GUIDE TO FOOD LABELLING AND ADVERTISING

Chapter 8

Health Claims

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Cross-References and Abbreviations in this Chapter

Cross-References

This chapter routinely refers to specific sections in the *Food and Drugs Act* and the *Food and Drug Regulations*. The references allow the reader to locate specific requirements within the *Food and Drugs Act* and the *Food and Drug Regulations*.

- Sections of the *Food and Drugs Act* are referenced in this Guide in one of the following manners: Section 2 of the Act; Section 2, FDA; subsection 5.(1) of the *Food and Drugs Act*; or subsection 5.(1) of the Act.
- The *Food and Drug Regulations* are numbered and are identified in this Guide in one of the following manners: section B.01.603, B.01.603 or [B.01.603].

Abbreviations

Acceptable Macronutrient Distribution Ranges	AMDR
Adequate Intake	AI
Canadian Food Inspection Agency	CFIA
Colony Forming Units	cfu
Daily Value	DV
Docosahexaenoic acid	DHA
Food and Drugs Act	FDA, Act
Food and Drug Regulations	FDR, Regulations
Guide to Food Labelling and Advertising	Guide
Natural Health Products	NHP
Natural Health Products Regulations	NHPR
Nutrition Facts table	NFT
Percent Daily Value	% DV
Reasonable Daily Intake (Part D, FDR; Schedule K)	RDI
Recommended Dietary Allowance	RDA

Chapter 8

Health Claims

8.1 Introduction

A health claim is any representation in labelling or advertising that states, suggests, or implies that a relationship exists between consumption of a food, or an ingredient in the food, and health. Health claims may be stated explicitly with words, or implied through symbols, graphics, logos or other means such as a name, trade mark or seal of approval. While the term 'health claim' is not formally defined in food regulations in Canada, health claims have been classed into three main categories: disease risk reduction and therapeutic claims; function claims; and general health claims.

Most disease risk reduction and therapeutic claims are drug claims. A drug claim is a claim that suggests that the product has the properties of a drug (e.g., the treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms) or that the product has an effect on the body that is beyond that which is normally associated with a food (e.g., restoring, correcting or modifying organic functions in the body). Disease risk reduction claims and therapeutic claims are allowed on food only where specifically permitted by the *Food and Drug Regulations* (FDR; the Regulations). **Disease risk reduction claims** are generally statements that link a food or a constituent of a food to reducing the risk of developing a diet-related disease or condition (e.g. osteoporosis, cancer, hypertension) in the context of the total diet. The composition of a food that carries the claim must contribute to a dietary pattern associated with the claimed benefit. One example of such a claim is "*A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis.*" Currently, there are several disease risk reduction claims permitted on food in Canada; these are discussed in 8.4 of this Guide. **Therapeutic claims**, on the other hand, are claims about treatment or mitigation of a disease or health-related condition, or about restoring, correcting or modifying body functions. At present, no therapeutic claims have been approved for food in Canada.

Broadly defined, **function claims** are claims about the specific beneficial effects that the consumption of a food or a constituent of a food (i.e. nutrient or other component) has on **normal** functions or biological activities of the body. Such claims relate to a positive contribution to health and to the maintenance of a physiological function or to physical or mental performance (see 8.5 of this Guide). Examples of function claims include "*Consumption of green tea helps to protect blood lipids from oxidation*" and "*1/4 cup of Product X contains 7 grams of coarse wheat bran, which promotes regularity*". Claims of this type must be clearly distinguishable from claims about disease risk reduction or therapeutic effects. **Nutrient function claims**, formerly known as biological role claims, are a subset of function claims that describe the well-established roles of energy or known nutrients that are generally **essential** for the maintenance of good health or for normal growth and development (see 8.6 of this Guide). An example of a nutrient function claim is "*Vitamin A aids in the development and maintenance of night vision*."

General health claims are broad claims that promote health through healthy eating or that provide dietary guidance. These claims do not refer to a specific or general health effect, disease, or health condition. In this Guide, 8.8 and 8.11-8.15 provide information on specific aspects of health claims as they relate to vitamin and mineral nutrients (8.8), body weight (8.11), the use of educational material (8.12), third-party endorsements and logos (8.13), heart symbols (8.14), and guidance for healthy eating (8.15).

Compatibility with International Policy

Codex Alimentarius, an international standard-setting body to which Canada is a signatory, has guidelines that set out categories of health claims and conditions for their use (*Guidelines for Use of Nutrition and Health Claims*, CAC/GL 23-1997, Rev. 1-2004 http://www.codexalimentarius.net/download/standards/351/CXG_023e_u.pdf).While there are some differences in the nomenclature and organization of the health claims categories, Canada allows for disease risk reduction claims, nutrient function claims, and function claims for other food substances, consistent with the categories in the Guidelines. Canada also allows the use of claims related to nutrition recommendations. More information on all of these types of claims is provided in this chapter of this Guide.

8.2 General Principles for Health Claims

8.2.1 Avoiding Misleading Claims

All health claims are subject to subsection 5.(1) of the *Food and Drugs Act* (FDA; the Act), which states:

> "No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."

The following principles will promote the use of health claims that are less likely to be misleading or misunderstood:

- The claim is meaningful. For example, claims that are too vague in nature may be misleading and may not provide clear and meaningful information to the consumer.
- The health claim is based on science and supported by adequate scientific evidence.
- It should be feasible to consume the effective amount of the food or the food constituent that is the subject of the claim in the context of a healthy, balanced diet.
- When a claim is made about disease risk reduction, the food carrying the claim should contribute to a dietary pattern associated with the claimed benefit.
- When a function claim is made about the benefit of a nutrient, the food carrying the claim should be at least a dietary "source" of the nutrient.
- Some food constituents do not have established recommended nutrient intakes (RNI's) and therefore source levels of these substances have not been set. Where these are the subject of a health claim the amount of the food constituent in a serving of stated size of the food should be shown in conjunction with the claim. The amount of the food constituent required to achieve the claimed effect or benefit should also be shown.

Applying these principles and conditions increases the likelihood of developing a claim that is truthful and not misleading under subsection 5.(1) of the Act.

Disease risk reduction claims and nutrient function claims are also governed by specific provisions under Part B and Part D of the *Food and Drug Regulations*. These requirements will be discussed in further detail later in this chapter in the sections dealing with these classes of claims.

Wording of Claims

Care must be given to ensure that the meanings of claims are clear and that consumers are not misled. The context in which a word or phrase is used may have a profound effect upon the message conveyed. For example, the words "soothe" and "relax" may be used to express the comforting qualities of a food (e.g. "a soothing hot drink for those cold days" and "relax with a cup of Earl Grey tea"). However, the same words used in a different context could suggest a health effect or benefit (e.g. "a soothing tea for a good night's sleep" or "helps to relax stiff muscles"). These latter claims would be considered health claims and would be subject to the requirements for health claims set out in this chapter.

Trade Marks, Brand Names, Logos, Slogans

Trade marks, brand names, logos and slogans are subject to subsection 5.(1) of the *Food and Drugs Act*, and must not be false, misleading or deceptive. Any trade mark, brand name, logo or slogan that suggests or implies a health benefit by any means, including through nuance, double meanings, or implied meanings, is generally considered a health claim.

8.2.2 Industry's Responsibility for Health Claims That Are Truthful and Not Misleading

- It is the responsibility of all food manufacturers and importers to ensure that their products comply with Canadian legislation.
- New disease risk reduction claims and therapeutic claims require an amendment to the *Food and Drug Regulations* to permit their use on food. Pre-market assessment of new claims of this type by the Food Directorate of Health Canada is mandatory.
- Health claims are subject to subsection 5.(1) of the *Food and Drugs Act* and should be scientifically validated. For health claims that have not been approved or considered acceptable by Health Canada (e.g., claims not listed in this Guide), companies should have acceptable scientific evidence to validate the claim prior to their use.
- The CFIA may request a company to provide scientific evidence in support of a health claim. This information will be used by the CFIA to verify compliance with the *Food and Drugs Act and Regulations*.

The regulation of health claims varies depending upon the type of health claim being made. In some cases a pre-market assessment of the health claim and the scientific evidence in support of the claim by the Food Directorate of Health Canada is mandatory, while in other cases it is voluntary but encouraged.

Disease risk reduction claims and therapeutic claims require an amendment to the *Food and Drug Regulations* to permit their use on food. Consequently, pre-market assessment of new claims of this type by the Food Directorate is mandatory. In the case of function claims, companies are encouraged to consult with the Food Directorate for guidance on the requirements to comply with subsection 5.(1) of the *Food and Drugs Act* that would pertain to specific claims that companies plan to use on their food products.

It is the responsibility of the industry to ensure that the composition, labelling and advertising of their products comply with Canadian legislation. As stated earlier, all health claims are subject to subsection 5.(1) of the *Food and Drugs Act*, which prohibits the labelling or advertising of a food in a manner that is

false, misleading or deceptive. In order for a health claim to be considered not misleading there must be scientific evidence that substantiates the claimed health effect. Consequently, in order to make a health claim, other than a claim set out in the *Food and Drug Regulations* or a claim set out in this Guide, it is expected that companies should have scientific evidence that validates the health claim prior to its use. This evidence may be requested by the CFIA while carrying out its inspection and compliance activities to evaluate compliance with the Act and Regulations. In these cases, the evaluation of the scientific data will be carried out in collaboration with Health Canada. See 8.5.4 and 8.6.5 of this Guide regarding the acceptability of new function claims and new nutrient function claims, respectively.

Companies should also consult the *Guidance Document for Preparing a Submission for Food Health Claims* (Health Canada, 2009)
http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php

This document provides guidance for identifying the available scientific evidence and determining the validity of claims. It also provides guidance on how to prepare a submission for review by the Food Directorate of Health Canada for all new claims, other than for nutrient function claims (formerly known as biological role claims). For guidance on submissions for new nutrient function claims, see 8.6.5 of this Guide.

Questions about the substantiation of health claims may be directed to the following mailing address or email address.

Nutrition Labelling and Claims Section, Nutrition Evaluation Division
Food Directorate, Health Products and Food Branch
Health Canada
251 Sir Frederick Banting Driveway
Postal Locator: 2202E
Ottawa, Ontario K1A 0K9

E-mail: healthclaims-allegationssante@hc-sc.gc.ca

As new claims are reviewed and accepted, they will be included in future updates of this Guide.

8.3 Food, Drugs, Natural Health Products and Claims

Definitions

In order to understand how health claims are regulated in Canada, one must first examine the definitions for a food, drug and natural health product.

The terms "food" and "drug" are both defined in the *Food and Drugs Act*. Natural health products (NHP), which are a subset of drugs, are defined and regulated under the *Natural Health Products Regulations* (NHPR). These definitions are central to determining the correct classification of a product (i.e. food, drug or NHP) and whether a specific claim is appropriate for a product.

