Food Labeling 101

Nicole Turner-Ravana, MS
Owner/Director, Strategic Nutrition Communications LLC

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**
  - http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm
- USDA's proposed rule draft released 12/1/16
  - http://www.usda.gov/wps/portal/usda/usdahome?contentid=2016/12/0253.xml&contentidonly=true

Key Information Considered

- Scientific evidence, such as consensus reports
- Public comments
- Citizen petitions
- Survey data
- Findings from consumer studies

NEW LABEL / WHAT'S DIFFERENT

Servings: larger, bolder type

Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Serving sizes updated

Amount per serving

Calories **230**

Calories: larger type

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	

Updated daily values

New: added sugars

Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

Change in nutrients required

Actual amounts declared

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

New footnote

FDA

Then vs Now

SIDE-BY-SIDE COMPARISON

Original Label

Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving	
Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 12g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. 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

New Label

Nutrition Facts

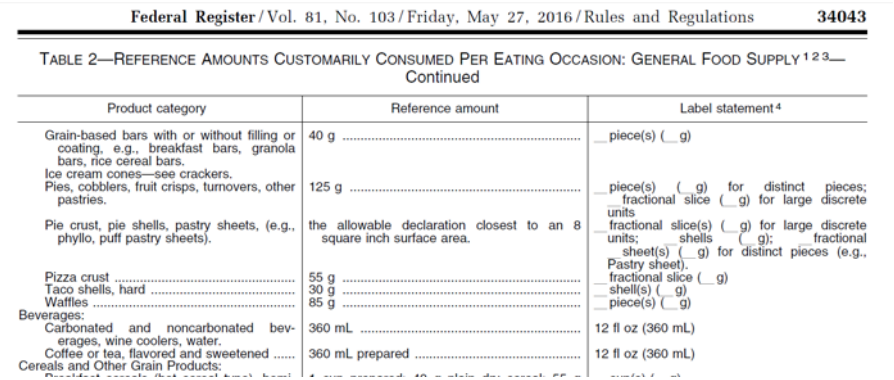
8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving	
Calories	**230**
	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

RACC & Serving Size Changes

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



Federal Register / Vol. 81, No. 103 / Friday, May 27, 2016 / Rules and Regulations 34043

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3]—Continued

Product category	Reference amount	Label statement [4]
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars.	40 g	__ piece(s) (__ g)
Ice cream cones—see crackers.		
Pies, cobblers, fruit crisps, turnovers, other pastries.	125 g	__ piece(s) (__ g) for distinct pieces; __ fractional slice (__ g) for large discrete units
Pie crust, pie shells, pastry sheets, (e.g., phyllo, puff pastry sheets).	the allowable declaration closest to an 8 square inch surface area.	__ fractional slice(s) (__ g) for large discrete units; __ shells (__ g); __ fractional __ sheet(s) (__ g) for distinct pieces (e.g., Pastry sheet).
Pizza crust	55 g	__ fractional slice (__ g)
Taco shells, hard	30 g	__ shell(s) (__ g)
Waffles	85 g	__ piece(s) (__ g)
Beverages:		
Carbonated and noncarbonated beverages, wine coolers, water.	360 mL	12 fl oz (360 mL)
Coffee or tea, flavored and sweetened	360 mL prepared	12 fl oz (360 mL)
Cereals and Other Grain Products:		

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

- http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm535368.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

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

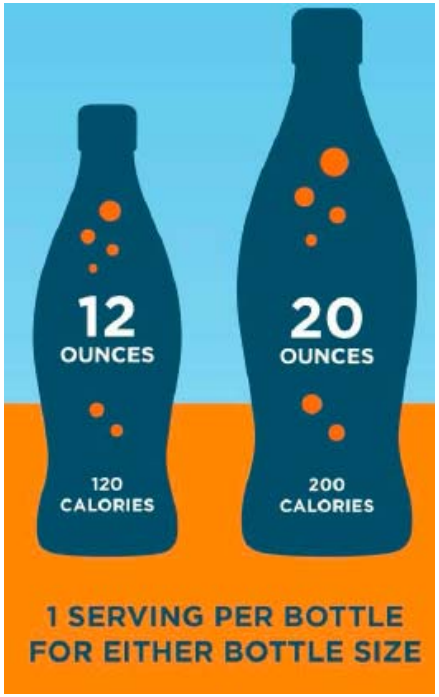
Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		**% DV***
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



