Guidelines for the Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish

Food and Drug Administration
Center for Food Safety and
Applied Nutrition
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Overview

- FDA's Mission
- Final Rule: Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish
- Data Sources to Update Nutrient Values
- Process of Developing Nutrition Label Values from Analytical Data

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The Food and Drug Administration (FDA)

- Oversees all domestic and imported food sold in interstate commerce except meat, poultry, and egg products.
- Is responsible for protecting the public health by ensuring that
  - Foods are safe, wholesome, sanitary, and properly labeled.
- Nutrition Labeling and Education Act of 1990 mandated that FDA provide nutrition labeling information for "raw agricultural commodities" and "raw fish" by issuing voluntary nutrition guidelines.

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Final Rule

- Final rule published July 25, 2006 (corrected August 17, 2006) to update the names and nutrition labeling values for the top 20 most frequently consumed raw fruits, vegetables, and fish in the US.
- Regulation updated 1991 and 1996 final rules
- Refers to labeling (charts) in retail stores and labels of individually packaged raw produce and fish.
  - Foods sold raw but may not be consumed raw.
  - Nutrient values are provided for *generic* varieties.
- Effective date when new values must be used:

  January 1, 2008

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Apple

Nutrition Facts

Serving Size 1 large apple (242 g/8 oz)

Amount Per Serving	
Calories 130	Calories from Fat 0
	% Daily Value *
Total Fat 0g	**0%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 0mg	**0%**
Potassium 260mg	**7%**
Total Carbohydrate 34g	**11%**
Dietary Fiber 5g	**20%**
Sugars 25g	
Protein 1g	

Vitamin A 2%	• Vitamin C 8%
Calcium 2%	• Iron 2%

* Percent Daily Values are based on a 2,000 calorie diet. Your calorie needs 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
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

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- The nutrition labeling of raw produce and fish is *voluntary, but* use of nutrient data that FDA provides in the Code of Federal Regulations is *mandatory*.
- In addition, *labeling at point of purchase* is *mandatory* if nutrient content claims or health claims are provided on the raw foods.

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- Nutrient content claims:
  - characterize the level of a nutrient in a food
  - "low fat," "high fiber," "good source of Vitamin C"
- Health claims:
  - describe a relationship between a substance in a food and reducing risk of a disease or health-related condition.
  - "Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors."

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Raw Fruits

- Apple
- Avocado, California
- Banana
- Cantaloupe
- Grapefruit
- Grapes
- Honeydew melon
- Kiwifruit
- Lemon
- Lime
- Nectarine
- Orange
- Peach
- Pear
- Pineapple
- Plums
- Strawberries
- Sweet cherries
- Tangerine
- Watermelon

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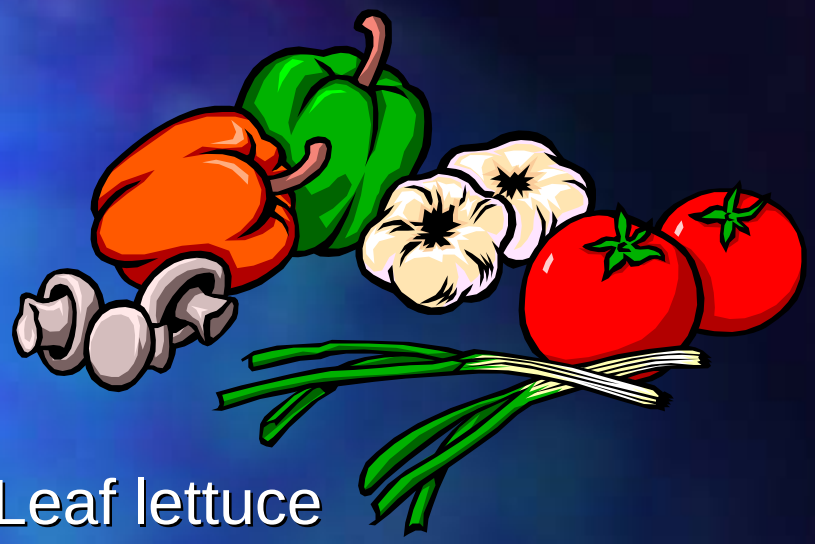
Raw Vegetables



- Asparagus
- Bell pepper
- Broccoli
- Carrot
- Cauliflower
- Celery
- Cucumber
- Green (snap) beans
- Green cabbage
- Green onion
- Iceberg lettuce
- Leaf lettuce
- Mushrooms
- Onion
- Potato
- Radishes
- Summer squash
- Sweet corn
- Sweet potato
- Tomato

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Raw Fish

- Blue crab
- Catfish
- Clams
- Cod
- Flounder/sole
- Haddock
- Halibut
- Lobster
- Ocean perch
- Orange roughy
- Oysters
- Pollock
- Rainbow trout
- Rockfish
- Salmon, Atlantic/Coho/ Sockeye/Chinook
- Salmon, Chum/Pink
- Scallops
- Shrimp
- Swordfish
- Tilapia
- Tuna

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Data Sources to Update Nutrient Values

- Primary Source:

  USDA submitted data for raw fruits and vegetables from its nationwide sampling studies of fruits and vegetables:
  - 16 of top 20 fruits
  - 13 of top 20 vegetables

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Data Sources

- USDA National Nutrient Databank (NNDB) for most of the raw fish, including Chinook salmon
- USDA Nutrient Database for Standard Reference (SR) for vitamin A and vitamin C in raw fish and for other nutrients in raw produce and fish when no analytical data were available

