

# THE REVISED NUTRITION FACTS PANEL AND UPDATE ON LABELING OF FOODS FROM GENETICALLY ENGINEERED PLANTS

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# FDA's Proposed Changes to the NFP – Compliance Date

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- In March 2014 and July 2015, the FDA proposed rules to update the Nutrition Facts Panel (“NFP”).
- In January 2016, Dr. Stephen Ostroff wrote that “when finalized,” the changes will give Americans updated nutrition information, reflecting the most current nutrition science.
  - NLEA of 1990 gave FDA the authority to require nutrition labeling
  - Final regulation for the Nutrition Facts label issued in 1993 and effective in 1994
  - Proposed updates issued in 2014; expected to be final in 2016, effective within 60 days, with 2 years for implementation
- The FDA is currently considering all comments and is expected to issue a final rule in 2016.

# Timing Barriers

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- Once the FDA releases a final rule, open issues are likely to remain, such as:
  - Revised standards for product claims, triggering a separate rulemaking process
  - If the dietary fiber definition remains as proposed by the FDA, without a list of grandfathered ingredients, whether a particular ingredient may be declared as dietary fiber may depend upon the FDA's time to respond to industry
    - *BUT the FDA has stated that its intent is to be “forward thinking” and “run a number of these substances through the process” in advance to avoid the timing issue.*
  - Continued changing standards within 2 year implementation period could create even more challenges for manufacturers, and significant additional costs

# Key Proposed Changes\*

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- No longer permit “Calories from fat”
- Mandatory listing of vitamins and minerals
- Mandatory listing of added sugars
- Updated Daily Values (DV) for vitamins and minerals
- Definition for dietary fiber
- DV for subpopulations
- Recordkeeping

\*Excerpted from FDA Public Meeting materials

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# Proposed Label

**PROPOSED LABEL / WHAT'S DIFFERENT**

Servings: larger, bolder type

Updated Daily Values

% DV comes first

New: added sugars

Change of nutrients required

| Nutrition Facts                 |                         |
|---------------------------------|-------------------------|
| <b>8 servings per container</b> |                         |
| Serving size                    | 2/3 cup (55g)           |
| Amount per 2/3 cup              |                         |
| <b>Calories</b>                 | <b>230</b>              |
| % DV*                           |                         |
| <b>12%</b>                      | <b>Total Fat</b> 8g     |
| <b>5%</b>                       | <b>Saturated Fat</b> 1g |
|                                 | <i>Trans Fat</i> 0g     |
| <b>0%</b>                       | <b>Cholesterol</b> 0mg  |
| <b>7%</b>                       | <b>Sodium</b> 160mg     |
| <b>12%</b>                      | <b>Total Carbs</b> 37g  |
| <b>14%</b>                      | <b>Dietary Fiber</b> 4g |
|                                 | Sugars 1g               |
|                                 | <b>Added Sugars</b> 0g  |
|                                 | <b>Protein</b> 3g       |
| <b>10%</b>                      | <b>Vitamin D</b> 2mcg   |
| <b>20%</b>                      | <b>Calcium</b> 260mg    |
| <b>45%</b>                      | <b>Iron</b> 8mg         |
| <b>5%</b>                       | <b>Potassium</b> 235mg  |


\* Footnote on Daily Values (DV) and calories reference to be inserted here.

Serving sizes updated

Calories: larger type

Actual amounts declared

New footnote to come



- Increased prominence of calories and serving size
- Changed order of Serving Size and Servings Per Container and increased prominence of Servings Per Container
- “Amount Per Serving” to become “Amount Per \_\_\_” (\_\_\_ = Serving Size)
- Removal of declaration of Calories from Fat
- % DV moves to left column
- Added Sugars becomes an indented line item under Sugars
- Declaration of absolute amounts for all vitamins and minerals, in addition to DV
- Footnote – likely to change with final rule
- Total Carbss instead of Total Carb

# Serving Size Changes

**FOOD SERVING SIZES GET A REALITY CHECK**

### 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  | PROPOSED SERVING SIZE   |
|---|---|
|  |  |

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### Packaging Affects Servings

Package size affects how much people eat and drink. So now, for example, both 12 and 20 ounce bottles will equal 1 serving, since people typically drink both sizes in one sitting.

|   |   |
|---|---|
|  |  |
|---|---|

**1 SERVING PER BOTTLE FOR EITHER BOTTLE SIZE**

# FDA's Proposed Changes – Serving Size

- Updated serving size requirements and labeling requirements for certain package sizes:
  - Reference values (Reference Amounts Customarily Consumed “RACC”) were set based on food consumption surveys in the late 1970s and 1980s. About 17% of current food categories need RACC values updated based on current consumption.
  - Products typically consumed in one sitting should be labeled as one serving (packages containing between 150% and 200% of RACC).
  - Larger packages that could be consumed in one OR multiple sittings (greater than 200% RACC and less than 400% RACC) should be labeled per serving AND per package in a dual column.

