



Silliker Nutrient and Health Claims U.S. and Canadian Regulatory Guide

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With over 40 years of experience and part of the Mérieux Alliance group of companies, Silliker, Inc. provides consulting, testing, auditing, research and education services that help assure food safety and nutrition worldwide. Log on to www.silliker.com to learn more about our safety and quality solutions.

Silliker Nutrient and Health Claims U.S. and Canadian Regulatory Guide

Label claims and statements can draw attention to products and increase product sales, but developing compliant claims can be tricky. This guidebook was developed to help product developers become familiar with the various types of label claims and statements available, and aid in recognizing which is best suited to a product's nutritional attributes and marketing objectives.

Nutrient Content Claims describe directly or by implication the level of a nutrient or dietary substance in a serving.

Statements of Fact can be made on labels as long as they do not make a nutrient content claim, health claim or other claim that requires specific FDA authorization.

Health Claims characterize the ability of a nutrient or functional component to reduce the risk of disease or a health-related condition.

Structure/Function Claims describe the role of a nutrient or functional component in affecting or maintaining normal body structure or function, or general well-being.

Dietary Guidance Statements typically explain the relationship between a group of foods (such as fruits and vegetables or whole grains) and health.

Regardless of the type of label claim or statement chosen, all labeling must be truthful and not misleading.



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Conventional Food vs. Dietary Supplement

Early in the product development process, manufacturers will want to determine if the product will be regulated as a conventional food or as a dietary supplement. This determination carries many ramifications for formulation, labeling and marketing (i.e., allowable/restricted ingredients, possible label claims, etc.).

Conventional foods are labeled with Nutrition Facts; dietary supplements are labeled with Supplement Facts. Though there is not a regulated FDA definition for conventional food, it is a term that FDA uses. Conventional foods are commonly understood to be all foods, beverages and chewing gums for human consumption that do not qualify as dietary supplements.

A **dietary supplement** is a product taken by mouth that contains a *dietary* ingredient intended to *supplement* the diet. Dietary ingredients include vitamins, minerals, herbs/botanicals, amino acids, enzymes, organ tissues, glandulars, metabolites, extracts or concentrates. Dietary supplements have many forms that include tablets, capsules, softgels, gelscaps, liquids and powders. They can also come in the form of a bar. Regardless of the form, the information on the label must not represent the product as a conventional food or a sole item of a meal or diet.

At this time, FDA has not established a regulatory definition for functional foods or nutraceuticals. All products must comply with regulatory requirements for conventional foods or dietary supplements.

Label Claims and Statements for Conventional Foods and Dietary Supplements

Type of Label Claim or Statement	Allowed on Conventional Foods?	Allowed on Dietary Supplements?
Nutrient Content Claims	Yes, as pre-approved by FDA except on labels for products intended for infants and children less than two years of age.	Yes, as pre-approved by FDA except on labels for products intended for infants and toddlers. Certain claims can be made only on products with over 40 calories per serving.
Statements of Fact	Yes	Yes
Health Claims		
SSA* Health Claims	Yes, as pre-approved by FDA.	Yes, as pre-approved by FDA. Requires specific FDA notification.
FDAMA† Health Claims	Yes. Requires FDA authorization via notification from a stakeholder.	No
Qualified Health Claims	Yes. Requires a petition to FDA.	Yes. Requires a petition to FDA.
Structure/Function Claims	Yes, except on USDA-regulated foods.	Yes. Requires specific FDA notification and label "disclaimer."
Dietary Guidance Statements	Yes	No

* SSA – Significant Scientific Agreement

† FDAMA – FDA Modernization Act



Disclosure Statement Requirements

Specific regulations have been established to help ensure that label claims and statements are not misleading to consumers.

When claims are made about a product's nutrition or health benefits on FDA-regulated products, a **disclosure statement** is required if one or more of the four nutrients shown in the chart below exceed threshold levels for the product's reference amount¹ or labeled serving size if larger, or per 50 grams for small servings². The disclosure statement must be placed adjacent to the claim without intervening material, and generally must be presented in a type size at least as large as the Net Contents statement, but never less than half of the size of the claim. (See example in shaded box below which calls the consumer's attention to the Nutrition Facts.)

Disclosure Statement Threshold Levels

Nutrient	Individual Foods ³ (includes small servings)	Main Dishes ⁴	Meals ⁵
Total Fat	13.0 g	19.5 g	26.0 g
Saturated Fat	4.0 g	6.0 g	8.0 g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

Definitions

¹ **Reference Amounts** are Reference Amounts Customarily Consumed per eating occasion (RACC).

² **Small Servings** are those with reference amounts of 30 grams or less, or 2 Tbsp or less.

³ **Individual Foods** are those with reference amounts of more than 30 grams, or more than 2 Tbsp.

⁴ **Main Dishes** are products that weigh at least 6 oz per serving, contain not less than 40 grams each of at least two different foods from at least two specified food groups, and are represented as main dishes.

⁵ **Meals** are products that weigh at least 10 oz per serving, contain not less than 40 grams each of at least three different foods from at least two specified food groups, and are represented as meals.

Example of a disclosure statement for a product low in sodium and high in fat:

LOW SODIUM
SEE NUTRITION PANEL
FOR FAT CONTENT

Use of disclosure statements is discussed further in the Nutrient Content Claims and Statements of Fact sections.



NUTRIENT CONTENT CLAIMS ...

- ... describe directly or by implication the level of a nutrient or dietary substance in a serving
- ... are limited to those authorized by FDA regulation; generally, this is limited to nutrients that are mandatory or voluntary in the Nutrition Facts and have an FDA-established Daily Value
- ... are used on labels without review by FDA, but must comply with all FDA definitions and regulations
- ... placed on labels for USDA-regulated products must always be submitted for USDA approval
- ... can be made for both conventional foods and dietary supplements
- ... are not allowed on products for infants and children less than two years of age
- ... must be accompanied by the following disclosure when fat, cholesterol, saturated fat or sodium threshold levels are exceeded: **SEE NUTRITION PANEL FOR (NAME OF NUTRIENT) CONTENT.**

Nutrients that qualify for nutrient content claims include: total calories, total fat, saturated fat, cholesterol, sodium, potassium, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, choline and ALA & DHA omega-3 fatty acids.

