

Guide to U.S. and Canadian Nutrition Labeling Regulations

Questions & Answers 2004 Update

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The Nutrition Labeling and Education Act of 1990 (NLEA) established specific requirements for nutrition labeling, including health and content claims, of retail food products in the United States. In January of 1993, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) published over 800 pages of regulations to ensure products are properly labeled. FDA regulations are printed in Title 21 of the Code of Federal Regulations (CFR) which are updated on April 1 of each calendar year.

Over time, numerous changes and technical amendments have been implemented in the U.S., such as requirements for dietary supplements (September 1997) and trans fat (July 2003).

🍁 *Health Canada's mandatory Nutrition Labeling went into effect on December 12, 2002. Under the mandate, Canadian companies with annual sales exceeding \$1 million have a three-year compliance period and those with annual sales under \$1 million must meet compliance requirements in 2007.*🍁

This booklet is designed to assist you in preparing nutrient labels that comply with FDA, USDA, and Health Canada requirements. This document cannot capture every nuance of the regulations. Thus, references for appropriate sections of the latest Code of Federal Regulations (CFR), along with a list of available FDA, USDA, and Health Canada nutrition labeling citations, are provided.

Silliker chemistry professionals can, of course, also answer many of your questions regarding nutrition labeling and claims and help you collect the information necessary to produce a compliant nutrition label. Our chemists are experienced in applying existing test methods and developing new methods. Please contact the laboratory nearest you.

1. Do I have to label my product?

The regulations require mandatory labeling of most retail packaged food products and dietary supplements under FDA and USDA jurisdiction. Important exceptions, for which labeling is voluntary (unless a nutrition claim is made) or is subject to other regulations, are as follows (see FDA CFR Title 21 101.9 (j); USDA CFR Title 9 317.400; Food and Drugs Act and Regulations, and Canada Gazette II).

FDA Exemptions

- Foods that provide insignificant nutrients such as plain coffee, tea, flavor extracts, and food ([see food allergen labeling guidelines](#))
- Foods that are not prepared on premises that are portioned to consumer specifications on-site (one pound potato salad, five rolls) unless the products are also packaged and sold in another part of the store
- Ready-to-serve foods (cheeses, cold cooked meats, and salads), bakery products, and confections that are sold to the consumer on the site from which they are prepared

- Small businesses (based on annual gross sales to consumers or sales volume and number of employees) ([See question 2](#))
- Restaurant and foodservice foods sold for immediate consumption (includes vending machines, sidewalk carts, etc)
- Bulk food to be further processed, packed, or labeled at other locations before retail sale
- The 20 most commonly consumed raw fruits, vegetables, and fish (subject to other "voluntary" regulations requiring point of sale materials)
- Individual units from a properly labeled multi-unit container, provided the individual units indicate that they are not labeled for retail sale
- Self-service foods sold from bulk containers, provided the original container is properly labeled
- Custom-processed fish and game (packaged single-ingredient fish or game may be labeled based upon a 3 ounce cooked portion ("as prepared"))
- Infant foods, formula, and medical foods (subject to separate regulations)
- Dietary supplements (must comply with 21 CFR 101.36)
- Donated food that is given to the consumer at no cost

USDA Exemptions

- Foods sold by businesses with less than 100 employees and less than 100,000 units annually (calculation of units is based on the most recent two-year average of business activity or reasonable estimates for new products or businesses)
- Products prepared and served or sold at retail that are:
 - Ready-to-eat and are packaged or portioned at retail (e.g., sliced bologna)
 - Multi-ingredient products (e.g., sausage) processed at a retail store
 - Restaurant or foodservice foods

🍁 Health Canada Exemptions

- *Foods for which all mandatory nutrients may be expressed as "0" (e.g., spices)*
- *Beverages with an alcohol content of more than 0.5%*
- *Fresh vegetables or fruits with no added ingredients*
- *Raw single ingredient meat, meat by-product, poultry or poultry meat by-product (but not if the meat or poultry is ground)*
- *Raw single ingredient marine or freshwater animal products*
- *Foods sold at retail where the product is prepared and processed, unless it is made from a premix with only water added*

- Foods sold at roadside stand, craft show, flea market, fair, farmers' market or sugar bush by the person who prepared and processed them
- Individual servings of food sold for immediate consumption, such as salads and sandwiches, that have not been treated or packaged to extend their durable life
- Foods sold at retail where the product is packaged, if the product is labeled with a sticker with an available display surface of less than 200 cm²
- One bite confections
- Prepackaged individual portions of food solely to be served with meals or snacks by a restaurant or other commercial enterprise
- A variety of cow and goat milk products sold in refillable glass containers.
- Formulated liquid diets, human milk substitutes, meal replacements, nutritional supplements.

(These products have specific nutrition labeling requirements under the Food and Drug Regulations).

Note: foods will lose their exempt status under the following conditions:

- if nutrient content or diet related health claims are made
- if vitamins or minerals have been added or declared as a component of an ingredient other than flour
- if the product contains added aspartame, sucralose or acesulfame-potassium
- if it is one of the following products; ground meat, ground meat by-product, ground poultry, or ground poultry meat by-product.🍁

🍁 *The manufacturer of foods used solely in the manufacture of other foods (FDR B.01.404) and multiple serving, ready-to-serve foods to be served by an institution, an industrial or commercial enterprise (FDR B.01.405) must provide the required nutrition information in absolute amounts per gram or per 100 grams, or per mL or per 100mL depending on the net quantity of product. It does not have to be in a Nutrition Facts table format.🍁*

2. How does the FDA small business exemption work, and how it differs in Canada?

Small businesses are defined in one of two ways: **a)** a retailer with annual gross sales to consumers of less than \$500,000 (determined by the most recent two-year average) or annual gross sales of only food to consumers of less than \$50,000 (such as a gift shop which sells a line of fruit preserves); or **b)** food manufacturers, packers, or distributors with fewer than 100 employees (based on the average full time equivalents) and product sales of less than 100,000 units for each product.

If a business does not meet the first definition, then it must comply with the second one for its products to be exempt from nutrition labeling (as long as no nutrient content claims or health claims are made). A "product" is defined as a food with the same brand name and statement of identity, and a "unit" is the package or form in which the product is offered for sale. The number of employees and volume of sales are based on the previous 12 months. Once a product or business exceeds either criteria, the exemption for the product(s) expires 18 months from that date. Reasonable estimates of projected sales for new products may be made. Firms utilizing the small business exemption must file an annual notice with FDA of such exemption (see 21 CFR 101.9 (j)(18)).

🍁 *In Canada, there are no exemptions for small businesses. A small business is defined as an operation with gross revenues from Canadian food sales of less than \$1 million dollars over the 12-month period prior to the proposed regulations going into effect. These companies have a five-year transitional period (Dec 12, 2007) to comply with the regulations. All other businesses have a three-year transitional period (Dec 12, 2005).🍁*

3. What nutrient information is required on the nutrition label?

The FDA and USDA agree upon an almost identical list of mandatory and voluntary nutrients for the nutrition label, as shown in **Table 1**. The only difference is that the USDA allows the voluntary declaration of stearic acid as a sub-component of saturated fat, while the FDA does not. (Trans fat is listed in Table 1 with the footnote that the food industry has until January 1 of 2006 to include this analyte on all nutrition labels.)

MANDATORY	VOLUNTARY
Total calories	Calories from saturated fat
Calories from fat	Polyunsaturated fat
Total fat	Monounsaturated fat
Saturated fat	Potassium
Trans fat*	Percent of vitamin A present as beta-carotene
Cholesterol	Soluble fiber
Sodium	Insoluble fiber
Total carbohydrate	Sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)
Dietary fiber	Other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol if declared)
Sugars	Other essential vitamins and minerals
Protein	
Vitamin A	
Vitamin C	
Calcium	
Iron	

* Effective January 1, 2006

Table 1a. Health Canada nutrition labeling disclosures

MANDATORY	VOLUNTARY
Calories	Calories from fat
Fat	Omega-6 polyunsaturated fats
Saturated fat	Omega-3 polyunsaturated fats
Trans fat	Monounsaturated fats
Cholesterol	Polyunsaturated fats
Sodium	Potassium
Carbohydrate	Starch
Fiber	Sugar alcohol
Sugars	Other essential vitamins and minerals
Protein	
Vitamins A	
Vitamin C	
Calcium	
Iron in a specified amount of	

If a claim is made about any of the voluntary nutrients, or if a food is fortified with them (except where the fortification is considered part of the Standard of Identity; e.g., enriched flour), nutrition information for these nutrients is mandatory. These mandatory and voluntary components are the only ones allowed on the nutrition facts panel for food (see question 8 on Dietary Supplements for required information on supplements).

Some elements of the Nutrition Facts table that are mandatory in the U.S. are optional in Canada: (i.e., servings per container, Calories from Fat, the footnote on % Daily Value.) Other differences include: the Daily Values for Vitamins and Minerals, the rounding rules for fat, trans fatty acids, saturates, cholesterol, and the labeling of trans fat.

