Quality is in our **nature**

Canada

Canada's Regulatory System for Foods with Health Benefits

— At a Glance

Companies wanting to promote the benefits of their products sometimes find it daunting to navigate Canada's regulatory system and keep up-to-date with the requirements. This fact sheet can point you in the right direction.

> Canadian companies are using innovative technologies to develop and enhance the nutritive value and functional properties of both plant and animal products.

> Canada's stringent regulatory requirements for foods with health benefits provide a competitive strength for companies wanting to promote the benefits of their products. Our internationally respected regulatory system results in standards that are world-class and products that are recognized as safe, effective and top-quality.

> Agriculture and Agri-Food Canada is committed to helping industry bring innovative products to market. This fact sheet aims to help clarify the appropriate processes for navigating Canada's regulatory system, and provides links to the background information, guidance documents, and other useful information.

The Food and Drugs Act

The *Food and Drugs Act* (FDA) is the primary legislation governing the safety and nutritional quality of food sold in Canada. Its scope includes food labelling, advertising and claims; food standards and compositional requirements; fortification; foods for special dietary uses; food additives; chemical and microbial hazards; veterinary drug residues; packaging material; and pesticides. The role of the FDA is to protect the public against health hazards and fraud from the sale of food (including beverages), drugs, medical devices and cosmetics.

Health Canada is the federal government department setting health and safety related requirements under the FDA and its accompanying regulations and guidelines. The Canadian Food Inspection Agency (CFIA) is responsible for enforcement of the FDA and its associated regulations.

Core Principles behind the FDA

Historically the FDA was enacted to prevent the adulteration of food and fraudulent practices affecting the safety and quality of foods. A key underlying premise is to enable consumers to make informed food choices based on information that is truthful and not misleading. All advertising and all statements on food packages are subject to subsection 5(1) of the FDA, 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."*

Food manufacturers and importers are responsible for ensuring that their products comply with Canadian legislation. As more food products are being promoted for their health benefits, it continues to be imperative that all advertising and label claims be scientifically validated and that statements provide meaningful information to the consumer.

Foods, Drugs, and Natural Health Products

The FDA categorizes consumed products as either foods or drugs; drugs include the subcategory of natural health products (NHPs). The regulatory requirements are different depending on how the product is categorized. Foods and drugs that are not NHPs are regulated under the *Food and Drug Regulations* (FDR); NHPs are regulated under the *Natural Health Products Regulations* (NHPR).

Food or NHP?

> NHPs are usually intended to be taken in a specified dosage for the purpose of diagnosing, treating or preventing disease; restoring or correcting function; or maintaining or promoting health. Due to the broad definition for a NHP there is an overlap between the two regulatory frameworks.

> To clarify the criteria used to determine if a product is a food or a NHP, 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*.

> Every product is assessed on a case-by-case basis. Public health and safety are taken into consideration when assessing a product's classification. Four key criteria used to make the decision are product composition; product representations; product format; and public perception and history of use.

CLASSIFICATION —FOOD OR NHP?	LEGISLATION THAT APPLIES
Products that are foods as defined in the FDA	• the FDA as it applies to food • Parts A, B and D of the FDR
Products that meet the definition for "natural health product" in the NHPR	• the FDA as it applies to drugs • the NHPR
Products that are both a natural health product and a food	• the NHPR • exempted from the FDR as applied to food

FDA=*Food and Drugs Act*; FDR=*Food and Drug Regulations*
NHPR=*Natural Health Products Regulations*

Food Labelling in Canada

Mandatory Nutrition Facts Table

Following regulations introduced in 2003, most pre-packaged food products require a Nutrition Facts table on their label.

> The standardized Nutrition Facts table is designed to provide nutrient information in an easy-to-find, standardized format. It must include information, based on the stated serving size, for Calories (energy content) plus 13 core nutrients in absolute amounts and as a % Daily Value (%DV). There are different presentation styles based on the nature of the product and the size.

> Additional nutrients may also be listed in the Nutrition Facts table, either voluntarily or when triggered by a nutrient content claim. For example, it becomes mandatory to display information on omega-6, omega-3 and monounsaturated fatty acids when any one of these is mentioned on the label. Information on other food constituents may appear outside of the Nutrition Facts table as a quantitative statement.

Exemptions

While the Nutrition Facts table appears on most pre-packaged foods, some products are exempt.

> For example, exemptions exist for fresh fruits and vegetables, raw meat and poultry (although ground meat must be labelled) and individual servings of foods sold for immediate consumption.

> Under certain conditions, such as the presence of a claim, these foods lose their exempt status and must carry a Nutrition Facts table.

Other mandatory information is required on food labels. The CFIA's *Guide to Food Labelling and Advertising*, Chapters 5 and 6, provides details to assist manufacturers with nutrition labelling requirements.