> **Food** includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever." (Section 2, FDA)

Drug includes any substance or mixture of substances manufactured, sold or represented for use in:
(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals;
(b) restoring, correcting or modifying organic functions in human beings or animals." (Section 2, FDA)

Natural health product (NHP) means a substance set out in Schedule 1 [NHPR; see Annex 8-1] or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
(b) restoring or correcting organic functions in humans; or
(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 [NHPR; see Annex 8-1], any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or traditional medicine that is or includes a substance set out in Schedule 2." (Section 1, NHPR)

Drug Claims

A claim that suggests that a food has an effect on the body that is beyond that which is normally attributed to a food is considered to be a claim reserved for a drug. This includes claims that a food may be used in the diagnosis, treatment, or prevention of a disease, disorder, abnormal physical state or its symptoms, or that a food may be used to restore, correct or modify an organic function. It is inappropriate for a food to carry a drug claim unless the claim is specifically permitted by the *Food and Drug Regulations*. However, it should also be noted that function claims about the specific effects that the consumption of a food or food constituent has on the normal functions or biological activities of the body are not considered drug claims. (See 8.5 and 8.6 of this Guide for information on function claims and nutrient function claims, respectively.)

Some examples of non-permitted drug claims on foods include:

- "lowers blood cholesterol"
- "lowers blood triglyceride levels"
- "regulates blood sugar levels"
- "is formulated to have the lowest potential for stomach upset and gas"
- "is a rehabilitative supplement"
- "balances hormone levels"
- "soothes bladder infections"
- "improves memory"

Due to the broad definition for a NHP there is an overlap between the two regulatory frameworks. Examples of products found in the overlap may include beverages and bars that carry health claims and certain substances listed in Schedule 1 of the NHPR (eg. vitamins, minerals and herbs). To clarify the criteria used to determine if a product is subject to the *Food and Drug Regulations* or *Natural Health Product Regulations*, Health Canada published principles and considerations in a guidance document entitled *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats* http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php for determination of its status as either a food or an NHP. Products that are determined to be foods are expected to comply with all applicable food regulations and policies. It is the responsibility of manufacturers or importers to ensure that their products meet all Canadian food legislation.

In addition, subsection 3.(1) of the *Food and Drugs Act* states that:

> "No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A." (See Annex 8-2 of this Guide for a list of Schedule A diseases.)

Subsection 3.(1) of the *Food and Drugs Act* was enacted to prevent claims directed at the general public concerning serious health problems, which should be diagnosed and treated by a medical practitioner. Cancer is an example of a Schedule A disease. Claims about such health conditions are prohibited on food products advertised to the general public unless the claim is specifically permitted by the *Food and Drug Regulations*.

Drug Claims That Are Permitted on Food

Certain disease risk reduction claims (see 8.4 of this Guide) are permitted on food. This has been made possible through specific regulatory exemptions in the *Food and Drug Regulations* that permit a closed list of drug-like claims on food. There are currently no therapeutic claims permitted on foods.

To enable additional or new drug-like claims for a food product, an amendment to the *Food and Drug Regulations* is required. Manufacturers or importers wanting to make such health claims on food must make a pre-market submission using the *Guidance Document for Preparing a Submission for Food Health Claims* (Health Canada, 2009 http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php) to the Food Directorate of Health Canada requesting a regulatory change to allow the claim (see 8.2.2 of this Guide for contact information).

8.4 **Disease Risk Reduction Claims** (formerly called Diet-Related Health Claims)

Objectives of Disease Risk Reduction Claims

The provisions for disease risk reduction claims are designed to help consumers make informed choices, thereby reducing their risk of developing chronic diseases. The standards also aim to ensure that these claims:

- are consistent and not deceptive;
- are based on recognized health and scientific criteria; and
- describe the characteristics of a diet associated with reduced risk of developing the chronic disease identified in the health claim.

In 2002, the *Food and Drug Regulations* were amended to allow disease risk reduction claims on food for the first time in Canada. These claims are based on sound scientific evidence that has established a relationship between certain elements of healthy diets and the reduction of risk of developing certain diseases.

Section 3 of the FDA makes it an offence to advertise or sell a food to the general public as a treatment, preventative or cure for any of the diseases referred to in Schedule A. Hypertension and cancer, which are the subjects of two of the permitted claims in the table following section B.01.603, are listed in Schedule A.

However, section B.01.601 of the FDR exempts certain foods bearing specified disease risk reduction claims from the provisions of subsections 3.(1) and 3.(2) of the FDA. In addition, food labelled in such a way is exempt from the provisions of the FDA and FDR applicable to drugs, except where the food would come within the definition of a "drug" for a reason other than the fact that its label or advertisement carries one of these claims. This means that although the Regulations allow for the use of the permitted disease risk reduction claims, other therapeutic statements or "drug" references would not be allowed on the same food, unless otherwise permitted.

A **disease risk reduction claim** is generally a statement that links a food or a constituent of a food to reducing the risk of developing a diet-related disease or condition (e.g. osteoporosis, cancer, hypertension) in the context of the total diet. The composition of a food that carries the claim must contribute to a dietary pattern associated with the claimed benefit.

For example, the label of or an advertisement for a food that is low in sodium might carry the following claim (provided that specific composition and labelling conditions are met): "*A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is low in sodium."*

8.4.1 Permitted Disease Risk Reduction Claims

The *Food and Drug Regulations* currently provide for claims related to the following relationships:

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

8.4.2 Prescribed Wording for Disease Risk Reduction Claims [B.01.601, B.01.603]

The Regulations prescribe the exact wording for the permitted disease risk reduction claims in the table following section B.01.603 (see Table 8-1 of this Guide). The wording of health claims cannot be modified, and no intervening information, graphic sign or symbol may come between parts of the claim. However, words, numbers, signs or symbols may come before or after the health claim, provided that they do not change the nature of the claim. And in the case of advertisements, all parts of the claim must be displayed in equal prominence with no parts highlighted.

Language Requirements

When disease risk reduction claims appear on a label, they must be present in both English and French unless the food is a “local food”, a “test market food”, or a “specialty food” within the meaning of the *Food and Drug Regulations* and the mandatory information is permitted to be shown in only one of those languages [Subsections B.01.012(3) and (7) and section B.01.600].

8.4.3 Presenting Required Information for Disease Risk Reduction Claims

When a disease risk reduction claim is made for a food, the information in column 3 of Table 8-1, *Summary Table of Disease Risk Reduction Claims*, must be provided as required. For example, if a manufacturer claims that the food "won't cause cavities" (see column 1, item 5 in Table 8-1 of this Guide), the amount of sugar alcohols must be declared, if present (see column 3, item 5 in Table 8-1). The *Food and Drug Regulations* prescribe how this must be done.

Declaration of a Nutrition Facts Table on Labels for Prepackaged Products or Advertisements Placed by Manufacturer

When a disease risk reduction claim **appears on the label of a prepackaged food** or **in advertisements placed by or on the direction of the manufacturer or importer** of the food, the label of the food must declare a Nutrition Facts table (NFT) [B.01.401]. Foods that are normally exempt from declaring a NFT under paragraphs B.01.401(2)(a) and (b) of the FDR, such as fresh fruit and vegetables, lose their exemption and are required to declare a NFT. In addition, the nutrition information required by column 3 of Table 8-1 in this Guide must appear in the NFT on the label [B.01.401(3)(e)(ii)].

Requirements for Claims in Advertisements for Prepackaged Products Placed by Someone Other Than the Manufacturer or Importer or for claims on the Label of or in Advertisements for Non-Prepackaged Products

When a disease risk reduction claim is declared in an advertisement for a prepackaged product (other than a radio or television advertisement) made by **someone other than the manufacturer or importer** (such as a marketing board), the accompanying information - namely the nutrition information required by column 3 of the table following B.01.603 (see table 8-1 below) - must appear in the advertisement adjacent to the most prominent claim in the advertisement (without any intervening material), and it must appear in letters of the same size and prominence as the claim [B.01.602(1)(a)].

Similarly, when a disease risk reduction claim appears on the label of or in an advertisement for a **non-prepackaged food** (such as bulk food) the nutrition information required by column 3 must appear on the label or the advertisement, respectively. The same requirements for placement of information would apply.

Radio Advertisements

When these claims are made in a **radio advertisement** the accompanying information must be communicated immediately preceding or following the claim [B.01.602(1)(b)].

Televison Advertisements

In the case of a **television advertisement**, the manner in which the accompanying information is communicated depends upon the manner in which the disease risk reduction claim is delivered, i.e., audio mode, visual mode, or both the audio and visual modes.

- When the claim is delivered in the **audio portion of the advertisement <u>only</u>** the accompanying information must be communicated immediately preceding or following the claim in audio mode or in both the audio and visual modes.

- When the claim is delivered in the **visual portion of the advertisement only** the accompanying information must be communicated immediately preceding or following the claim in the audio mode or in the visual mode. [B.01.602(1)(*c*)]

- In the case where the claim is made in **both the audio and visual portions of a television advertisement** the accompanying information must be in the audio mode or in both the audio and visual modes.

In the case where the accompanying information appears in the visual mode, it must appear at the same time and for the same length of time as the claim; must be adjacent to (without intervening material) the most prominent (or only) claim; and must be in letters of at least the same size and prominence as the claim. [B.01.602(2)]

8.4.4 Prohibitions on the Use of Disease Risk Reduction Claims

Foods Intended Solely for Children Under Two Years of Age

Disease risk reduction claims are not permitted on foods that are intended solely to be consumed by children less than two years of age, such as infant cereal and pureed fruits and vegetables. [B.01.601(1)(*c*)(i)]

Foods Represented for Use in a Very Low Energy Diet

Disease risk reduction claims are also not permitted on foods represented for use in very low energy diets. [B.01.601(1)(*c*)(ii)]

8.4.5 Summary Table of Disease Risk Reduction Claims

Table 8-1 describes permitted disease risk reduction claims, including compositional criteria for the food to qualify for the claim and labelling and advertising requirements. (For the compositional requirements for nutrient content claims that form part of the conditions for disease risk reduction claims, see Chapter 7 of this Guide.)

Summary Table of Disease Risk Reduction Claims
Table 8-1
(May 2009)

Column 1 **Claim**	Column 2 **Conditions - Food**	Column 3 **Conditions - Label or Advertisement**
1. Disease Risk Reduction Claims with Respect to Sodium and Potassium (1) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is sodium-free." (2) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is low in sodium." (3) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is a good source of potassium and is sodium-free." (4) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is a good source of potassium and is low in sodium." (5) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is high in potassium and is sodium-free." (6) "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is high in potassium and is low in sodium."	The food (*a*) other than a vegetable or fruit, does not meet the conditions set out in column 2 of the subject "low in energy" set out in item (b) of Table 7-3 of this Guide. (*b*) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient (see Table 6-5), (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal; *(c)* meets the conditions set out in column 2 of the subject "low in saturated fatty acids" set out in item (b) of Table 7-6 in this Guide (*d)* contains 0.5% or less alcohol; *(e)* meets the conditions set out in column 2 of the subject "free of sodium or salt" set out in item a) of Table 7-10 of this Guide, if the label of or advertisement for the food carries statement or claim (1), (3), or (5) set out in column 1 of this item; *(f)* meets the conditions set out in column 2 of the subject "low in sodium or salt" set out in item b) of Table 7-10, if the label of or advertisement of the food carries statement or claim (2), (4), or (6) set out in column 1 of this item; and *(g)* contains 350 mg or more of potassium, if the label of or advertisement for the food carries statement or claims (3), (4), (5), or (6) set out in column 1 of this item, (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal.	1. When the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the Nutrition Facts table shall include the amount of potassium, in accordance with item 9 of Table 6-2 of this Guide [B.01.402(2)]. 2. When the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of sodium and potassium per serving of stated sized, in accordance with B.01.602 if applicable. Nutrition Facts table required on products otherwise exempted by B.01.401(2) (a)&(b). [B.01.401(3)(e)(ii)] (See 5.3 of this Guide) **[Item 1, Table following B.01.603]**