🍁 *In Canada, the Nutrition Facts must be stated in English and French, and must contain the mandatory information shown in Table 1a. The nutrition label must declare the number of calories and 13 core nutrients that include: the amount of fat, saturated and trans fats, cholesterol, sodium, carbohydrate, fiber, sugars, protein, vitamins A and C, calcium and iron in a specified amount of food.*

Only Nutrition Facts tables that comply with the Canadian Food and Drug Regulations may appear on food labels in Canada. As the US label format does not meet the Canadian requirements, it cannot be used on foods sold in Canada (FDR B.01.401) and vice versa.

Nutrition Label with Optional Nutrients

In addition to the standard core nutrients, additional nutrients may also be declared. In certain cases, additional nutrients may be triggered. The manner of presentation of the optional nutrients is also prescriptive with regards to the order, terminology, and units. These are all detailed in the respective regulations.

In Canada, if omega-6 polyunsaturates, omega-3 polyunsaturates, monounsaturates or polyunsaturates are declared (or a claim is made regarding any of these fatty acids), all four must be declared. In the U.S., total polyunsaturates must be declared when monounsaturates are declared or a claim is made.

The amount of potassium must be declared if the food contains added potassium salts, less sodium, less salt, or a salt free related claim is made.

If a claim is made about an optional nutrient, that nutrient must be declared on the nutrition label.

Starch may be declared in the Canadian format. When representation of the amount of starch is made on the label or in advertising, the amount is required to be listed [FDR B.01.402(4)]. The U.S. declares "other carbohydrates" determined by difference.

The label must show the amount of any sugar alcohol, vitamin or mineral nutrient added to the food. 🍁

Nutrient Definitions

In 1993 and subsequent years, the chemical definitions of several nutrients changed from historical designations. These definitions are the same in U.S. and Canada, except where noted below.

- Total dietary fiber is included as part of total carbohydrate. Total carbohydrate is calculated by subtraction of the sum of crude protein, total fat, moisture, and ash from the total weight of the food.
- Calories can be calculated using the general factors of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat, respectively. Dietary fiber is included in the carbohydrates. 🍁 *However, as an option, except in Canada, insoluble fiber may be subtracted from the carbohydrates for the purpose of making this calculation. Calories can also be calculated using specific Atwater factors, FDA-approved food factors, and bomb calorimetry (see 21 CFR 101.9 (c) or 9 CFR 317.309 (c)). 🍁*
- Total fat is defined as the sum of the fatty acids expressed as triglycerides. AOAC procedure 996.06 and similar gas chromatographic methods quantify the concentration of individual fatty acids in a food matrix. These fatty acids are mathematically converted to triglycerides, the sum of which is expressed as total fat.
- Saturated fat is defined as the sum of all fatty acids containing no double bonds, and thus is not expressed as triglycerides. This quantity is determined from the same gas chromatographic fatty acid analysis used to determine total fat.
- Monounsaturated fatty acids is defined cis-monounsaturated fatty acids

- Polyunsaturated fatty acids is defined as cis-cis methylene interrupted polyunsaturated fatty acids. 🍁 *In Canada, the amount of omega-6 polyunsaturated fatty acids, omega-3 polyunsaturated fatty acids and monounsaturated fatty acids must be declared if the amount of any of these fatty acids groups or the amount of polyunsaturated fatty acids are included in the nutrition facts table.* 🍁
- Trans fat is defined as the sum of all unsaturated fatty acids that contain one or more isolate (i.e. nonconjugated) double bonds in a trans configuration. Thus, conjugated fatty acids (double bonds not isolated) like conjugated linoleic acid (CLA) are not included in trans fat. Again, this quantity is the sum of fatty acids, and is not expressed as triglycerides. It is obtained from the same gas chromatographic fatty acid analysis used to determine total fat.
- Sugars are defined as all free mono- and di-saccharides.
- In 1993, a new class of carbohydrate, called "other carbohydrate," was created for U.S. labels only. This voluntary analyte is defined as the difference between total carbohydrate and the sum of dietary fiber, sugar, and sugar alcohol (if declared).
- Major nutrients must be expressed not only in absolute amounts, but also as a percent of their Daily Value.

4. What are DRVs, RDIs, and Daily Values?

DRVs

Daily Reference Values (DRVs) are FDA-created guidelines for the consumption of eight nutrients: fat, saturated fat, cholesterol, total carbohydrate, fiber, sodium, potassium and protein. These guidelines were created to help consumers evaluate how a given food product might fit in their daily diet. For energy-producing nutrients, DRVs are based on the number of calories consumed per day. While scientific reports have confirmed the relationship between trans fat and an increased risk of coronary heart disease (CHD), none has recommended an amount of trans fat that FDA could use to establish a Daily Value (DV). Without a DV, a %DV cannot be calculated. As a result, trans fat will be listed with only a gram amount.

🍁 *In Canada, Daily Reference Values are established for seven nutrients: fat, the sum of saturated and trans fat, cholesterol, carbohydrate, fiber, sodium and potassium. No daily value for protein has been established. These values are the same in Canada and the US, except the daily value for trans fatty acids is combined with saturates in Canada.* 🍁

RDIs

In July 1990, the FDA proposed to revise its U.S. Recommended Daily Allowances (USRDA), the reference values it had established in 1973 for vitamin and mineral requirements. In doing so, the FDA also recommended that a new term,

Reference Daily Intake (RDI), replace the term USRDA. Congress, however, precluded the FDA from changing the USRDA values (for adults and children over four). As a result, vitamin and mineral contents are expressed as a percent of the old USRDA amounts. However, they are referred to as RDIs. As the National Academy of Sciences completes its recommendations, the FDA will review the current RDIs.

Note: RDI's for some vitamins and minerals in the U.S. differ from those in Canada. In particular, the RDI's for Vitamin A, calcium and iron in Canada are different than those for the U.S. For example, the Canadian RDI for Vitamin A is 1000 RE (retinol equivalents), while in the U.S. it is 5000 IU (international units). Similarly, the Canadian RDI for iron is 14mg, while the U.S. RDI for iron is 18mg, for example. Therefore, the calculated % RDI's for these nutrients may differ in Canada and the U.S.

Daily Values

In an effort to clarify terminology for consumers, the term Daily Value is used generically to refer to both types of reference values: DRVs and RDIs. Only the term Daily Value is used on food labels.

5. What format do I use for my nutrition information?

Basic Format (*packages with 40 or more sq. in. of available label space and approximately 3 in. or more of continuous vertical space.*)

The FDA and USDA have agreed on a basic format for displaying nutrient content per serving. This format is shown in [Exhibit 1](#). (This label is only an example; exact specifications, including required sizes, spacing, etc., are found in 21 CFR 101.9 (d) and 9 CFR 317.309 (d).)

For all nutrients, the absolute amount of the nutrient must be listed to the immediate right of the name of the nutrient. A separate column must also be provided to express major nutrient values (fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, and dietary fiber) as a percent of their Daily Value. (Vitamin A, vitamin C, calcium, and iron will continue to be labeled as a percent of their Daily Value.) The basic format also requires a table listing the mandatory DRVs for 2,000- and 2,500-calorie diets. A listing of the number of calories per gram provided by fat, carbohydrate, and protein was originally required, but was made voluntary by the technical amendments.

For larger packages with insufficient continuous vertical space (i.e., approximately 3 in.), the regulations provide for the use of a different format (either the footnote to the side or tabular [see 21 CFR 101.9 (d)(ii) or 9 CFR 317.309 (d)(ii)]).

Exhibit 1.

Nutrition Facts	
Serving Size 1 cup (228g)	
Servings Per Container 2	
Amount Per Serving	
Calories 260	Calories from Fat 120
% Daily Value*	
Total Fat 13g	20%
Saturated Fat 5g	25%
Trans Fat 2g	
Cholesterol 30mg	10%
Sodium 660mg	28%
Total Carbohydrate 31g	10%
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

Exhibit 2.

Nutrition Facts	
Per 125 mL (97 g)	
Amount	% Daily Value
Calories 90	
Fat 0.5 g	1 %
Saturated 0 g	0 %
+ Trans 0 g	
Cholesterol 0 mg	
Sodium 0 mg	0 %
Carbohydrate 18g	6 %
Fibre 2 g	8 %
Sugars 2 g	
Protein 3 g	
Vitamin A 2 %	Vitamin C 10 %
Calcium 0 %	Iron 2 %

Valeur nutritive	
par 125 mL (97 g)	
Teneur	% valeur quotidienne
Calories 90	
Lipides 0,5 g	1 %
saturés 0 g	0 %
+ trans 0 g	
Cholesterol 0 mg	
Sodium 0 mg	0 %
Glucides 18g	6 %
Fibres 2 g	8 %
Sucres 2 g	
Protéines 3 g	
Vitamine A 2 %	Vitamine C 10 %
Calcium 0 %	Fer 2 %

✦ The Canadian Regulations require that the standard vertical format" (shown in [Exhibit 2](#)) be used whenever the available display surface allows, and it must be shown in French and English. The conditions for the use of formats and versions are specified in the Regulation. Other formats (horizontal, linear) as presented in Schedule L of the Canadian Gazette, Part II may only be used if the standard vertical format cannot be accommodated.✦

Smaller Packet Formats

Alternative formats may be used on labels of less than 40 square inches (see 21 CFR 101.9 (j)(13) or 9 CFR 317.309 (g)). One alternative is identical to the format used on larger packages, except that it does not require the second sentence of the footnote and the summary chart of Daily Values. An abbreviated tabular format is also allowed, as is a linear format when the abbreviated tabular display cannot be accommodated.

