Declaring Voluntary Nutrients on Your Nutrition Facts Label

Presented by ESHA Research

Wednesday, June 8, 2022
11:00 AM PT | 1:00 PM CT | 2:00 PM ET
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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✓ All webinars available on our website
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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

- Not all label nutrients have a Daily Value, so %DV is not reported for all
- For those that have %DV listed, DRVs (Daily Reference Values) and RDIs (Reference Daily Intakes) are listed in the CFR

### Daily Reference Values (DRVs)

<table>
<thead>
<tr>
<th>Food component</th>
<th>Unit of measure</th>
<th>Adults &amp; children (4+ years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat</td>
<td>Grams (g)</td>
<td>78</td>
</tr>
<tr>
<td>Saturated fat</td>
<td>Grams (g)</td>
<td>20</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Milligrams (mg)</td>
<td>300</td>
</tr>
<tr>
<td>Total carbohydrate</td>
<td>Grams (g)</td>
<td>275</td>
</tr>
<tr>
<td>Sodium</td>
<td>Milligrams (mg)</td>
<td>2300</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>Grams (g)</td>
<td>28</td>
</tr>
<tr>
<td>Protein</td>
<td>Grams (g)</td>
<td>50</td>
</tr>
<tr>
<td>Added Sugars</td>
<td>Grams (g)</td>
<td>50</td>
</tr>
</tbody>
</table>

### Reference Daily Intakes (RDIs)

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

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When Must They Be Declared?

- Polyunsaturated or Monounsaturated
  - If either is declared, the other must also be declared
- Folic Acid
  - If added directly to the food, Folate and Folic Acid must be declared
- Claims
  - If claims are made about a nutrient, then that nutrient and in some cases, related nutrients must be declared

“Cholesterol Free” Mono and Polyunsaturated Fats might be required
“Sugar Free” Sugar Alcohol might be required
“High in Antioxidants...” list the specific vitamin(s)

Know the Claims conditions and requirements and report the necessary nutrients to support the claims
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

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Genesis R&D – Populate All Declared Fields

- Best practice is to populate all nutrient fields for which you have information.
- However, if you choose to declare voluntary nutrients, you **must** ensure that ingredients have been reviewed and report information for those voluntary nutrients appropriately.
- Contact suppliers for additional nutrient detail when needed.
- Populate nutrient information using the correct unit and corresponding field.
Nutrients to View

- Consider the nutrients that you need to populate for complete and correct labeling
- Label – US 2016 All
- Create a custom Nutrients to View set to include the nutrients that you must report for specific foods or formulations
Complete and correct entry of Ingredients contributes to accurate and compliant recipe analysis and labels. Review the Spreadsheet report for ALL Recipes to ensure that required information is reported. Identify missing values (indicated by dashes) and populate the **Ingredient record** to fill in the blanks.
Genesis R&D Uses Regulatory Label Units and Rounding

• Uses proper label units
• Applies proper rounding
• Label features provide allowed options for declaration
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

*(Prerequisite: Professional Training)

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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