

2003 GUIDE TO FOOD LABELLING AND ADVERTISING

Chapter 8

Diet-Related Health Claims

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Diet-Related Health Claims

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Chapter 8

Diet-Related Health Claims

8.1 Drugs Versus Foods: Definitions

The *Food and Drugs Act*, Section 2, defines food as follows:

“ ‘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.”

The definition of a drug under the *Food and Drugs Act*, Section 2, is:

“ ‘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 the symptoms thereof, in man or animal;

(b) restoring, correcting or modifying organic functions in man or animal.”

8.2 Drug Claims

In order for a food product to be regulated as a food, it must not carry a drug claim on its label or in an advertisement. A drug claim will bring a food product within the definition of a drug and the food product would then be subject to all the drug provisions of the *Food and Drugs Act and Regulations* (see 8.4 of this *Guide* for an exception).

A claim that suggests that the food may have an effect on the body (as described in the definition of a drug in the *Food and Drugs Act*) is considered to be drug claim. Some examples of claims that would bring the food within the definition of a drug include:

- “lowers blood cholesterol”
- “lowers blood triglyceride levels”
- “regulates blood sugar levels”
- “is formulated to have the lowest potential for stomach upset and gas”
- “promotes health of the immune system”
- “is a rehabilitative supplement”
- “balances hormone levels”
- “soothes bladder infections”
- “improves memory”

8.2.1 Claims Relating to Treatment for Schedule A Diseases

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 8-1 of this *Guide*, *Schedule A Diseases*).

For example, a claim stating that a product “prevents or cures cancer” may **not** be made, as cancer is a Schedule A disease. 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. Such claims are prohibited.

8.3 General Requirements for Diet-Related Health Claims and Biological Role Claims

Sections 8.4 and 8.5 of this *Guide* deal with the recently-permitted diet-related health claims (new) and biological role claims, respectively. Before moving into the specifics for these two types of claims, this section will deal with some of the generic requirements common to both types of claims.

8.3.1 Language Requirements

These claims must appear on the label in both English and French unless the mandatory information is permitted to be shown in only one of those languages, such as in the case of local foods permitted under B.01.012 [B.01.012(3) or (7), B.01.311(5), B.01.600].

8.3.2 Labelling Requirements

Where diet-related health claims or biological role claims appear on the label or in advertisements placed by or on the direction of the manufacturer of a food, the Nutrition Facts table is triggered on the label of foods otherwise exempted from showing the Nutrition Facts table under B.01.401(2) (a) and (b). The use of these claims may also trigger additional information in the Nutrition Facts table, as required. Refer to Sections 8.4.3 and 8.5.4 for the specifics.

8.3.3 Requirements for Claims for Non-Prepackaged Products or for Advertisements Placed by Someone Other Than the Manufacturer [B.01.312, B.01.602]

Where diet-related health claims or biological role claims appear on the label or in an advertisement for **non-prepackaged products** or in **advertisements for prepackaged products not made or placed by or on the direction of the manufacturer**, the required accompanying information - namely the required information outlined in Column 3 of the table following B.01.603 (see Table 8-1 below) in the case of diet-related health claims or the quantitative amount of the energy or nutrient value or the % DV of the vitamin or mineral nutrient value (per serving of stated size) that is the subject of the biological role claim - must also appear on the label or in the advertisement as outlined below.

Where these claims appear in an **advertisement other than radio or television**, and the required accompanying information does not already appear on the label, the accompanying information must appear adjacent to, without any intervening material, the most prominent claim in letters the same size and prominence.

Where these claims are made in a radio or in the audio portion of a television advertisement, and the required accompanying information does not already appear on the label, the accompanying information must immediately precede or follow the claim, and in the case of a television ad, the accompanying information must also be in the audio mode.

If the claim is made in the **visual portion of a television ad**, and the required accompanying information does not already appear on the label, the accompanying information may appear in

the either audio or visual mode. 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.

In the case where the claim is made in both the audio and visual portions of a television ad, the accompanying information must be in the audio mode.