Note: Even though there is no Daily Value for choline or ALA & DHA omega-3 fatty acids and these nutrients are not mandatory or voluntary for Nutrition Facts reporting (and cannot be included in Nutrition Facts), they are allowable per specific FDA notification. Choline claims are allowable per FDA's notification under FDAMA; ALA & DHA omega-3 claims are allowable per the "Martek Notification."

ABSOLUTE NUTRIENT CONTENT CLAIMS are direct statements about the level of a nutrient in the product.

- **Free** means a product's reference amount and labeled serving contains an insignificant amount of: total fat, saturated fat, cholesterol, sodium, sugars or calories. (Insignificant is defined as an amount that may be rounded to zero, per FDA rounding rules.) Synonyms include *zero*, *no*, *without*, *trivial source of*, *negligible source of* and *dietarily insignificant source of*. *Non fat* is a synonym for fat free.
- **Low** means a product could be eaten frequently without exceeding the guidelines for: total fat, saturated fat, cholesterol, sodium or calories. Synonyms include *little*, *few* (for calories), *contains a small amount of* and *low source of*. The term *very low* is also defined, but only with respect to sodium levels.

Notes about *free* and *low* claims:

- » When using *free* or *low* on a product that has not been specifically processed or altered to qualify for the claim, the manufacturer must indicate that the food inherently qualifies for the claim (e.g., peanut butter, a cholesterol-free food).
- » FDA has not defined nutrient content claims for trans fat, therefore it is not permissible to use the words *free* or *low* (or their synonyms) to describe trans fat levels (e.g., trans fat free, no trans fat and zero trans fat are unauthorized nutrient content claims). However, 0g trans fat per serving is allowed as a statement of fact.





- » FDA has not defined nutrient content claims for carbohydrate; therefore, it is not permissible to use the words *free* or *low* (or their synonyms) to describe carbohydrate levels (e.g., no carbs, carb free and low carb are unauthorized nutrient content claims). However Xg carb per serving is allowed as a statement of fact as long as it is simply a repeat of information from the Nutrition Facts and does not imply a level.
- » FDA has not provided a definition for *low sugar*, therefore this claim cannot be used. However, *sugar free*, *reduced sugar* and *no added sugar* claims are allowed as long as the food includes the required calorie and/or disclosure statements adjacent to the claim.
- » If a claim is made about fatty acids or cholesterol, then polyunsaturated fat and monounsaturated fat must be included in the Nutrition Facts (or Supplement Facts) unless the product is fat free. Additionally, specific disclosure about total fat and cholesterol levels must be included directly next to the claim when certain threshold levels are exceeded.
- » For dietary supplements: Claims for total fat, saturated fat and cholesterol can be made only if the product is greater than 40 calories per serving. Claims for calories can be made only when a similar product exists that contains over 40 calories per serving.
- **Lean** may be used to describe meat, poultry, seafood and game meat, and means less than 10g fat, 4.5g or less saturated fat, and less than 95mg cholesterol per reference amount or per 100 grams (whichever is larger). Criteria are different for mixed foods, main dishes and meals.
- **Extra Lean** may be used to describe meat, poultry, seafood and game meat, and means less than 5g fat, less than 2g saturated fat, and less than 95mg cholesterol per reference amount or per 100 grams (whichever is larger). Criteria are different for mixed foods, main dishes and meals.
- **Good Source** means the reference amount of a product contains 10 to 19% of the Daily Value of a particular nutrient (i.e., fiber, protein, or a vitamin or mineral). Synonyms include *contains* and *provides*.
- **High** means the reference amount of a product contains 20% or more of the Daily Value for a particular nutrient (i.e., fiber, protein, or a vitamin or mineral). Synonyms include *excellent source* and *rich in*.

Notes about good source and high claims:

- » *Good source* and *high* cannot be used to describe nutrients and functional components without an FDA-established Daily Value (i.e., cannot be used to describe carotenoids, flavonoids, etc.).
- » The term “antioxidant” can be used in a claim as long as the antioxidant is named, has an FDA-established Daily Value, and qualifies in level for the *good source* or *high* claim (e.g., high in antioxidant vitamin C).
- » If a fiber claim is made and the food does not qualify as a low fat food, then the fiber claim must be accompanied by a disclaimer that discloses the level of total fat per labeled serving.
- » If a protein claim is made, then the Nutrition Facts (or Supplement Facts) must include the % Daily Value from protein based on the protein-digestibility corrected amino acid score (PDCAAS).
- **High Potency** means the vitamin or mineral is present in a product at 100% or more of the RDI per reference amount; the nutrient in the claim must be identified (e.g., high potency vitamin C). *High Potency* can also be used to describe a conventional food or dietary supplement when the product contains 100% or more RDI for at least two-thirds of vitamins and minerals with Daily Values present in the product at 2% or more (e.g., high potency multivitamin/mineral supplement).



Nutrient Content Claim Definitions for *Free and Low*

Nutrient	Claim	Definition
Calories	Free	Less than 5 calories per serving
	Low	40 calories or less per serving Main dish/meal product: 120 calories or less per 100 grams
Total Fat	Free	Less than 0.5g fat per serving, and includes no ingredients that contain fat*
	Low	3g or less fat per serving Main dish/meal product: 3g or less fat per 100 grams, and not more than 30% of calories from fat
Saturated Fat	Free	Less than 0.5g saturated fat and less than 0.5g trans fat per serving, and includes no ingredients that contain saturated fat*
	Low	1g or less saturated fat per serving, and not more than 15% of calories from saturated fat Main dish/meal product: 1g or less saturated fat per 100 grams, and less than 10% of calories from saturated fat
Cholesterol	Free	Less than 2mg cholesterol and 2g or less saturated fat per serving, and includes no ingredients that contain cholesterol*
	Low	20mg or less cholesterol and 2g or less saturated fat per serving Main dish/meal product: 20mg or less cholesterol and 2g or less saturated fat per 100 grams
Sodium	Free	Less than 5mg sodium per serving, and contains no sodium chloride (table salt) or other ingredient that contains sodium*
	Very Low	35mg or less sodium per serving Main dish/meal product: 35mg or less sodium per 100 grams
	Low	140mg or less sodium per serving Main dish/meal product: 140mg or less sodium per 100 grams



“Per serving” means per reference amount or per labeled serving, whichever is larger. However, if a product has a small serving size (i.e., reference amount of 30 grams or less, or 2 Tbsp or less), then the nutrient levels for the claim must be met on a 50 gram basis.

