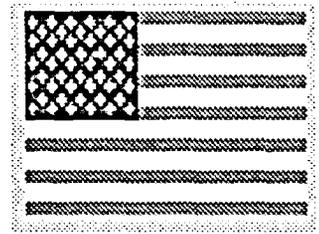
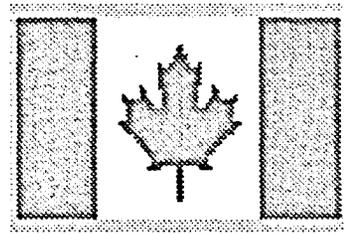


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How to Develop Acceptable NLEA Labeling

A presentation
by the
U.S. Food and Drug Administration
discussing the requirements
of the
Nutrition Labeling and Education Act of 1990

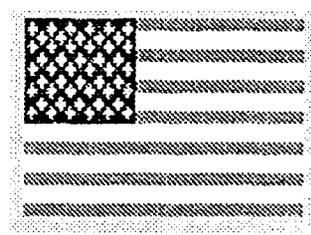
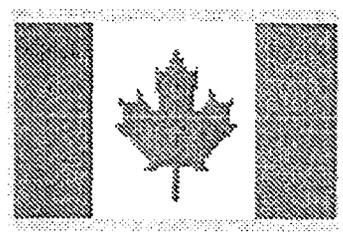


*Cross-Canada Labeling Seminars
presented by
External Affairs and International Trade
in cooperaton with the
Food and Drug Administration
April, 1993*

Dept. of External Affairs
Min. des Affaires extérieures
APR 16 1994
DEPT. OF EXTERNAL AFFAIRS
MINISTÈRE DES AFFAIRES ÉTRANGÈRES

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42-268 215

U.S. Food Labeling Regulations - New Label Format

Part 1

Cross-Canada Labeling Seminar



How to develop acceptable NLEA labeling

U.S. food regulation

Nutrient content
descriptors

General food labeling
requirements

Health claims

"Nutrition Facts" labeling

Effective dates

Serving sizes

U.S. Food Labeling Regulations - "the Basics"

- Food regulation in the United States
- General labeling requirements
- Nutrition Labeling and Education Act requirements

Federal Food Regulations

- U.S. Congress enacts legislation into laws
- Designates Federal agency to enforce them
- Agency establishes regulations

Federal Food Regulations

**Federal food laws enforced by -
USDA**

- Meat, poultry and unprocessed eggs
- Continuous inspection
- Label approval

Federal Food Regulations

Federal food laws enforced by -

EPA

- Clean environment responsibility
- Registers pesticide use (labeling, residues)
- Drinking water standards

Federal Food Regulations

Federal food laws enforced by -

FTC

- Deceptive practices in business
- Advertising

Federal Food Regulations

Federal food laws enforced by -

FDA

- All other foods
- Enforcement by inspection and sample collection
- No registration requirement nor label approval
- Legal actions against product and persons available
- Import coverage

Legal Requirements for Food Labels

- Label - on immediate container
- Labeling - accompanies article
- Package - container or wrapping for food used in delivery or display to retail purchaser

Label must contain -

- Principal display panel
- Information panel
- Identity labeling of food
- Name and place of business of manufacturer, packer, or distributor

Nutrition Labeling and Education Act of 1990

Amends the FD&C Act

Clear up consumers' confusion about food labels

Aid consumers in making healthy food choices,

Encourage product innovation by giving manufacturers an incentive to improve the quality of the food and make more healthy food choices available to consumers

Important Changes to the FD&C Act

Mandatory nutrition labeling for most foods

Regulation of nutrient content claims and health claims

Food labeling uniformity

***Labeling Uniformity Provisions
of NLEA***

- Percentage juice labeling**
- Metric declaration**
- Ingredient statements**

Percentage Juice

**Statute requires % total juice
declared prominently on
information panel**

Covered Products

- Carbonated**
- Non-carbonated**
- Concentrated**
- Full strength (100% juice)**
- Diluted**
- Beverages that purport to contain juice but
contain no juice**

Metric Requirements of the Technical Amendments

"Mass" = "Weight"

**Quantity of contents declaration:
Inch-pound and SI metric**

**Decimal fractions:
3 decimal places or less**

Exemptions/Exclusions from Metric Requirements

**Exempt:
Foods packed in retail stores**

**Excluded:
Unit pricing, advertising, recipe
programs, nutrition labeling, and general
pricing information**

Package sizes not affected

Provisions of Ingredient Final Rule

**Color additives and lakes required to be
certified must be declared by their
common or usual name**

**Abbreviated name is permissible -
"FD&C Blue No. 1", "Blue 1", "Blue 1
Lake"**

**Standardized foods must list all ingredients
in the ingredient list**

Provisions of Ingredient Final

Rule (continued)

