

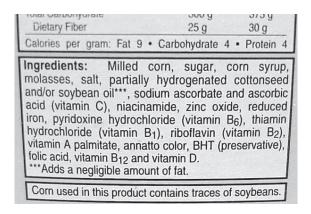
# What's on a Food Label?

### The Basics

Consumers can gain useful information by reading food labels. The label offers useful ingredient and nutrition information according to rules set by the Food and Drug Administration (FDA) of the Department of Health and Human Services and the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA). The label bears the name of the food product, net contents, and name and address of the manufacturer, packer, or distributor. Other components vary. Net contents represent the net weight, including liquid for a product such as canned corn, or the liquid measure for a fluid product such as tomato juice. Net weight is given in pounds, ounces, and grams.

# Ingredients

The food label must list ingredients by weight in descending order with food colorings listed separately. Flavorings do not have to be listed individually but may be included as "flavorings" or "natural flavors." Because some individuals may be sensitive to protein hydrolysates used as flavor enhancers, those ingredients must be listed separately. Protein sources must be designated. For example, soy, corn, or casein must be listed as "hydrolyzed soy protein," "hydrolyzed corn protein," or "hydrolyzed casein." Milk must be designated as the source of casein to alert consumers who may be allergic to milk protein or who avoid milk for religious purposes.



Sulfiting agents must be included in the ingredient list to protect individuals who react adversely to sulfites. Beverages that claim juice as an ingredient must list the percentage of juice in the formulation. Manufacturers also must state that the beverage is flavored by the named juice, such as "cranberry-flavored juice drink" or declare the amount of the named juice in a range within 5 percent, as "juice blend, 3 to 8 percent strawberry juice."

## **Spices**

Spices are defined as aromatic vegetable substances (whole, broken, or ground) whose main function is to season food rather than to provide nutrition. Spices "generally recognized as safe" by the American Spice Trade Association (ASTA) include allspice, anise, basil, bay leaves, caraway seed, cardamom, celery seed, chervil, cinnamon, cloves, coriander seed, cumin seed, dill seed, fennel seed, fenugreek, ginger, horseradish, mace, marjoram, mustard seed, mustard flour, nutmeg, oregano, paprika, parsley leaves, rosemary, saffron, sage, savory, star anise, tarragon, thyme, turmeric, and black, white, and red pepper.

# **Allergens**

Under the Food, Drug and Cosmetic Act, manufacturers are required to list all ingredients in a food. Although the term "allergen" is not defined, the FDA provides examples of foods known to cause serious allergenic responses, the most common being milk, eggs, fish, crustacean, mollusks, tree nuts, wheat, and legumes. The agency considers legal actions against products with allergens that have been misbranded or adulterated. Internationally, discussions about allergenic ingredients have resulted in several governments and the Codex Alimentarius Commission, an international body concerned with food safety and consumer protection, formulating policies for labeling foods containing such ingredients.

# **Open Dating**

Open dating is product dating that is clearly identifiable by consumers, thus, it is "open" for all

to see. The date allows consumers to know the date beyond which the quality of the product may fall below normal level. One type of open date is the "sell by" date, which represents the last day the product should be sold or used by the retailer. It is frequently seen on items such as meat or dairy products. The "expiration date" or "use by" date is the last day the product should be eaten. Examples of items with this

type of date are baby foods. A "freshness" date may be used on items with a short shelf life, such as bakery products. Products also may contain a "pack date," the day the product was packaged.



## **Code dating**

Code dating is used for products that have a long shelf life such as canned or packaged foods. Code dating is particularly useful if a food recall occurs. The dating contained in a code is not discernible by consumers. It is intended for the manufacturer's use and provides information such as the date and place of packing. This dating is required for low-acid, canned foods.

# **Universal Product Code (UPC)**

Virtually all products today carry UPC bar codes. The UPC is specific for each product. Computer scanners interpret the code to facilitate inventory control and product pricing. It also provides data to suppliers and retailers.



# **Religious symbols**

Two symbols used on foods are important for people of the Jewish faith: "K" within a circle means the food complies with Jewish dietary laws and was processed under the supervision of a rabbi. It is "Kosher." A "U" inside a circle means it complies with Jewish dietary laws and is authorized by the Union of Orthodox

Jewish Congregations of America, known as the Orthodox Union. The word "Parev" next to these symbols means the food contains neither meat nor dairy ingredients.

### Halal

In Arabic, the word halal means "permitted" or "lawful." Halal foods are foods that are approved to eat under the Islamic dietary guidelines, excluding blood or blood byproducts, pork or pork byproducts, and animals not slaughtered correctly. Halal foods go through certification systems which promise consumers that nothing in the food contains any prohibited elements. Halal is one of the most humane methods of animal slaughter. The goal through halal is to limit the amount of pain an animal will bear during slaughter. Facilities are inspected to ensure all halal standards are met. Halal foods can be found in many Middle Eastern grocery stores and in halal butcheries across larger cities. Some international supermarket chains also carry halal meats, including halal turkeys for holidays.