**Exceptions are allowed if the relevant ingredient is asterisked in the ingredient statement and footnoted as required.*



RELATIVE NUTRIENT CONTENT CLAIMS compare the level of nutrients of one product to another.

- **More** means that the reference amount of a product (whether altered or not) contains at least 10% more of the Daily Value of a nutrient than the reference product. This definition also applies to *fortified*, *enriched*, *added*, and *plus* claims but, unlike *more*, these terms can only be used to describe foods that have been altered.
- **Less** means that the reference amount of a product (whether altered or not) contains 25% less of a nutrient than the reference product. This definition also applies to *fewer*, which can be used to describe calories.
- **Reduced** means that the reference amount of a nutritionally-altered product contains 25% less of a nutrient than the reference product. This definition also applies to *lower*.
- **Light** means that the reference amount of a nutritionally-altered product contains 50% less fat or 1/3 fewer calories than the reference product.

Notes about *light* claims:

- » For products with greater than 50% calories from fat, the claim must be met on the basis of 50% less fat (not 1/3 fewer calories). For products with less than 50% calories from fat, the claim can be met on either the calorie or fat basis.
- » A *light* claim is not allowed on products when the reference product is low calorie (40 calories or less) or low fat (3g fat or less), unless the sodium of such a product is reduced by 50%.

FDA has specified **reference products** that may be used as a basis of comparison for each of the four relative claims above. For *more*, *less* and *reduced*, the reference product can be the company's regular brand, a competing regular brand, or a representative value for a broad base of products of that type. For *more* and *less*, the reference product may also be a similar product in the same product category (e.g., pretzels with 25% less fat than potato chips). For *light*, the reference product must be similar and the reference value must be a representative value for a broad base of products of that type. Relative claims trigger many disclosure and footnote requirements.

- The identity of the reference product and the percent/fractional difference for nutrient(s) that are the subject of the claim between the two comparison products must be declared adjacent to the claim. Example: half the calories and 60% less fat than [name of reference product].
- Quantitative information comparing level of nutrients (i.e., calories and fat, or sodium) in the product and reference product must be disclosed, either adjacent to the claim or on the information panel. Example: light soy sauce 500mg sodium per serving; regular soy sauce 1000mg sodium per serving.
- The following disclosure is required when total fat, cholesterol, saturated fat or sodium threshold levels are exceeded: **SEE NUTRITION PANEL FOR (NAME OF NUTRIENT) CONTENT.**



IMPLIED NUTRIENT CONTENT CLAIMS include:

- claims not explicitly stated but implied by association with an ingredient known to contain a particular nutrient or be free of that nutrient. Examples: (1) *good source of oat bran* is an implied fiber claim and is approved for foods that could make a good source of fiber claim, (2) *no tropical oils* is an implied low saturated fat claim and is approved for foods that could make such a claim.
- claims that characterize the level of a nutrient as a little or a lot. Examples: (1) *only* implies a little; therefore, *only 3g carbohydrate* is not allowed because low carbohydrate claims are not allowed, (2) *packed with antioxidants* implies high in antioxidants; this claim is not allowed because a specific antioxidant is not named. However, a statement such as *packed with antioxidant vitamin C* is allowed on a product that reports 20% or more Daily Value for this nutrient within the Nutrition Facts or Supplement Facts.
- equivalency claims such as *contains as much [nutrient] as a [food]*. This claim can be made if both the reference product and the labeled product are a *good source* of the nutrient on a per serving basis. Example: *contains as much vitamin C as an 8 ounce glass of orange juice* is allowed when the statement is truthful and not misleading.

Two common implied nutrient content claims:

- **Healthy** means a food that is low in fat and saturated fat, contains 480mg or less sodium and 60mg or less cholesterol per reference amount or labeled serving (whichever is larger), and provides at least 10% Daily Value per reference amount for one of these beneficial nutrients: vitamin A, vitamin C, calcium, iron, protein or fiber.

Notes and exceptions for *healthy* claims:

- » For products with a small serving size, the food must meet the criteria on a 50 gram basis.
 - » For products that qualify as a main dish or meal, the food must be low in fat and saturated fat, contain 600mg or less sodium, 90mg or less cholesterol, and at least 10% Daily Value per labeled serving of two beneficial nutrients.
 - » For products that qualify as a meal, the food must be low in fat and saturated fat, contain 600mg or less sodium, 90mg or less cholesterol, and at least 10% Daily Value per labeled serving of three beneficial nutrients.
 - » For single ingredient raw meat, poultry, seafood or game meat, the food must contain less than 5g fat, 2g saturated fat, and 95mg cholesterol per reference amount per 100 grams (whichever is larger); it must also contain at least 10% Daily Value of one of the beneficial nutrients. [Note that the criteria for “healthy” in these foods is the same as “extra lean” for fat, saturated fat and cholesterol.]
 - » Raw fruits and vegetables, canned or frozen single ingredient fruits and vegetables, mixtures of single ingredient raw, canned, or frozen fruits and vegetables, and enriched cereal grain products that conform to certain standards of identity are exempt from the requirement of providing at least 10% Daily Value for one of the beneficial nutrients.
- **Percent Fat Free** can be stated on foods which meet the low fat or fat free definition. However, *100% fat free* can be made only on foods that contain less than 0.5g fat per reference amount or per 100 grams (whichever is larger), and include no ingredients that contain fat.



STATEMENTS OF FACT ...

- ... can be made on labels as long as they do not make a nutrient content claim, health claim or other claim that requires specific FDA authorization
- ... are covered by free speech rights
- ... must not characterize the nutrient level by using terms that are defined or implied nutrient content claims (i.e., *free*, *zero*, *no*, *low*, *high*, *good source*, *only*, *packed with*, etc.)
- ... are allowed on conventional foods and dietary supplements as long as they are truthful and not misleading
- ... may be used to describe an amount of a nutrient or a functional component present in a product; this allows manufacturers to inform consumers about the level a nutrient or functional component present when a Daily Value has not been established
- ... taken from the Nutrition Facts panel and repeated elsewhere on the label require the following when total fat, cholesterol, saturated fat or sodium threshold levels are exceeded:
SEE NUTRITION PANEL FOR (NAME OF NUTRIENT) CONTENT

EXAMPLES AND EXPLANATIONS:

ALLOWED: 0g trans fat per serving (the numeral 0 is not a defined nutrient content claim)

NOT ALLOWED: zero trans fat, trans fat free, no trans fat (the terms *zero*, *free*, and *no* are defined nutrient content claims; there are no allowable defined nutrient content claims for trans fat at this time)

ALLOWED: 200mg isoflavones per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: excellent source of isoflavones (the term *excellent source* is a synonym for the nutrient content claim *high* which means 20% or more Daily Value per serving; since FDA has not established a Daily Value for isoflavones, this is an unauthorized nutrient content claim)

ALLOWED: 3g carb per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 3g carb per serving (the term *only* implies a low level, and low carbohydrate claims are not allowed)

ALLOWED: 100 Calorie Pack (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 100 Calories (the term *only* implies a low level and the definition for low calorie is 40 calories or less per serving; this statement requires the addition of a disclaimer "Only 100 calories, not a low calorie food.")