Require label declaration of sulfiting agents that have a functional effect in a standardized food or that are present at 10 ppm or more

Permit inclusion of food source in name of certain standardized sweeteners
Dextrose anhydrous may be declared as "corn sugar anhydrous"

Provisions of Ingredient Final

Rule (continued)

Require declaration of protein source of all protein hydrolysates

Require declarations of protein hydrolysates used for flavor-related purposes

Permit use of the terms "partially", "mildly", and "lightly" as part of the common or usual name of protein hydrolysates that are used for non-flavor related purposes

Provisions of Ingredient Final

Rule (continued)

Provide collective terms for declaring preservative coatings on fresh fruits and vegetables -

"coated with vegetable-, petroleum-, beeswax-, and /or shellac-based wax or resin", and "coated with animal-based wax"

Require identification of caseinate as a milk derivative when used in foods that claim to be nondairy

Exemptions from Nutrition Labeling

Small businesses

**(under \$500,000 total gross sales/year
or \$50,000 gross sales food/year)**

**Foods served for immediate consumption
(restaurants; delis, bakeries, &
confectioneries with facilities for
immediate consumption; food service
vendors; home delivered foods)**

Exemptions from Nutrition Labeling (continued)

**Ready-to-eat foods that are not for
immediate consumption that are:**

- primarily prepared on-site, and,**
- not offered for sale outside that location**

**Foods sold for use in restaurants and other
establishments where food is for immediate
consumption**

Exemptions from Nutrition Labeling (continued)

Foods of no nutritional significance

Raw fruit, vegetables, and fish

Custom-processed fish & game meat

Foods shipped in bulk form

Exemptions from Nutrition Labeling (continued)

- Donated foods**
- Individual units in multiunit packages**
- Infant formula**
- Medical foods**
- Dietary supplements**

Nutrition Label - Basis

Amounts based on product in package, before consumer preparation

Dual declaration allowed on "as prepared" basis, in combination with other foods, or for alternate amounts (e.g., per 100 g or per unit)

Nutrition Label - Mandatory Nutrients

- **Calories**
- **Calories from fat**
- **Total fat**
- **Saturated fat**
- **Cholesterol**
- **Sodium**
- **Total carbohydrate**
- **Dietary fiber**
- **Sugars**
- **Protein**
- **Vitamin A**
- **Vitamin C**
- **Calcium**
- **Iron**

Nutrition Label - Voluntary Nutrients

- Calories from saturated fat
- Polyunsaturated fat
- Monounsaturated fat
- Potassium
- Soluble fiber
- Insoluble fiber
- Sugar alcohol
- Other carbohydrate
- Other vitamins and minerals for which RDIs have been established
- Beta-carotene (as % of vitamin A)

Nutrition Label - Graphic Elements

- Single, easy-to-read type style
- Upper and lower case letters
- Bolding
- Type size: Nutrition information - 8 point
Footnotes - 6 point
- One point leading
- Type kerned no tighter than -4 setting
- Hairlines

Simplified Format

- Allowed when 7 required nutrients are present in insignificant amounts
- Core requirements: Calories, total fat, total carbohydrate, protein, and sodium
- Must also declare other required nutrients present in more than insignificant amounts
- If voluntary nutrients are declared, non-core required nutrients must be noted in sentence at bottom
"Not a significant source of calcium"
- Footnotes are not required

Shortened Format

- Allows non-core required nutrients to be omitted from horizontal list and placed in sentence at bottom of label
"Not a significant source of saturated fat, cholesterol, and calcium"
- Footnotes are required

Nutrition Labeling - Elements

Calories

5-calorie increments up to 50 calories

10-calorie increments above 50 calories

Kilojoules permitted as a voluntary option

"Energy" allowed as synonym of "Calories"

Fat

0.5 gram increments below 3 grams

1 gram increments above 3 grams

Methods for Calculating Caloric Content

1. Specific Atwater factors (USDA Handbook #74)
2. General factors of 4, 4, & 9 for protein, carbohydrate and fat, respectively
3. General factors of 4, 4, & 9 for protein, carbohydrate (minus insoluble fiber), and fat, respectively
4. Specific food factors approved & provided by FDA
5. Bomb calorimetry

Definitions

Total fat: Total lipid fatty acids expressed as triglycerides

Saturated fat: The sum of all fatty acids containing no double bonds

Polyunsaturated fat: *cis, cis* - methylene - interrupted polyunsaturated fatty acids

Monounsaturated fat: *cis*-monounsaturated fatty acids

Definitions

Total carbohydrate: Amount calculated by subtraction of the sum of crude protein, total fat, moisture, and ash from the total weight of food

Sugars: The sum of all free mono- and disaccharides

Other carbohydrate: The difference between total carbohydrate and the sum of dietary fiber, sugars, and, when declared, sugar alcohol

Definitions

Sugar Alcohol

The sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group

The sugar alcohol must be listed by FDA (e.g., mannitol) or generally recognized as safe (GRAS) (e.g., sorbitol, xylitol)

Sugar Alcohol

Label declaration:

Terminology: "Sugar alcohol" or, when only one sugar alcohol is present, the name of the specific product (e.g., "xylitol") may be used

Voluntary unless a claim is made about sugars or sugar alcohol and sugar alcohol is present in the food

Protein as a Percent of Daily Value

Voluntary: On foods intended for adults or children 4 or more years of age.