Dual Column Format

| <b>Nutrition Facts</b>          |                  |               |       |
|---------------------------------|------------------|---------------|-------|
| <b>2 servings per container</b> |                  |               |       |
| Serving size                    |                  | 1 cup (255g)  |       |
|                                 | Per 1 cup        | Per container |       |
| <b>Calories</b>                 | <b>220</b>       | <b>440</b>    |       |
|                                 | % DV*            | % DV*         |       |
| <b>Total Fat</b>                | <b>8%</b> 5g     | <b>15%</b>    | 10g   |
| <b>Saturated Fat</b>            | <b>10%</b> 2g    | <b>20%</b>    | 4g    |
| <b>Trans Fat</b>                | 0g               |               | 0g    |
| <b>Cholesterol</b>              | <b>5%</b> 15mg   | <b>10%</b>    | 30mg  |
| <b>Sodium</b>                   | <b>10%</b> 240mg | <b>21%</b>    | 480mg |
| <b>Total Carbs</b>              | <b>12%</b> 35g   | <b>23%</b>    | 70g   |
| <b>Dietary Fiber</b>            | <b>21%</b> 6g    | <b>43%</b>    | 12g   |
| <b>Sugars</b>                   | 7g               |               | 14g   |
| <b>Added Sugars</b>             | 4g               |               | 8g    |
| <b>Protein</b>                  | 9g               |               | 18g   |
| <b>Vitamin D</b>                | 25% 5mcg         | 50%           | 10mcg |
| <b>Calcium</b>                  | 15% 200mg        | 30%           | 400mg |
| <b>Iron</b>                     | 6% 1mg           | 10%           | 2mg   |
| <b>Potassium</b>                | 10% 470mg        | 20%           | 940mg |

\* Footnote on Daily Values (DV) and calories reference to be inserted here.

# Calories

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- More prominent, and in many instances, the total will increase due to changes to serving sizes.
- No changes to 2,000 reference calorie intake level as the basis for setting values for total fat, saturated fat, total carbohydrate, dietary fiber, and protein.
- The FDA has not proposed to set a DRV for calories or a resulting % DV for calories, given the lack of an appropriate quantitative intake recommendation upon which FDA could rely given differing needs within the general population.



# Fat

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- **Total Fat – No changes to mandatory declaration or current DRV of 30%**  
Remove “Calories from Fat” (while continuing to require “Total Fat,” “Saturated Fat,” and “Trans Fat.”)
  - A voluntary disclosure of Calories from Fat *would not* be permitted under the proposed rule.
  - Calories from Saturated Fat *could* still be voluntarily included under the proposed rule.
    - When declared, must be indented under the statement of calories.
- **Saturated Fat – No changes to mandatory declaration or DRV of 20g**
  - FDA has not agreed to exclude stearic acid from the definition of saturated fat, consistent with overall approach to rely on chemical definitions of nutrients as the basis for regulatory definitions for food labeling purposes
- **Trans Fat**
  - FDA sought comments on whether mandatory labeling would still be required if PHOs not GRAS and has since released its final determination regarding PHOs are not GRAS
  - Mandatory declaration of trans fat less than 0.5g as zero, no DRV or DV
- **Monounsaturated Fat and Polyunsaturated Fat declarations would continue to be voluntary**

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# Cholesterol & Total Carbs

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- Cholesterol
  - No proposed changes to current requirement for mandatory declaration
  - No proposed changes to the DRV for cholesterol of 300 mg
- Total Carbs
  - No proposed changes to current requirement for mandatory declaration of total carbohydrates; voluntary declaration of other carbohydrates to be removed
  - No proposed change to the current method of calculating total carbohydrates by subtracting the sum of protein, total fat, moisture and ash from the total weight of the food (*i.e.*, carbohydrate by difference)
  - Calories from Carbohydrates – changes to calculation
    - All soluble and insoluble non-digestible carbs are to be excluded from calculation