# Legal symbols

The ® and © symbols appear on some products. The ® means the trademark of the product is registered with the United States Patent and Trademark Office. The © means the text and art content of the label is protected under U.S. copyright laws and that copies of such labels have been filed with the Copyright Office of the Library of Congress.

# **Genetically Modified Organisms**

Genetically modified organisms (GMOs) are plants or animals genetically engineered with DNA from bacteria, viruses, or other plants and animals. In the U.S. about 80 percent of common processed foods contain GMOs. With no mandatory labeling requirement for GMOs, there is growing concern about the connection between GMOs and health problems and environmental damage. The Non-GMO project was created to help consumers choose products free of potentially hazardous ingredients. To receive the Non-GMO seal, products must go through an intense testing and verification process. Agricultural ingredients found to contain GMOs are posted on the project website. The most common GMOs are cotton, canola, corn, sugar beets, Hawaiian papaya, alfalfa, soy and squash. For more about the project, visit http://www.nongmoproject.org.

# **Meat Safety Label**

Raw or partially cooked meat and poultry products display "Safe Handling Instructions," food safety tips for temperature control, keeping raw and cooked food separate, cleaning surfaces and hands, cooking and holding hot foods hot and cold foods cold.



This product was prepared from inspected and passed meat and/ or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.



Keep refrigerated or frozen. Thaw in refrigerator or microwave.



Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.



Cook thoroughly.



Keep hot foods hot. Refrigerate leftovers immediately or discard.

# Inspection and Grading Symbols

Round inspection stamps on meat, poultry, and packaged meats mean that the food is wholesome and was slaughtered, packed or processed under sanitary conditions. Food grades on some types of meat, poultry, eggs, dairy foods, and produce are shield-shaped and reflect quality grades or evaluations based on appearance, texture, uniformity, and other characteristics.

## **Nutrition Labels**

As a result of the 1990 Nutrition Labeling and Education Act (NLEA), food labels must provide:

- nutrition labeling for many foods
- information on the amount per serving of saturated fat, cholesterol, dietary fiber, and other nutrients that are of major health concern
- nutrient reference values, expressed as "Percent of Daily Values," to help consumers see how a food fits into an overall daily diet
- uniform definitions for terms that describe a food's nutrient content: "light," "low-fat," "high fiber," and such
- claims about the relationship between a nutrient and a disease, such as calcium and osteoporosis, or fat and cancer

- standardized serving sizes that make nutritional comparisons of similar products easier
- declaration of total percentage of juice in juice drinks, and
- voluntary nutrition information for many raw foods: seafood, meats and poultry, fruits and vegetables.

## The "Nutrition Facts" Panel

Under the label's "Nutrition Facts" panel, manufacturers are required to provide information on certain nutrients. The mandatory (bold) and voluntary components, and the order in which they must appear include:

- total calories
- calories from fat
- calories from saturated fat
- total fat
- saturated fat
- trans fat
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)
- other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, if declared)
- protein
- vitamin A
- percent of vitamin A present as beta-carotene
- vitamin C
- calcium
- iron
- other essential vitamins and minerals

If a claim is made about any of the optional components, or if a food is fortified or enriched with any of them, nutrition information for these components becomes mandatory. These mandatory

Amount Per Serving Calories 250  Total Fat 12g  Saturated Fat			m Fat 110
Total Fat 12g	Cal		m Fat 110
Total Fat 12g Saturated Fat		0/ 0-	
		% Da	ily Value*
Saturated Fat			18%
	3g		15%
Trans Fat 3g			
Cholesterol 30m	ng		10%
Sodium 470mg			20%
Total Carbohydi	rate 31g		10%
Dietary Fiber (	)g		0%
Sugars 5g			
Proteins 5g			
Vitamin A			4%
Vitamin C			2%
Calcium			20%
Iron			4%
* Percent Daily Values Your Daily Values ma your calorie needs:			
	Calories:	2,000	2,500
Total Fat Saturated Fat	Less than Less than	65g 20g	80g 25g
Cholesterol	Less than Less than	300mg 2.400mg	300mg 2.400mg

For educational purposes only. This label does not meet the labeling requirements described in 21 CFR 101.9.

and voluntary components are the only ones allowed on the Nutrition Facts panel. The listing of single amino acids, maltodextrin, calories from polyunsaturated fat, and calories from carbohydrates, for example, may not appear as part of the Nutrition Facts on the label. The required nutrients were selected because they address today's health concerns. The order in which they must appear reflects the priority of current dietary recommendations.