ALLOWED: Contains 10mg lutein (factual statement with English use of the word *contains* preceding a quantitative amount)

NOT ALLOWED: Contains lutein (use of the word *contains* without the quantitative amount is a nutrient content claim that means 10% or more Daily Value per serving; since FDA has not established a Daily Value for lutein, this is an unauthorized nutrient content claim)

ALLOWED: Made with oat bran (factual as long as the product contains a significant amount of oat bran in the formulation, generally more than 2% by weight)

NOT ALLOWED: High in oat bran (implies a *high* level of fiber, which means 20% or more Daily Value per serving; if the product contains less than 20% Daily Value then the claim is not valid)

ALLOWED: Glycemic index of this product is 41

NOT ALLOWED: Low glycemic foods help control diabetes (this is an unauthorized health claim)



HEALTH CLAIMS ...

- ... are pre-authorized by FDA
- ... characterize the ability of the nutrient or functional component to **reduce the risk** of disease or a health-related condition (they are not about treating, curing or mitigating any disease)
- ... use “may” to characterize the relationship between the nutrient and the disease or health-related condition in order to indicate the disease or health-related condition is caused by many factors
- ... can be used for conventional foods and dietary supplements
- ... require that the manufacturer of a dietary supplement submit a notification to FDA no later than 30 days after the product goes to market; the notification must include the text of the claim (conventional foods do not require this notification)
- ... cannot be used on products that exceed disqualifying levels for total fat, saturated fat, cholesterol or sodium
- ... can be used only on foods that contain, without fortification, 10% or more Daily Value for Vitamin A, Vitamin C, calcium, iron or fiber
- ... must use tightly-controlled wording as set forth in the Code of Federal Regulations

SSA CLAIMS (based on Significant Scientific Agreement) can be used for conventional foods and dietary supplements. FDA authorizes SSA claims based on the Agency’s extensive review of the scientific literature. The Significant Scientific Agreement (SSA) standard* is used to determine that the nutrient/disease relationship is well-established. To use an SSA claim, the product must meet all requirements found in 21 CFR 101.72 to 101.83. Model claim examples† are shown below.

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1. Adequate calcium throughout life, as part of a well-balanced diet, may reduce their risk of osteoporosis later in life.
2. Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
3. Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
4. While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
5. 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.
6. 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.
7. Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. [Name of food] is high in vitamins A and C, and it is a good source of dietary fiber.
8. Healthful diets with adequate folate may reduce a woman’s risk of having a child with a brain or spinal cord birth defect.
9. Frequent between-meal consumption of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.
10. Diets low in saturated fat and cholesterol that include [X grams] of soluble fiber per day from [name of soluble fiber source] may reduce the risk of heart disease. One serving of [name of food] provides X grams of this soluble fiber.
11. 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. One serving of [food name] provides X grams of soy protein.
12. Foods containing at least 0.65g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies X grams of plant sterol esters.

†Adapted from U.S. Code of Federal Regulations



FDAMA CLAIMS (based on the FDA Modernization Act of 1997) can be used only for conventional foods and cannot be used on dietary supplements at this time. FDA authorizes the use of an FDAMA claim as a result of the notification from a stakeholder. The notification must include wording for a proposed claim that is based on an “authoritative statement” (of significant scientific agreement) from a scientific body of the U.S. Government or the National Academy of Sciences.

To date, only five health claims have been authorized for use under the FDA Modernization Act.

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. Whole Grains & Risk of Heart Disease and Certain Cancers (authorized via authoritative statement from National Academies of Science) 2. Potassium & Risk of High Blood Pressure and Stroke (authorized via authoritative statement from National Academies of Science) 3. Fluoride & Risk of Dental Caries (authorized via authoritative statement from multiple sources including U.S. Surgeon General) | <ol style="list-style-type: none"> 4. Saturated Fat, Cholesterol and Trans Fat & Risk of Heart Disease (authorized via authoritative statement from 2005 Dietary Guidelines for Americans) 5. Substitution of Saturated Fat with Unsaturated Fatty Acids & Risk of Heart Disease (authorized via authoritative statement from National Academies of Science) |
|---|--|



QUALIFIED HEALTH CLAIMS can be used for conventional foods and dietary supplements. Any interested party may petition FDA to issue a regulation regarding a health claim (see 21 CFR 101.70). FDA evaluates the petition according to the SSA standard.* When the evidence for a substance/disease relationship is credible but does not meet the SSA standard, FDA issues a Letter of Enforcement Discretion to the petitioner. Enforcement discretion means that FDA intends not to object to the use of the claim, provided that the claim is written exactly as the letter states and the label meets all requirements stated in the letter. In general, many product developers find that these claims have limited usability because of the required wording.

At this time there are 25 authorized qualified health claims (letters of enforcement discretion), 15 claim denials, and one withdrawn claim. The 25 authorized qualified health claims fit into one of the 16 substance/disease relationships shown below.

Cancer

- Antioxidant Vitamins & Certain Cancers
- Calcium & Colon/Rectal Cancer and Recurrent Colon/Rectal Polyps
- Green Tea & Certain Cancers
- Selenium & Certain Cancers
- Tomatoes & Certain Cancers

Cognitive Function

- Phosphatidylserine & Cognitive Dysfunction and Dementia

Diabetes

- Chromium Picolinate & Insulin Resistance and Type 2 Diabetes

Neural Tube Defects

- Folic Acid & Neural Tube Defects

Cardiovascular Disease

- Certain B Vitamins & Vascular Disease
- Nuts & Coronary Heart Disease
- Walnuts & Coronary Heart Disease
- Omega-3 Fatty Acids & Coronary Heart Disease
- Unsaturated Fatty Acids from Canola Oil & Coronary Heart Disease
- Corn Oil & Heart Health
- Monounsaturated Fatty Acids from Olive Oil & Coronary Heart Disease

Hypertension

- Calcium & Hypertension, Pregnancy-Induced Hypertension and Preeclampsia



* The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship; the validity of the relationship is not likely to be reversed by new and evolving science.