Packages under FDA and USDA jurisdiction, with labels smaller than 12 square inches, need not bear a nutrition label, but must display a phone number or address the consumer can write for nutrition information (unless a claim is made). Packages under USDA jurisdiction with net weights of less than 1/2 ounce also do not require nutrition information unless a claim is made.

Simplified Label Formats

Under FDA jurisdiction, if a food intended for adults contains insignificant amounts of eight or more of the mandatory nutrients and total calories, it may qualify for use of a simplified label ("Insignificant" means that the nutrient could be rounded to zero according to the FDA's rounding rules [see reference chart]; or for total carbohydrate, dietary fiber, and protein, the nutrient declaration could state "less than 1 gram.")

When the simplified FDA format is used, information on total calories, total fat, sodium, total carbohydrate, and protein is required, even if they are present in insignificant amounts. Other nutrients, along with calories from fat, must be shown if they are present in more than insignificant amounts, or if they have been added to the food. The table of daily values may be omitted.

USDA rules on simplified labeling differ slightly (see 9 CFR 317.309 (f)). The USDA's simplified format may be used when any required nutrient(s) other than the core nutrients (calories, total fat, total carbohydrate, protein, and sodium) is present in an insignificant amount. The insignificant nutrient(s) may be omitted from the vertical column in the display, provided a statement, "Not a significant source of _____," appears on the nutrition panel, with the blank space containing the name(s) of the insignificant nutrient(s). (Insignificant amounts are defined as less than 1 gram of total carbohydrate, sugars, dietary fiber, and protein and as amounts which can be rounded to zero for other nutrients.)

Because many meat and poultry products do not contain dietary fiber, sugars, or vitamin C in significant amounts, this is an important provision for minimizing the space required for nutrition labeling information.

Other Formats

Special formatting rules apply to products designed for children under 2 or 4 (see 21 CFR 101.9 (j)(5)). In Canada, refer to Canada Gazette, part II, or FDR B.01.403 / B.01.461 to B.01.466

6. What serving size do I use?

Background

A serving size is defined by FDA and USDA as “the amount of food customarily consumed per eating occasion” expressed in a common household measure.

Both FDA and USDA have established a system for determining serving size that is designed to ensure comparability between like products. Your serving size must now be carefully determined to comply with these requirements.

Serving size determination can be a complex undertaking, not adequately described in this space. The regulated reference amount along with the how the product is packaged must be taken into account. Please contact your local Silliker lab if you need further assistance in determining the correct serving size for your product.

Serving Size Determination

The FDA and USDA have established the amount of food product “customarily consumed per eating occasion” for over 139 product categories (“reference amounts”). Serving sizes are the amounts expressed in common household measures appropriate for these foods that most closely approximate these reference amounts. Reference amounts are found in Table 2 in sections 21 CFR 101.12 (b) and 9 CFR 317.312 (b) of the regulations.

🍁 *Canadian manufacturers and importers must follow serving size guidelines outlined in the “Guide to Food Labeling and Advertising” based on the Reference Amount of a food (listed in Schedule M, Canada Gazette, part II) which specifies the quantity, for each food, and reflects an amount that people usually consume at one sitting.* 🍁

The **first step** in determining your serving size is to locate the appropriate food category for your product in the reference amount tables. To increase uniformity, the FDA’s list of reference amounts includes suggested label statements that generally specify the household measure to be used on the label.

Most of the reference amounts are for foods in ready-to-eat form. If your packaged product, does not have a reference amount, you will need to determine your reference amount using sections 101.12 (c, d, e, f) which apply to products requiring preparation, imitation foods, aerated foods, and products that represent two or more foods packaged and presented to be consumed together.

The **second critical step** in determining serving size is to understand whether your product meets the definition of a single serving:

- Products packaged and sold individually that contain less than 200% of the reference amount must be labeled as a single serving. (For example, a 12 oz (360 mL) can of soft drink is considered a single serving because the reference amount for this product is 8 oz (240 mL)). However, if the product has a reference amount of 100 g or 100 mL or more, and the package contains more than 150% but less than 200% of the reference amount, the manufacturer may decide whether to declare one serving or two. (For example, 245 grams is the reference value for soups; therefore, a 15 oz (420 gram) can of soup may be labeled as one or two servings.) Packages sold individually that contain 200% or more of the reference amount may be labeled as a single serving if the package’s content can reasonably be eaten on one occasion.
- For meal-type products and main dish products in single serving containers, a serving is defined as the entire contents of the package. (Meal-type products are defined by the USDA as products weighing 6 oz or more and less than 12 oz per serving, containing ingredients from two or more of four food groups, and presented in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. The FDA uses slightly different definitions [see 21 CFR 101.13 (l) and (m)], but many products of this type fall under USDA jurisdiction.)

A few of the key rules for determining the serving size of multi-serving products are as follows:

- For products in discrete units (e.g., muffins, sliced bread, hot dogs, or individually packaged products in multi-unit containers), except for products that naturally vary in size (e.g., pickles), serving sizes are the number of units most closely approximating the reference amount for the category. If a unit weighs 50% or less of the reference amount, the serving size is the number of whole units which comes closest to the reference amount. If a unit weighs 67% or more, but less than 200% of the reference amount, the serving size is one unit. If a unit weighs more than 50% but less than 67% of the reference amount, you may, at your option, declare one or two units as a serving. If a unit weighs 200% or more than the reference amount, it may be declared as a serving if it could reasonably be eaten on one occasion.
- Serving size for most products that naturally vary in size (e.g., pickles, shellfish) is expressed as the amount in ounces that most closely approximates the reference amount for the category. A visual unit of measure should be given to describe the approximate amount of the ounce measure; e.g., 1 oz (28 g / about 1 cup).

- For products in large discrete units, generally divided between several people, the serving size is the fractional slice of the food that best approximates the reference amount for the category (e.g., 1/12 cake, 1/4 pizza, 1/6 cabbage). In expressing the fractional slice, you must use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions generated by further division by 2 or 3.
- Products which consist of two or more distinct ingredients packaged and presented to be consumed together (e.g., dry macaroni and cheese mix, cake and muffin mixes with separate ingredient packages, pancakes and syrup) may declare serving size and nutrition information either a) for each component, or b) as a composite. For products where one of the components is the “main ingredient” (e.g., pancakes and syrup), provisions exist for the serving size to be the amount of the main ingredient plus proportioned minor ingredients used to make the reference amount for the combined product. In addition, these products may declare the serving size in ounces with an appropriate visual unit of measure (see 21 CFR 101.9 (b)(2) and (5)).
- For products requiring cooking or the addition of water or other ingredients (e.g., baked goods mixes, dough, batter), and for which the regulations specify a reference amount only for the prepared form of the product, the reference amount is the amount required to make one reference amount of the final, prepared product. For such products where the entire contents of the package is used to prepare one large discrete unit typically divided for consumption (e.g., cake mix, pizza kit), the reference amount is the amount of unprepared product required to make the fraction of the large discrete unit closest to the reference amount for the prepared product. In this case, the serving size may be stated as a fraction of the package used to make the reference amount (see 21 CFR 101.9 (b)(5)).
- For variety packs of single servings, nutrition information must be provided for each variety or type of food based on the serving size for that food using the reference value for that food.

🍁 *In Canada, serving size ranges for a variety of foods are published in the Guide to Food Labelling & Advertising. These are based on reference amounts listed in Schedule M, Canada Gazette, part II.* 🍁

Expressing Serving Size—Common Household Measures

The serving size is expressed on the label first in common household measures. In choosing this measure, several rules must be followed:

- Cups, tablespoons, or teaspoons shall be used whenever possible and appropriate, except for beverages. (For beverages, you may use fl oz.) Cups are expressed in 1/4 or 1/3 cup increments. Tablespoons are expressed in whole numbers for quantities less than 1/4 cup but greater than or equal to two

tablespoons; in 1/3, 1/2, and 2/3 fractions between 1 and 2 tablespoons. Teaspoons are expressed in whole numbers for quantities less than a tablespoon but greater than or equal to a teaspoon, and in 1/4 teaspoon increments for quantities less than 1 teaspoon.

- If cups, tablespoons, or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction are used.
- If neither of the above is applicable, ounces may be used with an appropriate visual unit of measure; e.g., 1 oz (28 g/ about 1/2 pickle). Ounce measurements are expressed in 0.5 oz increments most closely approximating the reference amount.