8.4 Diet-Related Health Claims

The 2002 amendments to the *Food and Drug Regulations* allow diet-related health claims on foods 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 reduction of risk of certain diseases.

Section 3, *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. Heart disease, hypertension and cancer, which are the subjects of three of the permitted claims, are listed in Schedule A.

Objectives of Diet-Related Health Claims

The new provisions aim to ensure that diet-related health claims are useful to consumers. They are designed to help consumers make informed choices, thereby reducing their risk of developing chronic diseases. The standards also aim to ensure that any diet-related 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.

To permit the use of diet-related health claims, foods bearing the permitted claims are exempted from the provisions of subsections 3(1) and 3(2), *FDA*. In addition, foods labelled in such a way are exempt from the provisions of the Act and Regulations 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 diet-related health claims, other therapeutic statements or “drug” references would not be allowed on the same food. [B.01.601].

A diet-related health claim is a statement that describes the characteristics of a diet that may reduce the risk of developing a diet-related disease or condition, such as osteoporosis or stroke, and the properties of a food that make it a suitable part of the diet.

For example, the label of or an advertisement for a food which is low in sodium might carry the following diet-related health claim (providing 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 Diet-Related Health Claims

The Regulations now provide for claims which deal with the following relationships:

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

8.4.2 Prescribed Wording [B.01.601, B.01.603]

The Regulations prescribe the exact wording for the permitted diet-related health claims in the table following B.01.603 (see Table 8-1 of this *Guide*). The wording of the health claims cannot be modified, and no intervening information, graphic sign or symbol may come between parts of the claim. The whole claim must be stated, as prescribed in quotations. The claim cannot be separated or reordered and it must be displayed in equal prominence with no part highlighted. Words, numbers, signs or symbols may come before or after the health claim, provided that the nature of the claim is not changed.

8.4.3 Presenting Required Information

When a health claim is made for a food, the information in column 3 of Table 8-1 of this *Guide*, Summary Table of Diet-Related Health 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 Summary Table 8-1), the amount of sugar alcohols must be declared, if present (see column 3). The *Food and Drug Regulations* prescribe how this must be done.

When a **manufacturer** makes one of the diet-related health claims set out in column 1 of the table above, whether in an advertisement or on a label for a prepackaged product, the nutrition information required by column 3 must appear in the Nutrition Facts table on the label [B.01.401(3)(e)(ii)].

When the health claim is contained in an **advertisement made by someone other than the manufacturer** (such as a marketing board), or when the claim applies to any non-prepackaged food (such as bulk foods), the nutrition information required by column 3 must still be displayed. In these cases, it must be adjacent to the most prominent claim in the advertisement (without intervening material), and it must appear in letters of the same size and prominence as the claim [B.01.602(1)]. The specific requirements are outlined above in 8.3.3 of this *Guide*.

Note that 8.3.3 of this *Guide* lists how these claims are to be made for products that are not prepackaged or in advertisements placed by someone other than the manufacturer.

8.4.4 Prohibitions [B.01.601(1)(c)]

Foods Intended Solely for Children Under Two Years of Age. Diet-related health 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.

- **Foods Represented for Use in a Very Low Energy Diet.** These claims are also not permitted on foods represented for use in very low energy diets.

8.4.5 Summary Table of Diet-Related Health Claims

Table 8-1, *Summary Table of Diet-Related Health Claims*, describes permitted diet-related health 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 health claims, see Chapter 7 of this *Guide*.)