## **Serving Sizes**

The serving size remains the basis for reporting each food's nutrient content. However, unlike in the past, when the serving size was up to the discretion of the food manufacturer, serving sizes now are more uniform and reflect the amounts people actually eat. They also must be expressed in both common household and metric measures.

The FDA allows as common household measures: the cup, tablespoon, teaspoon, piece, slice, fraction (such as "¼ pizza"), and common household containers used to package food products (such as a jar or tray). Ounces may be used, but only if a common household unit is not applicable and an appropriate visual unit is given: for example, 1 oz (28 g /about ½ pickle). Grams (g) and milliliters (mL) are the metric units used in serving-size statements.

The serving sizes that appear on food labels are based on FDA-established lists of "Reference Amounts Customarily Consumed Per Eating Occasion." These reference amounts, which are part of the regulations, are broken down into 139 FDA-regulated food

product categories, including 11 groups of foods specially formulated or processed for infants or children under four. They list the amounts of food customarily consumed per eating occasion for each category, based on national food consumption surveys. FDA's list also gives the suggested label statement for serving-size declaration. For example, the category "breads (excluding sweet-quick type), rolls" has a reference amount of 50 g, and the appropriate label statement for sliced bread or roll is "\_\_\_\_ piece(s) (\_ g)" or, for unsliced bread, "2oz (56 g/\_ inch slice)."

The serving size of products that come in discrete units—such as cookies, candy bars and sliced products—is the number of whole units that most closely approximates the reference amount. Cookies are an example. Under the "bakery products" category, cookies have a reference amount of 30 g. The household measure closest to that amount is the number of cookies that comes closest to weighing 30g. Thus, the serving size on the label of a package of cookies in which each cookie weighs 13 g would read "2 cookies (26 g)."

If one unit weighs more than 50 percent, but less than 200 percent of the reference amount, the serving size is one unit. For example, the reference amount for bread is 50 g; therefore, the label of a loaf of bread in which each slice weighs more than 25 g would state a serving size of one slice.

Certain rules apply to food products that are packaged and sold individually. If such an individual package is less than 200 percent of the applicable reference amount, the item qualifies as one serving. Thus, a 360-mL (12-fluid-ounce) can of soda is one serving, since the reference amount for carbonated beverages is 240 mL (8 ounces).

However, if the product has a reference amount of 100 g or 100 mL or more, and the package contains more than 150 percent but less than 200 percent of the reference amount, manufacturers can decide whether to label the product as one or two servings. An example is a 15-ounce (420 g) can of soup. The serving size reference amount for soup is 245 g. The manufacturer can declare the can of soup as one or two servings.

## Daily Values – DRVs

The label reference value, Daily Value, comprises two sets of dietary standards: Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs). To make label reading less confusing, only the Daily Reference Value term appears on the label.

DRVs have been established for macronutrients that are sources of energy: fat, saturated fat, total carbohydrate (including fiber), and protein; and for cholesterol, sodium and potassium, which do not contribute calories.

DRVs for the energy-producing nutrients are based on the number of calories consumed per day. A daily intake of 2,000 calories has been established as the reference. This level was chosen because it approximates the caloric requirements for postmenopausal women. This group has the highest risk for excessive intake of calories and fat.

DRVs for the energy-producing nutrients are calculated as follows:

- fat based on 30 percent of calories;
- saturated fat based on 10 percent of calories;
- carbohydrate based on 60 percent of calories;
- protein based on 10 percent of calories; (Applies only to adults and children over 4. RDIs for special groups have been established.)
- fiber based on 11.5 g of fiber per 1,000 calories

Because of current public health recommendations, DRVs for some nutrients represent the uppermost limit considered desirable. The DRVs for total fat, saturated fat, cholesterol, and sodium are:

- total fat: less than 65 g
- saturated fat: less than 20 g
- cholesterol: less than 300 mg
- sodium: less than 2,400 mg

Nutrition	Amount/Serving	% DV*	Amount/Serving	%
Facts	Total Fat 1g	2%	Total Carb. 13g	4
Fat Cal. 10  Percent Daily Values (DV) are	Sat. Fat 1g	4%	Fiber 0g	0
	Cholest. 10mg	3%	Sugars 13g	
	Sodium 140mg	6%	Protein 9g	
	Vitamin A 10% • \ Iron 0% • Vitamin E	/itami ) 25%	n C 4% • Calcium	30
INGREDIENTS: LOWFAT PALMITATE, VITAMIN D DIST KS 6	T MILK, VITAMIN A 23. By J.I.C. INC. HUTCHINSON, 7501 PLANT 20-283			

## Daily Values - RDIs

"Reference Daily Intake" replaced the term "U.S. RDA," which was introduced in 1973 as a label reference value for vitamins, minerals, and protein in voluntary nutrition labeling. The name was changed because of confusion that existed over "U.S. RDAs," the values determined by FDA and used on food labels, and "RDAs" (Recommended Dietary Allowances), the values determined by the National Academy of Sciences for various population groups and used by the FDA to figure the U.S. RDAs.

