Final Rules to Update the Nutrition Facts Label

Dr. Douglas Balentine, Director
Office of Nutrition and Food Labeling
Food and Drug Administration
Nutrition Labeling and Education Act of 1990 (NLEA)

- Explicit authority for nutrition labeling
- Requires disclosure of certain nutrients
- Provides some discretion to add or remove nutrients that are required to be declared on the label
- Requires that information be provided in context of total daily diet
Why Update the Nutrition Facts Label?

- Scientific information on diet and health has improved, including link between diet composition and risk of chronic diseases and public health.

- Amount of foods consumed have changed and FDA’s Reference Amounts Customarily Consumed, used to set serving sizes, need adjustment.

- Priorities for dietary guidance have changed, with focus shifting to calories and serving sizes as two important elements in making healthier food choices.
Regulatory Process

• Two proposed rules issued in March 2014
• Supplemental proposed rule issued in July 2015
• Two final rules published on May 27, 2016
  – Revision of the Nutrition and Supplement Facts Label
  – Revision of Serving Size Requirements
Populations

• General population 4 years of age and older, including those at risk of chronic disease
  – At risk includes those overweight and obese (>2/3 of adults)
  – Label not meant to treat individuals with chronic disease

• Pregnant and lactating women
  – Different Daily Values

• Young children (1-3 years)
• Infants (through-12 months of age)
Key Information Considered

- Scientific evidence, including consensus reports
- Public comments to advance notices of proposed rulemaking
- Citizen petitions (e.g., manufacturers, advocacy groups, individuals)
- Data from National Health and Nutrition Examination Survey (NHANES)
- Findings from consumer studies
Key Changes

• Mandated declaration of added sugars with % DV
• Modernized the format to highlight calories and serving size information; updated footnote
• Updated the Daily Values
• Updated nutrients of public health significance
• *Trans* fat and dietary fiber
• Records requirements
Key Changes (cont.)

• Changed some reference amounts used to calculate serving sizes
• Require dual-column labeling with nutrition information listed per serving and per package or unit for certain products
• Changed the criteria for single serving packages
• Compliance date
NEW LABEL / WHAT'S DIFFERENT

Servings: larger, bolder type

New: added sugars

Change in nutrients required

Serving sizes updated

Calories: larger type

Updated daily values

Actual amounts declared

New footnote
Added Sugars Mandatory

• Based on evidence that:
  − High intake of added sugars decreases intake of nutrient dense foods and increases overall caloric intake
  − Dietary patterns lower in sugar-sweetened foods and beverages are associated with a reduced risk of cardiovascular disease

• Daily Value:
  − Meeting nutrient needs while staying within calorie limits is difficult with more than 10 percent of total daily calories from added sugar
Added Sugars Mandatory

- FDA adding “includes” to help clarify that “added sugars” is a subcomponent of “total sugars”
- Changed “Sugars” to “Total Sugars”
- Also removed part of the hairline between “total sugars” and “added sugars”
**Added Sugars Definition**

Includes sugars that are either added during processing of foods, or are packaged as such, and includes:

<table>
<thead>
<tr>
<th>- syrups</th>
<th>- honey</th>
</tr>
</thead>
<tbody>
<tr>
<td>- brown sugar</td>
<td>- molasses</td>
</tr>
<tr>
<td>- high fructose</td>
<td>- sucrose</td>
</tr>
<tr>
<td>corn syrup</td>
<td>- lactose</td>
</tr>
<tr>
<td>- invert sugar</td>
<td>- maltose sugar</td>
</tr>
<tr>
<td>- maltose</td>
<td>- concentrated</td>
</tr>
<tr>
<td>- trehalose</td>
<td>fruit juice*</td>
</tr>
</tbody>
</table>

*Sugars from concentrated fruit or vegetable juices in excess of what would be expected from 100 percent fruit or vegetable juice. Excludes fruit or vegetable juice concentrated from 100 percent fruit juice that is sold to consumers (e.g., frozen concentrated orange juice).*
Calories and Serving Sizes

• Focus attention on information that is important for addressing current public health problems like obesity

• Increase the type size of “Calories,” “servings per container,” and the “Serving size” declaration

• Reverse the order of “Serving size” and “servings per container”

• Bold the “Calories” and the “Serving size” declaration
Updated Footnote

- Updated footnote better explains the % Daily Value and helps put calories in context of the daily diet.
Updating the Daily Values

- Using most recent science
- Continue to use the population-coverage approach for Vitamins and Minerals
  - Total Fat: 65-78 g
  - Total Carbohydrate: 300-275 g
  - Dietary Fiber: 25 to 28 g
  - Sodium: 2,400-2,300 mg
  - Potassium: 3,500-4,700 mg
  - Calcium: 1,000-1,300 mg
  - Vitamin D: 400 IUs (10 µg)-20 µg
Nutrients of Public Health Significance

- Vitamin D and Potassium are now mandatory on the label
- Calcium and Iron will remain on the label
- Vitamins A and C are no longer mandatory on the label but can be declared voluntarily
- Including absolute amounts for nutrients of public health significance in addition to % Daily Value
Trans Fat

- Is remaining on label since ruminant sources can contribute to intake
- May also have small amounts of industrial produced trans fats if food additive petitions are approved
Dietary Fiber

• Updating the definition to reflect fiber that has physiological effects that are beneficial to human health

• Intend to publish a separate notice to provide a review of the research for about 25 fibers
Records Requirement

• Requires manufacturers, in certain circumstances, to make and keep records to verify mandatory declaration of added sugars as well as for certain fibers, vitamin E and folic acid and folate for which analytical methods not available

• First time records are needed to verify declaration of mandatory nutrients (added sugars and dietary fiber, if certain fibers are added)
Serving Size Changes

What’s considered a single serving has changed in the decades since the original nutrition label was created. So now serving sizes will be more realistic to reflect how much people typically eat at one time.

CURRENT SERVING SIZE

4 SERVINGS
1 PINT
200 CALORIES

NEW SERVING SIZE

3 SERVINGS
1 PINT
270 CALORIES
Serving Sizes

• Per Nutrition Labeling and Education Act, serving sizes are calculated based on the Reference Amounts Customarily Consumed (RACCs) and are required on the Nutrition Facts label

• Approximately 30 out of 158 RACCs will change, e.g.,
  – Bulk ice cream from 1/2 cup to 2/3 cup
  – Carbonated beverages from 8 ounces to 12 ounces
  – Yogurt from 8 ounce to 6 ounces

• Approximately 25 new RACCs
  – Petitions and new foods
Labeling Single-Serving Packages

Calories and other nutrients must be declared for the entire package rather than per serving because people typically consume the package in one sitting.
Dual Column Labeling

• Required on packages that can be consumed in one or multiple sittings
• Nutrition information presented per serving and per package
• For packages that contain 200% and up to and including 300% of the RACC
  • A 3oz (90g) bag of chips would be labeled per serving [1oz (30 g)] and per package [90 g]
Compliance Date

• Original proposal: 2 years for all manufacturers to comply

• Final Rule: 2 years for all manufacturers except:
  – Businesses with less than $<10M in revenue have 3 years to come into compliance.

• The additional year balances need for consumers to have this information and small businesses’ need for additional time to comply
Questions

Mailbox for questions on the rules: NutritionProgramStaff@fda.hhs.gov