Column 1 **Claim**	Column 2 **Conditions - Food**	Column 3 **Conditions - Label or Advertisement**
2. Disease Risk Reduction Claims with Respect to Calcium and Vitamin D (1) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is a good source of calcium." (2) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is high in calcium." (3) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is an excellent source of calcium." (4) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is very high in calcium." (5) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is an excellent source of calcium and vitamin D." (6) "A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is very high in calcium and vitamin D."	The food (*a*) other than a vegetable or fruit, does not meet the conditions set out in column 2 of the subject "low in energy" set out in item (b) of Table 7-3 of this Guide; (*b*) contains no more phosphorus, excluding that provided by phytate, than calcium; (*c*) contains 0.5% or less alcohol; (*d*) contains, if the label of or advertisement for the food carries statement or claim (1) or (2) set out in column 1, (i) 200 mg or more of calcium per reference amount and per serving of stated size, or (ii) 300 mg or more of calcium per serving of stated size, if the food is a prepackaged meal; (*e*) contains, if the label of or advertisement for the food carries statement or claim (3), (4), (5) or (6) set out in column 1, (i) 275 mg or more of calcium per reference amount and per serving of stated size, or (ii) 400 mg or more of calcium per serving of stated size, if the food is a prepackaged meal; and (*f*) contains 1.25 µg or more of vitamin D, if the label of or advertisement for the food carries statement or claim (5) or (6) set out in column 1, (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal.	1. When the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the Nutrition Facts table shall include the amount of vitamin D and phosphorus, in accordance with item 14 of Table 6-2 [B.01.402(2)]. **or** 2. When the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of vitamin D, calcium, and phosphorus per serving of stated sized, in accordance with B.01.602 if applicable. Nutrition Facts table required on products otherwise exempted by B.01.401(2) (a) & (b). [B.01.401(3)(e)(ii)] (See 5.3 of this Guide) **[Item 2, Table following B.01.603]**

Column 1 **Claim**	Column 2 **Conditions - Food**	Column 3 **Conditions - Label or Advertisement**
3. Disease Risk Reduction Claims with Respect to Saturated and *Trans* fats (1) "A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is free of saturated and trans fats." (2) "A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is low in saturated and trans fats."	The food (*a*) other than a vegetable or fruit, does not meet the conditions set out in column 2 of the subject "low in energy" set out in item (b) of Table 7-3 of this Guide; (*b*) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient (i) per reference amount and per serving of stated size, or (ii) per serving of stated size, if the food is a prepackaged meal; (*c*) contains 100 mg or less of cholesterol per 100 g of food; (*d*) contains 0.5% or less alcohol; (*e*) if it is a fat or an oil, meets the conditions set out in column 2 (i) of the subject "source of omega-3 polyunsaturated fatty acids" (item (a) of Table 7-8) or (ii) the subject "source of omega-6 polyunsaturated fatty acids" (item (b) of Table 7-8), or (iii) both (i) and (ii); (*f*) contains (i) 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or (ii) 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal; (*g*) meets the conditions set out in column 2 of the subject "free of saturated fatty acids" (item (a) of Table 7-6), if the label of or advertisement for the food carries statement or claim (1) set out in column 1 of this table; and (*h*) meets the conditions set out in column 2 of the subject "low in saturated fatty acids" (item (b) of Table 7-6) , if the label of or advertisement for the food carries statement or claim (2) set out in column 1 of this table.	If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of saturated fatty acids and *trans* fatty acids per serving of stated size, in accordance with B.01.602, if applicable. Nutrition Facts table required on products otherwise exempted by B.01.401(2)(a) & (b). [B.01.401(3)(e)(ii)] (See 5.3 of this Guide) **[Item 3, Table following B.01.603]**

Column 1 **Claim**	Column 2 **Conditions - Food**	Column 3 **Conditions - Label or Advertisement**
4. Disease Risk Reduction Claims with Respect to Cancer risk reduction "A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer."	The food (*a*) is one of the following vegetables, fruit, or juice and may contain only sweetening agents, food additives as permitted by these Regulations, salt, herbs, spices, seasonings or water: (i) a fresh, frozen, canned or dried vegetable, (ii) a fresh, frozen, canned or dried fruit, (iii) a vegetable or fruit juice, or (iv) a combination of the foods set out in subparagraphs (i) to (iii); (*b*) is not one of the following (i) potatoes, yams, cassava, plantain, corn, mushrooms, mature legumes and their juices, (ii) vegetables or fruit used as condiments, garnishes or flavourings, including maraschino cherries, glacé fruit, candied fruit and onion flakes, (iii) jams or jam-type spreads, marmalades, preserves and jellies, (iv) olives, and (v) powdered vegetables or fruit; and *(c)* contains 0.5% or less alcohol.	Nutrition Facts table required on products otherwise exempted by B.01.401(2)(a) & (b). **[B.01.401(3)(e)(ii)]** (See 5.3 of this Guide) **[Item 4, Table following B.01.603]**
Note: This claim can only be made on vegetables and fruits listed in Item (a). This claim could be made on a fresh fruit salad with fruit juice, a mixed vegetable juice, or mixed frozen vegetables (provided that they don't contain one of the vegetables not permitted to carry the claim, such as corn). This claim would not be allowed on foods listed in Item (b) and on foods that contain more than 0.5% alcohol, e.g. relish, ketchup, strawberry jam, wine, fruit juice based alcoholic beverage. It also can not be made on combination foods that have ingredients other than those listed in Item (a), e.g. cherry pie, vegetable lasagna. Under Item (b)(i) of Column 2 above, one of the items excluded from making the claim is mature legumes. This is to differentiate the mature seeds of legumes such as split peas, kidney beans, black eyed peas, from young pods of legumes, such as edible podded peas, and from immature seeds such as sweet peas, which are considered vegetables.		

Column 1 **Claim**	Column 2 **Conditions - Food**	Column 3 **Conditions - Label or Advertisement**
5. Disease Risk Reduction Claims with Respect to Dental Caries (1)"Won't cause cavities." (2) "Does not promote tooth decay." (3) "Does not promote dental caries." (4) "Non-cariogenic."	The food is a chewing gum, hard candy or breath freshening product that (a) contains 0.25% or less starch, dextrins, mono-, di- and oligosaccharides or other fermentable carbohydrates combined; or (b) does not, if it contains more than 0.25% fermentable carbohydrates, lower plaque pH below 5.7 by bacterial fermentation during 30 minutes after consumption as measured by the indwelling plaque pH test, referred to in "Identification of Low Caries Risk Dietary Components" by T.N. Imfeld, Volume 11, Monographs in Oral Science, 1983.	When the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the Nutrition Facts table shall include the amount of sugar alcohols, if present, in accordance with item 12 of Table 6-2 of this Guide. (B.01.402(2)). Nutrition Facts table required on products otherwise exempted by B.01.401(2) (a) & (b). **[B.01.401(3)(e)(ii)]** **[Item 5, Table following B.01.603]**

8.5 Function Claims

Food provides energy and the building blocks needed for growth, development, and the maintenance of life and health. Function claims relate to the specific beneficial effects that the consumption of a food or a constituent of a food (nutrient or other component) has on the normal functions or biological activities of the body. Such claims relate to a positive contribution to health and the maintenance of a physiological function or to physical or mental performance.

Function claims are based on the role that the food or the food constituent plays when consumed at levels consistent with normal dietary patterns. See additional information in this Guide regarding quantitative declarations (8.5.2) and standards of evidence (8.5.4(1)).

Nutrient Function Claims

Claims made about known nutrients and their well-established functions that are generally **essential** for the maintenance of good health or for normal growth and development are known as **nutrient function claims**. Nutrient function claims, formerly known as biological role claims, have been allowed on foods for a number of years in Canada. Examples of such claims include "*Protein helps build and repair body tissues" and "Vitamin D is a factor in the formation and maintenance of bones and teeth.*"

Nutrient function claims are considered a subset of function claims. They are discussed separately in this Guide (8.6) because there is a separate set of conditions for making such claims.

8.5.1 Conditions for Function Claims

As with all health claims, function claims are subject to subsection 5.(1) of the *Food and Drugs Act* that prohibits false, misleading or deceptive product representations (see 8.2.1 of this Guide).

A function claim about the physiological effects of food or food constituents **must not** refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or of their symptoms. Claims about restoring or correcting abnormal functions of the body or modifying body functions beyond the normal physiological effects of food are considered to be drug claims, not function claims (see 8.3 of this Guide). Such claims would require a pre-market review by Health Canada and (if the claim is supported by sufficient scientific evidence) an amendment to the *Food and Drug Regulations* to permit their use on food.

8.5.2 Labelling Information for Function Claims

Language Requirements

While there are no specific language requirements set out in the *Food and Drug Regulations* for general function claims, it is recommended that when a function claim is made on the label of a food, it appear in both English and French unless the food is exempt from bilingual labelling, such as in the case of local food, specialty food or test market food [B.01.012(3) or (7)].

Declaration of a Nutrition Facts Table

When a function claim **appears on the label of a prepackaged food** or **in advertisements placed by or on the direction of the manufacturer or importer** of the food, the label of the food must declare a Nutrition Facts table (NFT) [B.01.401]. Foods that are normally exempt from declaring a NFT under paragraphs B.01.401(2)(a) and (b) of the FDR, such as fresh fruit and vegetables, lose their exemption and are required to declare a NFT [B.01.401.(3)(e)(ii)].

Quantitative Declarations

Table 8-2, *Summary Table of Acceptable Function Claims as Applied to Food or Food Constituents,* outlines the labelling conditions for each function claim. In many cases, these conditions include a quantitative declaration.

While there are no requirements for quantitative declarations set out in the *Food and Drug Regulations* for general function claims, it is strongly recommended that when a function claim is made about a food constituent on the **label of a prepackaged product** or in **any advertisement for the food that is made or placed by or on the direction of the manufacturer or importer**, a quantitative declaration of the amount of the food constituent (per serving of stated size) appear on the label.

When a function claim appears on the label or in an advertisement for a **non-prepackaged product** or in any **advertisement for a prepackaged product not made or placed by or on the direction of the manufacturer or importer**, the quantitative amount of the food constituent (per serving of stated size) that is the subject of the function claim should also appear on the label or in the advertisement.

In certain situations the amount of the food or food constituent in a serving of food is less than that required to achieve the claimed physiological effect. In these cases, the amount of the food or food constituent required to produce the desired effect and the amount of the food or food constituent in a serving of stated size of the food should be declared as part of the function claim. (See Standards of Evidence, 8.5.4(1) of this Guide.)

8.5.3 Summary Table of Acceptable Function Claims as Applied to Food or Food Constituents

The function claims listed in Table 8-2 when used with the specified conditions would be acceptable. The table will be updated as new claims for food or food constituents are reviewed and found to be acceptable by Health Canada. See 8.5.4 of this Guide on acceptability of new function claims.