### **Nutrient Content Claims**

The regulations also spell out what terms may be used to describe the level of a nutrient in a food and how they can be used. These are the core terms:

Free. This term means that a product contains no amount of, or only trivial or "physiologically inconsequential" amounts of one or more of these components: fat, saturated fat, cholesterol, sodium, sugars, and calories. For example, "calorie-free" means fewer than 5 calories per serving, and "sugar-free" and "fat-free" both mean less than 0.5 g per serving. Synonyms for "free" include "without," "no" and "zero." A synonym for fat-free milk is "skim."

Low. This term describes foods that can be eaten frequently without exceeding dietary guidelines for one or more of these components: fat, saturated fat, cholesterol, sodium, and calories. Thus, descriptors are defined as follows:

- low-fat: 3 g or less per serving
- low-saturated fat: 1 g or less per serving
- low-sodium: 140 mg or less per serving
- very low sodium: 35 mg or less per serving
- low-cholesterol: 20 mg or less and 2 g or less of saturated fat per serving
- low-calorie: 40 calories or less per serving Synonyms for low include "little," "few," "low source of," and "contains a small amount of."

Lean and extra lean. These terms can be used to describe the fat content of meat, poultry, seafood, and game meats.

 $^{\circ}$  Lean: less than 10 g fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per serving and per 100 g

• Extra Lean: On seafood and game meat that contains less than 10g total fat, 4.5g or less saturated fat, and less than 95mg cholesterol per reference amount.

High, Rich In, or Excellent Source of: Contains 20 percent or more of the Daily Value (DV) to describe protein, vitamins, minerals, dietary fiber, or potassium per reference amount. May be used on meals or main dishes to indicate that product contains a food that meets definition. This claim may not be used for total carbohydrate.

Good Source of, Contains, or Provides: These foods contain 10 to 19 percent of the Daily Value per reference serving of a certain component.

Reduced. This term means that a nutritionally altered product contains at least 25 percent 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 requirement for a "low" claim.

Less. This term means that a food, whether altered or not, contains 25 percent less of a nutrient or of calories than the reference food. For example, pretzels that have 25 percent less fat than potato chips could carry a "less" claim. "Fewer" is an acceptable synonym.

Light. This descriptor has two definitions: First, that a nutritionally altered product contains one-third fewer calories or half the fat of the reference food. If the food derives 50 percent or more of its calories from fat, the reduction must be 50 percent of the fat. Second, that the sodium content of a low-calorie, low-fat food has been reduced by 50 percent. In addition, "light in sodium" may be used on food in which the sodium content has been reduced by at least 50 percent. The term "light" still can be used to describe such properties as texture and color, as long as the label explains the intent: for example, "light brown sugar" or "light and fluffy."

More, Added, Extra, or Plus: Foods with these claims must have 10 percent or more of the Daily Value per reference amount of a certain vitamin, mineral, protein, dietary fiber, or potassium.

Healthy. A "healthy" food must be low in fat and saturated fat and contain limited amounts of cholesterol and sodium. In addition, if it is a single-item food, it must provide at least 10 percent of one or more of vitamins A or C, iron, calcium, protein, or

fiber. Exempt from this "10-percent" rule are certain raw, canned and frozen fruits and vegetables and certain cereal-grain products. These foods may be labeled "healthy" if they do not contain ingredients that change the nutritional profile, and, in the case of enriched grain products, conform to standards of identity, which call for certain required ingredients. Meal-type products, such as frozen entrees and multicourse frozen dinners, must provide 10 percent of two or three of these vitamins or minerals or of protein or fiber, in addition to meeting the other criteria. The sodium content cannot exceed 360 mg per serving for individual foods and 480 mg per serving for meal-type products.

## Other Definitions

The regulations also address other claims. Among them:

#### **Antioxidants**

Antioxidants are vitamins, minerals, and other nutrients that protect and repair cell damage caused by free radicals. There are three major antioxidant vitamins: beta-carotene, vitamin C, and vitamin E. Most can be found in fruits and vegetables with color, including: apples, kale, blueberries, mangoes, sweet potatoes, prunes, peaches, tomatoes and watermelon. The FDA published guidelines to help companies comply with the labeling of products with antioxidants. The rule states that a nutrient content claim can be a description of antioxidant nutrients in a food; however, antioxidant nutrient claims can only be produced if the nutrients have an established RDI (reference daily intake). Some food labels claim that the product is "high in antioxidants." In order to do this, the food has to contain 20 percent or more of the Daily Reference Value (DRV) or RDI per serving. Other labels that state that the product has "good source" of antioxidants. In order to claim this, the food has to contain 10 to 19 percent of the DRV or RDI per serving. Antioxidants claims must also state the names of the nutrients that are antioxidants. For example: "High in Vitamin E and C."

