

Declaring Voluntary Nutrients on Your Nutrition Facts Label

Presented by ESHA Research



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

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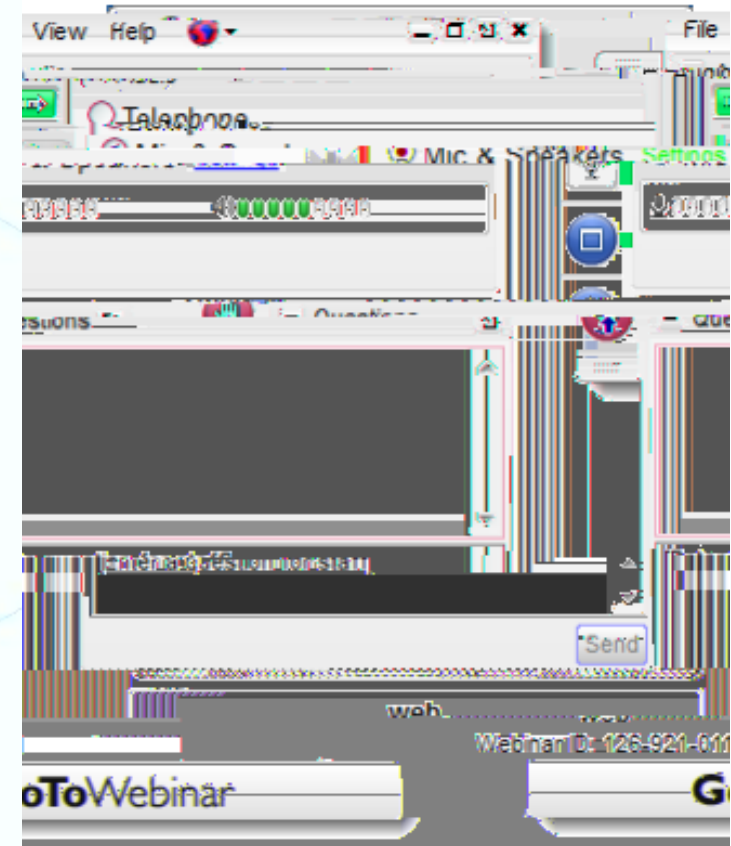
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and topics continue
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- We'll email a copy of the recording and the slides following the webinar



What We'll Cover Today



Allowed Voluntary Nutrients for U.S. labeling

When Voluntary Nutrients can or must be declared on the label

Nutrients that cannot be declared on the label and how to list them on packaging

How to include Voluntary Nutrients on your label using Genesis R&D

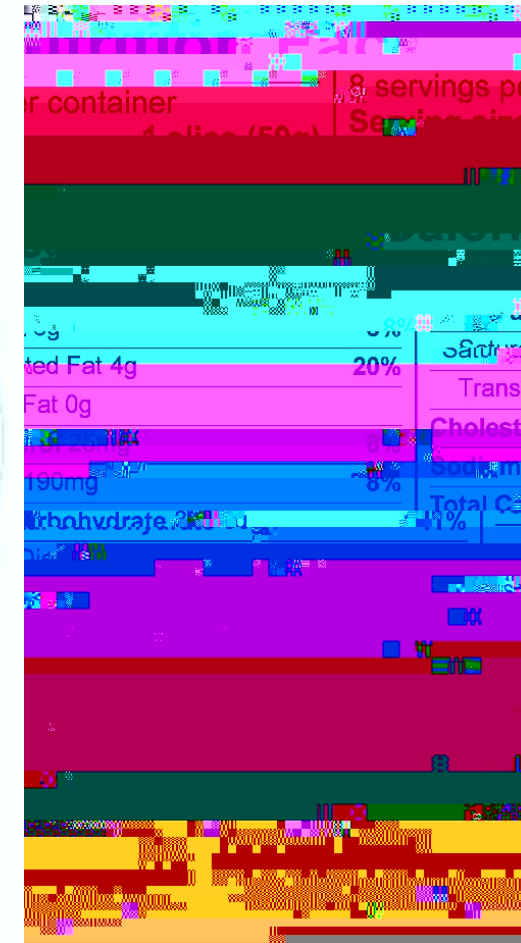
Q&A

Mandatory U.S. Label Nutrients



2016 FDA final rule lists the nutrients that must be reported on the majority of food product labels

Quantitative amount per serving is declared in most cases; %DV declared for those that apply