Summary Table of Diet-Related Health Claims
Table 8-1

Column 1 Claim	Column 2 Conditions - Food	Column 3 Conditions - Label or Advertisement
<p>1. Diet-Related Health Claims with Respect to Sodium and Potassium</p> <p>(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."</p> <p>(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."</p> <p>(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."</p> <p>(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."</p> <p>(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."</p> <p>(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."</p>	<p>The food</p> <p>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 <i>Guide</i>.</p> <p>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;</p> <p>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 <i>Guide</i></p> <p>d) contains 0.5% or less alcohol;</p> <p>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 <i>Guide</i>, 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;</p> <p>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</p> <p>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.</p>	<p>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 [B.01.402(2)].</p> <p>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 size, in accordance with B.01.602 if applicable.</p> <p>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 <i>Guide</i>)</p> <p>[Item 1, Table following B.01.603]</p>

Column 1 Claim	Column 2 Conditions - Food	Column 3 Conditions - Label or Advertisement
<p>2. Diet-Related Health Claims with Respect to Calcium and Vitamin D</p> <p>(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."</p> <p>(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."</p> <p>(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."</p> <p>(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."</p> <p>(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."</p> <p>(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."</p>	<p>The food</p> <p>(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 <i>Guide</i>;</p> <p>(b) contains no more phosphorus, excluding that provided by phytate, than calcium;</p> <p>(c) contains 0.5% or less alcohol;</p> <p>(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;</p> <p>(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</p> <p>(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.</p>	<p>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)].</p> <p>or</p> <p>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 size, in accordance with B.01.602 if applicable.</p> <p>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 <i>Guide</i>)</p> <p>[Item 2, Table following B.01.603]</p>

Column 1 Claim	Column 2 Conditions - Food	Column 3 Conditions - Label or Advertisement
<p>3. Diet-Related Health Claims with Respect to Saturated and <i>Trans</i> fats</p> <p>(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."</p> <p>(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."</p>	<p>The food</p> <p>(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 <i>Guide</i>;</p> <p>(b) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient</p> <p style="padding-left: 40px;">(i) per reference amount and per serving of stated size, or</p> <p style="padding-left: 40px;">(ii) per serving of stated size, if the food is a prepackaged meal;</p> <p>(c) contains 100 mg or less of cholesterol per 100 g of food;</p> <p>(d) contains 0.5% or less alcohol;</p> <p>(e) if it is a fat or an oil, meets the conditions set out in column 2</p> <p style="padding-left: 40px;">i) of the subject "source of omega-3 polyunsaturated fatty acids" (item (a) of Table 7-8) or</p> <p style="padding-left: 40px;">ii) the subject "source of omega-6 polyunsaturated fatty acids" (item (b) of Table 7-8), or</p> <p style="padding-left: 40px;">iii) both (i) and (ii);</p> <p>(f) contains</p> <p style="padding-left: 40px;">(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</p> <p style="padding-left: 40px;">(ii) 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal;</p> <p>(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</p> <p>(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.</p>	<p>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 <i>trans</i> fatty acids per serving of stated size, in accordance with B.01.602, if applicable.</p> <p>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 <i>Guide</i>)</p> <p>[Item 3, Table following B.01.603]</p>

Column 1 Claim	Column 2 Conditions - Food	Column 3 Conditions - Label or Advertisement
<p>4. Diet-related Health Claims with Respect to Cancer risk reduction</p> <p>"A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer."</p>	<p>The food</p> <p>(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:</p> <ul style="list-style-type: none"> (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); <p>(b) is not one of the following</p> <ul style="list-style-type: none"> (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 <p>(c) contains 0.5% or less alcohol.</p>	<p>Nutrition Facts table required on products otherwise exempted by B.01.401(2)(a) & (b). [B.01.401(3)(e)(ii)]</p> <p>(See 5.3 of this <i>Guide</i>)</p> <p>[Item 4, Table following B.01.603]</p>
<p>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.</p> <p>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.</p>		

Column 1 Claim	Column 2 Conditions - Food	Column 3 Conditions - Label or Advertisement
<p>5. Diet-Related Health Claims with Respect to Dental Caries</p> <p>(1) "Won't cause cavities." (2) "Does not promote tooth decay." (3) "Does not promote dental caries." (4) "Non-cariogenic."</p>	<p>The food is a chewing gum, hard candy or breath freshening product that</p> <p>(a) contains 0.25% or less starch, dextrins, mono-, di- and oligosaccharides or other fermentable carbohydrates combined; or</p> <p>(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.</p>	<p>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 <i>Guide</i>. (B.01.402(2)).</p> <p>Nutrition Facts table required on products otherwise exempted by B.01.401(2) (a) & (b). [B.01.401(3)(e)(ii)]</p> <p>[Item 5, Table following B.01.603]</p>

8.5 Biological Role Claims

Biological role claims are claims that refer to the generally recognized nutritional function of energy or nutrients as an aid in maintaining the functions of the body for the maintenance of good health, or for normal growth and development. Provisions for biological role claims are made in B.01.311, D.01.006 and D.02.004.