Summary Table of Acceptable Function Claims as Applied to Food or Food Constituents
Table 8-2
(May 2009)

Food or Food Constituent	Acceptable Claim	Conditions for Use
Coarse Wheat Bran[1]	a) (Naming the serving) of (naming the product) contains 7 grams (or naming the amount if more than 7 grams) of fibre from coarse wheat bran, which promotes laxation. b) (Naming the serving) of (naming the product) contains 7 grams (or naming the amount if more than 7 grams) of fibre from coarse wheat bran, which promotes regularity. c) (Naming the serving) of (naming the product) provides (naming the amount) of fibre from coarse wheat bran. Consuming 7 grams of fibre from coarse wheat bran (daily*) promotes laxation. d) (Naming the serving) of (naming the product) provides (naming the amount) of fibre from coarse wheat bran. Consuming 7 grams of fibre from coarse wheat bran (daily*) promotes regularity.	A Reasonable Daily Intake (RDI) (Part D; FDR; Schedule K) of the food or one serving contains a minimum of 7 grams of dietary fibre from coarse wheat bran. Where the RDI of a food product comprises one serving and the product provides a minimum of 7 grams of fibre from coarse wheat bran in one serving of stated size, claims (a) or (b) may be made. Where the RDI of a food product comprises more than one serving and the product provides less than 7 grams of fibre from coarse wheat bran in one serving of stated size, claims (c) or (d) may be made. See 8.10.2 of this Guide for more information on laxative and laxation claims.

Food or Food Constituent	Acceptable Claim	Conditions for Use
Green Tea (unfermented leaves and/or bud from *Camellia sinensis*)	Consumption of [1 cup (250 ml) of*] green tea helps to protect blood lipids from oxidation. [Consumption of 1 cup (250 ml) of*] green tea has an antioxidant effect in blood [or on blood lipids]. [Consumption of 1 cup (250 ml) of*] green tea increases antioxidant capacity in the blood.	A green tea infusion brewed following manufacturer directions, which contains at least: - 2.0 grams or more tea leaves per 250 ml, OR - 1 tea bag (containing 2 grams tea leaves) per 250 ml *OR* A reconstituted green tea product (e.g. iced green tea) containing at least 0.8 grams freeze dried or spray dried tea infusion per reference amount and serving of stated size when prepared according to manufacturer directions. Advertising and/or labelling may include a precautionary statement indicating that a maximum of 9 cups per day should not be exceeded due to the caffeine content.
Psyllium[1]	a) (Naming the serving) of (naming the product) contains 3.5 grams (or naming the amount if more than 3.5 grams) of fibre from psyllium seed, which promotes laxation. b) (Naming the serving) of (naming the product) contains 3.5 grams (or naming the amount if more than 3.5 grams) of fibre from psyllium seed, which promotes regularity. c) (Naming the serving) of (naming the product) provides (naming the amount) of fibre from psyllium seed. Consuming 3.5 grams of fibre from psyllium seed (daily*) promotes laxation. d) (Naming the serving) of (naming the product) provides (naming the amount) of fibre from psyllium seed. Consuming 3.5 grams of fibre from psyllium seed (daily*) promotes regularity.	A Reasonable Daily Intake (RDI) (Part D; FDR; Schedule K) of the food or one serving contains a minimum of 3.5 grams of dietary fibre from psyllium seed. Where the RDI of a food product comprises one serving and the product provides a minimum of 3.5 grams of fibre from psyllium seed in one serving of stated size, claims (a) or (b) may be made. Where the RDI of a food product comprises more than one serving and the product provides less than 3.5 grams of fibre from psyllium seed in one serving of stated size, claims (c) or (d) may be made. See 6.8.1 of this Guide for more information about the acceptability and labelling of fibre sources.

* Use of the phrase shown in parentheses is optional. For the claims for green tea, "Consumption of 1 cup (250 ml) of" may be replaced by "Consumption of 1 cup of" or "Consumption of 250 ml of".

[1] Cummings JH. 2001.The effect of dietary fiber on fecal weight and composition. In: *CRC Handbook of Dietary Fiber in Human Nutrition*. 3rd ed. Spiller GA (ed.), pp 183-252. Boca Raton (FL): CRC Press.

8.5.4 Acceptability of New Function Claims

> This section does not apply to new nutrient function claims (formerly known as biological role claims) for nutrients for which a Recommended Dietary Allowance (RDA), Adequate Intake (AI), or Acceptable Macronutrient Distribution Ranges (AMDR) have been established. See 8.6.5 of this Guide for relevant information on that type of function claim.

As discussed in 8.2.2, it is expected that companies, wanting to make function claims, have scientific evidence to validate the claim prior to its use on food labels or in advertisements. This evidence may be used by the CFIA, in collaboration with Health Canada, to evaluate product compliance with the *Food and Drugs Act and Regulations*. Consequently, manufacturers and importers are encouraged to contact the Food Directorate of Health Canada for advice regarding the acceptability of function claims on food products **prior** to their use (see 8.2.2 of this Guide for contact and resource information). Claims reviewed and found to be acceptable will be added to Table 8-2 of this Guide.

Health Canada considers the following factors in determining the acceptability of new function claims:

(1) Standards of Evidence

Manufacturers who make function claims on their food products should ensure that they meet acceptable standards of evidence in supporting their claims. The evidence should be applicable to the target group for the claim. For example, the physiological effect of a food or food constituent (e.g. promotes normal transit time) is **not** considered to be supported when the evidence is based on therapeutic (treatment) effects in sick populations (e.g. treatment of diarrhea).

The amount of the food or food constituent required to achieve the claimed physiological effect should be based on the evidence supporting the claim. In addition, it should be feasible for the target population to consume the amount of food or food constituent required to achieve the effect as part of a healthy, balanced diet. Consequently, it is expected that the amount of the food or food constituent required to achieve the claimed physiological effect could be consumed in a Reasonable Daily Intake (RDI) of the food. (Refer to Schedule K in Part D of the *Food and Drug Regulations* for information on RDI.) Where no RDI has been established, the amount of the food or food constituent to achieve the claimed physiological effect should be consumed in a single serving of stated size, unless the function claim is related to a food constituent that is available in a variety of foods. In this case, the amount of the food constituent in the food per serving of stated size and the amount of the food constituent required to achieve the claimed effect or benefit should be declared along with the claim.

(**2) Clearly Stated Specific Physiological Effect**

Acceptable function claims are claims about a food or food constituent that clearly state a specific and scientifically supported physiological effect (e.g. promotes regularity) associated with good health or performance. Claims that state a specific effect provide more useful information for the consumer and are less likely to be misleading or misunderstood than a claim about a general or broad effect.

Function claims also should not give the impression that the food is "healthier" than, or nutritionally superior to, other similar foods not bearing the claims.

Claims that state a general or broad effect (e.g. supports immune function/system) would not be considered acceptable function claims. As a general rule, a non-specific or broad claim is acceptable only

for a well-established role of energy or a known nutrient in maintaining the functions of the body essential for the maintenance of good health or for normal growth and development (i.e. a nutrient function claim; see 8.6 of this Guide). A non-specific or broad claim is also subject to interpretation and inference and in some cases could be considered a drug claim (see 8.5.1 of this Guide).

8.6 Nutrient Function Claims (Biological Role Claims)

Nutrient function claims, formerly known as biological role claims, describe the well-established roles of energy or known nutrients that are generally **essential** for the maintenance of good health or for normal growth and development. Provisions for nutrient function claims are made in B.01.311, D.01.006 and D.02.004 of the FDR.

"Nutrient" is not defined in the *Food and Drug Regulations* for the purposes of food labelling and advertising. A substance is considered a nutrient if it is recognized as such by the Institute of Medicine of the National Academies, Washington, DC (www.iom.edu).

The following two **general nutrient function claims** are permissible for all nutrients [B.01.311, B.01.312, D.01.006, D.02.004]:

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

Note: Nutrient function claims are not made for a food per se; they may only be made respecting the energy value or nutrients in a food.

Acceptable and Unacceptable Nutrient Function Claim Examples

The claims for the action or function of nutrients should not imply that consumption of the food, by itself, will have the effect attributed to the nutrient.

The following statement is an **acceptable** claim.

- "Milk is an excellent source of calcium, which helps build strong bones and teeth."

The following statement is an **unacceptable** claim.

- "Milk helps build strong bones and teeth."

In addition to the two general nutrient function claims listed above, Table 8-3, *Summary Table of Nutrient Function Claims*, lists specific nutrient function claims. The claims in the summary table refer to the scientifically recognized specific role each nutrient has in maintaining good health or in supporting normal growth and development. The following sections (8.6.1-8.6.4) describe the conditions that apply to specific nutrient function claims and the labelling and advertising requirements for all nutrient function claims.

8.6.1 Conditions for Nutrient Function Claims

The conditions for function claims as described in 8.5.1 of this Guide also apply to nutrient function claims.

Nutrient Function Claims for Protein [B.01.305(1)]

When nutrient function claims are made for protein, the food must meet the requirements for "source of protein", which includes having a minimum Protein Rating (PR) of 20 (See Item b of Table 7-4 of this Guide).

Nutrient Function Claims for Vitamin and Mineral Nutrients [D.01.004, D.02.002]

When nutrient function claims are made for vitamin and mineral nutrients, the vitamin or mineral nutrient must have an established Recommended Daily Intake and the food must contain a minimum of 5% of the Recommended Daily Intake for that vitamin or mineral (i.e. at least a dietary "source" of the nutrient). Recommended Daily Intakes for vitamins and mineral nutrients are found in Table 1 to Divisions 1 and 2 of Part D of the *Food and Drugs Regulations*, respectively.

8.6.2 Labelling Requirements for Nutrient Function Claims for Prepackaged Products and for Advertisements Placed by the Manufacturer or Importer

Language Requirements

When they appear on a label, nutrient function claims must be present in both English and French unless the food is exempt from bilingual labelling, such as in the case of local foods permitted under section B.01.012 [B.01.012(3) or (7), B.01.311(5)].

Declaration of a Nutrition Facts Table

When a nutrient function claim **appears on the label of a prepackaged food** or in **advertisements placed by or on the direction of the manufacturer or importer** of the food, the label of the food must declare a Nutrition Facts table (NFT) [B.01.401]. Foods that are normally exempt from declaring a NFT under B.01.401(2)(a) and (b) of the FDR, such as fresh fruit and vegetables, lose their exemption and are required to declare a NFT [B.01.401(3)(e)(ii)].

Quantitative Declarations

As a general rule, whenever a nutrient function claim is made the consumer must be informed as to the amount of the nutrient present in a serving of the food. This may be achieved through a declaration in the Nutrition Facts table (NFT) or in a quantitative statement outside the NFT; the manner in which the information is provided depends upon a number of factors. [B.01.311(4), B.01.401(3)(e), D.01.004(1)(c), D.02.002(1)(c)).

When a nutrient function claim is made on a **label of a prepackaged product** or in any **advertisement for the product that is made or placed on the direction of the manufacturer or importer**, the label of the food must declare a NFT (see above).

When a nutrient function claim is made for the energy value of a food or one of the nutrients listed in column 1 of the tables to B.01.401 and B.01.402 (which list the nutrients permitted in the NFT), the energy value or nutrient value must be declared in the NFT table on the label of the food.

However, the Regulations also permit nutrient function claims to be made for nutrients other than those listed in the tables to B.01.401 and B.01.402, e.g. fatty acids such as DHA. In these cases, a quantitative declaration of amount of the nutrient(s), in grams per serving of stated size, must appear on the label of the food. [B.01.311(4)]

See section 7.4 of this Guide for further information on quantitative statements.