# Dietary Fiber – What’s Behind the Change?

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- Currently, the FDA regulations do not define dietary fiber, and the FDA has proposed to add a definition of dietary fiber.
- The proposed definition departs from usual practice of relying upon chemical composition, in exchange, considering impact to human health.
- In reaching the proposed definition, the FDA considered Institute of Medicine recommendations, comments received, and relevant international guidelines, such as the Codex Alimentarius.
- *“The declaration of dietary fiber that accurately reflects the amount of fiber that provides a physiological effect that is beneficial to human health would assist consumers in maintaining healthy dietary practices.”*

# Dietary Fiber – Proposed Definition

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- Plain language summary of new definition:
  - Fiber intact in plants (*i.e.*, naturally occurring)
  - Isolates with beneficial physiological impact to human health
- Proposed new definition:
  - Non-digestible soluble and insoluble carbohydrates ( $\geq 3$  monomeric units) and lignin that are intrinsic and intact in plants;
  - Isolated and synthetic non-digestible carbohydrates ( $\geq 3$  monomeric units) that FDA has granted be included in the definition of dietary fiber, in response to a petition submitted to FDA under § 10.30 ([21 CFR 10.30](#)) [(*i.e.*, *citizen petition*)] demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health; or
  - Isolated and synthetic non-digestible carbohydrates ( $\geq 3$  monomeric units) that are the subject of an authorized health claim.

The FDA intends to issue guidance to industry on the demonstration of physiological effects that are beneficial to human health.

# Protein & Sodium

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- Protein
  - No proposed changes to required declaration of protein by weight, and voluntary declaration of %DV
  - Analytical methods – proposed update to *Official Methods of Analysis of the AOAC International*, 19th ed. (2012) (rather than outdated 1990 version)
  - DRV for protein will continue to be based on 10% of calories or 50 g
- Sodium
  - No proposed change to required declaration of sodium
  - Current DRV 2,400 mg
  - Proposed DRV 2,300 mg, though this could change as the FDA exhaustively discussed other options, including an RDI of 1,500 mg, and invited further comments

# Fluoride

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- Proposed change to add voluntary declaration of fluoride, but no proposal to add a DRV for fluoride
- Declaration would be mandatory when a claim about fluoride is made
- < 0.1 mg would be declared as 0
- 0.2-0.8 mg fluoride declared to the nearest 0.1 mg increment
- > 0.8 mg declared to the nearest 0.2 mg increment

# Declaration of Types of Vitamins and Minerals

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- Current
  - Required declaration of vitamins A and C and calcium and iron
  - Voluntary declaration of vitamins D, E, K, B<sub>6</sub>, and B<sub>12</sub>, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium (unless a claim is made, in which case, required)
- Proposed changes
  - Mandatory declaration of
    - Calcium, iron, vitamin D, potassium
  - Voluntary declaration of
    - Vitamins A and C (rather than required)
    - No change to voluntary declaration of vitamins E, K, B<sub>6</sub>, and B<sub>12</sub>, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride

## Not a Significant Source of ...

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- Proposed change – If a product contains < 2% RDI for a vitamin or mineral, the manufacturer must declare the quantitative amount of the vitamin or mineral and the % DV (*i.e.*, both quantitative amount and % DV; or a zero or asterisk directing the consumer to a statement such as, “*Not a significant source of...*” in place of both quantitative amount and % DV)
  - To eliminate the potential confusion generated by declaring quantitative amount as zero and then pointing to a statement at the bottom of the label