"Nutrients" are not defined in the *Food and Drug Regulations*. 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 biological role 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."**

In addition to the two general claims listed above, Table 8-2, *Summary Table of Biological Role Claims* lists specific biological role claims associated with nutrients (also see 8.4.2 of this *Guide*). The claims in the summary table refer to the scientifically recognized specific role each nutrient has in maintaining good health and normal growth and development.

Note: Biological role claims are not made for a food per se; they may only be made respecting the energy value or nutrients in a food. Claims **may not** be made for other components of food, such as lycopene, lutein, anthocyanins, etc. A quantitative statement would be permitted for these other components (e.g., "14 mg of lycopene per 50 g serving.").

8.5.1 Conditions for Biological Role Claims

A biological role claim **may not** refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or symptoms of same, **nor may it** refer directly or indirectly to correcting, restoring or modifying organic functions. In addition, the claim may not refer directly or indirectly to the treatment, prevention or cure of diseases listed in Schedule A of the *Food and Drugs Act*, subsection 3(1).

Examples of claims that are **unacceptable** on foods include the following statements.

- "This food will reduce the risk of cancer."
- "(Naming the nutrient) is a laxative."
- "Calcium fights bone disease such as osteoporosis."

Acceptable and Unacceptable Biological Role Claim Examples

The claims for the action or biological role 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."**

8.5.2 Biological Role Claims for Protein [B.01.305(1)]

When biological role 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*).

8.5.3 Biological Role Claims for Vitamin and Mineral Nutrients [D.01.004, D.02.002]

When biological role claims are made for vitamin and mineral nutrients, the vitamin or mineral nutrient must have an established Recommended Daily Intake (RDI) and the food must contain a minimum of 5% of the RDI for that vitamin or mineral. Where not already required, the percentage of the Daily Value (% DV) of the vitamin or mineral nutrient that is the subject of the claim must also appear in the Nutrition Facts table.

8.5.4 Biological Role Claims for Nutrients Not Listed in the Tables to B.01.401 and B.01.402

Biological role claims may be made for the energy value of a food or the nutrients listed in column 1 of the tables to B.01.401 and B.01.402, and the energy value or nutrient value must be declared as appropriate in the Nutrition Facts table on the label of the food, or as otherwise required (see 8.3.3 of this *Guide* for further information). The Regulations also permit biological role claims to be made about other nutrients that are not listed in the tables to B.01.401 and B.01.402, e.g.

essential fatty acids such as linolenic acid and DHA, however, a quantitative statement of the nutrient(s) in grams per serving must appear on the label or in the advertisement for the food, as applicable. See 7.4 of this *Guide* for further information on quantitative statements. Industry may submit data in support of new biological role claims directly to the Nutrition Evaluation Division of Health Canada for review and reply.

8.5.5 Labelling and Advertising Requirements

A biological role claim may appear in advertisements placed by someone other than the manufacturer (such as a marketing board), or the claim may be made for a non-prepackaged product. In these cases, as in the case of health claims, the claim must be accompanied by a quantitative declaration of the energy value or the nutrient(s) concerned. (See further details in 8.3.2 and 8.3.3 of this *Guide*)

8.5.6 Summary of Biological Role Claims

Summary Table of Biological Role Claims
Table 8-2

The examples of biological role claims listed in the table below have been considered to be acceptable by Health Canada and the CFIA. Other biological role claims for nutrients may also be acceptable and will be evaluated on a case-by-case basis.