Required: When a protein claim is made or when the food is intended for infants or children less than 4 years of age

Not allowed: On foods intended for infants that have a protein quality value of <40% of the reference standard

Protein as a Percent of Daily Value

Methods for calculation:

For infants: Protein Efficiency Ratio (PER)
(PER for food divided by PER for casein)

For adults and children 1 or more years of age: Protein Digestibility-Corrected Amino Acid Score (PDCAAS)
(protein content times amino acid score corrected for digestibility)

Daily Values

Two sets of label reference values

Reference Daily Intakes (RDIs)

Daily Reference Values (DRVs)

Persons 4 or more years of age

Daily Values: Reference Daily Intakes (RDIs)

Vitamin A	Iron	Phosphorus
Vitamin C	Vitamin D	Iodine
Thiamin	Vitamin E	Magnesium
Riboflavin	Vitamin B ₆	Zinc
Niacin	Folic Acid	Copper
Calcium	Vitamin B ₁₂	Biotin
		Pantothenic Acid

Daily Values: Daily Reference Values (DRVs)

Total Fat	65 grams*
Saturated Fat	20 grams*
Cholesterol	300 milligrams
Total Carbohydrate	300 grams*
Dietary Fiber	25 grams*
Sodium	2400 milligrams
Potassium	3500 milligrams
Protein	50 grams*

* Based on a 2000 calorie daily diet

Daily Values: Protein

Persons \geq 4 years	DRV	50 grams
Infants (\leq 12 months)	RDI	14 grams
Children < 4 years	RDI	16 grams
Pregnant women	RDI	60 grams
Lactating women	RDI	65 grams

Serving Size - Single Serving Container

If container < 200% Reference Amount:
Declared as One Serving

If Reference Amount > 100 grams and
container has > 150% (but < 200%) of RA:
Manufacturer may determine whether
container is 1 or 2 servings

Serving Size - Reference Amount (RA)

Basis for labeled serving size

Basis for nutrient "claims"

Serving Size - Labeled Serving Size

Yogurt:	1 cup (__ g)
Pie:	1/6 pie (__ g)
Pretzels:	4 pretzels (__ g)
Pancake mix	1/4 cup (__ g)

Serving Size - Basis for Claims

Criterion: Meet definition on basis of level per reference amount

If does not qualify on basis of level per labeled serving size: Needs qualifying statement

"Low sodium, 140 mg or less per 240ml/8 fl oz)"

Serving Size - Reference Amount (RA)

Derived from food consumption data

Developed jointly with USDA

Petition process to modify RA

Serving Size - Final Rule

Contains Reference Amount (RA) for 139 categories

Based on amounts customarily consumed

Sets procedures for determining labeled serving size from Reference Amount

Serving Size - Labeled Serving Size

Bulk products (e.g., flour, sugar, RTE breakfast cereals): Household measure closest to reference amount

Discrete large unit (e.g., pies, cakes): Fraction closest to reference amount

Discrete individual units (e.g., cookies, sliced bread):

> 50% but < 200% of RA = 1 unit

≤50% RA = Number of units closest to reference amount

Serving Size - Household Measures

Cups, tablespoons, teaspoons (fl oz for beverages)

Pieces, slices, fractions, etc.

Ounces (with appropriate visual unit)

Serving Size - Labeled Serving Size

Required : Household and metric measure

- 1 cup (___ g)
- 1 slice (___ g)
- 1 dinner (___ g)
- 2 oz (___ g/___ inch slice)

Optional: ounce or fluid ounce

- 1 cup (___ g/___ oz)

Serving Size - Labeled Serving Size

As packaged

In household measures

Based on Reference Amount

Serving Size - Second Column

Generally optional

Per 100 g (or fl oz)

Per Unit (cookie, slice)

Encouraged for "As Prepared"

Number of Servings Per Container

Exact serving size and approximate number of servings

Incremental rule:

- < 2: single serving**
- ≥ 2 but < 5: 0.5 servings**
- ≥ 5: whole number**

Small Package Rules

Less than 12 in² labeling area

- **Nutrition information not required on label**
- **Nutrition information available on request**
 - Telephone number, or
 - Address