Expressing Serving Size—Metric Measures

The expression of serving size in common household measures is followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams). (See Exhibit 1.) For nutrition labeling purposes, a teaspoon means 5 mL, a tablespoon means 15 mL, a cup means 240 mL, (in Canada, 1 cup = 250mL), 1 fl oz means 30 mL, and 1 oz in weight means 28 g. Gram or millimeter quantities are rounded to the nearest whole number, except for quantities less than 5 g (ml). Between 2 and 5 g (ml), quantities should be rounded to the nearest 0.5 g (ml); quantities below 2 g (ml) should be expressed in 0.1 g (ml) increments. In Canada, if it is less than 10g (mL), it is rounded to the nearest multiple of 0.1 g (mL). If it is over 10g (mL) it is rounded to the nearest multiple of 1 g (mL).

The serving size may also be declared in oz and fl oz in parenthesis, following the metric measure separated by a slash, where other common household measures are used as the primary unit for serving size (e.g., 1 slice (28 g/1 oz) for sliced bread). These quantities are expressed in 0.1 oz increments.

Label Products “As Packaged”

Under the mandatory labeling requirements, nutrition information, with few exceptions, must be presented on an “as purchased or packaged” basis. An exception to this rule is for products packed in liquid which is not normally consumed (e.g., olives). (For these products, the nutrition information is presented based on the drained solids.) The USDA has also granted exceptions for bacon and fresh pork sausage which allow these products to be labeled on an “as consumed” as opposed to an “as packaged” basis (based on a certain percent shrinkage in the cooking process).

The manufacturer may also voluntarily present the nutrient information on an “as consumed” basis (e.g., completed cake) using the package directions for preparation of the product. The regulations also allow the information to be presented on a per 100 g, 100 ml, 1 oz or 1 fl oz basis, per one unit for multi-serving containers when the serving size is more than one unit, and per cup of popped popcorn. In these cases, a specific format is required (see 21 CFR 101.9 (e)).

Servings Per Container 🍁 (Optional in Canada) 🍁

The number of servings per container is rounded to the nearest whole number except when the number of servings is between 2 and 5, in which case rounding is to the nearest 0.5 serving. Rounding of whole numbers above 5 is indicated by the use of the term “about” (e.g., about 6 servings). Special rules apply to products expressed on a drained solids basis or random weight products (see 21 CFR 101.9 (b)(8)).

7. What types of claims can I make?

Under the final regulations, two classes of claims are allowed by the FDA on foods for adults: nutrient content claims and health claims. Only approved claims may be used, and specific petitioning procedures have been put in place for future additions to the list of approved claims. (For both types of claims, there are a wide variety of type size, placement and footnote, and other requirements that are beyond the scope of this document [see 21 CFR 101.13 and 9 CFR 317.313], and FDR B.01.500 and B.01.512)

Restaurants making nutrient content claims or health claims either on menus or other means (such as table tents or promotional materials) must adhere to all of the definitions and regulations and must be able to furnish substantiating nutrition information upon request. However, the nutrition information required to substantiate the claim is less stringent than in the case of packaged foods (see 21 CFR 101.10).

Nutrient Content Claims

The completed sentence would appear as: The FDA and USDA agree on the terms that may be used to explicitly or implicitly characterize the level of a nutrient in a food and how these terms may be used. The key nutrient content claims are listed below. The trans fat regulations of July 2003 did not allow for any trans fat claims, but the FDA did indicate that it was collecting comments on potential “trans fat free” and “reduced trans fat” labeling. In addition, comments were being sought for disclosure and disqualifying levels of trans fat for products making nutrient content claims and health claims. U.S. food manufacturers have until January 1, 2006 to list trans fat on the nutrition label. Complete definitions and rounding rules of the other nutrients are found in the reference chart.

Absolute Claims—a direct statement about the level of a nutrient in the food

- **Free:** means a product’s reference amount and labeled serving contains no amount, or an insignificant amount of: fat, saturated fat, cholesterol, sodium, sugars, and calories. (Insignificant is defined as an amount that may be rounded to zero, according to the FDA’s rounding rules.) Synonyms include “without,” “zero,” and “no.”

- **Low:** means a product could be eaten frequently without exceeding the guidelines for: fat, saturated fat, cholesterol, sodium, or calories. Synonyms include “little,” “few,” and “low source of.” The term “very low” is also defined with respect to sodium levels.
- **Use of the term “free” or “low”** on a product that has not been specially processed or altered to qualify for these claims requires a statement indicating that all foods of that type inherently qualify for the claim (e.g., “corn oil, a sodium-free food”).
- **Lean and Extra Lean:** may be used to describe meat, poultry, seafood, and game meats.
- **Lean:** less than 10 g of fat, less than 4.5 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g.
- **Extra Lean:** less than 5 g of fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g.
- **High:** means one reference amount of a product contains 20% or more of the Daily Value for a particular nutrient.
- **Good Source:** means one reference amount of a product contains 10 to 19% of the Daily Value of a particular nutrient.
- **High Potency:** describes an individual vitamin or mineral which is present in a product at 100% or more of the RDI per reference amount. The claim must identify the vitamin or mineral that is the subject of the claim (e.g., “High Potency Vitamin E”). “High potency” can also be used to describe an entire product (whether a food or a dietary supplement) when the product contains 100% or more of the RDI for at least two-thirds of the vitamins and minerals listed in 21 CFR 101.9 (c)(8)(iv) that are present in the product at a level of 2% or more of the RDI (e.g., “High Potency Multivitamin”).
- **Antioxidant:** use of the term “antioxidant” is allowed as part of a nutrient content claim as long as there is an established RDI for the nutrient and scientific evidence demonstrates that following absorption of a sufficient quantity, the nutrient will inactivate free radicals or prevent free radical-initiated chemical reactions. The level of the nutrient must qualify for the absolute claim (i.e., “high” or “good source” as described above), and the name of the nutrient must be part of the claim (e.g., “High in Antioxidant Vitamin C”) or be linked by a symbol to the claim.

Relative Claims—a statement comparing the nutritional values of one food to another

- **More:** means that a reference amount of a food, whether altered or not, contains at least 10% more of the Daily Value of a nutrient than the reference food. This definition also applies to “fortified,” “enriched,” added,” “plus” claims; but in these cases, the food must be altered.

- **Less:** means that a food, whether altered or not, contains 25% less of a nutrient, or of calories, than the reference food. "Fewer" is an acceptable synonym for "less."
- **Reduced:** means that a nutritionally altered product contains 25% less of a nutrient, or of calories, than the regular or reference product. (However, a reduced claim cannot be made on a product if its reference food already meets the definition for a "low" claim.)

Light has several possible meanings:

- First, that a nutritionally altered product contains one third fewer calories or half the fat of the reference food. (If the food derives 50% or more of its calories from fat, the reduction must be 50% of the fat.)
- Second, that the sodium content of a low calorie, low fat food has been reduced by 50% or more. (The term "light in sodium" may be used on any food in which the sodium content has been reduced by 50% versus the reference product.)
- Third, the term "light" may also still be used to refer to specific properties such as texture and color, as long as the label explains the intent; for example, "light brown sugar" and "light and fluffy."
- Fourth, use of the term "light" for meal products or main dishes has specific requirements (see 21 CFR 101.56 (d)).

🍁 *Nutrient Content Claims have been updated in Canada. The regulations set out food composition and labeling requirements for over 40 nutrient content claims. The strict criteria established by Health Canada differ from those in the US. See Canadian Gazette, part II Nutrient Content Claims -B.01.500.* 🍁

Reference Foods for Relative Claims

For each of the relative claims ("light", "reduced", "less", and "more"), the FDA has defined which foods may be used as a basis of comparison, the so-called "reference foods."

- For a "light" claim, the reference food must be a similar food and the reference value must be representative of a broad base of values for foods of that type. It may be a value drawn from a valid database, the average of the three top national (or regional brands), a market basket norm, or the market leader if the leader is representative of that food type.
- For "reduced", "less", and "more" claims, the reference food can be your regular brand, another manufacturer's regular brand, or a representative value for a broad base of foods of that particular type. For the terms "less" and "more," the reference food may also be a dissimilar food in the same product category that can generally be substituted in the diet (e.g., pretzels that have 25% less fat than potato chips could bear a "less" claim).

Other Definitions

The FDA and USDA have also defined several other important claims:

- **Percent Fat Free:** Only products which meet the low fat or fat free definition may make this claim. The term 100% fat free can only be made on products that meet the criteria for "fat free," contain less than 0.5 g fat per 100 g, and contain no added fat.
- **Healthy:** Both FDA and USDA have similar definitions for the term "healthy." FDA regulates use of "healthy" to describe a food that meets the criteria for low fat and low saturated fat and contains no more than 480 mg sodium (maximum sodium value decreases to 360 mg as of January 1, 2000) or 60 mg cholesterol per serving. The product also needs to contain at least 10% of the RDI or DRV of vitamin A, vitamin C, calcium, iron, protein, or fiber per reference amount. USDA uses the same definition except for single ingredient raw products. For these products, USDA defines "healthy" as any raw meat or poultry product which contains less than 5 g fat, less than 2 g saturated fat, less than 95 mg cholesterol, and less than 480 mg sodium (360 mg as of January 1, 2000) per 100 g and per reference amount. The product must also contain at least 10% of the RDI or DRV of vitamin A, vitamin C, calcium, iron, protein, or fiber per reference amount. Meal type and main dish products for both FDA and USDA have different requirements in order to be called "healthy" (see 21 CFR 101.65 (d) and 9 CFR 317.363)).
- The term "**fresh**" is also defined when it is used to suggest that a food is unprocessed or unpreserved (see 21 CFR 101.95).

