Food Labeling 101
Nicole Turner-Ravana, MS
Owner/Director, Strategic Nutrition Communications LLC
FDA Legislation Updates - Nutrition Labeling

On May 27, 2016, the U.S. Food and Drug Administration published the new Nutrition Facts Label for packaged foods and Supplement Facts Label for supplements in order to reflect new scientific information and include the link between diet and chronic disease.

Notes:

- Compliance by July 2018. (<$10 million 2019)
- **21 CFR 101**
- USDA’s proposed rule draft released 12/1/16
Key Information Considered

- Scientific evidence, such as consensus reports
- Public comments
- Citizen petitions
- Survey data
- Findings from consumer studies
Then vs Now
RACC & Serving Size Changes

• Some reference amounts stayed the same.
• Some have been changed.
  • Confections
  • Drinks
  • Ice Cream
  • Check each time.

Draft Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category

Dual Column & Single Serving

- Required for packages that can be consumed in one sitting:
  - 200-300% of the serving size
  - lists the nutrition values per serving and for the entire package

- Required for packages that are between 1 & 2 servings:
  - List the nutrition values for the entire package
Nutrients to Declare

- Optional now: vitamin A, vitamin C
- Required now: potassium, vitamin D
- Changes the units used to declare folate, niacin, vitamin A, E and D
- For all required and voluntary vitamins and minerals, declaration needs to include the absolute amounts in addition to the %DV
  - The actual value won’t match exactly to the rounded % DV since rounding requirements for micronutrients will remain the same.
  - Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals (PAGE 21)
  
Updates to the Daily Reference Values and Reference Dietary Intake values (changes in blue)

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Unit of measure</th>
<th>Adults and children 1 year</th>
<th>Infants through 12 months</th>
<th>Children 1 through 5 years</th>
<th>Pregnant women and lactating women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Micrograms RAE</td>
<td>300</td>
<td>500</td>
<td>300</td>
<td>1,500</td>
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<td>Vitamin D</td>
<td>Micrograms</td>
<td>90</td>
<td>50</td>
<td>15</td>
<td>120</td>
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<td>Calcium</td>
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<td>260</td>
<td>700</td>
<td>1,300</td>
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<tr>
<td>Iron</td>
<td>Milligrams</td>
<td>13</td>
<td>7</td>
<td>27</td>
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<tr>
<td>Vitamin D</td>
<td>Micrograms</td>
<td>10</td>
<td>10</td>
<td>15</td>
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</tr>
<tr>
<td>Vitamin E</td>
<td>Milligrams</td>
<td>1</td>
<td>1</td>
<td>2</td>
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<tr>
<td>Vitamin K</td>
<td>Micrograms</td>
<td>3</td>
<td>3</td>
<td>9</td>
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<tr>
<td>Thiamin</td>
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<td>1</td>
<td>2</td>
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<tr>
<td>Riboflavin</td>
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<td>0.5</td>
<td>1.6</td>
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<tr>
<td>Niacin</td>
<td>Milligrams (NE)</td>
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<td>6</td>
<td>18</td>
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<tr>
<td>Vitamin B6</td>
<td>Milligrams</td>
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<td>2</td>
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<tr>
<td>Folate</td>
<td>Micrograms (DFE)</td>
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<tr>
<td>Vitamin B12</td>
<td>Micrograms</td>
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<td>0.5</td>
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<tr>
<td>Selenium</td>
<td>Milligrams</td>
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<td>0.04</td>
<td>0.08</td>
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<tr>
<td>Phosphorus</td>
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<td>270</td>
<td>460</td>
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<td>130</td>
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<td>250</td>
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<tr>
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<td>Milligrams</td>
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<td>0.05</td>
<td>0.05</td>
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<tr>
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<td>3,000</td>
<td>1,300</td>
<td>2,000</td>
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<td>Milligrams</td>
<td>2,300</td>
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<td>N/A</td>
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<tr>
<td>Dietary Fiber</td>
<td>Grams</td>
<td>20</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Protein</td>
<td>Grams</td>
<td>50</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
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<tr>
<td>Added Sugars</td>
<td>Grams</td>
<td>50</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
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</table>

1. RDIs are based on dietary reference intake recommendations for infants through 12 months of age.
2. Source: vitamin D, the same as for 2015-2016 RDIs, 90 micrograms (0.355 micrograms of 25-hydroxyvitamin D). For the 2015-2016 RDIs, 10 micrograms of vitamin D was considered to be sufficient (0.0375 micrograms of 25-hydroxyvitamin D).
3. Recommendations for infants through 12 months of age.
4. Source: vitamin D, the same as for 2015-2016 RDIs, 90 micrograms (0.355 micrograms of 25-hydroxyvitamin D). For the 2015-2016 RDIs, 10 micrograms of vitamin D was considered to be sufficient (0.0375 micrograms of 25-hydroxyvitamin D).
5. Based on the reference caloric intake of 2,600 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.
6. Based on the reference caloric intake of 1,800 calories for children 1 through 3 years of age.
Calculating Calories
Now

• Calories from carbohydrate will be calculated using a general factor of 4 calories/g of total carbohydrate less the amount of non-digestible carbohydrates and sugar alcohols, and the caloric value of each (the non-digestible carbohydrates and sugar alcohols) is then added to the sum of the carbohydrates.