- 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) http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM535372.pdf

Updates to the Daily Reference Values and Reference Dietary Intake values (changes in blue)

Nutrient	Unit of measure	RDI			
		Adults and children ≥4 years	Infants[1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin A	Micrograms RAE[2] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Vitamin D	Micrograms (mcg)[3]	20	10	15	15
Vitamin E	Milligrams (mg)[4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE[5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate[6]	Micrograms DFE[7] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	N/A	11	N/A	[8]71

[1] RDIs are based on dietary reference intake recommendations for infants through 12 months of age.
[2] RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 microgram supplemental *b*-carotene, 12 micrograms *b*-carotene, or 24 micrograms *a*-carotene, or 24 micrograms *b*-cryptoxanthin.
[3] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.
[4] 1 mg *a*-tocopherol (label claim) = 1 mg *a*-tocopherol = 1 mg RRR- *a*-tocopherol = 2 mg *all rac-a*-tocopherol .
[5] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.
[6] "Folate" and "Folic Acid" must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.

Food component	Unit of measure	Adults and children ≥ 4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Fat	Grams (g)	[1]78	30	[2]39	[1]78
Saturated fat	Grams (g)	[1]20	N/A	[2]10	[1]20
Cholesterol	Milligrams (mg)	300	N/A	300	300
Total carbohydrate	Grams (g)	[1]275	95	[2]150	[1]275

Food component	Unit of measure	Adults and children ≥ 4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300
Dietary Fiber	Grams (g)	[1]28	N/A	[2]14	[1]28
Protein	Grams (g)	[1]50	N/A	[2]13	N/A
Added Sugars	Grams (g)	[1]50	N/A	[2]25	[1]50

[1] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women
[2] Based on the reference caloric intake of 1,000 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

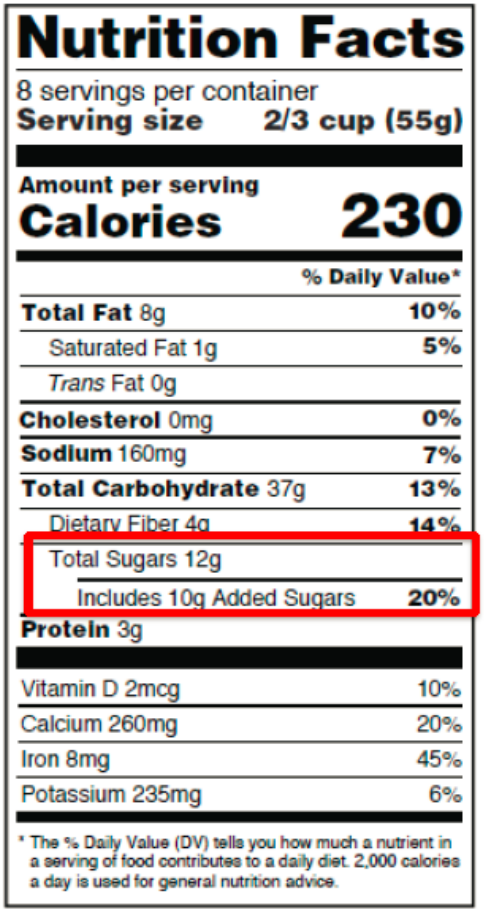
- only those dietary fibers that FDA has determined to have a physiological effect that is beneficial to human health would be considered to be ‘’dietary fiber’’
- FDA adopted a definition for dietary fiber that is equivalent to the IOM’s definition of ‘‘total fiber’’ and therefore would include fibers 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 defintion: 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



Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
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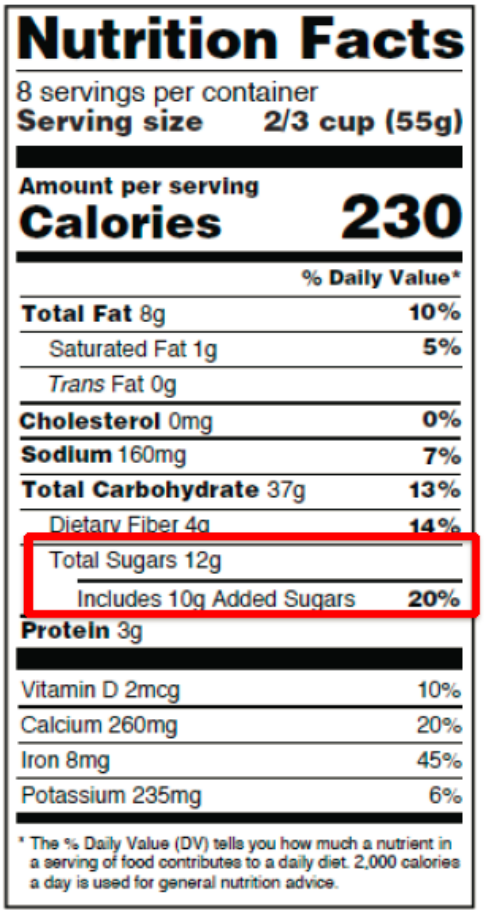
Added Sugars

- = 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.



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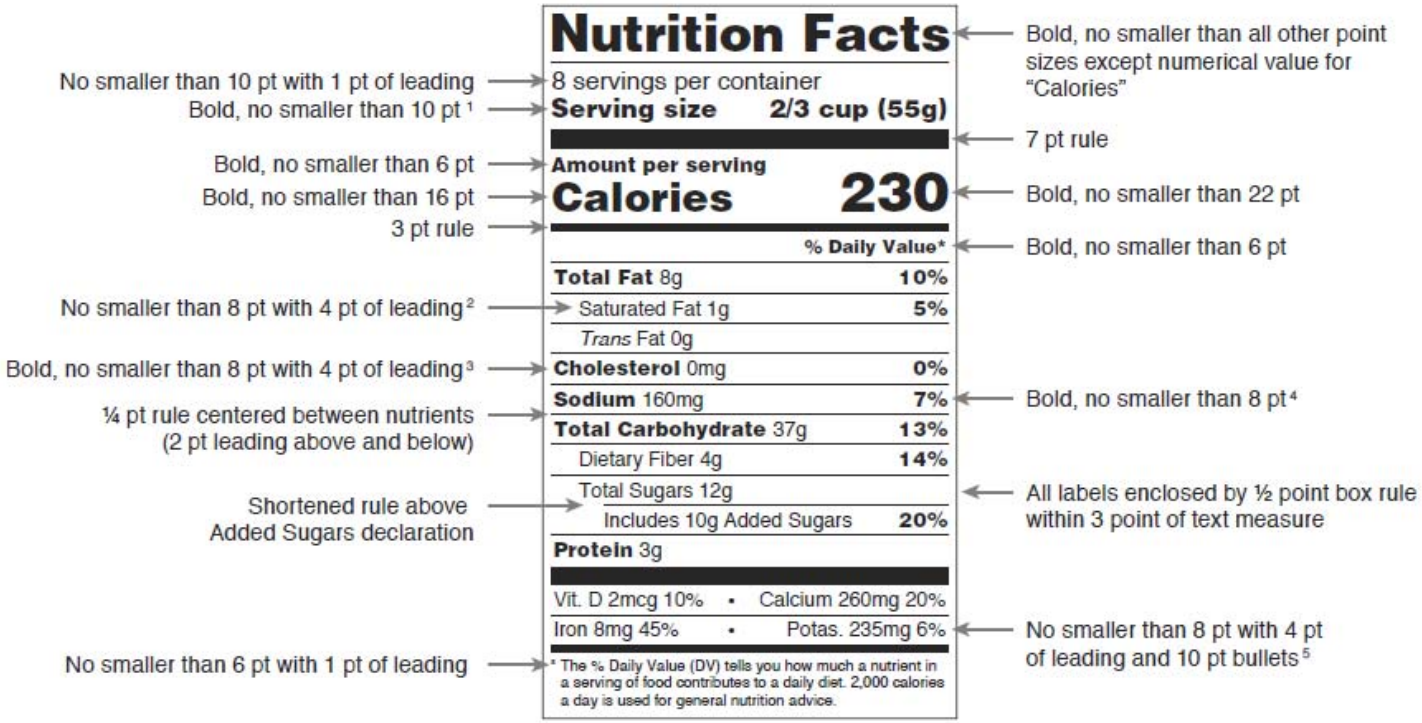
Records Compliance

- 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

"Oh, so you *do* keep track of where you bury things."

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.