STRUCTURE/FUNCTION CLAIMS ...

- ... describe the role of a nutrient or functional component in affecting or maintaining normal body structure or function, or general well-being
- ... cannot describe or imply that a nutrient or functional component affects a disease or health-related condition via diagnosis, cure, mitigation, treatment or prevention (a claim doing this is an unauthorized drug claim)
- ... can be used on FDA-regulated conventional foods and dietary supplements
- ... cannot be used on USDA-regulated products because USDA does not recognize these claims
- ... are not pre-approved by FDA; the manufacturer must have substantiation on file (clinical trials* or other research) to show that the claim is truthful and not misleading
- ... require that the manufacturer of a dietary supplement submit a notification to FDA no later than 30 days after the product goes to market; the notification must include the text of the claim (conventional foods do not require this notification)
- ... require that the label of a dietary supplement includes the following disclaimer placed adjacent to the statement with no intervening material, or enclosed in a box and linked to the statement with an asterisk or other symbol (labels for conventional foods do not require this disclaimer)

† 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.

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EXAMPLES AND EXPLANATIONS:

ALLOWED: Antioxidants help maintain cell integrity (no mention of disease)

NOT ALLOWED: Antioxidants prevent the onset of cancer (this is an unapproved drug claim)

ALLOWED: Echinacea supports the body's immune system (no mention of disease)

NOT ALLOWED: Echinacea is useful in preventing colds (this is an unapproved drug claim)

**Clinical trials are human studies designed to provide definitive answers to substantiate claims made for foods and dietary supplements, and ingredients used in these products. The amount and nature of the evidence needed to support a claim depends on the type of claim. FDA oversees labeling claims and FTC oversees advertising claims to ensure truthfulness for consumers.*

The first step in determining the study protocol is to understand the expressed and implied meaning of the claim being substantiated. This helps formulate the study hypotheses and measurable endpoints. For example, trials to support SSA or qualified health claims (which describe the relationship between a substance and a disease or health-related condition) are designed to support that relationship.

A well-designed clinical trial provides the credible scientific evidence that FDA and FTC need for evaluating claims. Animal studies, in-vitro studies, meta-analysis and anecdotal evidence provide useful background information but these alone may not be adequate to substantiate a claim. When determining whether there is adequate evidence to substantiate a claim, the marketer should consider the totality of the evidence, i.e., all relevant research (both favorable and unfavorable). This is the same standard used by FDA and FTC for determining appropriate use of a claim.

Additional information about substantiating claims is available at www.fda.gov and www.ftc.gov.



Examples of Allowable Structure/Function Claims*

Component Category	Component Sub-category	Structure or Function
Vitamins (Water-Soluble)	Vitamin B1 (Thiamin)	may contribute to maintenance of mental function helps regulate metabolism
	Vitamin B2 (Riboflavin)	helps regulate metabolism helps support cell growth
	Vitamin B3 (Niacin)	helps regulate metabolism helps support cell growth
	Vitamin B5 (Pantothenic Acid)	helps regulate metabolism helps regulate hormone synthesis
	Vitamin B6 (Pyridoxine)	may contribute to maintenance of healthy immune function helps regulate metabolism
	Vitamin B9 (Folate/Folic Acid)	supports healthy brain and spinal cord development may contribute to maintenance of heart health
	Vitamin B12 (Cyanocobalamin)	helps regulate metabolism supports blood cell formation may contribute to maintenance of mental function
	Biotin	helps regulate metabolism helps regulate hormone synthesis
	Vitamin C	functions as an antioxidant to neutralize free radicals may contribute to healthy immune function may contribute to maintenance of bone health
Vitamins (Fat-Soluble)	Vitamin A	may contribute to maintenance of healthy vision may contribute to maintenance of healthy immune function may contribute to bone health may contribute to cell integrity
	Vitamin D	helps regulate calcium and phosphorus helps contribute to bone health may contribute to healthy immune function helps support cell growth
	Vitamin E	functions as an antioxidant to neutralize free radicals may contribute to healthy immune function may contribute to maintenance of heart health
	Vitamin K	helps support normal blood clotting
Minerals	Calcium	builds strong bones
	Magnesium	contributes to bone health and healthy immune function
	Potassium	helps maintain a healthy blood pressure level, in combination with a low-sodium diet
	Selenium	neutralizes free radicals supports a healthy immune system



Component Category	Component Sub-category	Structure or Function
Carotenoids	Beta carotene	may neutralize free radicals may increase cellular antioxidant defense
	Lutein, Zeaxanthin	may help maintain healthy vision
	Lycopene	may help maintain prostate health
Fatty Acids	ALA, DHA/EPA (Omega-3 fatty acids)	may contribute to maintenance of heart health may contribute to maintenance of mental and visual function
	Conjugated linoleic acid	may contribute to maintenance of desirable body composition may contribute to maintenance of healthy immune function
Flavonoids	Anthocyanins (Cyanidin, Delphinidin, Malvidin)	supports antioxidant defenses may contribute to maintenance of brain function
	Flavanols (Catechins, Epicatechins, Epigallocatechin, Procyanidins)	may contribute to heart health
	Flavanones (Hesperetin, Naringenin)	neutralizes free radicals supports cellular antioxidant defenses
	Flavonols (Quercetin, Kaempferol, Isorhamnetin, Myricetin)	neutralizes free radicals supports cellular antioxidant defenses
	Proanthocyanidins	may contribute to urinary tract health and heart health
Isothiocyanates	Sulforaphane	bolsters cellular antioxidant defenses
Phenolic Acids	Caffeic acid, Ferulic acid	may contribute to maintenance of healthy vision may contribute to maintenance of a healthy heart may bolster cellular antioxidant defenses
Prebiotics	Inulin, Fructo-oligosaccharides (FOS), Polydextrose	may improve gastrointestinal health may improve calcium absorption
Probiotics	Yeast, Lactobacilli, Bifidobacteria, and other specific strains of beneficial bacteria	may improve gastrointestinal health and systemic immunity (benefits are strain-specific)
Phytoestrogens	Isoflavones (Daidzein, Genistein)	may contribute to maintenance of bone health may contribute to a healthy brain may contribute to healthy immune function may contribute to maintenance of menopausal health for women
	Lignans	may contribute to maintenance of heart health may contribute to healthy immune function
Sulfides/Thiols	Diallyl sulfide, Allyl methyl trisulfide	may enhance the body's detoxification process may contribute to maintenance of heart health may contribute to a healthy immune function
	Dithiolthiones	may enhance the body's detoxification process may contribute to maintenance of healthy immune function



* Adapted from "Functional Foods" by International Food Information Council Foundation (www.ific.org)



DIETARY GUIDANCE STATEMENTS ...