Implied Claims —This is a statement that suggests that a nutrient is absent or present in a food (e.g., "High in Oat Bran" suggests the food is high in fiber). The food must meet the regulations regarding the implications of the claim.

Health Claims

A health claim is defined as a statement, endorsement, or symbol (e.g., a heart) that characterizes the relationship of a substance to a disease or health-related condition. FDA regulations authorize the use of 12 specific health claims for food labels:

- calcium and osteoporosis
- sodium and hypertension
- saturated fat and cholesterol and coronary heart disease
- fat and cancer
- fiber-containing grain products, fruits and vegetables and cancer
- fruits, vegetables, and grain products that contain fiber and coronary heart disease

- fruits and vegetables and cancer
- folic acid and neural tube defects
- soluble fiber from whole oats or psyllium and risk of coronary heart disease
- dietary sugar alcohols and dental caries
- soy protein and coronary heart disease and
- plant sterol and stanol esters and coronary heart disease

To use a health claim, a product must meet the specific definition established for that claim. These definitions require that the product be “high” or “low” for the nutrient in question and often contain other requirements (see 21 CFR 101.14). Health claims are not allowed on products that contain more than 13 g of fat, 4 g of saturated fat, 60 mg cholesterol, or 480 mg sodium per reference amount, per serving size, and for foods with a reference amount of 30 g or less, per 50 g.

For each health claim, the FDA has specified certain information that must be conveyed and information that may not be included. The FDA has provided sample claims to assist manufacturers in meeting the regulations (see 21 CFR 101.72 - 101.81).

USDA

The USDA does not yet permit health claims that link food attributes to diet-related disease and health-related conditions. In 1994, the FSIS published a proposed rule regarding health claims, but to date no final rule has been issued.

The USDA does allow statements informing consumers that a food can be part of a specific dietary pattern to meet an organization’s dietary guidelines (e.g., “This food was specifically developed to help you follow the current U.S. Dietary Guidelines for sodium, fat, and cholesterol. For further information on the U.S. Dietary Guidelines, call ...”).

🍁 Health Canada

Health Canada permits only the following five diet related health claims. The exact order and wording of permitted health claims is specified in the Food & Drug Regulations (see table following B.01.603) and these claims cannot be reworded or paraphrased; the order of the sentences cannot be reversed. The use of the following diet related health claims must be accompanied by a declaration of the nutrient in the Nutrition Facts Table.

- sodium, potassium and hypertension
- calcium, vitamin D and osteoporosis
- saturated and trans fat and coronary heart disease
- fruits and vegetables and some types of cancer
- sugar alcohols and dental caries 🍁

8. What are the special requirements for dietary supplements?

A food product is consumed as part of an individual’s daily dietary intake for the purposes of satiety, taste, basic nutritional needs, and pleasure. A dietary supplement is used to augment an individual’s dietary intake. FDA defines a dietary supplement as “a product, other than tobacco, intended to supplement the diet that contains at least one or more of ... a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of ...” the above listed ingredients. While some of the regulations pertaining to foods also regulate dietary supplements, some differences warrant special mention. Below are some of the major issues relating to the nutrition labeling of dietary supplements in the U.S. For full details, refer to 21 CFR 101.36.

When must a dietary supplement be labeled?

The exemptions for nutrition labeling of a dietary supplement are fewer than those for food. A dietary supplement must include nutrition labeling on its package except for:

- manufacturers or distributors who qualify for the small business exemption as explained in question 2
- products which are shipped in bulk form and are not for direct distribution to the consumer
- products which are to be further processed, labeled, or repacked
- individual units from a properly labeled multi-unit container, provided the individual units indicate that they are not labeled for retail sale
- foods sold from bulk containers, provided the container is properly labeled

For small packages, under 12 square inches, nutrition labeling is still required. There are special type size requirements for these packages to accommodate all of the required information.

What information is required on the label of a dietary supplement?

Statement of Identity

The labeling of a dietary supplement must include the term “dietary supplement” as part of the statement of identity, unless the actual name of the dietary ingredient or nutrient is used in place of the word “dietary” (e.g., “Vitamin C Supplement”). For example, a multivitamin product with a brand name such as “Vital Formula One” would need to be worded as “Vital Formula One Dietary Supplement” or “Vital Formula One Multivitamin Supplement.” Generic terms such as “Food Supplement” are not allowed.

Ingredient Listing

The ingredients must be located directly below the nutrition panel or immediately to the right of the nutrition panel. If an ingredient is included in the nutrition panel, then it may be omitted from the ingredient list. Use of the common or usual name of botanicals as listed in the publication "Herbs of Commerce" 1992 edition is required (available from American Herbal Products Association, 4733 Bethesda Avenue, Suite 345, Bethesda, MD 20814). If the botanical is not listed in "Herbs of Commerce," then the latin binominal name must also be included. When listing an herb or botanical, the part of the plant must be identified; e.g., Gingseng (root).

Nutrition Panel

The nutrition panel includes essentially the same information as it does for food products; however, there are some significant additions:

- The list of mandatory and voluntary nutrients is the same, except "other dietary ingredients" such as herbs or botanicals (for which there is no RDI or DRV) must be included.
- The source of the nutrient may be listed (e.g., Calcium [as Calcium Carbonate]), but the quantitative amount declared is based only on the dietary ingredient, not the source.
- A dietary ingredient for which FDA has not established an RDI or DRV shall include a symbol under the DV column referenced at the bottom of the nutrition panel by the statement "Daily Value not established." In addition, when a statement is made about the percentage level of these types of dietary ingredients, the actual amount per serving of the dietary ingredient must also be given (e.g., 40% omega-3 fatty acids, 10 mg per capsule).
- A proprietary blend of dietary ingredients must be listed in the nutrition panel with the quantitative amount for the entire blend. The dietary ingredients contained in the blend must be listed in descending order of predominance by weight. For more specific requirements, refer to 21 CFR 101.36 (b)(c)(d). (See Exhibits 3 and 4.)

The nutrition panel must include the following:

- Title of "Supplement Facts"
- Serving Size - the reference amount for dietary supplements is defined as "the maximum amount recommended, as appropriate, on the label for consumption per eating occasion, or, in the absence of recommendations, 1 unit; e.g., tablet, capsule, packet, teaspoonful, etc."
- Servings per Container - not required when stated in the Net Contents declaration

- Nutrients and Dietary Ingredients - includes the name of the nutrient or dietary ingredient which may also indicate the source, i.e., Vitamin C (as ascorbic acid); the quantitative amount by weight (declared and rounded as for food with amounts for vitamins and minerals given in the units and level of significance as stated in 21 CFR 101.9 (c)(8)(iv)); and the DV (calculated using the RDIs and DRVs as for food)

What claims can be made on dietary supplements?

Dietary supplements are governed by the same regulations regarding nutrient content claims and health claims as are foods. However, an additional provision was made for dietary supplements via the Dietary Supplement Health and Education Act of 1994 (DSHEA). These products are allowed to make statements of nutritional support, sometimes referred to as "structure/function" claims. These claims fall into four categories:

- describes a benefit related to a classical nutrient deficiency disease in the United States and discloses the prevalence of such disease in the U.S. (e.g., Vitamin C and scurvy)
- describes the role of a nutrient or dietary ingredient as related to the structure or function in humans (e.g., Calcium and bone structure)
- characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain a particular structure or function (e.g., thiamine and energy metabolism)
- describes general well-being from consumption of the nutrient or dietary ingredient (e.g., protein and overall health)

The manufacturer must have documentation substantiating that the statement is truthful and not misleading. In addition, the claim must include a disclaimer that reads "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." The disclaimer should be immediately adjacent to the claim in boldface type not smaller than 1/16 of an inch (see 21 CFR 101.93).

Most important, the manufacturer must notify FDA within 30 days of marketing a dietary supplement that includes a statement of nutritional support. A letter outlining specific information as described in 21 CFR 101.93 must be sent to: Office of Special Nutritionals, HFS 450, Center for Food Safety and Applied Nutrition, FDA, 200 C Street SW, Washington, DC 20204.

✳️ *In Canada, dietary supplements are covered under separate regulations in the Food & Drug Regulations.* ✳️

What about dietary ingredients?

When a manufacturer of a dietary supplement is producing a product which contains a new dietary ingredient, they must notify FDA at least 75 days prior to introducing or delivering the new product into interstate commerce. Required information includes: the basis that the ingredient is reasonably expected to be safe, including history of use and evidence of safety; name and address of the manufacturer; name and level of the new ingredient; description of the dietary supplement; and conditions when the supplement is recommended for use (see 21 CFR 190.6).