### **Gluten Free**

Gluten is a protein found in foods that have been processed from wheat and other related grains, including barley and rye. Gluten gives dough elasticity, helps dough rise, and helps keep its shape. Gluten is associated with celiac disease, also known as gluten intolerance, that affects 1 in 133 Americans. Celiac disease is a condition that damages the lining of the small intestine and prevents it from absorbing parts of food that are necessary to stay healthy. Left untreated, celiac disease can lead to auto immune disorders, malnutrition, neurological damage and some forms of cancer. Gluten-free diets are only recommended for those who have celiac disease because eliminating gluten from a normal diet means excluding whole grains, which are rich in a variety of vitamins, minerals, and iron. Studies have shown whole grains as a part of a healthy diet can lower the risk of heart disease, diabetes and some forms of cancer. As of August 5, 2014, all manufacturers must comply with the FDA final rule defining "gluten-free" for labeling. The new federal law requires that in order to use the term "gluten-free" on its label, a food must meet all requirements of the definition, including that the food is less than 20 parts per million. The rule also requires foods with the claim "no gluten," "free of gluten," or "without gluten" to meet the "gluten-free" definition.



### **Percent Fat-Free**

A product bearing this claim must be a low-fat or a fat-free product. The claim must accurately reflect the amount of fat in 100 g of the food. If a food contains 2.5 g fat per 50 g, the claim must be "95 percent fat-free."

Implied: These types of claims are prohibited when they wrongfully imply that a food contains or does not contain a meaningful level of a nutrient. For example, a product claiming to be made with an ingredient known to be a source of fiber (such as "made with oat bran") is not allowed unless the product contains enough of that ingredient (for example, oat bran) to meet the definition for "good source" of fiber. As another example, a claim that a product contains "no tropical oils" is allowed, but only on foods that are "low" in saturated fat because consumers have come to equate tropical oils with high saturated fat.

Meals and main dishes: Claims that a meal or main dish is "free" of a nutrient, such as sodium or cholesterol, must meet the same requirements as those

for individual foods. Other claims can be used under special circumstances. For example, "low-calorie" means the meal or main dish contains 120 calories or less per 100 g. "Low-sodium" means the food has 140 mg or less per 100 g. "Low-cholesterol" means the food contains 20 mg cholesterol or less, per 100 g and no more than 2 g saturated fat. "Light" means the meal or main dish is low-fat or low-calorie.

Standardized foods: Any nutrient content claim, such as "reduced fat," "low calorie," and "light," may be used in conjunction with a standardized term if the new product has been specifically formulated to meet FDA's criteria for that claim, if the product is not nutritionally inferior to the traditional standardized food, and if the new product complies with certain compositional requirements set by the FDA. A new product bearing a claim also must have performance characteristics similar to the referenced traditional standardized food. If the product does not, and the differences materially limit the product's use, the label must state the differences (for example, not recommended for baking) to inform consumers.

## **Health Claims**

The intended purpose of health claims on the food label is to aid consumers by providing information on healthful eating patterns that may help reduce the risk of heart disease, cancer, osteoporosis, high blood pressure, dental cavities, or certain birth defects. These claims (statements) alert consumers to a product's health potential by stating that certain foods or food substances, as part of an overall healthy diet, may reduce the risk of certain diseases. Examples include folic acid in breakfast cereals, fiber in fruits and vegetables, calcium in dairy products, and calcium or folic acid in some dietary supplements. But food and food substances can qualify for health claims only if they meet FDA requirements. Use of health claims requires sufficient scientific agreement among qualified experts that the claims are factual and truthful. They can be used on conventional foods or dietary supplements.

## **FDA-Authorized Health Claims**

## **Dietary Supplements**

A dietary supplement is a product intended for ingestion that contains a "dietary ingredient" that is designed to add nutritional value to a normal diet. The "dietary ingredients" in these products may include:

vitamins, minerals, herbs, amino acids, and substances such as enzymes, organ tissues, or metabolites. The Dietary Supplement Health and Education Act requires that a manufacturer or distributor notify the FDA if it intends to market a dietary supplement in the U.S. that contains a "new-dietary ingredient," which must be one or any combination of the following: a vitamin or mineral; a herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; a metabolite, constituent or extract. FDA regulations also require that specific information appear on dietary supplement labels which include: a descriptive name of the product, stating that it is a "supplement;" the name and place of the manufacturer; a complete list of ingredients; and the net contents of the product. Ingredients not listed on the "Supplement Facts" panel must be listed in the "other ingredients" statement.

