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
Upcoming Webinars

• July 14, 2021 | How to Comply with the FASTER Act using Genesis R&D Foods
• August 11, 2021 | Using the Moisture Adjustment Feature for Baked Products
• September 15, 2021 | Database Organization, Groups vs Attributes

To view archived webinars or sign up to receive notifications, visit: www.esha.com/news-events/webinars
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
What We’ll Cover Today

- Overview of the RACC
- Servings on the Nutrition Facts Label
- Volume vs. Weight Measures
- Dual Column Labels
- Servings per Container
- Q&A
Serving Sizes

Nutrition Facts

Serving: varied, Serv. size: 1 oz (28g),
Amount per serving: Calories 110, Total Fat 9g (12% DV), Saturated

Nutrition Facts

Serving size 1/16 of Package (28g Mix)

Amount/serving Mix Prepared
Calories 90 120
% DV% DV

Nutrition Facts

Serving size 1 bagel (113g)

Amount per serving Calories 240
% Daily Value

Nutrition Facts

About 3 servings per container
Serving size 12 fl oz (360mL)

Amount per serving Calories 180 490
% Daily Value

©2021 ESHA Research
Reference Amounts Customarily Consumed (RACC)

- U.S. labeling uses the RACC to base serving sizes
  - Product serving might not match the RACC exactly, but serving size should be as close to the RACC as possible
  - Unit size may determine serving size or how many units are closest to the RACC
- RACC is listed by food category and in most cases for ready to serve or almost ready to serve form
- For foods that require preparation (e.g. a dry mix), serving size = the amount needed to make one serving of the RACC
- Serving size on the Nutrition Facts lists a household and a metric amount
Working with the RACC

- Table 1: foods for Infants (0 – 12 months) and Young Children (1 – 3 Years)
- Table 2: for General Food Supply
- See Footnotes

21 CFR 101.12

Table 2 - Reference Amounts Customarily Consumed Per Eating Occasion: General Food Supply

<table>
<thead>
<tr>
<th>Product category</th>
<th>Reference amount</th>
<th>Label statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakery Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bagels, toaster pastries, muffins (excluding English muffins)</td>
<td>110 g</td>
<td>_ piece(s) (_ g)</td>
</tr>
<tr>
<td>Biscuits, croissants, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies, scones, crumpets, English muffins</td>
<td>55 g</td>
<td>_ piece(s) (_ g)</td>
</tr>
<tr>
<td>Breads (excluding sweet quick type), rolls</td>
<td>50 g</td>
<td>_ piece(s) (_ g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/inch slice) for unsliced bread</td>
</tr>
<tr>
<td>Bread sticks - see crackers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toaster pastries - see bagels, toaster pastries, muffins (excluding English muffins)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brownies</td>
<td>40 g</td>
<td>_ piece(s) (_ g) for distinct pieces; fractional slice (e.g., ½) for bulk</td>
</tr>
</tbody>
</table>

Example: 1 bagel (113 g)
Example: 2 slices (56 g)

*The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in §101.9(b) using the reference amount determined according to § 101.12(c).
Volume vs. Weight Measures

- Some foods express serving size in volume
- Some foods express serving size in weight
- Refer to the category and the reference amounts

<table>
<thead>
<tr>
<th>Product category</th>
<th>Reference amount</th>
<th>Label statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverages:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbonated and noncarbonated beverages, wine coolers, water</td>
<td>360 mL</td>
<td>12 fl oz (360 mL)</td>
</tr>
<tr>
<td>Coffee or tea, flavored and sweetened</td>
<td>360 mL prepared</td>
<td>12 fl oz (360 mL)</td>
</tr>
<tr>
<td>Cereals and Other Grain Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakfast cereals (hot cereal type), hominy grits</td>
<td>1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal</td>
<td>_cup(s) (_g)</td>
</tr>
<tr>
<td>Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains</td>
<td>15 g</td>
<td>_cup(s) (_g)</td>
</tr>
<tr>
<td>Breakfast cereals, ready-to-eat, weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g</td>
<td>40 g</td>
<td>_cup(s) (_g)</td>
</tr>
</tbody>
</table>
Household and Metric Measures

Regulations require the serving size be displayed as a common household measure (e.g. cup, teaspoon, piece, slice) next to the metric weight (in grams) or metric volume (in milliliters).