9. Can I use commercially available computer databases to determine nutrient content values for my product, or do I need to use analytical testing?

FDA-Regulated Products

The FDA does not prescribe a method for determining label values. The FDA's litmus test is whether label values are in compliance with the regulations, not the manner in which the values are developed. However, because the FDA's compliance procedures are still based on analytical testing (see question 10), the role of databases is somewhat limited and use of analytical testing is recommended. As the FDA states: "...FDA's policy recommends that the nutrient values for labeling be based on product composition as determined by laboratory analysis of each nutrient conducted under good laboratory practice."

The only exception to the FDA's analytical compliance procedures is for products with nutrition labeling founded on a FDA-approved database. Guidelines for producing such databases are found in the revised "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases." To date, the FDA has not approved, and does not have the resources to approve, the commercially available ingredient composition software packages for nutrition analysis. As a result, use of these nutrition analysis software programs does not allow the analytical compliance procedures to be waived.

The FDA has reviewed numerous databases for single ingredient foods (produce, frozen vegetables, canned vegetables) which were submitted by trade associations. The American Institute of Baking and the Chocolate Manufacturers Association / National Confectioners Association are the only organizations that have submitted an ingredient database with nutrition analysis software. These have been accepted (not approved) on an interim basis. Contact your respective trade association regarding databases available for your type of products.

While the commercially available nutrition analysis software programs may not obviate the need for testing, they can be very valuable in the labeling effort. These programs can be used to provide estimates of nutrient content that are then validated

through analytical testing. If the results are comparable, you may gain confidence in their use, particularly in labeling flavor variations, re-formulations, or line extensions. Again, your own risk profile must determine your willingness to use this approach. The FDA's compliance test will still be based on analytical results. This is especially critical for companies making nutrient content claims and/or health claims.

USDA-Regulated Products

The USDA no longer prescribes a particular method for determining label values; it simply holds manufacturers responsible for maintaining "records to support the validity of nutrient declarations contained on product labels" (see 9 CFR 317.309 (h)(8)).

The USDA is more lenient with regards to the use of databases to support label values. Compliance records may consist of "results of direct product analyses, database values and/or recipe calculations, or a combination" of these. The USDA permits and encourages the use of databases and recipe analyses using databases (including USDA's Nutrient Database for Standard Reference [Handbook 8], commercially available systems, and companies' proprietary databases), as well as analytical testing, to determine nutrient content value. The USDA has published a manual on the use of databases, but will not certify or approve particular databases.

Regardless of the method used to determine nutrient content values, the USDA will test products for compliance using laboratory analysis. Any discrepancy between their results and label values will still need to be addressed.

10. How does the FDA and the USDA determine if my nutrient values are in compliance?

FDA-Regulated Products

As set forth in 21 CFR 101.9 (g) for foods, the FDA inspector will collect 12 consumer packages, one from each of 12 randomly selected shipping cases of the same code or lot. A composited sample will be created from these 12 subsamples and will, in turn, be subjected to analytical testing according to Association of Official Analytical Chemists (AOAC) methods. (A composited sample is used to "average out" some of the variability that may exist between individual units. If no AOAC method is available or appropriate, other "reliable and appropriate analytical procedures" may be used.) The FDA will then compare the label values with the results from laboratory analysis. Compliance procedures for dietary supplements are similar, but do not require 12 different shipping cases and allow for less than 12 subsamples if fewer than 120 packages are available from the same lot (see 21 CFR 101.36 (f)).

For the purposes of compliance, nutrients are divided into two basic classes.

Class I: Added nutrients in fortified or fabricated foods

Class II: Naturally occurring (indigenous) nutrients

For Class I “beneficial” nutrients—vitamins, minerals, protein, dietary fiber, and potassium—the nutrient analysis must demonstrate that the product contains 100% or more of the label declaration.

The FDA recognizes that more variation is expected in naturally occurring nutrient levels. Accordingly, for Class II “beneficial” nutrients—vitamins, minerals, protein, total carbohydrate, other carbohydrate, dietary fiber, unsaturated fat, and potassium—the nutrient analysis of the test sample must demonstrate that the product contains 80% or more of the label value. (In both cases, these nutrients may fall below the level required by a factor less than the analytical variability recognized for the method.)

For a third group of nutrients (the “detrimental” ones—calories, sugars, total fat, saturated fat, cholesterol, or sodium), the nutrient analysis of the test sample must demonstrate that the product contains no more than 120% of the label declaration (again with provisions for analytical variability).

Compliance is based on the metric measure specified in the statement of serving size. Reasonable excesses of the “beneficial” nutrients, and deficiencies of the “detrimental” nutrients, are allowed as long as they are within current good manufacturing practice (GMP). (The terms “beneficial” and “detrimental” are not terms used in the regulations. We offer them simply as an aid to remembering the compliance regulations.)

USDA-Regulated Products

The USDA’s compliance system is similar to the FDA’s. The sample for nutrient analysis is a composite of: **A)** a minimum of six consumer units (preferably 12) each from a production lot, or **B)** a composite of a minimum of six units each chosen randomly to be representative of a lot (to “average” lot-to-lot variation). (Six units are used when products are difficult to mail, store, or properly composite.) Testing is performed according to procedures outlined in the USDA’s “Chemistry Laboratory Guidebook,” AOAC methods, or other methods deemed appropriate.

The USDA uses the same Class I and Class II nutrient definitions and “100% rule” for Class I nutrient content. The USDA’s “80/120 rule” for other nutrients differs slightly from the FDA’s rule. The USDA allows leeway not only for analytical variability, but for “inherent nutrient variation in a product.” A manufacturer may be provided an exemption from the “80/120” rule if it can demonstrate that nutrient variability is unavoidably high due to inherent variability in a product or ingredient which cannot be controlled under normal processing. Demonstrating this variability, however, could involve significant analytical testing.

Based on these compliance regulations, Silliker recommends that you submit samples that have been composited according to the appropriate FDA or USDA regulations. If you have any questions regarding compositing procedures or if you require assistance in compositing, please contact one of our laboratories.

Restaurant Foods

Compliance requirements for restaurant foods are not as stringent as those for retail packaged food products. The nutrition information provided by a restaurant to substantiate a nutrient content claim and/or health claim made on one of its food items may be, but need not be, determined via analytical testing. The data may also be based on recipe analysis using nutrition analysis software, cookbooks, or other reasonable bases that assure the food meets the nutrient requirements for the claim.

11. Can I use the analytical results of one composited sample to determine my nutrient content label values?

Yes, but you will be taking an unquantifiable, perhaps substantial, risk that your product will be out of compliance if it is tested by the FDA or USDA. Every food product (and analytical method) has some inherent variability, even if your production process is in control. The more variability in your product, the more risk you run of the FDA’s sample being out of compliance if you label your product using the results of just one sample, or even an average value from just a few composited samples.

Many companies choose to “round down” Class I nutrients and the “beneficial” Class II nutrients (which must be present at 100% and 80% of the label values, respectively) and “round up” the “detrimental” nutrients (which must not be present at more than 120% of the label value).

If you understand the extent of variability for each nutrient, you can choose “rounded” label values with an understanding of the level of risk you are taking that any sample chosen by the FDA might be out of compliance. Some companies, for example, use a 95% prediction interval, meaning that nutrient values are chosen such that 95% of any composites that might be tested by the FDA are predicted to be in compliance.

The USDA expects label values to represent average nutrient values. Depending on your product’s inherent variability, analysis of one composited sample may, or may not, yield a result sufficiently close to the average to meet compliance standards. Several carefully chosen samples would improve the probability of meeting compliance standards.

12. How can I estimate the variability in the nutrient content of my products? How many samples will I need to analyze?

Unfortunately, there is no pat answer to this question. The number of samples you will need to analyze depends on your product's variability, and your risk profile. If you wish to label conservatively, through rounding, you will need fewer samples. If you wish to be aggressive on important claims (e.g., caloric content for a diet product), you may wish to estimate your product's variation in these nutrients more precisely by analyzing additional samples for these nutrients only. No laboratory can make these risk assessments for you.

Even under normal circumstances, the rigorously correct (in a statistical sense) number of samples necessary to accurately estimate a product's nutrient content variability can be as high as 50-100 samples. Clearly, this is a financial burden to most companies. In practice, we recommend making estimates of your product's variability based on a pilot study of a few samples; if necessary, supplementing these estimates with additional tests (especially on key nutrients); and choosing label values conservatively (see question 11).

13. How can I develop an economical sampling plan?

We recommend that you take the following steps:

- A.** Review any historical data you may have on your product's nutrient content and its variability. Refer to a company-derived or a commercially available database. If you have already been labeling your product, you may only need data for a few nutrients. This will save considerable resources.
- B.** Prepare a pilot study of a few composited samples to determine variability of key nutrients. Consider your ingredient statement carefully and analyze only for those nutrients which can logically be present (e.g., many dairy and meat products do not contain dietary fiber). Consider the likely sources of variation in your product (e.g., seasonality, plant / process, key raw material, etc.) and try to include composited samples that reflect this variability. These samples may need to be submitted over a long time frame. (Silliker can help by keeping your results in a database and updating the database as samples are submitted.)
- C.** If the pilot study indicates little nutrient variability, you may be able to determine your label values without additional testing. By using the resulting estimated variations and by choosing the level of confidence you wish to have that you will pass the FDA compliance test (e.g., 95% prediction interval), you can statistically derive the appropriate label values.