8.6.3 Requirements for Nutrient Function Claims for Non-Prepackaged Products or for Advertisements Placed by Someone Other Than the Manufacturer or Importer [B.01.312]

When a nutrient function claim appears on the label of or in an advertisement for a **non-prepackaged product** or in an **advertisement for a prepackaged product not made or placed by or on the direction of the manufacturer or importer**, the quantitative amount of the subject of the claim (i.e., energy or nutrient), shall be declared per serving of stated size and shall appear on the label or in the advertisement, where the claim is made.

The quantitative value shall be expressed in calories in the case of energy; in percent Daily Value for vitamins and minerals nutrients; in milligrams for potassium, sodium, and cholesterol; and in grams for any other case. [B.01.300, B.01.311(3), B.01.312, D.01.004(1)(c), D.02.002(1)(c)]

Radio Advertisements

When these claims are made in a **radio advertisement,** the quantitative statement shall be communicated immediately preceding or following the claim [B.01.312(3)].

Televison Advertisements

In the case of a **television advertisement**, the manner in which the quantitative statement is communicated depends upon the manner in which the nutrient function claim is delivered, i.e., audio mode, visual mode, or both audio and visual modes.

- When the claim is delivered in the **audio portion of the advertisement <u>only</u>** then the quantitative statement must be communicated immediately preceding or following the claim in the audio mode or in both the audio and visual modes [B.01.312(4)(a)].

- When the claim is delivered in the **visual portion of the advertisement <u>only</u>** the quantitative information must be communicated immediately preceding or following the claim in the audio mode or in the visual mode.

- In the case where the claim is made in **both the audio and visual portions of a television advertisement** the accompanying information must be in the audio mode or in both the audio and visual modes.

In the case where the quantitative statement appears in the visual mode, it must appear at the same time and for the same length of time as the claim; must be adjacent to (without intervening material) the most prominent (or only) claim; and must be in letters of at least the same size and prominence as the claim.

8.6.4 Summary Table of Acceptable Nutrient Function Claims

The nutrient function claims listed in Table 8-3 are considered to be acceptable. Other nutrient function claims may also be acceptable and will be evaluated case by case. The table will be updated as new nutrient function claims are reviewed and found to be acceptable by Health Canada. See 8.6.5 of this Guide on acceptability of new nutrient function claims.

Summary Table of Acceptable Nutrient Function Claims
Table 8-3
(**updated May 2009)**

NUTRIENT	ACCEPTABLE NUTRIENT FUNCTION CLAIMS[1]
PROTEIN	- helps build and repair body tissues - helps build antibodies
FAT	- supplies energy - aids in the absorption of fat-soluble vitamins
DHA	- 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.[2]
ARA	- 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.[2]
CARBOHYDRATE	- supplies energy - assists in the utilization of fats
VITAMIN A	- 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	- factor in the formation and maintenance of bones and teeth - enhances calcium and phosphorus absorption and utilization
VITAMIN E	- a dietary antioxidant - a dietary antioxidant that protects the fat in body tissues from oxidation
VITAMIN C	- 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 B_1)	- releases energy from carbohydrate - aids normal growth
RIBOFLAVIN (VITAMIN B_2)	- factor in energy metabolism and tissue formation
NIACIN	- aids in normal growth and development - factor in energy metabolism and tissue formation
VITAMIN B_6	- factor in energy metabolism and tissue formation
FOLATE	- aids in red blood cell formation - a factor in normal early fetal development[3] - a factor in the normal early development of the fetal brain and spinal cord[3]
VITAMIN B_{12}	- aids in red blood cell formation

NUTRIENT	ACCEPTABLE NUTRIENT FUNCTION CLAIMS[1]
PANTOTHENIC ACID	- factor in energy metabolism and tissue formation
CALCIUM	- aids in the formation and maintenance of bones and teeth
PHOSPHORUS	- factor in the formation and maintenance of bones and teeth
MAGNESIUM	- factor in energy metabolism, tissue formation and bone development
IRON	- factor in red blood cell formation
ZINC	- factor in energy metabolism and tissue formation
IODINE	- factor in the normal function of the thyroid gland
SELENIUM	- a dietary antioxidant involved in the formation of a protein that defends against oxidative stress

1. The following two **general nutrient function claims** are permissible for all nutrients [B.01.311, B.01.312, D.01.006, D.02.004]:
   - **"Energy (or Name of the nutrient) is a factor in the maintenance of good health."**
   - **"Energy (or Name of the nutrient) is a factor in normal growth and development."**

2. Note that this is a change from the claim previously allowed for DHA. This claim is based on available scientific evidence indicating that the development of the brain, eyes, and nerves in the human infant takes places very early starting in late pregnancy and up to 2 years of age. The Institute of Medicine in their 2005 report* stated that "The developing brain accumulates large amounts of DHA during the pre- and postnatal development and this accumulation continues throughout the first 2 years after birth". **Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, (DC): National Academies Press; 2005. P. 444-5

3. In order to make these two claims for folate, the food must contain at least 40 micrograms of folate (20% Daily Value) per reference amount and per serving of stated size. This is a higher minimum amount than usual for a nutrient function claim for a vitamin because the function referred to in these two claims is associated with an intake that is higher than the Daily Value. These claims should not be used on foods intended solely for children under 2 years of age.

8.6.5 Acceptability of New Nutrient Function Claims

This section applies to nutrients that meet the following criteria:

a) the nutrient is one for which a Recommended Dietary Allowance (RDA), Adequate Intake (AI), or Acceptable Macronutrient Distribution Ranges (AMDR) have been established by the Institute of Medicine of the US National Academies,

AND

b) the function reflects consensus among the broad scientific community and has been published by an authoritative scientific body as its current position with regard to the function(s) within the past 15 years.

Authoritative scientific bodies include the Institute of Medicine (Dietary Reference Intake report series) and the European Food Safety Authority.

To seek advice on the acceptability of a new function claim for a nutrient that meets the above criteria, manufacturers are encouraged to contact the Food Directorate of Health Canada with the following information:

(a) the name of the authoritative body;
(b) the exact wording of the statement;
(c) a copy of the source document in which the statement is published;
(d) a description of the review process undertaken by the authoritative body to develop the statement; and
(e) an indication that there is no conflicting authoritative statement.

See 8.2.2 of this Guide for contact information for the Food Directorate.

See 8.5.4 of this Guide for information on how function claims are assessed for nutrients for which no Recommended Dietary Allowance (RDA), Adequate Intake (AI), or Acceptable Macronutrient Distribution Ranges (AMDR) have been established by the Institute of Medicine of the US National Academies (e.g. DHA).

8.7 Probiotic Claims

Probiotics are microorganisms that are beneficial to human health. Due to the special nature of probiotic microorganisms, Health Canada has prepared a guidance document, *The Use of Probiotic Microorganisms in Food* (Health Canada, 2009), that sets out the conditions under which health claims about probiotics would be considered acceptable.

Probiotic claims that are therapeutic in nature or that are considered “drug” claims are required to undergo a pre-market assessment by the Food Directorate of Health Canada and a regulatory amendment to the *Food and Drug Regulations* to allow their use.

Probiotics are defined as "live microorganisms which when administered in adequate amounts confer a health benefit on the host" (FAO/WHO, 2001; see reference list in Annex 8-3 of this Guide). The term "probiotics" and similar terms or representations (e.g. "with beneficial probiotic cultures", "contains bacteria that are essential to a healthy system", and a Latin name of a microbial species modified to suggest a health benefit) in text or graphics on food labels or in advertising that suggest a food confers a health benefit are examples of health claims.

Two types of probiotic claims can be made on food: strain-specific claims and non-strain-specific claims.

- **Strain-specific claims** are claims about the health benefits or effects of specific strains of probiotics. At the present time, no strain-specific claims have been accepted by Health Canada. As these claims are reviewed and accepted, Health Canada will update a list of acceptable strain-specific claims that will be available on its website.

- **Non-strain-specific claims** are statements about the nature of probiotics. A closed list of non-strain-specific probiotic claims that would be acceptable without the need for the manufacturer to conduct a detailed review of the scientific basis for the claim is provided in 8.7.2 of this Guide.

See 8.2.2 and 8.5.4 of this Guide for more information on the acceptability of new health claims, including new function claims.

8.7.1 Conditions for Probiotic Claims

Health Canada has prepared a guidance document, *The Use of Probiotic Microorganisms in Food* (Health Canada, 2009), that sets out the conditions under which health claims about probiotics would be considered acceptable. The following is a summary of the guidance; the guidance document should be consulted for specific details.

- The use of "probiotic" and other similar terms and representations (including trade names that suggest a health benefit) should be accompanied by specific, validated statements about the benefits or effects of the probiotic. This will reduce the possibility of these statements being vague, uninformative or misleading.
- Validated health claims about the health benefits or effects of probiotics are statements that are supported by strain-specific evidence.
- When making any probiotic claim, the manufacturer or importer of the product should have documentation supporting the identification, safety, viability, concentration and stability of the probiotic strain added to the food product.
- The manufacturer or importer should follow all requirements applicable to the sale of food, including those related to the use and labelling of ingredients used in novel technology in the delivery of a viable microorganism for food application.
- The food should contain, at a minimum, the amount of the probiotic microorganism(s) required to result in the claimed effect or health benefit throughout the shelf life of the product. Documentation to support the functionality aspects of the product (i.e. stability and viability of the probiotic strain or mixed culture) should be maintained.

General information about evidence requirements applicable to health claims of all types, including function claims, also apply to probiotic claims (see 8.2.2 and 8.5.4 of this Guide).

Specific Labelling Guidelines

Specific labelling guidelines relevant to products containing probiotic microorganisms are listed below.

(1) Identification of Strain

A probiotic claim should be accompanied by the Latin name of the microorganism (i.e. genus and species), along with the identity of the strain of the microorganism, using acceptable nomenclature (see Table 8-4 of this Guide for nomenclature of selected bacterial species. For consistency, it is recommended that the strain be identified by using the number assigned by an internationally recognized culture repository (e.g. American Type Culture Collection; ATCC 2008; see reference list in Annex 8-3 of this Guide).

In the case of advertising, if the probiotic microorganism is identified or referred to in the advertisement, then the identity of the microorganism (genus, species and strain) should be declared using acceptable nomenclature. For example, the claim "contains two probiotics" would trigger the identification of both microorganisms in the advertisement.

(2) Quantitative Declaration

The amount of the probiotic microorganism(s) contained in the product at the end of its shelf life must be declared in colony forming units (cfu) per serving of stated size of the food. This statement should appear adjacent to the Nutrition Facts table or the list of ingredients, or in close proximity to the claim.

In mixed culture, if multiple probiotic genera are used, declaration of the quantity of each genus is generally expected. If multiple species or strains of the same genus are added to a food, the need for the separate declaration of individual species would be determined case by case.

(**3) Ingredient List**

Food containing probiotic microorganism(s) must be labelled with a list of ingredients in accordance with sections B.01.008-B.01.010, FDR (see 2.8 of this Guide). The probiotic microorganism(s) must be identified by its (their) common name(s) or by a class name set out in section B.01.010. The class name "bacterial culture" may be used to describe all bacterial species added to a food product. When the class name (e.g. bacterial culture) is used in the list of ingredients, the identity (i.e. the genus, species and strain) of the probiotic bacterial culture(s) should be declared in close proximity to the claim using acceptable nomenclature.