- ... focus on general dietary patterns, practices and recommendations that promote health
- ... typically explain the relationship between a group of foods (e.g., fruits and vegetables, whole grains) and health
- ... can mention either a specific nutrient or functional component, or a disease or health-related condition (but not both)
- ... may link a food or category of foods to a non-disease endpoint such as a healthy lifestyle
- ... may relate a category of foods to a reduced risk of disease or health-related condition
- ... can be used on conventional foods only (not dietary supplements)
- ... are not pre-approved by FDA; the manufacturer has the responsibility to assure that they are truthful and not misleading
- ... can be based on Dietary Guidelines for Americans, MyPyramid and other dietary recommendations made by recognized governmental and private health organizations

EXAMPLES AND EXPLANATIONS:

Fruits and vegetables can protect your health. This statement mentions groups of food based on the Center for Disease Control and Prevention's Fruits & Veggies – More Matters™ campaign.

MyPyramid recommends that children ages 6-11 years old eat 1½ cups of fruit each day. This statement is based on USDA's MyPyramid.



Canada's Requirements for Food Labels

Canada and the U.S. have a long history of attempting to harmonize food label regulations on both sides of the border. As a result, Canadian regulations are often similar to those of the U.S. Still, it is not possible to create one label that will satisfy both U.S. and Canadian labeling requirements. This is because: each country has different requirements for formatting the Nutrition Facts, the rounding rules are different, the units for reporting nutrients sometimes differ, and the countries have established different Daily Values for some nutrients. Also, the requirements for ingredient/allergen declarations are different, and there are some differences relating to net contents statements, nutrition/health claims and other aspects of the label.

This section of the guide highlights key differences between Canadian and U.S. regulations with respect to placing nutrition and health-related claims on food labels.

Almost all Canadian food labels must be represented in both of Canada's official languages: English and French. There are only a few exceptions such as local foods, test market foods and specialty foods. This bilingual requirement includes claims and other statements about a product's nutritional benefits used in labeling or advertising. The province of Quebec has additional requirements concerning the use of the French language on all products marketed within its jurisdiction.

NUTRIENT CONTENT CLAIMS IN CANADA ...

- ... are statements or expressions which describe (directly or indirectly) the level of a nutrient in a food or a group of foods
- ... are limited to those defined in *Food & Drug Regulations* (FDR)
- ... must meet all conditions and follow prescriptive wording set out in the FDR
- ... are possible only for nutrients that have defined intake standards or recommendations
- ... apply to all foods whether sold to the trade, at retail, at restaurants or to other food service establishments
- ... are always evaluated for validity against the serving size shown in the Nutrition Facts on the label, *and* the reference amount established for the food category in Schedule M of the FDR
- ... are often conditional upon the level of other nutrient(s) in the food. (In the U.S., disclosure statements are required in such instances. In Canada, disclosure statements are not required since claims cannot be made when certain nutrients exceed threshold levels.)
- ... when placed on a food label or advertisement, must show same size and prominence of all words, numbers, signs or symbols that are part of the claim
- ... trigger the requirement for a Nutrition Facts table in products that would be exempt from nutrition labeling if no claims were made
- ... require that the quantitative value for the nutrient that is the subject of the claim appears in the Nutrition Facts table. (If a Nutrition Facts table is not present, as for example in the case of a shelf tag or a food advertisement, then the quantitative declaration must be provided on the label or in the advertisement.)



Highlights for nutrient content claims in Canada, as summarized from *CFIA Guide to Food Labelling & Advertising* (CFIA Guide):

- Claims are permitted for trans fatty acids, omega-3 and omega-6 polyunsaturated fatty acids.
- *Free* claims are based on amounts of nutrients that are nutritionally-insignificant or trivial in relation to current dietary recommendations.
- Criteria for saturated fatty acid claims are linked to the trans fatty acid content of the food. Likewise, criteria for cholesterol claims are also linked to saturated and trans fatty acid content.
- The claim *X% fat free* is permitted on foods that meet the criteria for *low fat*, as long as the low fat statement accompanies the claim.
- Modifiers such as *ultra* or *extra* cannot be used with claims such as *low fat* or *high fibre* to make them appear to be lower than low or higher than high.
- The nutrient content claim *light* can only be used for foods that are *reduced in fat* or *reduced in energy*.
- The claim *lightly salted* is also permitted.
- The word *light* may be used in reference to a sensory characteristic. However, when used in this manner, the name of the sensory characteristic being described must accompany the light claim (e.g., *light tasting* or *light colour*).
- Only a limited number of nutrient content claims can be made on foods for children under the age of two.
- For claims made about vitamins and minerals: If a vitamin or mineral is not on the allowed list of fortificants for the product category and is added for functional purposes, then the nutrient content claim must be based only on the amount naturally present in the ingredients.
- The use of the words *diet* or *dietetic* is restricted to “foods for special dietary use” (as defined by Division 24 of the FDR) that qualify as *free of calories*, *low in calories*, *reduced in calories* or *free of sugars*, and are labelled as such.
- *Healthy* is not allowed as a nutrient content claim. (In Canada, use of the word healthy on food labels can only be used when it is used in the wording of an approved health claim.)
- The claims *calorie-reduced*, *low calorie*, *free of sugars* and *low in sodium* or *low in salt* are no longer restricted to foods for special dietary use.*
- Claims such as *low carbohydrate*, *source of complex carbohydrates*, *source of polyunsaturates* and *source of monounsaturates* are no longer permitted on foods.*

* *promotes harmonization with U.S. food label regulations*

Comparative nutrient content claims use words such as *lower*, *reduced*, *higher*, *more* and *light* to compare the nutrient values of one product to another. Comparative nutrient content claims must:

- Involve similar foods, or foods of the same food group depending on the type of claim.
- Be based on differences that are both nutritionally-significant and analytically-significant.
- Clearly identify the foods being compared and the differences between them.
- Be labelled so that the information required to accompany the claim is placed immediately adjacent to the most prominent claim on the principal display panel of the food package (PDP), with letters of the same size and prominence as the claim. If the claim is not on the PDP, then the required accompanying information must be grouped with the most prominent claim elsewhere on the label or advertisement with letters of the same size and prominence as the claim.