D. If you have substantial variability in just a few nutrients, you may need to perform additional tests only for these nutrients, again substantially cutting your costs. If you have substantial variation in all nutrient levels, you may want to review your process. Otherwise, you will need to analyze more samples, label more conservatively, and/or accept more risk of being out of compliance.

E. Be conservative in your labeling by adjusting down the Class I and "beneficial" Class II nutrients, and by adjusting up the "detrimental" nutrients, especially for products under FDA jurisdiction. By understanding your product's own variation, you will understand just how conservative you are being.

F. Compare analytical results with any predicted database results to judge the accuracy and reliability of your database and to determine its role in the labeling of other products.

14. What nutrition labeling services does Silliker offer?

Silliker laboratories in the U.S. and Canada can help guide you through the labeling process from start to finish.

Planning

Our chemists can help you in the planning stages by:

- Developing an economical testing plan which avoids unnecessary analyses,
- Properly preparing your composited samples, and
- Building a database of your results that helps you understand your product's nutrient variability.

Accurate Testing

When it comes to testing, Silliker can provide you with the accurate, reliable results you need. We are fully equipped to provide complete nutrition labeling testing.

Our 70 chemists specialize in food analysis and possess extensive experience with the most difficult food matrices. As participants in numerous AOAC INTERNATIONAL committees on nutrition labeling methods, we are familiar with the most appropriate and up-to-date techniques for analyzing every food type. Our U.S. and Canadian operations are ISO 17025 accredited and we employ ISO 17025 accredited testing methods. The quality of our results are monitored through a rigorous internal process control system for each test, and each lab participates in several proficiency programs to provide an external measure of accuracy. Rigorous internal auditing by our quality assurance team, as well as the regular use of reference materials, rounds out the basic foundation of the Silliker quality system.

Reliable Reporting

After completing your testing, we provide you with a complete report of your raw analytical data, as well as the data for your serving size rounded according to the FDA / USDA and Canadian regulations in label order. We invite you to contact the laboratory nearest you or to visit our laboratories. We would be happy to discuss your individual nutrition labeling needs.

Mandatory Items (in label order)	Claims ¹	Criteria ²	Insignificant Amount / When Zero Permitted	Rounding Rules	Methods	Comment / Reference
Serving Size	Not applicable	Not applicable	Not applicable	<ul style="list-style-type: none"> • cups: 1/4, 1/3 cup increments • tbsps: whole numbers from 2 tbsps to 1/4 cup, 1/3, 1/2, increments between 1 and 2 tbsps • tsps: 1/4 increments to 1 tsp, whole numbers to 1 tbsp • tsps: express as 1/8, 1/4, 1/2, 3/4, 1 or 2 	<ul style="list-style-type: none"> • amount, expressed in common household measures, that best approximates FDA/USDA "reference amount" (r.a.) • followed by equivalent metric quantity in parenthesis (mL or g). 	<ul style="list-style-type: none"> • see question #6 and 21 CFR 101.9 and 101.12.
Servings Per Container	Not applicable	Not applicable	Not applicable	<ul style="list-style-type: none"> • the number of servings in the package rounded to the nearest whole number except, if the servings are between 2 and 5, then round to the nearest 0.5 servings and use the term "about" (e.g. "about 3.5 servings") 	<ul style="list-style-type: none"> • See rounding rules 	<ul style="list-style-type: none"> • see question #6 and 21 CFR 101.9 (b) (8). Not required in single serve containers as defined in and 21 CFR 101.9 (b) (6).
Calories	<ul style="list-style-type: none"> • free • low, few, low source of • reduced, fewer, (less)⁵ • light⁵ 	<ul style="list-style-type: none"> • <5 cal per reference amount (r.a.) and labeled serving • ≤ 40 cal per r.a. and if r.a. 30 gor 2T, per 50 grams • ≥ 25% of reduction vs, reference food • see footnote 6 	<ul style="list-style-type: none"> • < 5 cal per svg. 	<ul style="list-style-type: none"> • < 5 calories per svg., may use zero • ≥ 5 ≤ 50 calories per svg., use nearest 5 calories • > 50 calories per svg., use nearest 10 calories 	<ul style="list-style-type: none"> • calculated using Atwater food factors of 4, 4, and 9 calories per g of protein, carbohydrate and fat respectively. Insoluble fiber may be subtracted from carbohydrate for the purposes of this calculation. Other methods are also available, see 21 CFR 101.9 (c) (2) 	<ul style="list-style-type: none"> • see 21 CFR 101.60 (b) and 21 CFR 101.9 (c) (1)
Calories from fat	Not applicable	Not applicable	<ul style="list-style-type: none"> • <5 calories from fat per svg. 	<ul style="list-style-type: none"> • same as calories 	<ul style="list-style-type: none"> • calculated as calories are 	<ul style="list-style-type: none"> • not required for products with < 0.5 g fat / svg. See footnote 4 and 21 CFR 101.9 (c) (2)
Total fat	<ul style="list-style-type: none"> • free, no, zero, etc.. • 100% fat • low, little, small amts of • reduced / less⁵ • xx% fat free • light⁵ • lean, extra lean 	<ul style="list-style-type: none"> • < 0.5 g per (r.a.) and labeled serving, no added fat (unless noted as trivial)³ • < 0.5 g fat/100 g and no added fat • ≤ 3 g per r.a. and if r.a. ≤ 30 g or 2T, per 50 grams • ≥ 25% of reduction vs reference food • product must meet low fat requirement • see footnote 6 • see question #7 	<ul style="list-style-type: none"> • <0.5 g from fat per svg. 	<ul style="list-style-type: none"> • < 0.5 per svg., use zero • < 5 per svg., use nearest 1/2 gram • ≥ 5 g per svg., to nearest gram 	<ul style="list-style-type: none"> • AOAC 996.06, 17th ed. 	<ul style="list-style-type: none"> • This method is a gas chromatographic procedure that quantitates the individual fatty acid concentrations in food, and mathematically converts them to triglycerides, phospholipids • See 21 CFR 101.9 (c) (2) and 21 CFR 101.62 (b)

Note: Reference chart is based on FDA / USDA regulations. While a preponderance of U.S. and Canadian regulations are compatible, minor, but pointed, differences do exist. Please refer to "Differences Between Canada and the U.S." section on the Health Canada website to ascertain those areas.

Chart continued on next page

Mandatory Items (in label order)	Claims ¹	Criteria ²	Insignificant Amount / When Zero Permitted	Rounding Rules	Methods	Comment / Reference
Saturated Fat	<ul style="list-style-type: none"> • free • low • reduced fat / less 	<ul style="list-style-type: none"> • < 0.5 g fat and < 0.5 g trans fatty acid per r.a. / labeled serving, no added saturated fat (unless noted as trivial)³ • ≤ 1 g per r.a. and 15% of calories from sat. fat • ≥ 25% of reduction vs reference food • claims must be accompanied by disclosure of total fat and cholesterol content. Cholesterol may be omitted if content is < 2 mg / r.a., fat may be omitted if content is < 0.5 g / r.a. for free claims, ≤ 3 g / r.a. for other claims 	<ul style="list-style-type: none"> • < 0.5 g saturated fat per svg. 	<ul style="list-style-type: none"> • Same as total fat 	<ul style="list-style-type: none"> • AOAC 996.06, 17th ed. 	<ul style="list-style-type: none"> • Fatty acids without double bonds are summed. Subclasses of the total fat are not expressed as triglycerides. This quantity is determined by the same fatty acid profile used for total fat. • Not required for products with <0.5 g total fat, if no fat or cholesterol related claims are made, and calories from saturated fat are not declared. • The statement, "Not a significant source of saturated fat" shall be placed at the bottom of the table of nutrient values.
Trans Fat	Not applicable	Not applicable	<ul style="list-style-type: none"> • < 0.5 g trans fat per serv. 	<ul style="list-style-type: none"> • Same as total fat 	<ul style="list-style-type: none"> • AOAC 996.06, 17th ed. 	<ul style="list-style-type: none"> • fatty acids possessing one or more isolated (i.e., nonconjugated double bonds in a trans configuration are summed. Subclasses of total fat are not expressed as triglycerides. This quantity is determined by the same fatty acid analysis used for total fat. • not required for products with < 0.5 g total fat, if no fat or cholesterol related claims are made. • The statement, "Not a significant source of saturated fat" shall be placed at the bottom of the table of nutrient values.
Cholesterol	<ul style="list-style-type: none"> • free, zero, no • low, little, small amts of • reduced / less⁵ 	<ul style="list-style-type: none"> • < 2 mg r.a. and labeled svg., no added cholesterol (unless noted as trivial)³ • ≤ 20 mg of r.a. and if r.a. ≤ 30 g or 2T, per 50 grams • ≥ 25% of reduction vs reference food • a product must also have ≤ 2 mg sat. fat to make a cholesterol claim • if the product contains > 13 g fat per svg./ r.a. and if r.a. ≤ 30 g or 2T, per 50 grams, the cholesterol claim must be accompanied by a statement disclosing fat content 	<ul style="list-style-type: none"> • < 2 mg cholesterol per svg. And no fat, fatty acid or cholesterol claims are made 	<ul style="list-style-type: none"> • <2 mg per svg., may use zero • 2-5 mg per svg., may use "less than 5 milligrams" • >5 mg per svg., to nearest mg 	<ul style="list-style-type: none"> • AOAC 994.10, 17th ed. 	<ul style="list-style-type: none"> • This procedure is a direct saponification gas chromatographic method. Cholesterol analysis need not be performed if the product logically contains no cholesterol. • Not required on products meeting zero definition and making no fat or cholesterol-related claims. • See footnote 4 and 21 CFR 101.9 (c) (3) and 21 CFR 101.62 (d)