# Proposed RDIs for Vitamins and Minerals

| Nutrient                | Current RDIs                | Proposed RDIs       |
|-------------------------|-----------------------------|---------------------|
| <i>Vitamins:</i>        |                             |                     |
| Biotin                  | 300 micrograms              | 30 micrograms.      |
| Choline                 | 550 <sup>1</sup> milligrams | 550 milligrams.     |
| Folate                  | 400 micrograms              | 400 micrograms DFE. |
| Niacin                  | 20 milligrams               | 16 milligrams NE.   |
| Pantothenic acid        | 10 milligrams               | 5 milligrams.       |
| Riboflavin              | 1.7 milligrams              | 1.3 milligrams.     |
| Thiamin                 | 1.5 milligrams              | 1.2 milligrams.     |
| Vitamin A               | 5,000 International Units   | 900 micrograms RAE. |
| Vitamin B <sub>6</sub>  | 2.0 milligrams              | 1.7 milligrams.     |
| Vitamin B <sub>12</sub> | 6 micrograms                | 2.4 micrograms.     |
| Vitamin C               | 60 milligrams               | 90 milligrams.      |
| Vitamin D               | 400 International Units     | 20 micrograms.      |
| Vitamin E               | 30 International Units      | 15 milligrams.      |
| Vitamin K               | 80 micrograms               | 120 micrograms.     |
| <i>Minerals:</i>        |                             |                     |
| Calcium                 | 1,000 milligrams            | 1,300 milligrams.   |
| Chloride                | 3,400 milligrams            | 2,300 milligrams.   |
| Chromium                | 120 micrograms              | 35 micrograms.      |
| Copper                  | 2.0 milligrams              | 0.9 milligrams.     |
| Iodine                  | 150 micrograms              | 150 micrograms.     |
| Iron                    | 18 milligrams               | 18 milligrams.      |
| Magnesium               | 400 milligrams              | 420 milligrams.     |
| Manganese               | 2.0 milligrams              | 2.3 milligrams.     |
| Molybdenum              | 75 micrograms               | 45 micrograms.      |
| Phosphorus              | 1,000 milligrams            | 1,250 milligrams.   |
| Potassium <sup>2</sup>  | 3,500 milligrams            | 4,700 milligrams.   |
| Selenium                | 70 micrograms               | 55 micrograms.      |
| Zinc                    | 15 milligrams               | 11 milligrams.      |

# Added Sugars

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- In 2014, the FDA proposed adding “Added Sugars” to mandatory declarations
- In July, the FDA proposed including the % DV for added sugars on the NFP
- Based on the recommendation that the daily intake of calories from added sugars not exceed 10% of total calories (or 50 g for adults and children 4 and older)
- Grocery Manufacturers Association: Proposed DV based on DGAC instead of IOM recommendations, which reflect a more rigorous approach to developing recommended nutrient intakes
- American Bakers Association: Body does not distinguish and process added sugar any differently from natural sugar; baked products have added complexity of fermentation, which utilizes sugar as part of baking process
- National Confectioners Association: Unnecessary and confusing

# Added Sugars

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- Any sugar added during processing or consumed separately (sugars, syrups, other caloric sweeteners)
- Reasoning: To make room for more nutrient dense foods.
  - No more than 5-15% of calories (for most people) should come from solid fats and added sugars
  - Currently, most Americans consume between 13% and 16% added sugars

# Added Sugars

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- Less than 0.5 g can be declared as zero
- Applies to:
  - Brown sugar
  - Corn sweetener
  - Corn syrup
  - Dextrose
  - Fructose
  - Fruit juice concentrates
  - Glucose
  - High-fructose corn syrup
  - Honey
  - Invert sugar
  - Lactose
  - Maltose
  - Malt sugar
  - Molasses
  - Raw sugar
  - Turbinado
  - Sugar
  - Trehalose
  - Sucrose

# Recordkeeping

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- In part, FDA's recognition of limitations of testing
- Recordkeeping required for:
  - Naturally occurring and added sugars
  - Folate and folic acid
  - Dietary fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber
  - Synthetic and natural vitamin E

# Impact of Proposed Rule – Changes to Product Claims

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- Changes to serving sizes could cause a product to no longer meet requirements for a health or nutrient content claim.
- Changes to daily values could also allow new or disallow current claims.
- The FDA has recognized that changes to the list of nutrients declared on the Nutrition Facts label or the RDIs or DRVs of nutrients will likely affect other regulations.
- Other regulations that are impacted will be addressed in separate rulemakings, and therefore, issues related to nutrient content claims and health claims are outside of the scope of the current proposed rule.