Quick Comparison of Commonly-Used Nutrient Content Claims Canadian vs. U.S. Qualifying Criteria

Claim Category	Nutrient Content Claim	Canadian Qualifying Criteria	U.S. Qualifying Criteria
Fat-Related	Free of Fat	Less than 0.5g fat per serving	Less than 0.5g fat per serving, and includes no ingredients that contain fat*
	Low in Fat	3g or less fat per serving	3g or less fat per serving
	Free of Saturated Fat	Less than 0.2g saturated fat and less than 0.2g trans fat per serving	Less than 0.5g saturated fat and less than 0.5g trans fat per serving, and includes no ingredients that contain saturated fat*
	Low in Saturated Fat	2g or less of the sum of saturated + trans fats per serving, and not more than 15% of calories from the sum of saturated + trans fats	1g or less saturated fat per serving, and not more than 15% of calories from saturated fat
	Free of Trans Fat	Less than 0.2g trans fat per serving, and meets criteria for "Low in Saturated Fat"	Not permitted in U.S.
Cholesterol-Related	Free of Cholesterol	Less than 2mg cholesterol per serving, and meets criteria for "Low in Saturated Fat"	Less than 2mg cholesterol and 2g or less saturated fat per serving, and includes no ingredients that contain cholesterol*
	Low in Cholesterol	20mg or less cholesterol per serving, and meets criteria for "Low in Saturated Fat"	20mg or less cholesterol and 2g or less saturated fat per serving
Sodium- or Salt-Related	Free of Sodium	Less than 5mg sodium per serving	Less than 5mg sodium per serving, and does not contain salt or other sodium-containing ingredients*
	Very Low in Sodium	Not permitted in Canada	35mg or less sodium per serving
	Low in Sodium	140mg or less sodium per serving	140mg or less sodium per serving
Fibre-Related	Source of Fibre	2g or more fibre per serving	Not permitted in U.S.
	High Source of Fibre (Good Source of Fiber in U.S.)	4g or more fibre per serving	2.5-4.9g fiber per serving
	Very High Source of Fibre (Excellent Source of Fiber in U.S.)	6g or more fibre per serving	5g or more fiber per serving
Vitamins and Minerals	Source of [Vitamin/Mineral]	At least 5% of RDI per serving	Not permitted in U.S.
	Good Source of [Vitamin/Mineral]	At least 15% of RDI per serving (at least 30% of RDI for vitamin C)	10-19% DV per serving
	Excellent Source of [Vitamin/Mineral]	At least 25% of RDI per serving (at least 50% of RDI for vitamin C)	At least 20% DV per serving



"Per serving" means per reference amount and per labelled serving. However, if a product has a small serving size (i.e., reference amount of 30g or 30mL or less in Canada – or 30g or 2 Tbsp or less in U.S.), then the nutrient levels for the claim must be met on a 50 gram basis. Also, there are different criteria for "main dishes" and "meals" (for U.S.) and "prepackaged meals" (for Canada).

**Exceptions are allowed if the relevant ingredient is asterisked in the ingredient statement and footnoted as required.*



QUANTITATIVE DECLARATIONS OUTSIDE NUTRITION FACTS ...

- ... can be used both for nutrients and food constituents required or permitted within the Nutrition Facts table, as well as for those not permitted inside the Nutrition Facts table (e.g., named amino or fatty acids)
- ... are not limited to nutrients that have defined standards or recommendations (this is in contrast to nutrient content claims)
- ... may include a % Daily Value for nutrients that have an established Daily Value
- ... may not include glycemic index or glycemic load values (glycemic claims are not allowed in Canada)
- ... when placed on a food label or advertisement, must show same size and prominence of all words, numbers, signs or symbols that are part of the claim
- ... must be declared on an unrounded basis
- ... must include the serving size in the quantitative declaration
- ... must use established units for declaration; specifically:
 - Energy in Calories
 - Vitamins and Minerals (except Sodium and Potassium) in milligrams (mg), micrograms (μg), retinol equivalents (RE) or niacin equivalents (NE) as applicable and defined through the FDR
 - Sodium, Potassium and Cholesterol in milligrams (mg)
 - Mineral ion content of pre-packaged water or ice in parts per million (ppm)
 - All other nutrients in grams (g)



EXAMPLES AND EXPLANATIONS:

ALLOWED: 0 g carbohydrates per 250 ml serving (factual statement with no nutrient content claims)

NOT ALLOWED: Contains 0 g carbohydrates per 250 ml serving (*contains* is a quantifying word that is not permitted with this statement)

ALLOWED: 21 mg cholesterol per 30 g serving (uses unrounded data, as required)

NOT ALLOWED: 20 mg cholesterol per 30 g serving (uses rounded data from the Nutrition Facts table, which is not allowed)

ALLOWED: 0.2 g taurine per 250 ml serving (units are expressed in grams, as required)

NOT ALLOWED: 215 mg taurine per 250 ml serving (units are expressed in milligrams, which is not allowed for amino acids)

HEALTH CLAIMS IN CANADA ...

- ... suggest or imply that a relationship exists between consumption of a food (or an ingredient in the food) and health
- ... may be stated explicitly with words, or implied through symbols, graphics, logos or other means such as a name, trademark or seal of approval
- ... are often conditional upon the level of other nutrient(s) in the food. (In the U.S., disclosure statements are required in such instances. In Canada, disclosure statements are not required since claims cannot be made when certain nutrients exceed threshold levels.)
- ... must not emphasize or set apart individual words in the prescribed claim wording from other words by sizing differences, font, style or use of different colours
- ... must be truthful and not misleading
- ... trigger the requirement for a Nutrition Facts table in products that would be exempt from nutrition labeling if no claims were made
- ... are required to be represented in both English and French for disease risk reduction claims and nutrient function claims (unless the label is exempt from bilingual requirements) and are recommended to be represented in both languages for food or food constituent function claims
- ... are broadly categorized into two areas: (1) disease risk reduction claims, and (2) function claims
- ... sometimes include a third area – general health claims – that promote health through healthy eating or that provide dietary guidance, though these claims do not refer to a specific or general health effect, disease or health condition

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1. Disease risk reduction claims (formerly called *diet-related health claims*) link a food or food constituent to reducing the risk of developing a diet-related disease or condition within the context of the total diet. As such, more criteria apply to disease risk reduction claims than nutrient content claims. They require pre-approval, and the FDR prescribes the exact wording to be used. These claims are not permitted on foods that are intended solely for children under two years of age or represented for use in very low calorie diets.