Standard Vertical

- These format notations are requirements for how to create a compliant Nutrition Facts box now.
- Specific rounding requirements

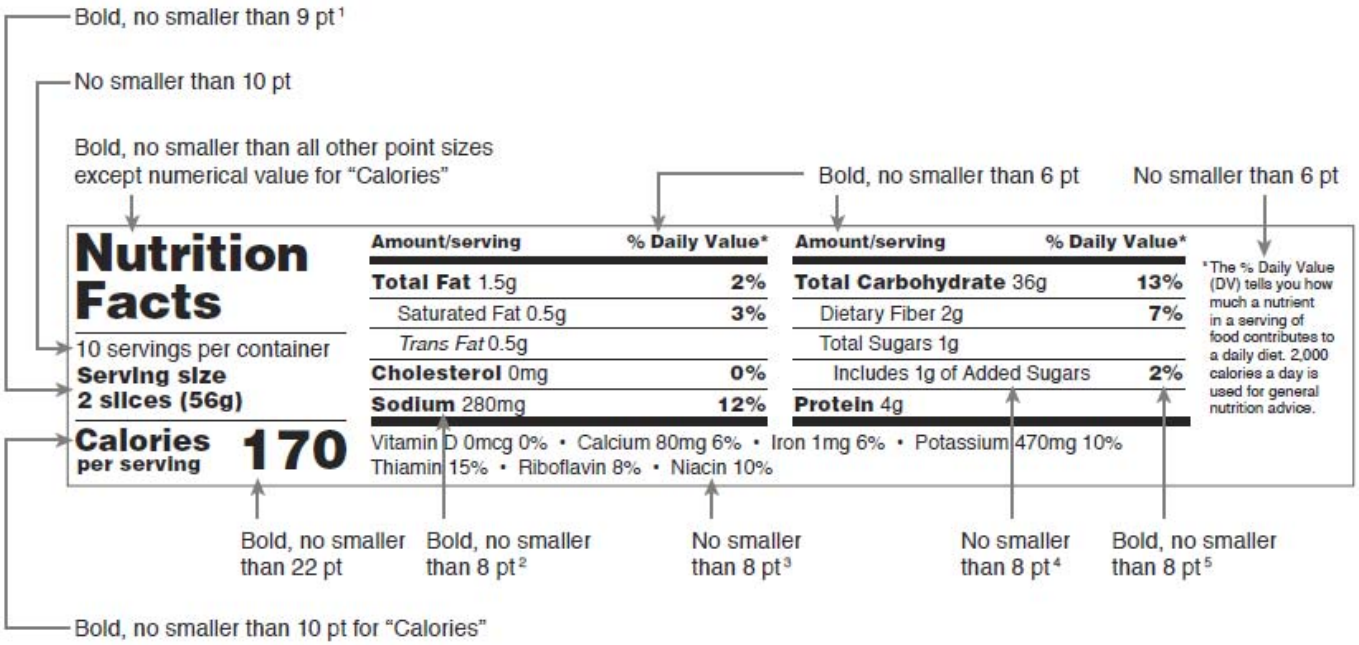
[1] "Serving size" declaration may be decreased to no smaller than 8 pt bold if additional space is needed for the declaration

[2] Saturated fat, *Trans* Fat, Dietary Fiber, Total Sugars, Added Sugars, voluntary nutrients (if listed) and their g/mg values: No smaller than 8 pt with 4 pt of leading

[3] Total Fat, Cholesterol, Sodium, Total Carbohydrate, and Protein: Bold, no smaller than 8 pt with 4 pt of leading

[4] % Daily Values for nutrients above lower 7 pt rule: Bold, no smaller than 8 pt

[5] Vit. D, Calcium, Iron, Potas., voluntary nutrients (if listed) and their mg/mcg values and % Daily Values: No smaller than 8 pt and with 4 pt of leading



[1] "Serving size" declaration may be decreased to no smaller than 8 pt bold if additional space is needed for the declaration

[2] Total Fat, Cholesterol, Sodium, Total Carbohydrate, and Protein: Bold, no smaller than 8 pt

[3] Vitamin D, Calcium, Iron, Potassium, voluntary nutrients (if listed) and their mg/mcg values and % DV values: No smaller than 8 pt