# Fiber-Containing Grain Products, Fruits and Vegetables, and Cancer

Both genetic and environmental factors play a role in the incidence of cancer. Scientific evidence establishes that diets low in fat and high in fiber containing fruits, vegetable, and grain are associated with a lower incidence of some forms of cancer. The role of the fiber in reducing the risk is not yet completely understood. Current recommendations state that decreasing the intake of fat in the diet and increasing the consumption of fruits and vegetables may reduce the risk factor of some forms of cancer.

Typical Foods: Whole grain breads, buns, bagels, muffins, bran flakes, shredded wheat, barley, popcorn, oatmeal, brown rice, apricots, dates, prunes, raisins, berries such as blackberries, raspberries, and strawberries, oranges, apples with skin, broccoli, spinach, dried peas, kidney beans, lima beans, chick peas, and lentils.

Sample 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."

## Soy Protein and Risk of Coronary Heart Disease

Coronary heart disease (CHD), one of the most common and serious forms of cardiovascular disease, is a major public health concern because it causes more deaths in the U.S. than any other disease. Risk factors for CHD include high total cholesterol levels and high levels of low density lipoprotein (LDL) cholesterol.

This new health claim is based on evidence that including soy protein in a diet low in saturated fat and cholesterol may also help to reduce the risk of CHD. Recent clinical trials have shown that consumption of soy protein compared to other proteins such as those from milk or meat, can lower total and LDL-cholesterol levels.

Scientific studies show that 25 grams of soy protein daily in the diet is needed to show a significant cholesterol lowering effect. In order to qualify for this health claim, a food must contain at least 6.25 grams of soy protein per serving, the amount that is one-fourth of the effective level of 25 grams per day. Because soy protein can be added to a variety of foods, it is possible for consumers to eat foods containing soy protein at all three meals and in snacks.

Typical Foods: Soy beverages, tofu, tempeh, soy-based meat alternatives, and possibly some baked goods. Foods that carry the claim must also meet the requirements for low fat, low saturated fat, and low cholesterol content. Foods made with the whole soybean may also qualify for the health claim if they contain no fat in addition to that present in the whole soybean.

Sample Claim: "Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of (name of food) provides \_\_\_\_\_ grams of soy protein."

## Plant Sterol/Stanol Esters and Risk of Coronary Heart Disease

The term "phytosterols" covers plant sterols and plant stanols. Plant sterols are naturally occurring substances present in the diet principally as minor components of vegetable oils. Plant stanols, occurring in nature at a lower level, are hydrogenated compounds of the respective plant sterols. An elevated level of blood cholesterol is one of the well-established risk factors for coronary heart disease. Both plant sterols and plant stanols are effective in lowering plasma total and low density lipoprotein (LDL) cholesterol, and this occurs by inhibiting the absorption of cholesterol from the small intestine. In order to achieve a cholesterol-lowering benefit, approximately 1g per day of plant sterols or plant

stanols should be consumed. In comparison, normal dietary intake is between 200 and 400 mg per day plant sterols, while the normal dietary intake of plant stanols is negligible. Margarines on the market contain plant sterols and stanols, which have been shown to reduce cholesterol.

*Typical Foods*: These sterols and stanols are found in margarines that denote their presence on the package.

## **Calcium and Osteoporosis**

Low calcium intake is one risk factor for osteoporosis, a condition of reduced bone mass, or density. Lifelong adequate calcium intake helps maintain bone health by increasing as much as genetically possible the amount of bone formed in the teens and early adult life and by helping to slow the rate of bone loss that occurs later in life.

*Typical Foods*: Low-fat and skim milks, yogurts, tofu, calcium-fortified citrus drinks, and some calcium supplements.

Sample Claim: "Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health, and may reduce high risk of osteoporosis later in life."

## **Sodium and Hypertension**

## (High Blood Pressure)

Hypertension is a risk factor for coronary heart disease and stroke deaths. The most common source of sodium is table salt. Diets low in sodium may help lower blood pressure and related risks in many people. Guidelines recommend daily sodium intakes of not more than 2,400 mg. Typical U.S. intakes are 3,000 to 6,000 mg.

Typical Foods: Unsalted tuna, salmon, fruits and vegetables, and low-fat milks, low-fat yogurts, cottage cheeses, sherbets, ice milk, cereal, flour, and pastas (not egg pastas).

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

## **Dietary Fat and Cancer**

Diets high in fat increase the risk of some types of cancer, such as cancers of the breast, colon and prostate. Scientists don't know how total fat intake affects cancer development, but low-fat diets reduce the risk. Experts recommend that Americans consume

30 percent or less of daily calories as fat. Typical U.S. intakes are 37 percent.

Typical Foods: Fruits and vegetables.