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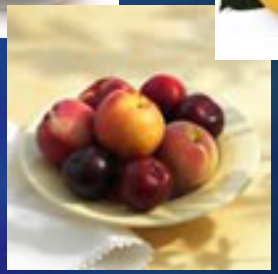
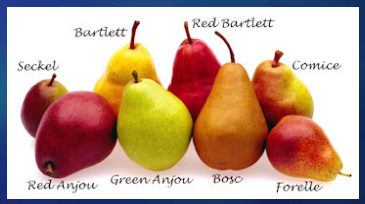
Data Sources: Commodity Groups



- California Avocado Commission
- California Cherry Advisory Board
- California Strawberry Commission
- California Table Grape Commission
- California Tree Fruit Agreement
- Citrus Research Board
- Food Research, Inc on behalf of kiwifruit growers (Chile, US, & New Zealand)
- Pear Bureau Northwest
- US Apple Association
- American Tilapia Association



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Developing Nutrition Labeling Values

- FDA recommends that the nutrient values for nutrition labeling be based on product composition, as determined by laboratory analysis using AOAC methods.

- Nutrition label values may differ from published nutrient values (mean values) found in the USDA Nutrient Database for Standard Reference (SR).

Raw data for raw foods . . .

- Where possible, we used "raw" nutrient data points provided by laboratory analysis of food samples as the basis for nutrition labels.
- To those raw data, we applied *compliance calculations* based on *95% prediction intervals*.
- We considered the resulting adjusted values as well as the mean values.

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Q: WHY use 95% prediction intervals?

- They take into consideration the *variability* in the nutrient levels.
- The predicted value provides the *minimum or maximum amount* of a nutrient that may be expected in the product.
- Thus, predicted values are often more *conservative* and will ensure that label values will have a higher probability of being in compliance with FDA nutrition labeling regulations.

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Basic Process for Developing Nutrition Label Values from Analytical Data

Guidance for Industry

FDA Nutrition Labeling Manual -- A Guide for Developing and Using Databases

1998 Edition

Available online at:

www.cfsan.fda.gov/~dms/nutrguid.html

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Steps: Developing Label Values

1. Calculate the mean nutrient content from the analyzed nutrient values.
2. Calculate the standard deviation.
3. Convert the mean and standard deviation from a "per 100 g" basis to the label serving size.

When data are available, we use *weighted estimates*:

- Market share of various varieties
- Seasonal variation
- Combining data from various sources

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Steps: Developing Label Values

4. Construct a one-sided 95% prediction interval.

(3 Algorithms for Class I, Class II, and Third Group nutrients)

predicted value =

$$(\text{mean} - t_{(0.95;df)} (\text{composite size}/k + 1/n)^{1/2} (s))$$

$$(\text{mean} - t_{(0.95;df)} (\text{composite size}/k + 1/n)^{1/2} (s)) (5/4)$$

$$(\text{mean} + t_{(0.95;df)} (\text{composite size}/k + 1/n)^{1/2} (s)) (5/6)$$

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Quick FDA Compliance Overview – 21 CFR 101.9(g)

- Class I Nutrients
  - those added in fortified or fabricated foods
    - **vitamin, mineral, protein, dietary fiber, potassium**
  - must be present at 100% or more of the value declared on the label
- Class II Nutrients
  - naturally occurring
    - Vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium
  - must be present at 80% or more than the label value

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Quick Overview - 21 CFR 101.9(g)

- Third Group Nutrients
  - calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, sodium
  - must be present at 120% or less than the label value

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Q: What is the impact on nutrient levels with 95% prediction intervals?

- Class I and II nutrients:

  There may be more of a nutrient than what is on the label.

- Third Group nutrients:

  There may be less of a nutrient than what is on the label.

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Example: Dietary Fiber in a Raw Vegetable (12 samples of 12 units)

Predicted Value =

$= (\text{mean} - t_{(0.95;df)} (\text{composite size}/k + 1/n)^{1/2} (s)) (5/4)$
$= (4.6003 - 1.796 (12/12 + 1/12)^{1/2}(.6165770)) (5/4)$
$= (4.6003 - 1.796 (1.040833) (.6165770)) (5/4)$
$= (4.6003 - 1.1525896)(5/4)$
$= 3.4477104 (1.25)$
$= 4.309638$

mean = 4.6003 = 4.6 g

predicted value = 4.309638 = 4.3 g

Mean or Predicted Value?

- For Class I and Class II Nutrients
  - Select the *lower* of the mean or the predicted value

predicted value = 4.3 g = 4 g

mean = 4.6 g = 5 g

- For Third Group Nutrients
  - Select the *higher* of the mean or the predicted value

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Sometimes we found with predicted values . . .

- predicted value = mean
- complete absence of a nutrient or a negative value that didn't make sense
- unreasonable values with small sample sizes

New Decision Factor . . .

- The calculated 95% predicted value must fall within the range of the interval of the raw data points.
  - → It must be a viable number.

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Steps: Developing Label Values

5. Select the mean or predicted value.
6. Calculate the % daily value for each nutrient.
7. Round the values according to FDA rounding rules.

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Q: What about labeling of other raw produce and fish *not* in the top 20?

- Databases may be used to develop nutrient values for specific varieties, species, or cultivars.
- Clearly state name of food on package or on signage:
  - "Red Delicious Apple"
  - "Golden Delicious Apple"
  - "Granny Smith Apple"
  - "Fuji Apple"
  - "Gala Apple"

FDA encourages . . .

- the produce and fish industries, as well as USDA, academia, and other interested organizations to:
- Reevaluate the top 20,
- Conduct additional nutrient analyses to support the labeling of raw fruits, vegetables, and fish, and,
- Start submitting those data to FDA for the next update of the nutrition labeling values.

- Estimated publication of next proposed rule or notice that the values have not changed: 2010

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