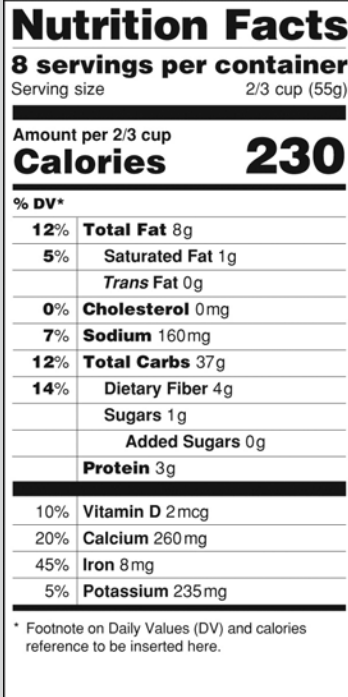
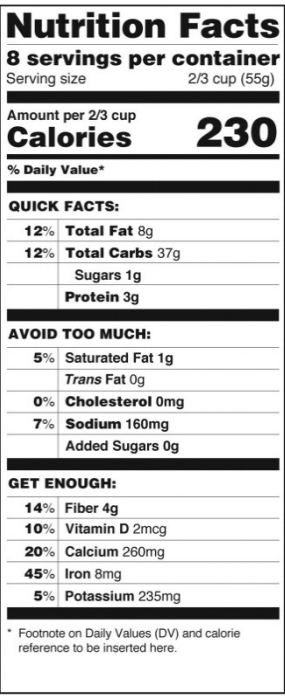
## Impact of Proposed Rule – Vignettes

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- Throughout the proposed rule, the FDA references the overall impression given by a product's labeling, including vignettes.
- The references indicate the FDA's continued focus on the net impression of labeling taken as a whole.
- The FDA's recent guidance on GE labeling similarly suggests a continued focus on the net impression of labeling taken as a whole.
- If product claims change as a result of the proposed rule and resulting changes to FDA's regulations concerning various claims, then the FDA is likely to expect vignettes and other ancillary labeling material to change.

# Impact – Refreshed Design

- Refreshed design of the Nutrition Facts Panel:
  - Increasing size and bolding font of CALORIES; shifting %DV to the left of the label; declaring actual amount (and % DV) of vitamins and minerals; changing “Amount Per Serving” to “Amount Per \_\_\_\_\_;” modifying the footnote.

| Current Panel   | Proposed Panel    | Alternate Panel |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |
|---|-------------------|-----------------|-------|-----------|---------------|-----|---------|---------------|-----|-------------|-----------------|-------|--------|-------------------|---------|--------------------|------|------|---------------|-----|-----|--|--|
|  <p><b>Nutrition Facts</b><br/>Serving Size 2/3 cup (55g)<br/>Servings Per Container About 8</p> <hr/> <p><b>Amount Per Serving</b></p> <p><b>Calories 230</b>      Calories from Fat 72</p> <hr/> <p><b>% Daily Value*</b></p> <p><b>Total Fat 8g</b>      <b>12%</b><br/>Saturated Fat 1g      <b>5%</b><br/>Trans Fat 0g</p> <p><b>Cholesterol 0mg</b>      <b>0%</b><br/><b>Sodium 160mg</b>      <b>7%</b><br/><b>Total Carbohydrate 37g</b>      <b>12%</b><br/>Dietary Fiber 4g      <b>16%</b><br/>Sugars 1g</p> <p><b>Protein 3g</b></p> <hr/> <p>Vitamin A      10%<br/>Vitamin C      8%<br/>Calcium      20%<br/>Iron      45%</p> <p><small>* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.</small></p> <table border="1"> <tr> <td>Calories:</td> <td>2,000</td> <td>2,500</td> </tr> <tr> <td>Total Fat</td> <td>Less than 65g</td> <td>80g</td> </tr> <tr> <td>Sat Fat</td> <td>Less than 20g</td> <td>25g</td> </tr> <tr> <td>Cholesterol</td> <td>Less than 300mg</td> <td>300mg</td> </tr> <tr> <td>Sodium</td> <td>Less than 2,400mg</td> <td>2,400mg</td> </tr> <tr> <td>Total Carbohydrate</td> <td>300g</td> <td>375g</td> </tr> <tr> <td>Dietary Fiber</td> <td>25g</td> <td>30g</td> </tr> </table> | Calories:         | 2,000           | 2,500 | Total Fat | Less than 65g | 80g | Sat Fat | Less than 20g | 25g | Cholesterol | Less than 300mg | 300mg | Sodium | Less than 2,400mg | 2,400mg | Total Carbohydrate | 300g | 375g | Dietary Fiber | 25g | 30g |  <p><b>Nutrition Facts</b><br/><b>8 servings per container</b><br/>Serving size      2/3 cup (55g)</p> <hr/> <p><b>Amount per 2/3 cup</b></p> <p><b>Calories 230</b></p> <hr/> <p><b>% DV*</b></p> <p><b>12% Total Fat 8g</b><br/><b>5% Saturated Fat 1g</b><br/>Trans Fat 0g</p> <p><b>0% Cholesterol 0mg</b><br/><b>7% Sodium 160mg</b><br/><b>12% Total Carbs 37g</b><br/><b>14% Dietary Fiber 4g</b><br/>Sugars 1g<br/>Added Sugars 0g</p> <hr/> <p><b>Protein 3g</b></p> <hr/> <p><b>10% Vitamin D 2mcg</b><br/><b>20% Calcium 260mg</b><br/><b>45% Iron 8mg</b><br/><b>5% Potassium 235mg</b></p> <p><small>* Footnote on Daily Values (DV) and calories reference to be inserted here.</small></p> |  <p><b>Nutrition Facts</b><br/><b>8 servings per container</b><br/>Serving size      2/3 cup (55g)</p> <hr/> <p><b>Amount per 2/3 cup</b></p> <p><b>Calories 230</b></p> <hr/> <p><b>% Daily Value*</b></p> <p><b>QUICK FACTS:</b></p> <p><b>12% Total Fat 8g</b><br/><b>12% Total Carbs 37g</b><br/>Sugars 1g<br/>Protein 3g</p> <hr/> <p><b>AVOID TOO MUCH:</b></p> <p><b>5% Saturated Fat 1g</b><br/>Trans Fat 0g<br/><b>0% Cholesterol 0mg</b><br/><b>7% Sodium 160mg</b><br/>Added Sugars 0g</p> <hr/> <p><b>GET ENOUGH:</b></p> <p><b>14% Fiber 4g</b><br/><b>10% Vitamin D 2mcg</b><br/><b>20% Calcium 260mg</b><br/><b>45% Iron 8mg</b><br/><b>5% Potassium 235mg</b></p> <p><small>* Footnote on Daily Values (DV) and calorie reference to be inserted here.</small></p> |
| Calories:   | 2,000             | 2,500           |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |
| Total Fat   | Less than 65g     | 80g             |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |
| Sat Fat   | Less than 20g     | 25g             |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |
| Cholesterol   | Less than 300mg   | 300mg           |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |
| Sodium  | Less than 2,400mg | 2,400mg         |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |
| Total Carbohydrate  | 300g              | 375g            |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |
| Dietary Fiber   | 25g               | 30g             |       |           |               |     |         |               |     |             |                 |       |        |                   |         |                    |      |      |               |     |     |  |  |