Voluntary U.S. Label Nutrients



Calories from saturated fat

Polyunsaturated fat

Monounsaturated fat

Fluoride

Soluble fiber

Insoluble fiber

Sugar alcohol

Individual sugar alcohol may be listed within the label if the food only contains one type

Vitamin A

Beta Carotene % from

Vitamin C

Vitamin E

IU

Vitamin K

Thiamin

Riboflavin

Niacin

Vitamin B6

Folate

Folic Acid

Vitamin B12

Biotin

Pantothenic acid

Phosphorus

Iodine

Magnesium

Zinc

Selenium

Copper

Manganese

Chromium

Molybdenum

Chloride

Choline

Vitamin D IU

DRVs and RDIs Reference Amounts

Reference Daily Intakes (RDIs)		
Nutrient	Unit of measure	Adults & children (4+ years)
Vitamin D	Micrograms (mcg)	20
Calcium	Milligrams (mg)	1,300
Iron	Milligrams (mg)	18
Potassium	Milligrams (mg)	4,700
Vitamin A	Micrograms RAE (mcg)	900
Vitamin C	Milligrams (mg)	90
Vitamin E	Milligrams (mg)	15
Vitamin K	Micrograms (mcg)	120
Thiamin	Milligrams (mg)	1.2
Riboflavin	Milligrams (mg)	1.3
Niacin	Milligrams NE (mg)	16
Vitamin B6	Milligrams (mg)	1.7
Folate	Micrograms DFE (mcg)	400
Vitamin B12	Micrograms (mcg)	2.4
Biotin	Micrograms (mcg)	30
Pantothenic acid	Milligrams (mg)	5
Phosphorus	Milligrams (mg)	1,250
Iodine	Micrograms (mcg)	150
Magnesium	Milligrams (mg)	420
Zinc	Milligrams (mg)	11
Selenium	Micrograms (mcg)	55
Copper	Milligrams (mg)	0.9
Manganese	Milligrams (mg)	2.3
Chromium	Micrograms (mcg)	35
Molybdenum	Micrograms (mcg)	45
Chloride	Milligrams (mg)	2,300
Choline	Milligrams (mg)	550



Rounding and Declarations

Fats and Fatty Acids, Carbohydrates – Fiber, Sugar, Sugar Alcohols, Protein, etc.

Rounding rules listed in each nutrient section of 101.9

Vitamins and Minerals

Final Rule

Using levels of significance given in the CFR; additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts

FDA Guidance – December 2019

Includes options and instruction for levels of significance and rounding

The table provides recommendations for the declaration of quantitative amounts of vitamins and minerals. It lists various nutrients and their corresponding rounding rules, such as 'Nearest 1 mg', 'Nearest 0.1 mg', 'Nearest 10 mg', etc. The table is organized into columns for different nutrient categories and their respective rounding instructions.





When Must They Be Declared?

Polyunsaturated or Monounsaturated

If either is declared, the other must also be declared

Folic Acid

Declaration of Components Outside of the Nutrition Facts

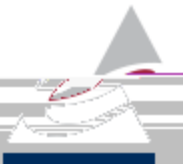
Nutrients and components that do not have an RDI/DRV and are not allowed within the Nutrition Facts label can be declared on packaging

Outside of the Nutrition Facts label

Factual statement regarding the amount or percent of content per serving is allowed

Must be truthful and not misleading

May not characterize the level of nutrient or component, such as with a “High in” or “Excellent source of” type claim