8.7.2 Acceptable Non-Strain-Specific Claims for Probiotics

Probiotic microorganisms generally have been isolated from the gastrointestinal tract of healthy individuals. A limited number of **non-strain-specific** claims about the nature of probiotics (e.g. that they naturally form part of the gut flora) have been accepted for use on food. Any of the statements listed in Table 8-4 of this Guide may be made for one or more of the specific bacterial species included in the table when the guidance specified below is followed.

Conditions of Use for These Claims

(1) General Conditions

When making any of the claims listed in Table 8-4 of this Guide, the manufacturer or importer of the product should follow guidelines outlined in 8.7.1 of this Guide regarding documentation supporting the identification, safety, viability, concentration and stability of the probiotic strain added to the food product, as well as specific labelling requirements.

(2) Specific Conditions

a) Eligible species
These claims can be used only when the product contains one or more of the specific species listed in Table 8-4 of this Guide.

b) Minimum levels in the product
A serving of stated size of a product should contain a minimum level of 1.0×10^9 cfu of one of the eligible microorganism(s) that is(are) the subject of the claim (Gill and Prasad 2008; Hawrelak 2006; Lenoir-Wijnkoop et al. 2007; Picard et al. 2005; Reid et al. 2003; see reference list in Annex 8-3 of this Guide).

8.7.3 Summary Table of Acceptable Non-Strain-Specific Claims for Probiotics and Eligible Species for the Claims

The non-strain-specific probiotic claims listed in Table 8-4 are considered to be acceptable when the guidance outlined in 8.7.1 and 8.7.2 of this Guide is followed.

Summary Table of Acceptable Non-Strain-Specific Claims for Probiotics and Eligible Species for the Claims
Table 8-4

Eligible bacterial species[1] **Latin name (acceptable nomenclature[2]) and synonym where applicable**	**Acceptable Non-Strain-Specific Probiotic Claims for Food**
Bifidobacterium adolescentis	Probiotic that naturally forms part of the gut flora.[4] Provides live microorganisms that naturally form part of the gut flora.[4] Probiotic that contributes to healthy gut flora.[4] Provides live microorganisms that contribute to healthy gut flora.[4]
Bifidobacterium animalis subsp. *animalis*	
Bifidobacterium animalis subsp*. lactis* -synonym: *B. lactis*	
Bifidobacterium bifidum	
Bifidobacterium breve	
Bifidobacterium longum subsp*. infantis* comb. nov.[3]	
Bifidobacterium longum subsp*. longum* subsp. nov.[3]	
Lactobacillus acidophilus	
Lactobacillus casei	
Lactobacillus fermentum	
Lactobacillus gasseri	
Lactobacillus johnsonii	
Lactobacillus paracasei	
Lactobacillus plantarum	
Lactobacillus rhamnosus	
Lactobacillus salivarius	

1 References reviewed for the bacterial species included: EFSA 2007, Gilliland 2001, Reid 2001 (see Annex 8-3 of this Guide).

2 References reviewed for acceptable nomenclature: ATCC 2008, Euzéby 2008, Skerman et al. 1989 (see Annex 8-3 of this Guide).

3 In product labelling, *Bifidobacterium longum* subsp*. infantis* and *Bifidobacterium longum* subsp. *longum* would be considered acceptable nomenclature.

4 The word "gut" may be replaced by the expression "digestive tract" in these claims.

8.8 Testimonials and Guarantees Regarding Vitamin and Mineral Nutrients

In an advertisement or on a label of a food that is represented as containing a vitamin or mineral nutrient, it is prohibited to give any assurance or guarantee of any kind with respect to the result that may be, has been or will be obtained by the addition of the vitamin or mineral nutrient to a person's diet. It is also prohibited to refer to or reproduce any testimonial [D.01.012, D.02.008].

8.9 Other Information About Diet and Disease

In certain situations, information may be provided about nutrition, diet and disease, even if this information is identified with a corporation or business, (such as part of corporate announcements, corporate sponsorships, or corporate brand sponsorships). For example:

- Messages describing the role of diet in disease prevention which are not product-specific (e.g., public service announcements).

- Books and educational material describing the role of diet in disease prevention providing that the material is not deemed to be an advertisement for a food product. (See Educational Material Versus Advertising Material, 8.12 of this Guide, for more information.)

- Dietary guidelines/recommendations on food labels and in advertising which are endorsed by a non-governmental health agency provided there is no mention of disease prevention, treatment or cure. (See *Third-Party Endorsements, Logos and Seals of Approval,* 8.13 of this Guide, for more information.)

Example of a Permissible General Statement

The following general statement is only permissible if **no** linkage is made to a specific product. This is a statement that would meet the first two bullets above.

"**A diet high in vitamin D may help reduce the risk of rickets."**

Such claims should be used with caution to avoid positioning a food as a drug, or offending Section 3 of the *Food and Drugs Act* concerning Schedule A diseases. The same message placed on a food label, in a product-specific advertisement, or positioned adjacent to a food that is offered for sale would be deemed to offend subsections 3.(1) and 3.(2) of the *Food and Drugs Act*.

8.10 Some Examples of Non-Permitted Drug Claims for Foods

8.10.1"Medicated" Claims

A product cannot be sold as a **food** if it is described on the label as "**medicated**". Since this term is used to describe products containing an added medicinal substance to treat or prevent a disease, the product falls within the definition of a drug under the *Food and Drugs Act*. It must be labelled and advertised as a drug as required by the *Food and Drug Regulations*.

8.10.2 Laxative and Laxation Claims

Products represented as laxatives fall within the definition of a drug. The mention of "**laxative**" or "**relief of constipation**" on a label or advertisement characterizes the product as a drug.

On the other hand, the term "**laxation**" and the action of "**promoting laxation**" are **not** considered to be drug claims when used in connection with certain foods. The term "**laxation**" is accepted as referring to the normal softness and bulking of the stool resulting from such factors as increased undigested residue or bacterial mass, trapping of gases or water retention.

Claims for the promotion of "**laxation**" or "**regularity**" are acceptable for foods when a reasonable daily intake of the food contains a minimum of **7 g** of dietary fibre from **coarse wheat bran**. Such claims may be made for **other foods** provided that the claim is substantiated by evidence from clinical studies that a Reasonable Daily Intake of the foods has a laxation effect and no adverse effects. If a Reasonable Daily Intake is made up of **several servings**, the amount of the food required to produce the laxation effect and the number of servings it comprises should be declared as part of the claim. (See 6.8.1 of this Guide, Dietary Fibre, and 7.24, Fibre Claims, for further information on fibre sources and claims.)

8.10.3 Tonic Foods

The term "**tonic**" has been used in the past to describe a class of foods believed to have the power to restore a normal degree of vigour or to restore good health. Today, this term should not be used, as no food can be described as an effective tonic. However, exceptions may be made due to long term use, such as "**tonic water**".

8.11 Obesity, Weight Loss, Weight Reduction and Maintenance

8.11.1 Obesity: Diet Plans

As obesity is included in Schedule A of the *Food and Drugs Act*, foods may not be advertised as a treatment, preventative or cure for this condition. However, a distinction has been made between being obese and being overweight. For the purposes of Schedule A, anyone with a body mass index (BMI) of 30 or higher is considered to be suffering from obesity. The BMI is a measurement tool that relates body weight to health. More information on BMI is available on Health Canada's web site at: www.hc-sc.gc.ca

The only foods allowed to be advertised for use in weight-reduction plans are described under Division 24, FDR:

a) specially formulated meal replacements,
b) prepackaged meals represented for weight reduction,
c) foods sold by weight-reduction clinics, and
d) foods represented for use in very low-energy diets.

See *Foods for Special Dietary Use*, 9.9 of this Guide.

The labels of meal replacements which do **not** make up the entire diet, as well as prepackaged meals for weight reduction, must include in the directions for use a seven-day menu plan which, if followed, would result in a daily energy intake of at least 1200 Calories (5040 kJ). Advertisements for these meals must state, as required by regulation, that adherence to the directions for use may reduce energy intake, which is a requirement for weight loss. Testimonials claiming rapid weight loss, which is considered hazardous

to health, and testimonials for weight reduction by people who were obese, are unacceptable. (See 8.1 and 8.2, and Annex 8-1, *Schedule A Diseases.*)

8.11.2 Foods Represented for Use in Weight Maintenance

[Information Letter No. 793, Health Canada, 1991]

Foods may be represented for use in achieving and maintaining a healthy body weight. However, they should meet the following five conditions.

1. The principal display panel of the label of the food and any advertisements for the food should carry the statement, "**As part of healthy eating, this food may assist in achieving and maintaining a healthy body weight because it is...** (e.g., "**lower in energy than...**", "**low in fat**", "**portion controlled**", etc.).

2. The label must display the Nutrition Facts table (see Chapter 5 of this Guide for the general requirements for declaring the Nutrition Facts table).

3. Labels or advertisements may make reference to the Statements from *Health Canada's Eating Well with Canada's Food Guide,* see Health Canada's web site General Principles for the Use of Content from Canada's Food Guide Resources in Labelling and Advertising for the use of statements.

4. The label, packaging or advertisements should not give the impression that the food is for use in a weight-**reduction** diet. Requirements regarding foods represented for use in a weight-reduction diet are set out in Division 24, FDR and summarized in 9.9 of this Guide.

5. Brand and trade names traditionally considered as claims for weight reduction should be qualified with the statement "**for weight maintenance**" next to the brand or trade name on the principal display panel.

8.12 Educational Material Versus Advertising Material

[Based on the Policy – *Educational Material versus Advertising Material,* Food Division, Consumer and Corporate Affairs Canada, March 1991.]

It can sometimes be difficult to distinguish between material which promotes or advertises a product and material intended only to educate or inform. However, it is important to do so in order to determine whether the *Food and Drugs Act* and the *Food and Drug Regulations* apply.

"**Advertisement**", as defined in Section 2 of the *Food and Drugs Act* " includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food". (For further definitions, see Chapter 1 of this Guide.) The recipient of the representation is "anyone" as no exclusions are mentioned.

Printed and broadcast material will be assessed on a case-by-case basis as to whether it promotes the sale of a food and is considered to be advertising, or whether it is uniquely for educational purposes.

In general, information or material produced or sponsored by the food industry **may** be considered "educational" rather than "advertising" when it meets the following five criteria.

- The material should be obviously designed for the purpose of **informing** consumers in a factual manner rather than **promoting** the sale of a product. That is, the material is a statement or presentation of fact without commercialization. It gives relevant facts and points of view, not just

those that favour the sponsor.

- While the sponsor may be identified, the content should be generic in nature and should not mention product brand names, other than in the sponsorship statement which should not be given undue prominence.

- If the material focuses on a class of foods (such as poultry), or a food group (such as vegetables and fruit), the class/group of foods should be presented in the context of the recommended pattern of eating in *Canada's Food Guide* (see section 8.15 of this Guide).

- Educational material as described above will usually cease to be considered educational when linked to a product, (e.g., by being displayed with a specific product or shown in close proximity to it at point-of-sale). However, depending upon the circumstances, it may be acceptable for educational material to be displayed away from a food which is the generic subject of the educational material (e.g., in another area of a store or restaurant). (**Note:** *Advertising* material may be displayed with or in close proximity to a food at point-of-sale provided it is not misleading, does not refer to the prevention of disease, and meets the requirements of the *Food and Drugs Act and Regulations*.)