# Impact – Brand Image, Label Designs and Formats

- Brand Image
  - Does an “Added Sugars” declaration change the way consumers think about a brand?
- Label Designs and Formats
  - New packages will have to be printed with reformatted NFPs.
  - Should other packaging changes be made to bring label design in line with NFP design? Font size, typeface, spacing?

| <b>Nutrition Facts</b>  |                           |
|---|---------------------------|
| Serving Size 2/3 cup (55g)<br>Servings Per Container About 8  |                           |
| Amount Per Serving  |                           |
| <b>Calories</b> 230   | Calories from Fat 72      |
| % Daily Value*  |                           |
| <b>Total Fat</b> 8g   | <b>12%</b>                |
| Saturated Fat 1g  | <b>5%</b>                 |
| Trans Fat 0g  |                           |
| <b>Cholesterol</b> 0mg  | <b>0%</b>                 |
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| Calcium   | 20%                       |
| Iron  | 45%                       |
| * Percent Daily Values are based on a 2,000 calorie diet.<br>Your daily value may be higher or lower depending on your calorie needs. |                           |
|   | Calories: 2,000 2,500     |
| Total Fat   | Less than 65g 80g         |
| Sat Fat   | Less than 20g 25g         |
| Cholesterol   | Less than 300mg 300mg     |
| Sodium  | Less than 2,400mg 2,400mg |
| Total Carbohydrate  | 300g 375g                 |
| Dietary Fiber   | 25g 30g                   |

| <b>Nutrition Facts</b>  |                         |
|---|-------------------------|
| <b>8 servings per container</b>   |                         |
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| <b>5%</b>   | <b>Potassium</b> 235mg  |
| * Footnote on Daily Values (DV) and calories reference to be inserted here. |                         |

# Impact – Reformulation?

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- The FDA has recognized that industry may be prompted to reformulate products to maintain health claims and nutrient content claims.
- The FDA has similarly recognized that industry may reformulate products that appear less attractive to consumers under the proposed rules.