Chart continued on next page

Mandatory Items (in label order)	Claims ¹	Criteria ²	Insignificant Amount / When Zero Permitted	Rounding Rules	Methods	Comment / Reference
Sodium	<ul style="list-style-type: none"> • free, no, zero • Very low • Low • reduced / less⁵ • light⁵ • Light in sodium 	<ul style="list-style-type: none"> • < 5 mg per r.a. and labeled svg., no added sodium (unless noted as trivial)³ • ≤ 35 mg per r.a. and if r.a. < 30 g or 2T, per 50 g • ≤ 140 mg per r.a. and if r.a. ≤ 30 g or 2T, per 50 g • ≥ 25% of reduction vs reference food • see footnote 6 • ≥ 50% reduction vs. reference food 	<ul style="list-style-type: none"> • < 5 mg sodium per svg. 	<ul style="list-style-type: none"> • < 5 mg per svg. use zero • ≥ 5 ≤ 140 mg per svg., to nearest 5 mg • > 140 mg per svg., to nearest 10 mg 	<ul style="list-style-type: none"> • Inductively Coupled Plasma (ICP) procedure, AOAC 984.27, 17th ed. 	<ul style="list-style-type: none"> • See special rules apply to the terms "salt free" and "no salt added." • See 21 CFR 101.9 (c) (4) and 21 CFR 101.61
Total Carbohydrate	Not applicable	Not applicable	<ul style="list-style-type: none"> • < 0.5 g total carbohydrate per svg. 	<ul style="list-style-type: none"> • < 0.5 g per svg., may use zero • ≥ 0.5 g < 1 g per svg., may use "less than one gram" • ≥ 1 g per svg., use nearest gram 	<ul style="list-style-type: none"> • calculated by subtraction of the sum of crude protein, total fat moisture and ash from the total weight of the food (requires proximate analyses) 	<ul style="list-style-type: none"> • total dietary fiber is considered a component of the total carbohydrates. This distinction affects the calorie calculation. See calories, methods section. • See 21 CFR 101.9 (c) (6)
Dietary Fiber	<ul style="list-style-type: none"> • High, rich, excellent source • Good source, provides • more⁵ 	<ul style="list-style-type: none"> • > 20% of D.R.V. per r.a. • ≥10% mg ≤ 19% of D.R.V. per r.a. • 10% more of the D.R.V. per r.a. than reference food 	<ul style="list-style-type: none"> • < 0.5 g dietary fiber per svg. 	<ul style="list-style-type: none"> • same as total carbohydrate 	<ul style="list-style-type: none"> • AOAC 991.43, 17th ed. 	<ul style="list-style-type: none"> • Total dietary fiber need not be performed on products which logically do not contain fiber, such as products containing no material of plant origin (e.g., meat, cheeses) • Not required for products with <1 g dietary fiber per svg. See footnote 4 and CFR 101.9 (c) (6) and 21 CFR 101.54 (d) • If a fiber claim is made and the food is not low fat, the level of total fat per svg. must be disclosed.
Sugars	<ul style="list-style-type: none"> • free, no zero • no sugars added • reduced / less 	<ul style="list-style-type: none"> • < 0.5 gram per r.a. and labeled svg., no added sugars ((unless noted as trivial)³ • must be accompanied by a low calorie claim or statement product is not low calorie • no sugar added in processing, no ingredients containing added sugar, • no enzyme alterations for sweetness, reference product normally has added sugar, and must be accompanied by a low calorie claim or a statement that the product is not low calorie • ≥ 25% reduction vs reference food 	<ul style="list-style-type: none"> • 0.5 g sugars per svg. 	<ul style="list-style-type: none"> • same as total carbohydrate 	<ul style="list-style-type: none"> • HPLC procedure, AOAC 982.14, 17th ed. 	<ul style="list-style-type: none"> • sugars are defined as the sum of all free mono- and disaccharides • not required for products with <1 g sugars per svg. and if no sugar, sweetener, or sugar-alcohol related claims are made • see footnote 4 and CFR 101.9 (c) (6) and 21 CFR 101.60 (c)

Mandatory Items (in label order)	Claims ¹	Criteria ²	Insignificant Amount / When Zero Permitted	Rounding Rules	Methods	Comment / Reference
Protein	<ul style="list-style-type: none"> same as dietary fiber 	<ul style="list-style-type: none"> same as dietary fiber, except RDI is used instead of D.R.V. claim is determined on corrected protein value using Protein Digestibility Values 	<ul style="list-style-type: none"> < 0.5 protein per svg. 	<ul style="list-style-type: none"> same as total carbohydrate 	<ul style="list-style-type: none"> total nitrogen is determined by the appropriate AOAC Kjeldahl or combustion procedure for that matrix and a factor is applied to convert nitrogen to protein 	<ul style="list-style-type: none"> when an adult product has a protein digestibility corrected amino acid score of < 20%, other rules apply (see 21 CFR 101.9 (c) (7))
Vitamin A Vitamin C Calcium and Iron	<ul style="list-style-type: none"> same as dietary fiber 	<ul style="list-style-type: none"> same as dietary fiber, except RDI is used instead of D.R.V. 	<ul style="list-style-type: none"> < 2% RDI per svg. 	<ul style="list-style-type: none"> < 2% RDI per svg., may use zero or asterisk to "Contains less than 2% of the DRV of this nutrient." ≥ 2% ≤ 10% RDI per svg., use 2% increments > 10 ≤ 50% RDI per svg., use 5% increments > 50% RDI per svg., use 10% increments 	<ul style="list-style-type: none"> Retinol is analyzed by HPLC (Reynolds and Judd, 1994. Analyst, April 109:489) as is beta carotene (O'Connor, 1990. Waters Tech. Bulletin. Summer, 1). Vitamin C is performed by a fluorometric procedure, AOAC 967.22, 17th ed. Calcium and iron are performed by ICP procedure, AOAC 984.27, 17th ed. 	<ul style="list-style-type: none"> AOAC 974.29 (Carr-Price method) is not appropriate for foods which contain carotenes. The HPLC assays for Vitamin A are more effective at removing interfering compounds. See footnote 4 and 21 CFR 101.9 (c) (8) and 21 CFR 101.54

Footnotes:

- Any claim for the absence of a nutrient, or that a food is low in a nutrient, when the food has not been specially processed to qualify for the claim, must contain a statement indicating that all foods of this type are able to make this claim (e.g., "leaf lettuce, a low sodium food.") The claims "free" and "low" are to be used only on specially processed foods.
All nutrient claims trigger typestyle and footnote requirements. See 21 CFR 101.13.
Nutrient content claim compliance is based on the same analytical testing procedures as nutrition labeling. The reference amount is used to determine whether a product meets the criteria for a claim. If the serving size differs from the reference amount, and the amount of the nutrient in a serving does not meet the criteria for the claim, the claim must be followed by the criteria for the claim (e.g., "very low sodium, 35 mg or less per 240 ml [8 fl oz]").
- Criteria differ for meal type or main dish products (21 CFR 101.13).
- If nutritionally insignificant amount of this nutrient is added, or is part of an ingredient commonly understood to contain the nutrient, the ingredient must be followed by an asterisk and a statement such as "adds a trivial amount of..." must be placed below the ingredient statement.
- It is not necessary to list these nutrients if they are labeled as zero (or are below the level noted). If the listing is omitted, except for the Simplified Form, the statement "Not a significant source of..." must be placed at the bottom of the table for nutrient values.
- Complete definitions of relative claims ("light," "less," "fewer," "reduced," and "more") are found in question 7 and 21 CFR 101.54 and CFR 101.56. relative claims trigger many disclosure and footnote requirements.
- Contains 1/3 fewer calories or half the fat of the reference food. If 50% or more of the foods calories are from fat, the reduction must be 50% of the fat. Additionally, "light" may refer to a low fat, low calorie, product (< 40 cal and 3 g fat per r.a.) whose sodium content has been reduced by 50% or more.



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