- When educational material is produced solely by an organization which does not sell food (e.g., a health-related organization, producer group, marketing board, etc.), the retailer, restaurateur, etc. who has placed or displayed the material in close proximity to the food referenced in the material may be deemed responsible for its use as advertising.

Example of an Educational Brochure

A carrot grower wants to publish a brochure to inform consumers about the role of the diet in disease prevention. The brochure may focus on a food group or class of foods (vegetables and fruits), but must be presented in the context of *Canada's Guidelines for Healthy Eating.*

The grower may identify its corporate brand (Brand X) of carrots on the cover of the brochure without giving it undue prominence. However, the manufacturer may **not** mention Brand X carrots, or its other products or brands, within the brochure.

The brochure may not be displayed at point-of-sale in close proximity to either Brand X carrots or to any other brand of carrots.

This policy applies to printed and broadcast materials produced, sponsored or distributed by persons advertising or selling food, including manufacturers, retailers, restaurateurs, producer organizations and advertisers, with or without, the collaboration of health associations. If educational material is produced solely by an organization which does not sell foods, the retailer, restaurateur, etc., who has displayed the material may be deemed responsible for its use as advertising.

8.13 Third-Party Endorsements, Logos and Seals of Approval

[Based on the *Policy on the Use of Third-Party Endorsements, Logos, and Seals of Approval*, Food Division, Consumer and Corporate Affairs Canada, March 1991.]

"Third-party endorsement" means the approval or sanction of a food by any health professional or health organization, or any individual or group. The use of a name, statement, logo, symbol, seal of approval or other proprietary mark of a third-party organization, whether on a food label or in an advertisement, may lead consumers to believe that the food is endorsed by this third party.

Third-party endorsements may be considered misleading or deceptive when a food bearing an endorsement is perceived as being superior in terms of health, safety and/or nutrition to foods not bearing the endorsement. They may also be considered misleading if they are used in such a way as to suggest that consuming the food may, in and of itself, confer health benefits or prevent, treat or cure a disease.

Minimizing the Potential for Misrepresentation

Third-party endorsements or logos should be used with caution. The reason for their presence on the food label or advertisement should be made clear. Consumers must not be misled or confused about the merits of a food, and they should be able to judge the merit of the endorsing organization. The following principles should be followed:

- Does not give the impression that a single food or brand of food is "healthier" than, or nutritionally superior to, other foods not bearing the third party's name, statement, logo, symbol, seal of approval or other proprietary mark. Health is imparted by a person's total diet rather than by the consumption of individual foods.

- Does not give the impression that the food is a treatment, preventative or cure for disease. A third party's name, statement, logo, etc. must not suggest that a food may prevent, cure or treat a disease, including Schedule A diseases. Such a suggestion is false and specifically prohibited by the *Food and Drugs Act*.

As such, at least one of the following should appear on the label:

a) **A statement that clearly explains the reason for the appearance of the third party's name, statement, logo, etc**. (For example, is this a joint education program of Company X and Organization Y? Has Company X provided financial support, or is it a sponsor of a campaign such as a Nutrition Week Campaign of Organization Y? Is the symbol present because a certain amount of the proceeds from the sale of the product will go towards an organizational charity?)

b) **The name of the third party (with or without its logo, symbol, or other proprietary mark) clearly shown, in conjunction with its nutrition recommendations or dietary guidelines or those it endorses**. The nutrition recommendations of this third party must be consistent with the recommended pattern of eating presented in *Eating Well with Canada's Food Guide* (see 8.15 of this Guide).

c) **A clear indication that the name, statement, logo, etc. of the third party does not constitute an endorsement of the food**.

When a health-related name, statement, logo, symbol, seal of approval or other proprietary mark **appears on the label of a prepackaged food** or in **advertisements placed by or on the direction of the manufacturer or importer** of the food, the label of the food must declare a Nutrition Facts table (NFT)

[B.01.401]. Foods that are normally exempt from declaring a NFT under B.01.401(2) (a) and (b) of the FDR, such as fresh fruit and vegetables, lose their exemption and are required to declare a NFT [B.01.401(3)(e)(iii)].

This policy applies to third-party endorsements by organizations providing health and nutrition information for a **single food** or **single brand of food**. It applies whether the endorsement appears on food labels or in food advertisements, and whether the food is displayed in retail outlets, restaurants or food service establishments.

The policy does **not** apply to third-party endorsements by organizations providing health and nutrition information for **groups or classes of foods** (e.g. the Dairy Association providing nutrition information for dairy products). It also does not apply to the gluten-free symbol of the Canadian Celiac Association. This symbol is recognized by consumers with celiac disease and is unlikely to be perceived by the general public as an endorsement by a health organization. Additional exceptions will be considered case by case.

8.14 Heart Symbols and Heart Health Claims

The use of heart symbols and heart healthy claims to describe a food or food choice (whether on labels, menus or in advertising) are generally not acceptable. They may give an erroneous impression that consuming a single food or menu selection will provide heart health or prevent heart disease (a “Schedule A” disease).

Health authorities do agree that a single **pattern** of healthy eating should be recommended to the public. However, although a healthy diet may help reduce the risk of cardiovascular disease, it is only one factor in the multiple etiology of the disease.

8.14.1 Heart Symbols

Heart symbols may be acceptable on a food label or advertisement when they appear in the logo or name of a health organization, or are used in conjunction with that organization’s health information program, provided that

- no impression is given that the food may help prevent, treat or cure heart disease, and
- the appearance of the health organization's name or logo itself satisfies the conditions on the use of Third-Party Endorsements, Logos and Seals of Approval (see 8.13 of this Guide).

Terms employing the word "heart" may be acceptable as part of the name of an information program of a health organization provided the program is identified as such (e.g., "The Heart Smart program is a public education program of the Heart and Stroke Foundation of Canada.").

Heart symbols may be acceptable when used in a traditionally recognized manner to indicate affection or endearment. For example, there is no objection to heart-shaped cinnamon candies, or heart-shaped boxes of chocolates, or heart illustrations on food products sold for Valentine’s Day.

Nutrition information programs incorporating heart health in restaurants may not identify menu items with hearts. Menu items can be identified using a check mark (√) to draw attention to good or healthy choices if the information provided satisfies the requirements outlined in this section and the reason for the program is made clear. For example, the menu might state: "The Heart Smart program is a public education program of the Heart and Stroke Foundation of Canada".

8.14.2 Heart Symbols and Disease Risk Reduction Claims

Objection will not be taken to the use of heart symbols in conjunction with the new diet-related health claim "A healthy diet low in saturated and trans fats may help reduce the risk of heart disease. (Naming the food) is low in saturated and trans fats." The use of these symbols should not give the impression that the food itself may have a positive effect on health, or that there is a role beyond the disease risk reduction claim.

See Annex 8-4 for the *Policy Respecting the Use of Heart Symbols and Heart Health Claims on Food Labels and in Food Advertisements.*

8.15 Eating Well with Canada's Food Guide and Eating Well with Canada's Food Guide: A Resource for Educators and Communicators

See Annex 8-5 of this *Guide*: *Eating Well with Canada's Food Guide*.

Information detailing the policies around *Eating Well with Canada's Food Guide and Eating Well with Canada's Food Guide: A Resource for Educators and Communicators* can be found on the following Health Canada web site:

http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/index-eng.php

In order to refer to or quote *Eating Well with Canada's Food Guide and Eating Well with Canada's Food Guide: A Resource for Educators and Communicators,* the official title should be used and complete quotations should be used. The *General Principles for the Use of Content from Canada's Food Guide Resources in Labelling and Advertising* can be found on the following Health Canada web site:

http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/gen_prin-eng.php

8.15.1 Reproduction of Eating Well with Canada's Food Guide

Information on Health Canada's web site has been posted with the intent that it be readily available for personal and public non-commercial use and may be reproduced, in part or in whole and by any means, without charge or further permission from Health Canada.

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1. Users exercise due diligence in ensuring the accuracy of the materials reproduced;

2. Health Canada be identified as the source; and,

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8.16 References

See Annex 8-6 of this Guide for a reference list of historical policy documents that are the basis of the information provided in this chapter. See Annex 8-3 of this Guide for a list of references related to probiotic claims.

Annex 8-1

Schedule 1 (Subsection 1(1)) - INCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2	An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3	Any of the following vitamins: biotin folate niacin pantothenic acid riboflavin thiamine vitamin A vitamin B6 vitamin B12 vitamin C vitamin D vitamin E
4	An amino acid
5	An essential fatty acid
6	A synthetic duplicate of a substance described in any of items 2 to 5
7	A mineral
8	A probiotic

Schedule 2 - (Subsection 1(1)) - EXCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1	A substance set out in Schedule C to the Act
2	A substance set out in Schedule D to the Act, except for the following: (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3	A substance regulated under the *Tobacco* Act
4	A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
5	A substance that is administered by puncturing the dermis
6	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic

Annex 8 - 2
Schedule A Diseases from the Food and Drugs Act [Section 3]

Acute alcoholism
Acute anxiety state
Acute infectious respiratory syndromes
Acute, inflammatory and debilitating arthritis
Acute psychotic conditions
Addiction (except nicotine addiction)
Appendicitis
Arteriosclerosis
Asthma
Cancer
Congestive heart failure
Convulsions
Dementia
Depression
Diabetes
Gangrene
Glaucoma
Haematologic bleeding disorders
Hepatitis
Hypertension
Nausea and vomiting of pregnancy
Obesity
Rheumatic fever
Septicemia
Sexually transmitted diseases
Strangulated hernia
Thrombotic and Embolic disorders
Thyroid disease
Ulcer of the gastro-intestinal tract

Annex 8 - 3
Reference List for Probiotic Claims

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Annex 8 - 4
Policy Respecting the Use of Heart Symbols and Heart Health Claims on Food Labels and in Food Advertisements

Background

Historically, representations such as the use of "**heart**" **symbols** and statements such as "**heart healthy**" on food labels or in advertising have been considered likely to offend the *Food and Drugs Act* because they can be potentially misleading under subsection 5.(1) and/or may represent the product as a preventative for heart disease [3.(1), FDA].

As a result of the work of the Ad Hoc Intersectoral Committee on Health Information Programs Involving the Sale of Foods and on the Use of Nutrition Recommendations in Food Labelling and Advertising, policies were issued on March 1, 1991 under the title "**Guidelines for Health Information Programs Involving the Sale of Foods**"

One of the policies contained in this document addressed label and advertising claims relating to disease prevention. This policy statement reiterated the government's commitment to upholding section 3 of the *Food and Drugs Act*, confirmed that the practice of relating a specific food product to disease prevention is prohibited under section 3 of the Act and described several situations in which the food industry could deliver information on disease prevention without offending section 3. The document did not, however, specifically address the issue of the use of "**heart**" **symbols** and "**heart health**" claims in food labelling and advertising.

The following policy is intended to further clarify the position concerning the use of "**heart**" **symbols** and "**heart health**" claims, and complements the more general policies of the aforenoted Ad Hoc Intersectoral Committee on Health Information Programs.

Scope

The policy will apply to the use of "**heart**" **symbols** and "**heart health**" statements or claims on food labels and food advertisements.