For example: 1 cup (245g) or 12 fl oz (360 mL)

- The **household measure** may be listed as a standard unit (tbsp, cup, fl oz, oz) Or a unit that is descriptive of the food (slice, piece, roll, cookie)
- The **metric unit** relates to the household unit and provides context and consistency
Standard and Descriptive Units

• **For most food items**, Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate (except for beverages, use fl oz)
  - Cups shall be expressed in 1/4-cup or 1/3-cup increments
  - Tablespoons shall be expressed as 1, 1 1/3, 1 1/2, 1 2/3, 2, or 3 tablespoons
  - Teaspoons shall be expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teaspoons
  - If cups, tablespoons or teaspoons are not applicable, then use units such as piece, slice, tray, jar

• **For single serving containers**, a description of the container or package is used: can, bottle, box, pouch, etc.

• **For beverages**, a manufacturer may use fluid ounces

• **For composite items**, like dry mix consisting of multiple components, like macaroni and cheese, use the composite weight, and descriptive info in parenthesis: 4 oz (112 g/about 2/3 cup macaroni and 2 tbsp dry cheese mix

• **For large items usually divided for consumption**, like a whole cake, pie, pizza, use a fraction of the whole

• **If none other applies**, then weight in ounces may be used with a visual reference, e.g. 1 oz (28 g/½ pickle)
Unit Abbreviations and Definitions

If using abbreviations, the following shall be used:
  • tbsp for tablespoon
  • tsp for teaspoon
  • g for gram
  • mL for milliliter
  • oz for ounce
  • fl oz for fluid ounce

For nutrition labeling:
  • a teaspoon means 5 milliliters (mL)
  • a tablespoon means 15 mL
  • a cup means 240 mL
  • 1 fl oz means 30 mL
  • 1 oz means 28 g
Unit and Serving Size is Clear to Consumers

Would This Be:
- 1 piece?
- 1 each?
- 2 squares?
- 1 bar?
- 1 brownie?
Serving Size ≠ RACC

• What do you do when your portion, unit, or container size is significantly different from the RACC?
  • Unit weighs \( \leq 50\% \) of RACC: serving = number of units closest to RACC
  • >50% to <67% of RACC: serving = 1 or 2 units
  • 67% to <200% of RACC: serving = 1 unit
  • 200% to 300% of RACC: serving = closest to RACC
    • Dual column label required
      • 1\textsuperscript{st} column shows RACC based serving size
      • 2\textsuperscript{nd} column shows the entire unit or container
Dual Column Requirements

**Unit:** If a unit weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, the serving size shall be the amount that approximates the reference amount. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving size, the manufacturer shall provide a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per individual unit. The first column would be based on the serving size for the product and the second column would be based on the individual unit.

**Example:**
- Cookie RACC = 30g
- 1 cookie weighs 70g
- = 233% of RACC

**Result:**
- Serving size = portion closest to RACC;
- Dual column required

**Container:** Products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable reference amount must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values for the entire package, as well as a column listing the quantitative amounts and percent Daily Values for a serving that is less than the entire package (i.e., the serving size derived from the reference amount). The first column would be based on the serving size for the product and the second column would be based on the entire contents of the package.

**Example:**
- Soup RACC = 245g
- 1 cup weighs 255g
- Container weighs 510g = 208% of RACC

**Result:**
- Serving size = portion closest to RACC;
- Dual column required
Dual Column Exemptions

Does not apply to:

• Products that meet requirements to use tabular or linear label format
• Voluntarily labeled products: fruits, vegetables, seafood
• Products that already provide an additional column
  • Bears label with “as packaged” and “as prepared” columns
  • Bears label with columns for more than one age group
  • Popcorn with two columns; unpopped and popped information
  • Varied weight products – servings per container varies, so containing 200% to 300% of RACC wouldn’t be be consistent
Servings Per Container

• Servings per Container based on serving size and net contents of container
• Rounded to the nearest whole number
  • Except when number of servings is between 2 and 5
    • Between 2 and 5, then round to the nearest 0.5 serving
    • Rounding between 2 and 5 should be indicated by “about”, e.g., “about 2 servings” or “about 3.5 servings”
• Varied – random weight products that vary in size, e.g., cheese
Genesis R&D Training

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)

<table>
<thead>
<tr>
<th>Date</th>
<th>Training Session Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 22-24, 2021</td>
<td>Genesis R&amp;D Foods Professional and/or Advanced</td>
</tr>
<tr>
<td>July 20-22, 2021</td>
<td>Genesis R&amp;D Foods Professional and/or Advanced</td>
</tr>
<tr>
<td>Sept. 21-23, 2021</td>
<td>Genesis R&amp;D Foods Professional and/or Advanced</td>
</tr>
</tbody>
</table>

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

Phone: 503-585-6242
Sales: sales@esha.com
Support: support@esha.com
Consulting Services: cs@esha.com
Training: training@esha.com

HELPFUL RESOURCES

LinkedIn: linkedin.com/company/esha-research/
eLearning Center: esha.com/resources/esha-elearning-center/
Blog: esha.com/blog
eNewsletter: esha.com/esha-newsletter