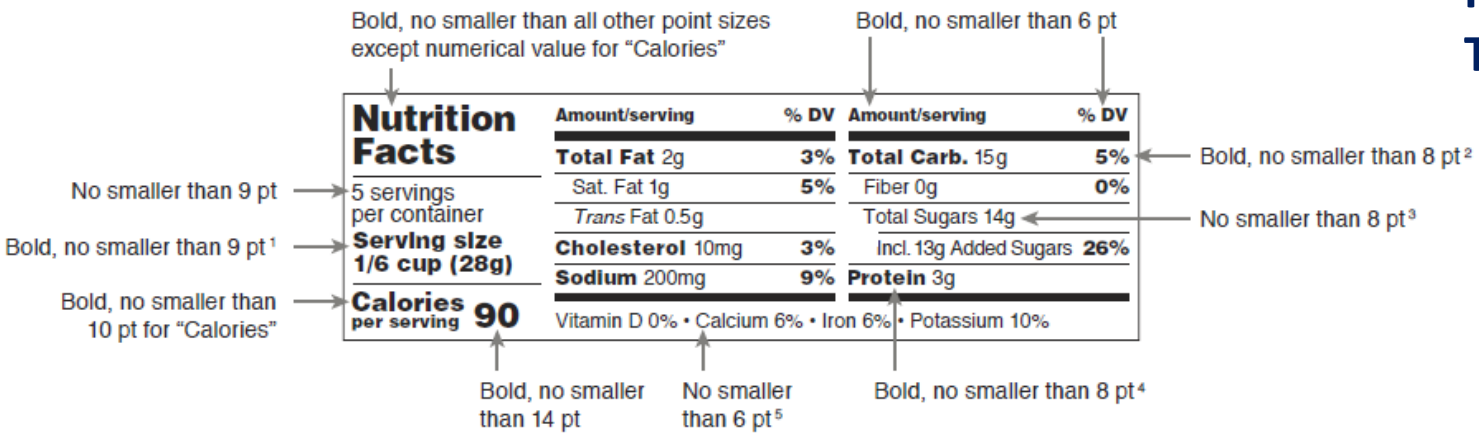
[4] Saturated fat, *Trans* Fat, Dietary Fiber, Total Sugars, Added Sugars, voluntary nutrients (if listed) and their g/mg values: No smaller than 8 pt

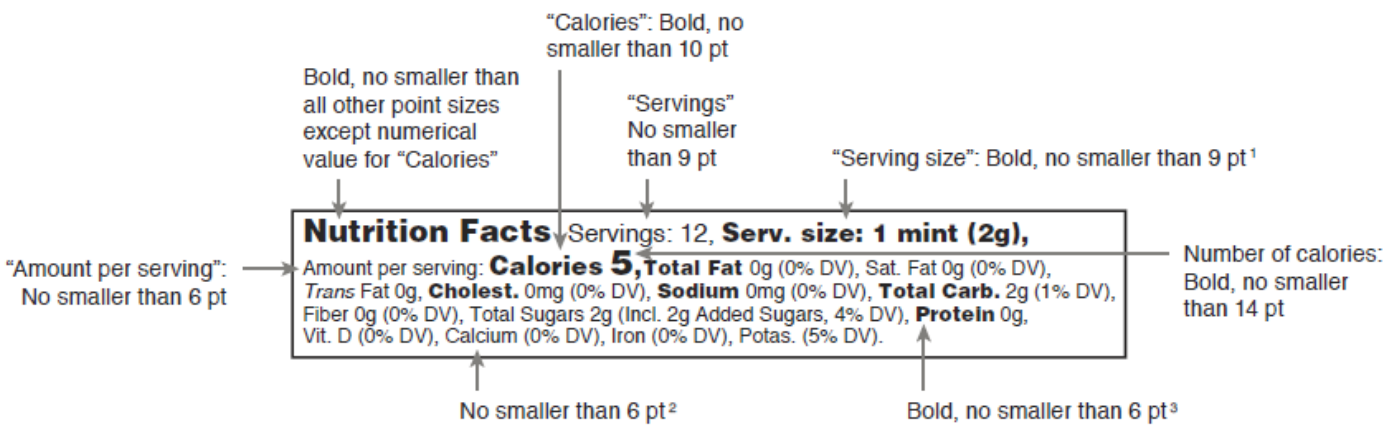
[5] % DV values for nutrients above thick bar: Bold, no smaller than 8 pt

Tabular

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

WARNING:

This product can expose you to chemicals including lead, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

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

Strategic Nutrition communications, llc