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

# Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease

Diets high in saturated fat and cholesterol increase total and low-density (bad) blood cholesterol levels and, thus, the risk of coronary heart disease. Diets low in saturated fat and cholesterol decrease the risk. Guidelines recommend that American diets contain less than 10 percent of calories from saturated fat and less than 300 mg of cholesterol daily. The average American adult diet has 13 percent saturated fat and 300 to 400 mg of cholesterol a day.

Typical Foods: Fruits, vegetables, skim and low-fat milks, cereals, whole-grain products, and pastas (not egg pastas).

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

# Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer

Diets low in fat and rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer. The exact role of total dietary fiber, fiber components, and other nutrients and substances in these foods is not fully understood.

*Typical Foods*: Whole-grain breads and cereals, fruits, and vegetables.

Sample 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."

## Fruits, Vegetables, and Grain Products that Contain Fiber, Particularly Soluble Fiber, and Risk of Coronary Heart Disease

Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, may reduce the risk of coronary heart disease. (It is impossible to adequately distinguish the effects of fiber, including soluble fiber, from those of other food components.) *Typical Foods*: Fruits, vegetables, and whole-grain breads and cereals.

Sample 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."

## Fruits and Vegetables and Cancer

Diets low in fat and rich in fruits and vegetables may reduce the risk of some cancers. Fruits and vegetables are low-fat foods and may contain fiber, vitamin A (as beta-carotene), or vitamin C. (The effects of these vitamins cannot be adequately distinguished from those of other fruit or vegetable components.)

Typical Foods: Fruits and vegetables.

Sample 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 types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber."

#### **Folate and Neural Tube Birth Defects**

Defects of the neural tube (a structure that develops into the brain and spinal cord) occur within six weeks after conception, often before the pregnancy is known. The U.S. Public Health Service recommends that women of childbearing age consume 0.4 mg of folic acid daily to reduce the risk of having a baby affected by spina bifida or other neural tube defects.

Typical Foods: Enriched cereal grain products, some legumes (dried beans), peas, fresh leafy green vegetables, oranges, grapefruit, and many berries.

Sample Claim: "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect."

## **Dietary Sugar Alcohol and Dental Caries (cavities)**

Between-meal eating of foods high in sugar and starches may promote tooth decay. Candies and gums made with sugar alcohols do not.

Typical Foods: sugarless candy and gum.

Sample Claim: "Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in this food do not promote tooth decay." Shortened claim (on small packages only): "Does not promote tooth decay."

# Dietary Soluble Fiber, as Found in Whole Oats and Psyllium Seed Husk, and Coronary Heart Disease

When included in a diet low in saturated fat and cholesterol, soluble fiber may affect blood lipid levels, such as cholesterol, and reduce the risk of heart disease. However, because soluble dietary fibers constitute a family of very different substances that vary greatly in their effect on the risk of heart disease, FDA has determined that sources of soluble fiber for this health claim need to be considered case-by-case.

To date, FDA has reviewed and authorized two sources of soluble fiber eligible for this claim: whole oats and psyllium seed husk.

Typical Foods: Oatmeal cookies, muffins, breads and other foods made with rolled oats, oat bran or whole oat flour; hot and cold breakfast cereals containing whole oats or psyllium seed husk; and dietary supplements containing psyllium seed husk.

Sample Claim: "Diets low in saturated fat and cholesterol that include 3 g of soluble fiber from whole oats per day may reduce the risk of heart disease. One serving of this whole-oats product provides \_\_\_\_ grams of this soluble fiber."

## Soy Protein and Coronary Heart Disease

Including soy protein in a diet low in saturated fat and cholesterol may help to reduce the risk of coronary heart disease. Recent clinical trials have shown that the consumption of soy protein compared to other proteins such as those from milk or meat, can lower total and LDL-cholesterol levels.

Typical Foods: Soy beverages, tofu, tempeh, soy-based meat alternatives, and possibly some baked goods. Foods that carry the claim also must meet the requirements for low fat, low saturated fat, and low cholesterol content. Foods made with the whole soybean may also qualify for the health claim if they contain no fat in addition to that present in the whole soybean.

Sample Claim: "Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of (name of food) provides \_\_\_\_\_ grams of soy protein.

## **Food Additives**

Food additives are chemical substances added to foods to improve flavor, texture, color appearance and consistency. They are also used as preservatives during processing. Food additives can be taken from natural resources like fruit or egg yolks or they can be processed in a lab.

#### **DATEM**

DATEM, or diacetyl tartaric (acid) ester of monoglyceride, is an emulsifier adopted from soy, palm, and canola oil that is widely used in baking. DATEM builds strong gluten networks in dough, helping to strengthen it. DATEM comes from a chemical process involving vegetable oils, alcohol or other chemicals. Emulsifiers prevent the separation of oil and water-based ingredients in mixtures. The FDA labeled DATEM as "generally recognized as safe" with the requirement that the acronym DATEM appear on package labels as the alternate common or usual name of the ingredient diacetyl tartaric acid esters of mono-and diglycerides. The FDA also adopted "canola oil" as the alternate common or usual name for low erucic acid rapeseed oil.