At this time, disease risk reduction claims are limited to the following five categories:

- A diet low in sodium and high in potassium & the reduction of risk of hypertension
- A diet adequate in calcium and vitamin D & the reduction of risk of osteoporosis
- A diet low in saturated fat and trans fat & the reduction of risk of heart disease
- A diet rich in vegetables and fruits & the reduction of risk of some types of cancer
- Maximal fermentable carbohydrates in gum, hard candy or breath-freshening products & the reduced risk of dental caries



2. Function claims focus on specific beneficial effects that the consumption of a food or constituent of a food (i.e., nutrient or other component) has on normal functions or biological activities of the body. It is expected that manufacturers wanting to make function claims have scientific evidence that validates the claim prior to its use. This evidence may be used by CFIA, in collaboration with Health Canada, to evaluate product compliance with FDR. Thus, manufacturers and importers are encouraged to seek advice from Health Canada regarding acceptability of function claims on food products prior to their use. Claims reviewed and found to be acceptable will be added to the CFIA Guide.

Food or food constituent function claims are one type of function claims. There are currently three foods or food constituents with approved claims listed in the CFIA Guide. Examples of acceptable claims for these foods/food constituents are:

- (Serving size) of (product) contains X grams of fibre from coarse wheat bran, which promotes laxation.
- Consumption of 1 cup of green tea has an antioxidant effect on blood lipids.
- (Serving size) of (product) provides (X grams) of fibre from psyllium seed. Consuming 3.5 grams of fibre from psyllium seed daily promotes regularity.

Nutrient function claims (formerly called *biological role claims*) are a second type of function claims. This type of claim describes well-established roles of energy or other nutrients that are essential for the maintenance of good health, or normal growth and development. These claims may be general or specific:

Two *general nutrient function claims* are permissible for all nutrients:

- Energy (or another nutrient) is a factor in the maintenance of good health.
- Energy (or another nutrient) is a factor in normal growth and development.

An example of a *specific nutrient function claim* is:

- DHA, an omega-3 fatty acid, supports the normal physical development of the brain, eyes and nerves primarily in children under two years of age.

Other acceptable nutrient function claims shown in the following table are summarized in the CFIA Guide (including the new claims using the word “antioxidant” for vitamin C, vitamin E and selenium).



Acceptable Nutrient Function Claims for Canada*

Nutrient	Nutrient Function
PROTEIN	<ul style="list-style-type: none"> • helps build and repair body tissues • helps build antibodies
FAT	<ul style="list-style-type: none"> • supplies energy • aids in the absorption of fat-soluble vitamins
DHA	<ul style="list-style-type: none"> • DHA, an omega-3 fatty acid, supports the normal physical development of the brain, eyes and nerves primarily in children under two years of age
ARA	<ul style="list-style-type: none"> • ARA, an omega-6 fatty acid, supports the normal physical development of the brain, eyes and nerves primarily in children under two years of age
CARBOHYDRATE	<ul style="list-style-type: none"> • supplies energy • assists in the utilization of fats
VITAMIN A	<ul style="list-style-type: none"> • aids normal bone and tooth development • aids in the development and maintenance of night vision • aids in maintaining the health of the skin and membranes
VITAMIN D	<ul style="list-style-type: none"> • a factor in the formation and maintenance of bones and teeth • enhances calcium and phosphorus absorption and utilization
VITAMIN E	<ul style="list-style-type: none"> • a dietary antioxidant • a dietary antioxidant that protects the fat in body tissues from oxidation
VITAMIN C	<ul style="list-style-type: none"> • a factor in the development and maintenance of bones, cartilage, teeth and gums • a dietary antioxidant • a dietary antioxidant that significantly decreases the adverse effects of free radicals on normal physiological functions • a dietary antioxidant that helps to reduce free radicals and lipid oxidation in body tissues
THIAMINE (VITAMIN B1)	<ul style="list-style-type: none"> • releases energy from carbohydrates • aids normal growth
RIBOFLAVIN (VITAMIN B2)	<ul style="list-style-type: none"> • a factor in energy metabolism and tissue formation
NIACIN	<ul style="list-style-type: none"> • aids in normal growth and development • a factor in energy metabolism and tissue formation
VITAMIN B6	<ul style="list-style-type: none"> • a factor in energy metabolism and tissue formation
FOLATE	<ul style="list-style-type: none"> • aids in red blood cell formation • a factor in normal early fetal development* • a factor in the normal early development of the fetal brain and spinal cord* <p><i>* for foods that contain at least 20% Daily Value per serving</i></p>
VITAMIN B12	<ul style="list-style-type: none"> • aids in red blood cell formation
PANTOTHENIC ACID	<ul style="list-style-type: none"> • a factor in energy metabolism and tissue formation
CALCIUM	<ul style="list-style-type: none"> • aids in the formation and maintenance of bones and teeth
PHOSPHORUS	<ul style="list-style-type: none"> • a factor in the formation and maintenance of bones and teeth
MAGNESIUM	<ul style="list-style-type: none"> • a factor in energy metabolism, tissue formation and bone development
IRON	<ul style="list-style-type: none"> • a factor in red blood cell formation
ZINC	<ul style="list-style-type: none"> • a factor in energy metabolism and tissue formation
IODINE	<ul style="list-style-type: none"> • a factor in the normal function of the thyroid gland
SELENIUM	<ul style="list-style-type: none"> • a dietary antioxidant involved in the formation of a protein that defends against oxidative stress

* Adapted from CFIA Guide to Food Labelling & Advertising



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Technical content to this booklet has been provided by Food Consulting Company, the largest independent provider of food label development and FDA regulatory support. Since its beginning in 1993, Food Consulting Company has partnered with more than 1,000 clients worldwide ranging in size from early stage start-ups to Fortune 500 companies. Here's what Food Consulting Company clients have to say:

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