• calories calculated from sugar alcohols has been revised as follows:
  • Isomalt—2.0 kcal/gram, lactitol—2.0 kcal/gram, xylitol—2.4 kcal/gram, maltitol—2.1 kcal/gram, sorbitol—2.6 kcal/gram, hydrogenated starch hydrolysates—3.0 kcal/gram, and mannitol—1.6 kcal/gram.
Dietary Fiber

- only those dietary fibers that FDA has determined to have a physiological effect that is beneficial to human health would be considered to be “dietary fiber”

- FDA adopted a definition for dietary fiber that is equivalent to the IOM’s definition of “total fiber” and therefore would include fibers that the IOM defines as “dietary fiber” and “functional fiber:”

- Intact, Intrinsic
Dietary Fiber

• The new definition of dietary fiber removes inulin (for now), oligofructose, polydextrose and fructooligosaccharides.

• Included in the dietary fiber definition: Psyllium husk, Cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose.

• Fibers not currently covered in the new dietary fiber definition while FDA is seeking additional comment and data on them includes: inulin, bamboo fiber, soy fiber, pea fiber, wheat fiber, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber.

• Fibers that are added for functionality but are outside of the definition of “dietary fiber” can still be added as long as they are GRAS but they should not be counted in the dietary fiber calculation, rather only included in the Total Carb listing.

• New guidance: enforcement discretion for mixed plant cell wall fibers; arabinoxylan; alginate; inulin and inulin type fructans; high amylose starch (resistant starch 2); galactooligosaccharide; polydextrose; and resistant maltodextrin/dextrin.
Added Sugars

- A percent Daily Value for added sugars of 10% of total energy intake from added sugars
  - 50 grams in children and adults 4 years of age and older
  - 25 grams for foods purported to be for children 1 through 3 years of age
- Exclude naturally occurring sugars
Added Sugars

- = sugars that are added during the processing of foods
- Does not include
  - 100% fruit or vegetable juices (single strength as well as frozen fruit juice concentrates from 100% juice [additional sugar contributed to fruit juice concentrates not reconstituted to full strength would have to be declared as an added sugar])
  - concentrated fruit or vegetable juices are included in the added sugar definition.
- Naturally occurring dairy ingredients.
Records Compliance

- Additional record keeping is required for nutrients that do not have analytical verification available.
- Includes:
  - Added sugars
  - Certain types of fibers
  - Vitamin E
  - Folic acid / folate
What was left behind.....

- This legislation did not address
  - health claims
  - front of pack labeling
  - GMO labeling
  - use of “natural”
  - any changes to allergen labeling, whole grains, nutrient content claims, expiration dates, artificial sweeteners.
- The new DRV’s could impact existing claims though.
These format notations are requirements for how to create a compliant Nutrition Facts box now.

- Specific rounding requirements
If there is insufficient vertical space (about 3 inches) to accommodate the vertical format, a tabular layout can be used.
For Small Packages: Tabular & Linear

Small packaging format can be used if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the label will not accommodate a tabular display.
Other required elements not to forget:

- Accurate identity
- Net Wt
- Ingredients
- Address – manufacturer or distributor
- Country of origin
- Accurate claims
Unique to States

- California’s Prop 65
- Eggs
- Alcohol
- Dairy
Cottage Foods

- Eligibility
- Specific ingredient designations
- Specific labeling requirements
- https://www.colorado.gov/pacific/cdphe/cottage-foods-act
Truth In Advertising

- Claims
  - Nutrition related
  - Allergen related
  - Romance copy
  - Images
  - “More”, “Better”
  - Organic
  - GMO
- FTC
  - Made in the USA
- Litigation
- All messaging applies
  - Social Media too!
Creating a Positive Brand Image

Know Your Customers
- What do they value?
- What are they looking for?

What is your Persona
- Images
- Logos
- Graphics

Key Messages
- Positive Yes vs No statements
  - High in Fiber vs No Trans Fats

How are you sharing all of this
- Packaging
- Website
- Marketing
Nicole Turner-Ravana
Nicole@strategicnutrition.org
818.825.9136 / 970.219.2202