Nutrition Labeling Intermediate-sized Package

40 in² or less labeling area

- **Footnotes not required**
- **Placement allowed on any panel**
- **Specified abbreviations allowed**
- **Tabular or linear display allowed**

Nutrition Facts

Serving Size 1/2 cup (114g)

Servings Per Container 4

Amount Per Serving

Calories 260 Calories from Fat 120

% Daily Value*

Total Fat 13g 20%

Saturated Fat 5g 25%

Cholesterol 30mg 10%

Sodium 660mg 28%

Total Carbohydrate 31g 11%

Dietary Fiber 0g 0%

Sugars 5g

Protein 5g

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

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

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

Tabular Display

Nutrition Facts

Serv. Size 1/3 cup (56g)

Servings about 3

Calories 80

Fat CaL 10

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

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	2%	Total Carb. 0g	0%
Sat.Fat 0g	0%	Fiber 0g	0%
Cholest. 10mg	3%	Sugars 0g	
Sodium 200mg	8%	Protein 17g	
Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%			

Simplified format (Soft Drink)

Nutrition Facts

Serving Size 1 can (240 ml)

Amount Per Serving

Calories 145

% Daily Value*

Total Fat 0g 0%

Sodium 20mg 1%

Total Carbohydrate 36g 12%

Sugars 36 g

Protein 0g 0%

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

Simplified format (Vegetable oil)

Nutrition Facts

Serving Size 1 Tbsp (14g)

Servings Per Container 64

Amount Per Serving

Calories 130 Calories from Fat 130

% Daily Value*

Total Fat 14g **22%**

Saturated Fat 2g **10%**

Polyunsaturated Fat 4g

Monounsaturated Fat 8g

Sodium 0mg **0%**

Total Carbohydrate 0g **0%**

Protein 0g

Not a significant source of cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron.

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

Sample labels with dual declaration

Nutrition Facts

Serving Size 1/12 cup (45g)

Servings Per Container 12

Amount Per Serving	Mix	Balanced
Calories	190	280
Calories from Fat	45	135

	% Daily Values**	
Total Fat 5g*	13%	36%
Saturated Fat 2g	10%	13%
Cholesterol 0mg	0%	23%
Sodium 300mg	8%	8%

Total Carbohydrate 34g	9%	9%
Dietary Fiber 0g	0%	0%
Sugars 18g		

Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

*Amount in Mix

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

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

Dual declaration with footnote of nutrients added by combination of foods

Nutrition Facts		
Serving Size 1 cup (35g)		
Servings Per Container 10		
Amount Per Serving	Cereal	Cereal with 1/2 cup Skim Milk
Calories	130	170
Calories from Fat	0	0
% Daily Value**		
Total Fat 0g	0%	0%
Saturated Fat 0g	0%	0%
Cholesterol 0mg	0%	0%
Sodium 200mg	8%	11%
Total Carbohydrate 30g	10%	12%
Dietary Fiber 4g	16%	16%
Sugars 18g		
Protein 3g		
Vitamin A	25%	25%
Vitamin C	25%	25%
Calcium	0%	15%
Iron	10%	10%
*Amount in Cereal. One half cup skim milk contributes an additional 40 calories, 65 mg sodium, 6g total carbohydrate (6g sugar), and 4g protein.		
**Percent Daily Values are based on a 2,000 calorie diet. Your daily values 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
Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4		

Sweet potatoes, Canned

Nutrition Facts

Serving Size 1/2 cup (95g)

Servings Per Container 4

Amount Per Serving

Calories 90 Calories from Fat 0

% Daily Value*

Total Fat 0g 0%

Saturated Fat 0g 5%

Cholesterol 0mg 0%

Sodium 55mg 2%

Total Carbohydrate 21g 7%

Dietary Fiber 2g 8%

Sugars 5g

Protein 2g

Vitamin A 160% (100% as Beta Carotene)

Vitamin C 40% • Calcium 2% • Iron 4%

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

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

Shortened Format- Vegetable Soup

Nutrition Facts

Serving Size 1 cup (245g)

Servings Per Container 2

Amount Per Serving

Calories 55 **Calories from Fat 20**

% Daily Value*

Total Fat 1g **2%**

Sodium 800mg **33%**

Total Carbohydrate 31g **11%**

Dietary Fiber 4g **16%**

Sugars 0g

Protein 2g

Vitamin A 20% • Vitamin C 4% • Iron 2%

Not a significant source of saturated fat, cholesterol, and calcium.