### **MSG**

Monosodium glutamate or MSG is used as a flavor enhancer. Manufacturers add it to foods to keep the sodium content low while maintaining the flavor. While the FDA has included MSG on the list of ingredients and labeled it as "generally recognized as safe," some people may be hypersensitive to it. Large intakes of MSG may cause headaches, dizziness, nausea, sweating and tingling or numbing. MSG can be found in canned soups, salad dressings, seasoning blends and prepared pasta products. Even organic foods stores such as Whole Foods may carry products with high levels of MSG, including frozen, bagged, or bottled foods. The best way for consumers to avoid MSG is to purchase only whole foods and prepare it themselves.

### **Sulfites**

Sodium sulfite is a chemical that is naturally present and/or used in food processing as a preservative and sanitizing agent. It inhibits bacterial growth and the browning of exposed foods. It also prevents the growth of unwanted microorganisms during fermentation and food processing. The FDA banned the use of sulfites on fruit and vegetables eaten raw, including lettuce and apples. Manufacturers are required to label the use of sulfites in their processed products and list the compounds on their product labels. The USDA also prohibits the use of sulfites on

meat because it restores the red color to raw meat and it could be mistaken as "fresh." Currently, sulfiting agents are not considered "generally recognized as safe" (GRAS) for use in meats, vegetables or fruits intended to be served raw. Sulfite-containing ingredients to look for on food labels include: sulfur dioxide, sugars and syrups, dried fruit, frozen vegetables, wine, condiments, fresh non-organic grapes, and peeled potatoes.

#### **Color Additives**

A color additive is any dye, pigment, or substance that when added to a food or drink, admits color. The FDA is responsible for regulating all color additives to certify that foods containing color additives are safe to eat, contain only approved ingredients, and are accurately labeled. Color additives are used in foods for different reasons: to offset color loss due to exposure to light or extreme temperatures; to correct natural variations in color; to enhance colors that occur naturally; or to provide color to colorless "fun" foods such as candies or gelatins. Due to the 1986 study that concluded one out of 10,000 people suffered from hives after consuming the colorant Yellow No. 5, which is derived from coal tar, the law now requires that the colorant has to be clearly stated in the ingredient statement. Yellow No. 5 can be found mostly in candy, soft drinks, baked goods, ice cream, energy drinks, jam, pickles, custard, pudding, flavored chips, cereal, and snack foods.

### **Fresh**

The FDA regulates use of the term "fresh" because of concern over the term's possible misuse on some food labels. The regulation defines the term "fresh" when it is used to suggest that a food is raw or unprocessed. In this context, "fresh" can be used only on a food that is raw, has never been frozen or heated, and contains no preservatives. (Irradiation at low levels is allowed.) "Fresh frozen," "frozen fresh," and "freshly frozen" can be used for foods that are quickly frozen while still fresh. Blanching (brief scalding before freezing to prevent nutrient breakdown) is allowed. Other uses of the term "fresh," such as in "fresh milk" or "freshly baked bread," are not affected.

# **Nutrition Labeling Exemptions**

Under current law, foods exempt from nutrition labeling include:

• food served for immediate consumption, such as

that served in hospital cafeterias and airplanes, food sold by service vendors;

- ready-to-eat food not for immediate consumption but prepared primarily on site—for example, bakery, deli, and candy store items;
- food shipped in bulk, as long as it is not for sale in that form to consumers;
- medical foods, such as those used to address the nutritional needs of patients with certain diseases and;
- plain coffee and tea, some spices, and other foods that contain insignificant amounts of nutrients.

Food produced by small businesses also may be exempt. They may carry nutrition information, when appropriate, as long as it complies with regulations. These foods lose their exemption if labels carry a nutrient content or health claim or other nutrition information.

Nutrition information about game meats such as deer, bison, rabbit, quail, wild turkey, and ostrich, is not required on individual packages. Instead, it can be given on counter cards, signs, or other point-of-purchase materials. Few nutrient data exist for these foods. This makes it easier for game meat producers to collect and update information as it becomes available.

### References

More information on food labeling: http://www.fda.gov/Food/ IngredientsPackagingLabeling/default.htm

Labeling & Nutrition, http://www.fda.gov/Food/ IngredientsPackagingLabeling/LabelingNutrition/ default.htm

Labeling/Label Approval, http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling

Revised by Fadi Aramouni, Ph.D., Professor; Karen Blakeslee, M.S., Extension Associate; and Katie Alstadt, undergraduate student, Food Science, from original by Karen P. Penner, Ph.D., Professor Emeritus, Food Science, Department of Animal Sciences and Industry

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