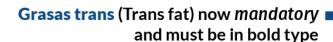


Changed from Información Nutrimental (Nutritional Information) to Declaración **Nutrimental** (Nutritional Declaration)

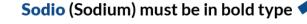
Contenido energético (Calories) must be in bold type and also declared por envase (per container)



Grasas saturadas (Saturated Fat) must be in bold type



Azucares añadidos (Added Sugars) now mandatory and must be in bold type



Declaración Nutrimental

Tamaño de la Porción 1 tazo (245 g) Porciones por Envase 8

Contenido energético por		
envase	1 780 kg	cal (7 482 kJ)
	Por 100 ml	Por Porción
Contenido energético	96 kcal (405 kJ)	222 kcal (931 kJ)
Proteínas	3 g	7 g
Grasas totales	3.5 g	8 g
Grasas saturadas	2 g	4.5 g
Grasas trans	0 mg	0 mg
Hidratos de carbono disponi	bles 14 g	32 g
Azúcares	14 g	32 g
Azúcares añadidos	9 g	22 g
Fibra dietética	0 g	0 g
Sodio	45 mg	100 mg
%\	/NR Por Po	rción*
Vitamina B12	50 %	1 ua

*Valores Nutrimentales de Referencia para la Población Mexicana

15 %

108 µg

NUTRIENT DECLARATION

Changed from Por 100 g/mL OR Por Porción OR Por Envase to Por 100 g/mL with the option to also display a Por Porción or Por Envase column

FONT SIZE

Must be at least 1.5 mm (~5.6 pt) in height, unless:

- PDP area is less than 32 cm²
- More than 20 nutrients must be declared and the PDP area is < 32 cm²
- In returnable packages where nutrition facts is on the cap

VITAMINS & MINERALS

- If declared as quantitative amounts, must reflect por 100 g/mL. If declared as %VNR, must be por Porción
- Voluntary and only permitted if %VNR ≥ 5%
- IDS value for Vitamin D increased to 10mcg

Changes to the Nutrition Facts Label



Mandatory Nutrients

- Kilocalories (kcal) and Kilojoules (kJ)
- Protein
- Total Fat
- Saturated Fat
- Trans Fatty Acid*
- Carbohydrate (Available)
- Total Sugars
- Added Sugar*
- Total Dietary Fiber
- Sodium

Serving Size

- Nutrition Information is listed per 100g or 100mL
- Information may also be listed per portion amount
- Table of Reference Amounts for Food

Declaración Nutrimental		
Tamaño de la Porción 1 tazo Porciones por Envase 8	o (278.19 g)	
Contenido energético por		
envase	1 780 kd	cal (7 482 kJ)
	Por 100 ml	Por Porción
Contenido energético	96 kcal	253 kcal
	(405 kJ)	(1 063 kJ)
Proteínas	3 g	8 g
Grasas totales	3.5 g	9 g
Grasas saturadas	2 g	5 g
Grasas trans	0 mg	0 mg
Hidratos de carbono disponi	bles 14 a	37 a

Nutrient Changes



Mandatory Nutrients

- Trans Fat is a new mandatory nutrient and is reported in mg.
- Added Sugars is a new mandatory nutrient and is reported in g.

Voluntary Vitamins and Minerals

- Vitamin B1, Vitamin B2, Vitamin B6, and Copper are now reported in μg instead of mg.
- The IDS value for Vitamin D has increased from 5 mcg to 10mcg.
- Voluntary vitamins and minerals will only appear on the label if the %VNR is 5% or greater.





Nutrient	Conversion Factor
Available Carbohydrates	4 kcal/g and 17 kJ/g
Protein	4 kcal/g and 17 kJ/g
Fats	9 kcal/g and 37 kJ/g
Alcohol (ethanol)	7 kcal/g and 29 kJ/g
Polyols (sorbitol, xylitol, manitol, isomaltitol, lactitol)	2,4 kcal/g and 10 kJ/g
Erythritol	0 kcal/g and 0 kJ/g
Allulose	0 kcal/g and 0 kJ/g
Tagatose	1,5 kcal/g and 6,276 kJ/g

Genesis R&D

- Allulose and Tagatose, when populated, will be used to calculate calories. Polydextrose can be displayed as a voluntary label nutrient.
- Allulose, Polydextrose, and Tagatose have been added to the nutrients available in the database.

Ingredient Statements



- Ingredients listed in descending order of predominance by weight and composite ingredients must disclose subingredients in parenthesis when they represent more than 5% of the product.
- When Added Sugars are used in the product, the ingredient statement must group them together and display "Added sugars" followed by a list of the specific names, listed by weight, in parenthesis.

Allergens



If the product contains any of these allergens, they must be listed after the ingredient statement in a **bold** font:

- Gluten
- Crustaceans and products
- Eggs and byproducts
- Fish and byproducts
- Molluscs (New)
- Peanut and byproducts
- Soy and byproducts
- Milk/dairy
- Tree nuts and derived products
- Sulfite (in concentrations of 10 mg / kg or more)



Tree nuts must be listed by specific type. Example: Almonds, walnuts, hazelnuts, pecans, etc. When contamination is possible during production, the label must use a "may contain" statement.

Genesis R&D Training (Online)



2-day Professional Training

This 2-day 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.

1-day Advanced Training

This session covers advanced topics such as Advanced Labels, PDCAAS (protein digestibility score), range formulas, international labels, and much more. This session also covers a comprehensive regulatory review.

2-day Professional Dates	1-day Advanced Dates
January 19-20, 2021	January 21, 2021
February 23-24, 2021	February 25, 2021
March 23-24, 2021	March 26, 2021

Contact <u>training@esha.com</u> with any questions or to inquire about personalized training for your organization See the Training Schedule at: https://esha.com/news-events/training-schedule/

QUESTIONS?



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