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

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

Format for foods for children less than 4 years of age (Fruit Dessert)

Nutrition Facts

Serving Size 1 jar (140g)

Servings Per Container 1

Amount Per Serving

Calories 110 **Calories from Fat** 0

Amount

Total Fat 0g

Saturated Fat 0g

Cholesterol 0mg

Sodium 10mg

Total Carbohydrate 27g

Dietary Fiber 4g

Sugars 18g

Protein 0g

Vitamin A 6% • Vitamin C 45%

Calcium 2% • Iron 2%

**Format for same
food represented
to be specifically
for children less
than 2 years of age
(Fruit Dessert)**

Nutrition Facts

Serving Size 1 jar (140g)

Servings Per Container 1

Amount Per Serving

Calories 110

	Amount
Total Fat	0g
Sodium	10mg
Total Carbohydrate	27g
Dietary Fiber	4g
Sugars	18g
Protein	0g

Vitamin A 6% • Vitamin C 45%

Calcium 2% • Iron 2%

Helvetica Regular 8 point with 1 point of leading

Franklin Gothic Heavy or Helvetica Black, flush left & flush right, no smaller than 13 point

3 point rule

7 point rule

8 point Helvetica Black with 4 point of leading

6 point Helvetica Black

1/4 point rule centered between nutrients (2 points leading above and 2 points below)

All labels are enclosed by 1/2 point box rule within 3 points of text measure

8 point Helvetica Regular with 4 points of leading

1/4 point rule

Type below vitamins and minerals (footnotes), is 6 point with 1 point of leading

8 point Helvetica Regular, 4 points of leading with 10 point bullets

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving

Calories 200 Calories from Fat 120

	% Daily Value*
Total Fat 13g	20%
Saturated Fat 5g	25%
Cholesterol 30mg	10%
Sodium 600mg	20%
Total Carbohydrate 31g	11%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
<hr/>	
Vitamin A 4%	Vitamin C 2%
Calcium 15%	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories: 2,000	2,800
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

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

***U.S. Food Labeling Regulations -
New Label Format***

Part 2

***Cross-Canada Labeling
Seminar***



***General Requirements for Nutrient
Content Claims (Descriptors)***

- Claim may not be used unless provided for in regulations
- Nutrition labeling required
- Allowed on food intended for infants and toddlers only if specifically authorized
- Claim can be no larger than two times the statement of identity

Exemptions

- Brand names used before 10/25/89 that use undefined terms
- "Diet" in brand names of soft drinks used before 10/25/89
- Medical foods and infant formulas
- Claims on restaurant foods must meet definitions but disclosure and referral statements are not required and compliance determined using reasonable basis for claims
- "Fluoridated" on bottled water

General Criteria for Claims

- Consistent with dietary recommendations
- Consistency across terms and nutrients, where possible
- General philosophy for each term applied to individual nutrients

Core Descriptors

- Free
- Low
- High
- Good Source
- Lean
- Extra Lean
- Reduced/Less
- Light/Lite
- Modified
- More/Added

Referral Statement

- Required for all claims
- Located immediately adjacent to claim on every panel except panel bearing nutrition labeling
- Bold face print or type
- Generally not less than net quantity of contents statement but never less than 1/16 inch

("See side panel for nutrition information")

Disclosure Statement

- Identifies nutrients present at levels that may "increase risk of disease or health-related condition" based on consideration of the total diet
- Required if food contains more than following per reference amount, per labeled serving and if serving size is small, per 50 g
 - 13 g fat
 - 4 g saturated fat
 - 60 mg cholesterol
 - 480 mg sodium

("See back panel for information about sodium and other nutrients")

Expressed Claims

Direct statement about level (or range) of a nutrient in a food

("Low sodium")

"High" and "Good Source" Claims

- To show presence of beneficial nutrients
- Not defined for total carbohydrate
- Definitions
 - "High" $\geq 20\%$ DV per reference serving
 - "Good Source" 10% - 19% of DV per reference amount

("High in vitamin C") ("Good Source of dietary fiber")

“Free” Claims

- Based on amount per reference amount
- Nutritionally trivial - Frequent consumption has no physiological consequence
- Declared as zero on nutrition label
- If ingredient containing trivial amount of nutrient is added to product, statement “adds a trivial amount of _____” must be asterisked to ingredient
- Synonyms - “No”, “Zero”, “Without”
“Trivial source of”, “Dietarily insignificant”, “Negligible source of”

“Low” Claims

- Start with 2 percent DV (a measurable amount) and adjust for distribution across food categories
- Based on amount per reference amount and per 50 g (except for saturated fat) when reference serving size is small ($\leq 30\text{g}$ or 2 tbl)
- Synonyms: “Little” (“few”, for calories), “Contains a small amount of”, “Low source of”

Claims on Foods Inherently Free Of, or Low In, a Nutrient

- Must refer to all foods of that type
“Lettuce, a fat free food”
“Apples, a low sodium food”