# GE Labeling – FDA Final Guidance: An Update

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- On November 19, 2015, the FDA released Final Guidance on Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.
- To assist food manufacturers who wish to voluntarily label *plant-derived* food products or ingredients as having been made with or without bioengineering.
- Typically, the FDA does not consider the method of development of a new plant variety to be material, or information that is required to be disclosed.

# GE Labeling – FDA Final Guidance: Suggested Statements

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- “[A]n accurate statement about whether a food was not produced using bioengineering is one that provides information in a context that clearly refers to bioengineering technology.”
- The FDA provided the following examples of acceptable statements:
  - Not bioengineered.
  - Not genetically engineered.
  - Not genetically modified through the use of modern biotechnology.
  - We do not used ingredients that were produced using modern biotechnology.
  - This oil is made from soybeans that were not genetically engineered.
  - Our corn growers do not plant bioengineered seeds.

# GE Labeling – FDA Final Guidance: Use GE, not GMO

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- The FDA wants manufacturers to use labeling terminology that preserves the integrity and meaning of scientific terminology.
- “*GMO*” and “*Non-GMO*”
  - The FDA pointed out that “O” refers to organism. Since most foods – with limited exceptions such as yogurt – do not contain entire organisms – the FDA does not encourage the use of “*GMO*” or “*Non-GMO*”
- As to “*GMO Free*”, “*GE Free*”, “*Does not contain GMOs*” and similar claims:
  - “Free” conveys zero or total absence.
  - In light of the challenges of substantiating a “free” claim, the FDA recommends such statements not be used.

# GE Labeling – FDA Final Guidance: Cautions

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- Cautions:
  - Labeling is misleading if it fails to reveal facts that are material *in light of representations made or suggested*
    - *E.g.*, a claim that is truthful could be misleading if, for example, a manufacturer specifies that one ingredient *is not* bioengineered, but fails to state that a major ingredient *is* bioengineered.
  - “None of the ingredients in this food is genetically engineered”
    - Could be misleading where ingredients are incapable of being genetically engineered (*e.g.*, salt)
  - Labeling could be misleading if it suggests or implies that a food product or ingredient is safer, more nutritious or otherwise has different attributes than other comparable foods because the food was not genetically engineered.
    - Beware the use of vignettes that may imply such attributes.

# GE Labeling – FDA Final Guidance: Ingredients

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- Ingredient listings –
  - The FDA noted its interpretation that descriptive terms like “pure” or “certified non-GE” are intervening material that violates FDA regulations.
  - The FDA specified that the ingredient’s attribute could be described elsewhere on the label.
    - *E.g.*, PDP stating “*Made from certified non-GE soybeans*”, with ingredient listing stating common or usual name without intervening material.
- Statements about foods that *are* derived from GE plants:
  - If an ingredient is showcased as having a benefit, the food should contain more than a small amount of the ingredient if the statement implies that the overall quality of the food is improved.

# GE Labeling – FDA Final Guidance: Attributes that Should be Labeled

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- GE labeling is material (and therefore required) if a food derived from GE plants:
  - Is significantly different from a traditional counterpart
    - *E.g.*, an oil with a different fatty acid profile
  - Behaves differently than its traditional counterpart when used in a similar way, like frying or canning
  - Has a significantly different nutritional property
    - *E.g.*, a bioengineered vegetable with B12 would be labeled as such if traditional counterpart did not have B12
  - Contains an allergen that consumers would not expect to be present in the food



# GE Labeling – FDA Final Guidance: Substantiation

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- Documentation of handling practices and procedures
  - Requires supply chain control and/or transparency
  - A Manufacturer can rely on certifications or affidavits from farmers, processors, distributors and others in the food production and distribution chain
- Use of certified organic food
  - Compliance with NOP can be used to support labeling claims about food production without the use of bioengineering
  - Subject to documentation of compliance with USDA organic certification and recordkeeping requirements
- Use of validated test methods
  - Tests more likely to be helpful to validate the *presence*, rather than the *absence* of bioengineered material in food

# GE Labeling – Consumer Litigation Risk Continues

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- Demand letters and claims for false or misleading GE-related claims or “natural” claims in the presence of GE ingredients persist.
- Beware of targeted ingredients, such as soy or corn.
- Following the FDA’s recent Final Guidance could support a preemption defense.