Policy

1. Heart Symbols

(1) Representations which state, suggest or imply that a particular food is nutritionally superior to or healthier than other foods are considered misleading, since one's entire food intake, not a single part of it, is the critical variable in determining the nutritional adequacy of the diet and its contribution to reducing risk for chronic disease. Accordingly, the use of heart symbols in food labelling or advertising (including the "hearting" of restaurant menu items), may create an erroneous impression regarding the merit or value of the food by suggesting that consumption of the specific food or menu selection will, by itself, provide health as it relates to the heart and cardiovascular system. As the use of these symbols in this manner is considered to constitute a potential violation of subsection 5.(1) of the *Food and Drugs Act*, they should not be used.

(2) A heart symbol which appears in the logo/word mark of, or is used in conjunction with, the name of a non-governmental health organization, or a health information program of a health

organization, **may** be acceptable on a food label or in a food advertisement on condition that: (a) no impression is given that the food may help prevent heart disease, and (b) the appearance of the health organization's name or logo itself satisfies the conditions outlined in the "**Policy on the Use of Third-Party Endorsements, Logos and Seals of Approval**".

(3) No objection will be taken to heart symbols used in a manner traditionally-recognized as indicating affection or endearment, e.g., heart shapes on the label of Valentine candies.

2. "Heart Healthy", "Heart Healthy (Naming the Food)" or "Heart Healthy Choice" Statements or Claims

As in the case of heart symbols, the use of the term "**heart healthy**" to describe a food or food choice in food labelling and advertising, may create an erroneous impression regarding the merit or value of the food, by suggesting that it will, by itself, provide heart health. As such terms are considered to constitute a potential violation of subsection 5.(1) of the *Food and Drugs Act*, they should not be used.

3. "Heart Healthy Eating" or "Heart Healthy Diet"

The use of the terms "**heart healthy eating**" or "**heart healthy diet**" on the labels and/or in the advertisements for specific foods (e.g., "**choose X-brand margarine for your heart healthy diet**") may give an erroneous impression about the merit or value of the subject food(s). Objection is taken to the use of these terms in association with individual foods for the following reasons:

(1) the consumer may incorrectly conclude that the food itself is "good for the heart" or that it has particular usefulness in providing heart health;

(2) health authorities agree that a single pattern of healthy eating should be recommended to the public to meet the needs for essential nutrients while minimizing risk for chronic disease. The term "**heart healthy diet**" suggests and promotes the concept of disease- or organ-specific patterns of eating; this is considered confusing and potentially misleading to the public;

(3) a healthy diet may help reduce the risk of cardiovascular disease, but it is only one factor in the multiple etiology of the disease. Promotion of a "heart healthy" diet to the exclusion of other lifestyle factors in the labelling and advertising of a food, may give an erroneous impression of the impact of both the diet and that food on heart health.

4. Misleading Words or Phrases Employing the Term "Heart"

(1) Objection is taken to the use of terms employing the word "**heart**", such as "**heart beat**", "**whole hearted**" and "**heart smart**" to describe individual foods, menu selections or patterns of eating, where the use of such terms or phrases suggests or implies that the food or diet is "**heart healthy**".

(2) Terms employing the word "**heart**" may be acceptable as part of the name of an information program of a health organization provided the program is identified as such, e.g., "**the Heart Smart program is a public education program of the Heart and Stroke Foundation of Canada**".

Implementation

Steps should be taken by food manufacturers, importers and marketers to ensure the correction of domestic and imported product labels, advertisements and menus now bearing heart symbols and heart health statements or claims in contravention of this policy.

In this regard, the removal or correction (i.e., over-stickering) of existing heart symbols (item #1 of this annex) and label or menu claims (items #2, 3 and 4 of this annex) will be expected within six months from the date of this policy or at the time of next label or menu printing, whichever occurs first. The subject symbols and claims should not be used on new labels, menus or advertisements produced subsequent to the date of this policy.

In the case of the "Heart Smart" Restaurant Program of the Heart and Stroke Foundation of Canada, a new program is currently being introduced which is in keeping with this policy. Restaurants are being informed of the changes by the provincial Heart and Stroke Foundations, and no additional corrective action is required at this time.

Food Directorate
Health Protection Branch
Health Canada

Food Division
Consumer Products Branch
Consumer and Corporate Affairs Canada*
October 9, 1992

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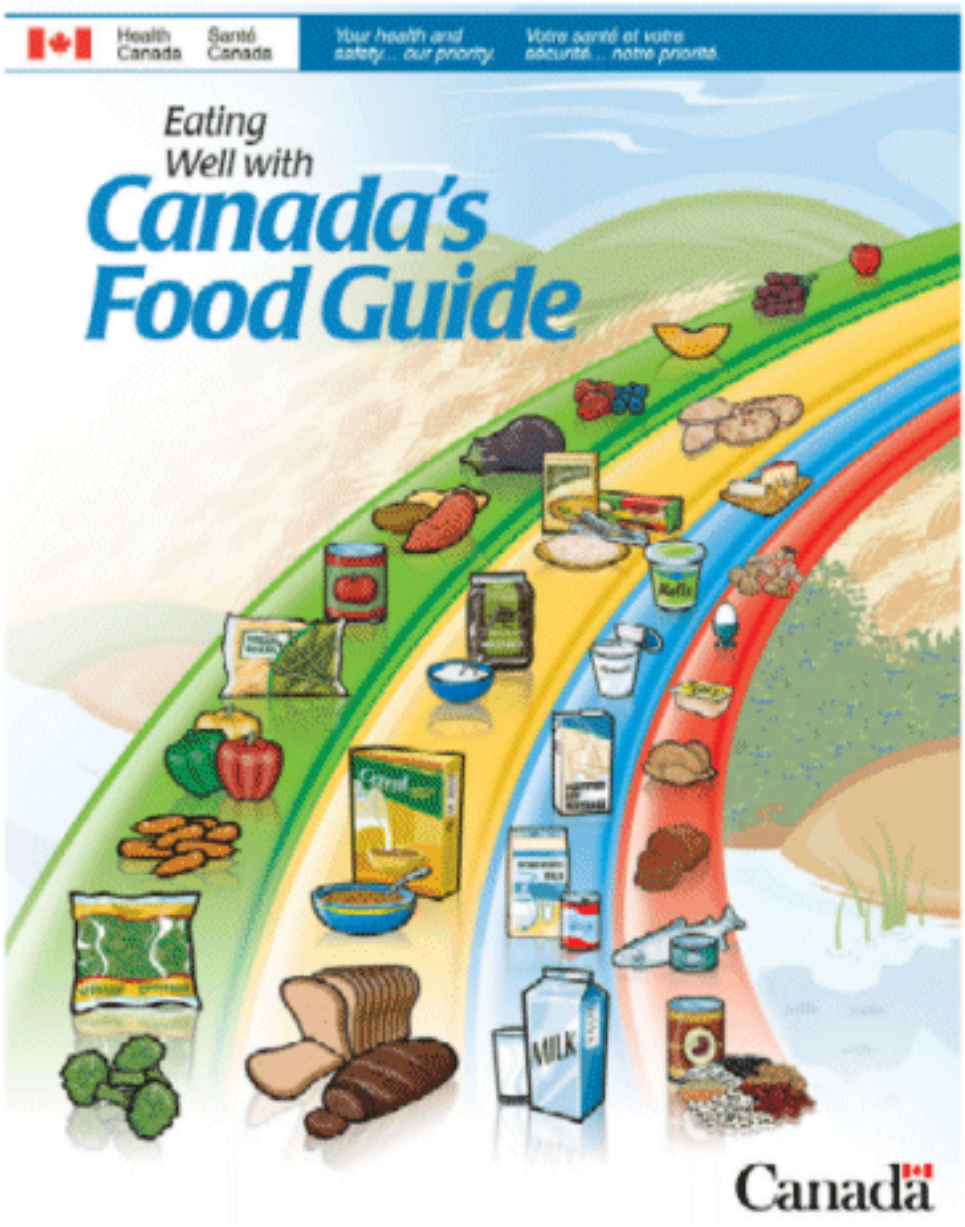
* Consumer and Corporate Affairs ceased to exist as of June 25, 1993. Its responsibilities respecting food labelling and advertising were transferred to Agriculture and Agri-Food Canada and later, on April 1, 1997, to the Canadian Food Inspection Agency. The former Food Division is now known as the Bureau of Food Safety and Consumer Protection, CFIA.

Annex 8 - 5
Eating Well with Canada's Food Guide



Recommended Number of Food Guide Servings per Day

	Children			Teens		Adults			
Age in Years	2-3	4-8	9-13	14-18		19-50		51+	
Sex	Girls and Boys			Females	Males	Females	Males	Females	Males
Vegetables and Fruit	4	5	6	7	8	7-8	8-10	7	7
Grain Products	3	4	6	6	7	6-7	8	6	7
Milk and Alternatives	2	2	3-4	3-4	3-4	2	2	3	3
Meat and Alternatives	1	1	1-2	2	3	2	3	2	3

The chart above shows how many Food Guide Servings you need from each of the four food groups every day.

Having the amount and type of food recommended and following the tips in *Canada's Food Guide* will help:

- Meet your needs for vitamins, minerals and other nutrients.
- Reduce your risk of obesity, type 2 diabetes, heart disease, certain types of cancer and osteoporosis.
- Contribute to your overall health and vitality.

Annex 8 - 6
Reference List of Historical Policy Documents

The following historical policy documents are the basis of the information provided in this chapter.

- *Guide for Food Manufacturers and Advertisers*. Consumer Products Branch, Consumer and Corporate Affairs Canada, Revised Edition, 1988.
- *Guidelines on Nutrition Labelling*. Food Directorate, Health Protection Branch, Health and Welfare Canada, November 1989.
- *Canada's Guidelines for Healthy Eating* in *Nutrition Recommendations ... A Call for Action*. Health and Welfare Canada, 1989.
- *Guidelines for Health Information Programs Involving the Sale of Foods.* Food Directorate, Health Canada, March 1995.
- *General Principles for Labelling and Advertising Claims that Relate to the Nutrition Recommendations and Canada's Food Guide to Healthy Eating* (GP). Food Directorate, Health Canada, *revised* December 1993; **and** *Guidelines on the Application of the General Principles.* Food Division, Consumer and Corporate Affairs Canada, April 1993.
- *Policy – Advertising Claims Relating to Nutrition Recommendations made by Organizations which do not Control Food Packaging or Labelling (OWLs)*. Food Division, Agriculture and Agri-Food Canada, December 1995.
- *Policy – Educational Material versus Advertising Material*. Food Division, Consumer and Corporate Affairs Canada, March 1991.
- *Policy on the Use of Third-Party Endorsements, Logos, and Seals of Approval*. Food Division, Consumer and Corporate Affairs Canada, March 1991.
- *Policy Respecting the Use of Heart Symbols and Heart Health Claims on Food Labels and in Food Advertisements*. Food Division, Consumer and Corporate Affairs Canada, October 1992.
- *Nutrition Recommendations for Canadians* in *Nutrition Recommendations, The Report of the Scientific Review Committee* (SRC Report). Canadian Government Publishing Centre, Public Works and Government Services Canada, Ottawa, 1990.
- *IL 793 – Guidelines for Foods Represented for Use in Achieving and Maintaining Healthy Body Weights.* Food Directorate, Health Canada, April 1991.
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Available from
http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php