“Lean” Claims

Use on seafood or game meat if meets criteria per reference amount and 100 g

- < 10 g total fat
- < 4 g saturated fat
- < 95 mg cholesterol

“Extra Lean” Claims

Use on seafood or game meat if meets criteria per reference amount and 100 g

- < 5 g total fat
- < 2 g saturated fat
- < 95 mg cholesterol

Percent and Amount Claims

Percent or amount of other nutrients may be declared if:

- It implies a nutrient level and is consistent with a defined term
(*“Less than 100 mg sodium per serving”*)
- It implies a nutrient level, is not consistent with a defined term but bears a disclaimer
(*“Only 200 mg sodium, not a low sodium food”*)
- It does not imply a level and is not otherwise false and misleading
(*“200 mg sodium”*)

Synonyms

- Free - no, zero, without, trivial source of, negligible source of, dietarily insignificant source of
- Low - little (few, for calories), contains a small amount of, low source of
- High - rich in, excellent source of
- Good Source - contains, provides

Relative (or Comparative) Claims

- Light or Lite
- Reduced/Less (Fewer, for calories)
- More/Added (enriched, fortified)
- Modified

Accompanying Information for Relative Claims

- Percentage or fraction of change - Principal Display Panel
- Identity of reference food - Principal Display Panel
- Amount of nutrient in product and reference food - Information Panel

Accompanying Information for Relative Claim (continued)

- Adjacent to most prominent claim
- Generally not less than net quantity of contents statement and never less than 1/16"

"This tomato soup contains 25 percent less sodium than our regular tomato soup."

On information panel:

"Sodium content has been lowered from 600 to 450 mg per serving."

Reference Foods

- **Light**
A food representative of type of food bearing claim, e.g.,
 - Average of top 3 brands representative value from valid data base)
 - Similar food (potato chips to potato chips)
 - Not low in nutrient which is basis of claim

"Light" or "Lite" Claims (Unqualified)

- If more than half of the calories come from fat:
Reduction of fat $\geq 50\%$
- If less than half of the calories come from fat:
 $\geq 50\%$ fat, or,
 $\geq 33.3\%$ fewer calories
- If low calories and low fat:
 $\geq 50\%$ reduction in sodium
- Reference foods
 - Representative of type of food bearing claim
 - Similar food
 - Not low in nutrient which is basis of claim
- State percent reduction of both fat and calories if not low in that nutrient

"Light" or "Lite" Claims (Qualified)

- "Light in Sodium"
≥ 50 % reduction in sodium
- Entire term must be in same type size, style, color, and prominence
- If food not reduced in fat (calories, or sodium as applicable) - Specify physical or organoleptic attribute (e.g., "Light", "Light in color", "Light in texture")
- Longstanding uses are allowed without modification ("Light corn syrup")

"Reduced/Less" Claims

- Nutritionally meaningful reduction
- ≥ 25% reduction in nutrients
- Reference food may not be "low" in nutrient
- Reference foods:
Established regular product or average representative product
- "Less" also used to compare dissimilar foods within a food category (pretzels to potato chips)

"More" and "Added" (or "Fortified" and "Enriched" Claims

- To show presence of beneficial nutrients
- Definition - ≥ 10% more per reference amount of DV for protein, vitamins, minerals, dietary fiber, or potassium than reference food
- Reference foods - An established regular product or average representative product
- "More"- also used to compare dissimilar foods within a food category (pretzels to potato chips)

“More” Claims

- **Accompanying statement:**
 - Identity of reference food, percent change on PDP**
- **Amount of nutrient in both foods on Information Panel**
- **If claim is for an added nutrient, must meet fortification policy (§ 104.20)**

“Modified”

- **May be used in name of foods making relative claims**
- **Accompanying statement required as with all relative claims**
 - Principle Display Panel:**
 - “Modified sodium gravy mix – Contains 40% less sodium than our regular gravy mix.”***
 - Information Panel:**
 - “Sodium has been reduced from 375 mg to 225 mg per serving.”***

Calorie Claims

- **“Calorie free ” means < 5 calories/reference amount**
- **“Low calorie” means \leq 40 calories/reference amount and per 50 g if small reference amount**
- **“Reduced/fewer calories” means reduction \geq 25% and reference food not low calorie**

Sugars Claims

- "Sugar Free" means < 0.5 g sugars/reference amount (Does not include sugar alcohols)
 - No added ingredients that is a sugar without asterisked statement
 - Disclose calorie profile (e.g., "Low calorie")
- "Reduced/Less Sugar" means $\geq 25\%$ reduction

Sugars Claims

- "No Added Sugar" means:
 - No sugars (or ingredient containing sugar that functionally substitutes for added sugar) added during processing
 - Food it resembles usually contains sugars
 - No ingredient containing added sugars
 - Sugars content not increased by other means
 - Disclose calorie profile