## GE Labeling – Vermont

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- Requires all processed foods with GE ingredients to utilize a designated labeling statement, such as:
  - “*Produced with genetic engineering.*”
  - “*Partially produced with genetic engineering.*”
  - “*May be produced with genetic engineering.*”
- Labeling must be conspicuous, contrasting font color, in **bold** and no smaller than “Serving Size” on the NFP (currently 8 point font).
- A sticker or separate packaging is likely permissible.
- Bans “natural” on foods with GE-derived ingredients.
- Contains a \$1,000/day penalty for each product that manufacturer markets.
- Litigation ongoing, but effective date set for July 1, 2016.
- Vermont Attorney General does not plan on enforcement activity prior to January 1, 2017.

# Additional Resources

- **FDA Nutrition Food Label Public Meeting Webcast:**  
<http://fda.yorkcast.com/webcast/Play/d71a3c28aa3a45149657d320eee5c7ce1d>
- **Proposed Rule:** <https://www.federalregister.gov/articles/2014/03/03/2014-04387/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels>
- **Supplemental Proposed Rule:**  
<https://www.federalregister.gov/articles/2015/07/27/2015-17928/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels-supplemental-proposed-rule-to>
- **IFT Food and Nutrition Labeling Resources:** <http://www.ift.org/Knowledge-Center/Focus-Areas/Food-Health-and-Nutrition/Food-and-Nutrition-Labeling/Food-and-Nutrition-Labeling-Resources.aspx>

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With a focus on regulatory compliance, supply chain management and strategic growth, Suzie Trigg represents food, restaurant, cosmetic and medical device companies in product distribution and supply chain matters and mergers and acquisitions, and by advising on matters concerning the FDA and USDA.

On FDA and USDA regulatory matters, Suzie's clients have looked to her for advice on a variety of issues, including:

- Acquiring an FDA-regulated company and conducting assessments of a target company's labeling, claims, food safety practices, consumer complaints, demands and litigation
- Ensuring supply chain safety and quality
- Implementing new regulations
- Product labeling and claims, such as using "natural," "organic," or "gluten-free," and the impact of animal husbandry practices on product labeling and promotion
- Website and social media promotions
- An effective and timely response to regulatory concerns, such as an FDA Form 483

Suzie serves on the Food and Dietary Supplements Committee of the Food and Drug Law Institute (FDLI) and previously served on FDLI's Writing Awards Committee. Suzie has completed coursework in international food law through Michigan State University's Institute for Food Laws and Regulations and is a member of the Institute of Food Technologists (IFT).

Suzie was recently selected as Best in Supply Chain Negotiations – USA, Acquisition International 2015 Legal Awards, AI Global Media Ltd., 2015.

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## Haynes and Boone, LLP:

### FDA – Food, Dietary Supplements, Cosmetics and Medical Devices

Haynes and Boone attorneys serve as trusted business advisors delivering timely, accurate and innovative counsel to FDA- and USDA-regulated companies on a variety of transactional and regulatory matters. Our attorneys address complex regulatory and compliance challenges, risk management and multifaceted transactions for:

- Food manufacturers and processors;
- Restaurant chains, food retailers and other food distributors;
- Agricultural producers and cooperatives;
- Dietary supplement manufacturers;
- Medical device manufacturers; and
- Cosmetic product manufacturers.

Our practitioners represent clients in the following areas:

- Private labeling, co-branding, co-packing, supply, processing, and other agreements;
- Mergers, acquisitions and dispositions, with a particular focus on strategic acquisitions;
- Provide counsel on a wide range of international distribution issues and regulatory hurdles encountered in different parts of the world (e.g., new China FDA or “CFDA”) and facilitate the completion of transactions requiring review and input by counsel in multiple countries;
- Develop regulatory and distribution strategies for novel products that will or may be FDA-regulated;
- Provide risk management counseling, including self-evaluative audits, designing corrective action plans, and handling of possible past or existing regulatory violations;
- Provide guidance and crisis management during threatened or actual recalls;
- Strategic planning and food labeling and marketing review and substantiation, regulatory compliance, and risk management with respect to consumer and competitor actions;
- Reviews of labeling and marketing claims;
- Review and advise on allergen disclaimers and warnings;
- Review and advise on food preparation and handling and safety issues;
- Counseling on compliance with the Food Safety Modernization Act (FSMA) and other recent developments.

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