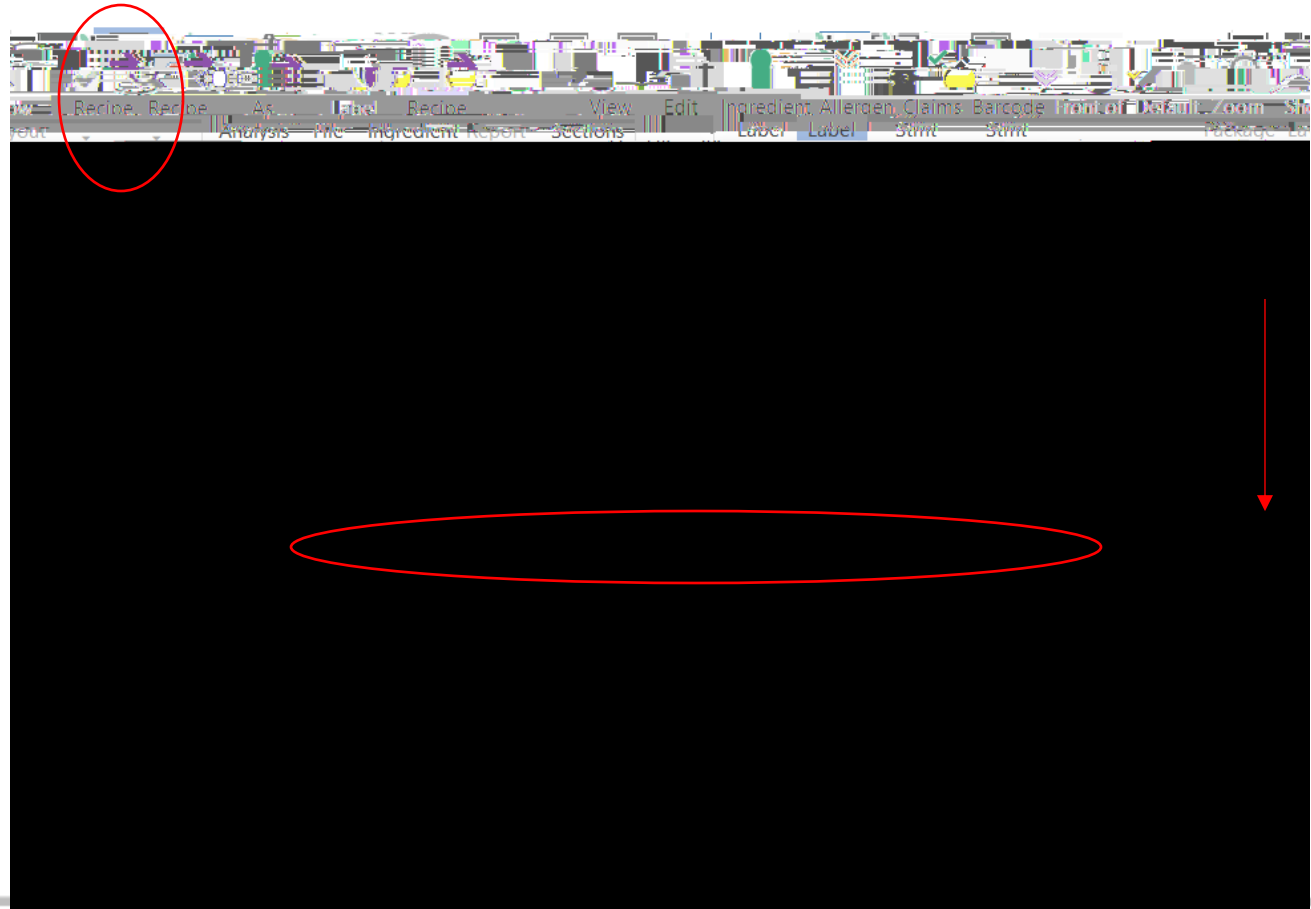
Genesis R&D – Populate



Vitamins and Minerals Rounding

To select the FDA Guidance rounding for vitamins and minerals option:

- Edit Label
- Format Options
- U.S. section





Best Practices for Documentation

Supplier sheets for ingredients that you add to your software

Lab results and notes regarding any determinations or adjustments that you've applied to your Recipes

Use the User-Code field in Genesis R&D to help track Ingredients and Recipes

Use the Attachments function to link supporting documentation directly to Ingredient and Recipe records in Genesis R&D

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

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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.

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