Fiber Claims

If fiber claims are made on a food not low in total fat, must disclose amount of total fat

"High in dietary fiber. Contains 5 g of total fat/serving. See side panel for nutrition information"

Fat Claims

- "Fat free" means < 0.5 g per reference serving
- "Low fat" means ≤ 3 g per reference amount and per 50 g if reference serving is small
- "Reduced fat" means reduction $\geq 25\%$,
- " % fat free" - Can only be used on "low fat" foods

Saturated Fat Claims

- "Saturated Fat Free" means < 0.5 g/reference amount and $\leq 1\%$ of the total fat is *trans* fatty acid
- "Low Saturated Fat" means ≤ 1 g/reference amount, and not more than 15% of calories from saturated fat
- "Reduced Saturated Fat" means reduction $\geq 25\%$
- Must disclose amount of total fat and cholesterol adjacent to claim

Cholesterol Claims

May only be used on foods containing
 ≤ 2 g saturated fat per reference amount

Cholesterol Claims

- "Cholesterol Free" means < 2 mg/reference amount
- "Low Cholesterol" means ≤ 20 mg/reference amount and per 50 g if reference amount is small
- "Reduced Cholesterol" means reduction of $\geq 25\%$

Cholesterol Claims

For foods containing > 13 g total fat per reference serving or per 50 g if reference amount is small

- Disclose amount of total fat adjacent to claim
- "Free" and "low" claims allowed only if cholesterol reduced by 25% or more with accompanying statement
- Accompanying information: Identity of reference food, percent change, and amount of nutrient in both foods

Sodium Claims

- "Sodium free" means < 5 mg/reference amount (No ingredient that is sodium chloride or generally understood to contain sodium without asterisk statement)
- "Very low sodium" means ≤ 35 mg/reference amount and 50 g if small reference serving
- "Low sodium" means ≤ 140 mg/reference amount and 50 g if small reference amount
- "Reduced sodium" means reduction $\geq 25\%$ and reference food is not "low sodium"

Sodium Claims

- "Salt free" - Meets criteria for sodium free
- "No salt added", "unsalted" - No salt added during processing

Food it resembles normally processed with salt

If not sodium free, declare "Not a sodium free food" on information panel
- "Lightly salted" - at least 50% less sodium than normally added to reference food. If not "low sodium", so state on information panel"

Claims for Meals and Main Dishes

- "Free" - Same as for individual foods (except calories)
- "Low" - Definition for individual food but on 100 g basis (except "low calorie" is ≤ 120 calories/100 g)
- "Light" - Meets definition for "low calorie" or "low fat" meal and label states which definition food meets, or meets definition for "low in sodium" and uses term "Light in sodium" in uniform type size, style, color, and prominence
- "Reduced/Less" - Means $\geq 25\%$ reduction and reference food may not be "low" in nutrient
- "High" and "Good Source" - Not defined for meals and main dishes but may describe individual food in product

Meal-type Products

- Meals-
 - Weighs at least 10 oz per labeled serving
 - Contains not less than 40 g of 3 foods from 2 or more of the 4 food groups
 - Is represented as breakfast, lunch, dinner or meal
- Main Dish
 - Weighs at least 6 oz per labeled serving
 - Contains not less than 40 g of 2 foods from 2 or more of the 4 food groups
 - Is represented as a main dish (not beverage or dessert)

“Lean and Extra Lean” Claims

On meals if meets criteria per 100 g & per labeled serving

- < 10 g or 5 g total fat
- < 4 g or 2 g saturated fat
- < 95 mg cholesterol

Implied Claims

- Statement about ingredient known to contain nutrient permitted if food is "low" or "good source" of implied nutrient ("Good source of oat bran")
- If other descriptive term used, must meet definitions for term ("High in oat bran = high fiber")
- Equivalence claims - "Contains as much Vitamin C as a [glass of orange juice]"

Permitted if reference food and labeled food are good sources per serving

Implied Claims

Describes food (or ingredient) in a manner that suggests :

- A nutrient is absent, or present, in certain amount ("*No tropical oils*", "*High in oat bran*")
- Food may be useful in maintaining healthy dietary practices if made with explicit claim ("*Healthy, contains 3 g fat*")

Health Claims – Definition

Any claim made on the label or in the labeling of a food that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition

Health Claims – Implied Claims

"Third party" references

Brand names

"Heart Healthy"

Symbols or vignettes

Heart-shaped symbol

Health Claims – Application

Apply to:

Conventional foods

Dietary supplements (vitamins, minerals, herbs, and other nutritional substances)

But not to:

Medical foods

Exempt infant formulas

Health Claims – Dietary Supplements Act of 1992

Health claims for dietary supplements:

Moratorium through December, 1993

Proposed regulations by June 15, 1993

Final regulations by December 31, 1993

Health Claims – Regulations

Only claims authorized by regulation are permitted

Specific regulations provide model health claims

Manufacturers may use model claims or craft appropriate claims

Health Claims – General Requirements

Nutrient levels to support a claim must be safe and lawful

Claim must help consumers understand the claim within the context of a total daily diet

***Health Claims – Authorized
Nutrient Claims***

**Dietary Saturated Fat and Cholesterol and
Coronary Heart Disease**

Dietary Fat and Cancer

**Sodium and Hypertension (High Blood
Pressure)**

Calcium and Osteoporosis

***Health Claims – Authorized
Claims for Substances in Foods***

**Fiber-containing Grain Products, Fruits,
and Vegetables and Cancer**

**Fruits, Vegetables, and Grain Products that
contain Fiber, particularly Soluble Fiber,
and Coronary Heart Disease**

Fruits and Vegetables and Cancer

***Health Claims – Claims Not
Authorized***

Dietary Fiber and Cancer

Dietary Fiber and Cardiovascular Disease

Antioxidant Vitamins and Cancer

Folic Acid and Neural Tube Defects

Omega-3 Fatty Acids and Coronary Heart Disease

Zinc and Immune Function in the Elderly

***Health Claims – General Criteria
for All Authorized Claims***

Uses "may" or "might"

Does not quantify degree of risk reduction

Indicates that the disease depends on many factors

***Health Claims – General Criteria
for All Authorized Claims***

Except for dietary supplements, foods must contain at least 10% of the Daily Value (DV) of one of six nutrients:

<u>Nutrient</u>	<u>10% DV</u>
Vitamin A	500 IU
Vitamin C	6 mg
Iron	1.8 mg
Calcium	100 mg
Protein	5 g
Fiber	2.5 g

***Health Claims – Disqualifying
Nutrient Levels***

NLEA requirement:

"... food for which the claim is made does not contain ... any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition ..."

Health Claims – Disqualifying Nutrient Levels

Nutrients: fat, saturated fat, cholesterol, sodium

Disqualifying levels:

- Foods:** $\geq 20\%$ of DV per reference amount (RA), per serving, and per 50 g (foods with RAs ≤ 30 g or ≤ 2 Tbsp)
- Main dish products:** $\geq 30\%$ of DV per serving
- Meal products:** $\geq 40\%$ of DV per serving

Health Claims – Disqualifying Nutrient Levels

Specific disqualifying levels:

<u>Nutrient</u>	<u>Foods</u>	<u>Main Dish Products</u>	<u>Meal Products</u>
Fat *	13 g	19.5 g	26 g
Saturated Fat *	4 g	6 g	8 g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

* Reference diet of 2,000 calories

Health Claims – Definitions

Substance:

Specific food or component of food

Disease or health-related condition:

General population or subgroup at risk in United States; or

Explain the prevalence of the disease in the United States and the total diet context

Health Claims – General Requirements

Consistent with regulations

Describe value of ingestion, as part of a total dietary pattern

Complete, truthful, and not misleading

All information in one place

Comprehensible to the public

Health Claims – General Requirements

Substance meets "low" or "high" requirements

Claim states any differences from RACC

Restaurant foods: Reasonable basis that food meets requirements

Nutrition labeling required

Health Claims – Additional Requirements

No expressed or implied claims unless:

Authorizing regulation

Conformance to general and specific provisions

No disqualifying levels exceeded

No substance at inappropriate level

Food not for infants and toddlers

Food has nutritive value

Health Claims – Sodium and Hypertension

Model claim:

Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.

Health Claims – Calcium and Osteoporosis

Model claim:

Regular exercise and a healthy diet with enough calcium helps teens & young adult White and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

Health Claims – Dietary Fat and Cancer

Model claim:

Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

Health Claims – Dietary Saturated Fat and Cholesterol and Coronary Heart Disease

Model claim:

While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.

Health Claims – Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer

Model claim:

Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

Health Claims – Fruits, Vegetables, and Grain Products that contain Fiber, Particularly Soluble Fiber, and Coronary Heart Disease

Model claim:

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.

Health Claims – Fruits and Vegetables and Cancer

Model claim:

Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, or vitamin C) may reduce the risk of some cancers, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.

Effective Dates

- **May 8, 1994**
 - **Mandatory Nutrition Labeling**
 - **Nutrient Content Claims**
 - **Ingredient and Juice Labeling**
- **May 8, 1993**
 - **Health Claims**
 - **Percent Juice Labeling**
 - **Ingredient Labeling of Standardized Foods and Certified Colors**
- **February 14, 1994**
 - **Metric Labeling**

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