ACCEPTABLE BIOLOGICAL ROLE CLAIMS FOR NUTRIENTS	
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 development of the brain, eyes and nerves
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	- protects the fat in body tissues from oxidation
VITAMIN C	- factor in the development and maintenance of bones, cartilage, teeth and gums
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

ACCEPTABLE BIOLOGICAL ROLE CLAIMS FOR NUTRIENTS	
FOLATE	- aids in red blood cell formation
VITAMIN B ₁₂	- aids in red blood cell formation
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

8.6 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, reproduce any testimonial [D.01.012, D.02.008].

8.7 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, 8.10 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*, 8.11 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*.

8.8 Some Examples of Non-Permitted Drug Claims for Foods**8.8.1 "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*.

8.8.2 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.)

8.8.3 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**".

8.9 Obesity, Weight Loss, Weight Reduction and Maintenance

8.9.1 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 it. 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 website 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*.)

8.9.2 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 should 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 *Nutrition Recommendations for Canadians* and/or *Canada's Guidelines for Healthy Eating* provided that when one or more statements are used, they are positioned as components of the recommendations.
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 9.12 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. (See 9.9 of this *Guide*)

8.10 Educational Material Versus Advertising Material

[*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, *Canada's Guidelines for Healthy Eating*.
- 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. 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.

8.11 Third-Party Endorsements, Logos and Seals of Approval [*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, 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.

Minimizing the potential for misrepresentation

Third-party endorsements should be used with caution. 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 the total diet rather than by 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 a Schedule A disease. Such a suggestion is false and specifically prohibited by the *Food and Drugs Act*.

- Clearly explains the reason for the appearance of the third party's name, statement, logo, and so on. (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?)
- Clearly shows the name of the third-party (with or without its logo, symbol, or other proprietary mark), 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 *Canada's Guidelines for Healthy Eating*.
- Clearly indicates that the name, statement, logo, etc. of the third party does **not** constitute an endorsement of the food.
- Provides a Nutrition Facts table on the food label, including where the food would otherwise have been exempted under B.01.401(2)(a) and (b) [B.01.401(3)(c)(iii)]. See 5.3 of this *Guide* for a list of foods exempted by these provisions.

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**. It also does **not** apply to the gluten-free symbol of the Canadian Celiac Association or the Food Choice Values and Symbols of the Canadian Diabetes Association. These symbols are recognized by consumers with celiac disease and diabetes respectively, and are unlikely to be perceived by the general public as an endorsement by a health organization. Additional exceptions may be considered on a case-by-case basis.

Note: The Canadian Diabetes Association has advised that their Food Choice Values and Symbols system will be phased out and it is expected that these symbols will no longer appear on food labels in Canada once the transition period for the new nutrition labelling requirements is completed.

8.12 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.

8.12.1 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 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 8.11 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".

8.12.2 Heart Symbols and Diet-Related Health 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."

See Annex 8-2 for the *Policy Respecting the Use of Heart Symbols and Heart Health Claims on Food Labels and in Food Advertisements*.

8.13 Canada's Food Guide to Healthy Eating and Nutrition Recommendations

See Annex 8-3 of this *Guide: Canada's Food Guide to Healthy Eating*.

Information detailing the policies around *Canada's Food Guide to Healthy Eating*, the *Nutrition Recommendations for Canadians* and *Canada's Guidelines to Healthy Eating* can be found on the following Health Canada web site

http://www.hc-sc.gc.ca/hpfb-dgpsa/onpp-bppn/food_guide_e.html

In order to refer to or quote *Canada's Food Guide to Healthy Eating*, the *Nutrition Recommendations for Canadians*, and *Canada's Guidelines to Healthy Eating*, the official title should be used and complete quotations should be used.

8.13.1 Reproduction of *Canada's Food Guide to Healthy Eating*

To encourage the reproduction of *Canada's Food Guide to Healthy Eating*, the following note was added to the notice of copyright: "No changes permitted. Reprint permission not required." This means that *Canada's Food Guide to Healthy Eating* may be reproduced in its entirety (both sides) without permission.

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8.14 References

See Annex 8-4 for a list of applicable references.