Food Allergen Labelling

Health Canada is moving toward enhanced labelling requirements for substances most frequently associated with food allergies and allergic-type reactions. Interim guidance is as follows:*

> Health Canada is urging food manufacturers and importers to declare (a) **priority food allergens** (see Table), (b) **gluten sources** and (c) **added sulphites** on food labels without exception, either in the list of ingredients or in a statement such as "Allergy and Intolerance Information; Contains (name of allergen)."
  - The **gluten source** will need to be declared when a food contains gluten protein or modified gluten protein from barley, oats†, rye, triticale, or wheat, including kamut or spelt.
  - **Added sulphites** need to be declared when directly added to a food, or when the total amount of added sulphites in the food is 10 parts per million or more.

This approach is consistent with the amendments to the FDR proposed in July 2008 and consistent with the food labelling requirements recently enacted by Canada's major trading partners.

PRIORITY FOOD ALLERGENS IN CANADA (2008)*, †
Peanuts
Tree nuts (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts)
Sesame seeds
Wheat, kamut, spelt or triticale
Eggs
Milk
Soybeans
Fish
Crustaceans (e.g. crab, crayfish, lobster, shrimp)
Shellfish (e.g. clams, mussels, oysters, scallops)

* The food or protein derived from the food

† The addition of mustard to the list of priority food allergens is being considered in 2010.

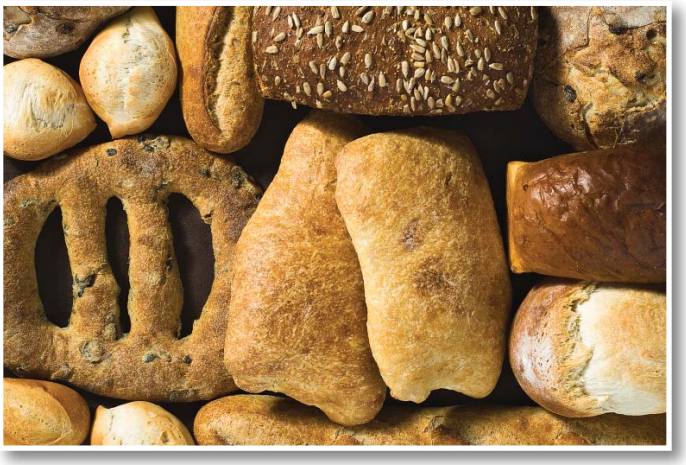
The CFIA has developed and will maintain a guidance document to assist food manufacturers and importers in following this recommendation (*Questions and Answers Regarding the Labelling of Food Allergens and the Use of Precautionary Statements*).

* Monitor the *Canada Gazette, Part II* for the final ruling.

† Except for hulless oats, such as Avena®.

Health Claims Permitted in Canada

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 food constituent (including an ingredient in the food), and a person's health. Health claims may be stated explicitly with words, or implied through symbols, graphics, logos or other means such as a name, trademark or seal of approval. While the term "health claim" is not formally defined in food regulations in Canada, health claims are grouped into three main categories: **disease risk reduction claims** and therapeutic claims; **function claims**; and **general health claims** (see Summary Table on page 7).



The regulation of health claims varies depending upon the type of health claim being made. Despite some international differences, Canada's nutrition claims and health claims remain aligned with the international standards of *Codex Alimentarius*.

Disease Risk Reduction Claims

Disease risk reduction claims (formerly called diet-related health 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.

> Since 2003, Health Canada has allowed disease risk reduction claims to be used on food labels or in advertisements that reflect five substantiated relationships.

> The list of permitted claims, including the wording prescribed in the FDR, can be found in Chapter 8 of the *Guide to Food Labelling and Advertising* (8.4).

> To obtain authorization for any new disease risk reduction claims, industry must prepare a scientific submission to Health Canada's Food Directorate, according to a standardized format outlined in the *Guidance Document for Preparing a Submission for Food Health Claims.*

> Submissions require a systematic scientific literature review with emphasis on randomized clinical trials and observational studies in humans. Submissions must include information on the dose required to achieve the intended effect, the likelihood of consuming adequate amounts based on Canadian consumption patterns, and safety data.

DISEASE RISK REDUCTION CLAIMS CURRENTLY PERMITTED IN CANADA

Diet–Disease Relationship	Examples of Permitted Claims
1. a healthy diet low in sodium and high in potassium and reduced risk of high blood pressure	"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."
2. a healthy diet with adequate calcium and vitamin D and reduced risk of osteoporosis	"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."
3. a healthy diet low in saturated and trans fats and reduced risk of heart disease	"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."
4. a healthy diet rich in vegetables and fruit and reduced risk of some types of cancer	"A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer."
5. non-fermentable carbohydrates in gums and hard candies and reduction in dental caries (cavities)	"Does not promote tooth decay."

Function Claims

Function claims are health claims that describe the beneficial effects of foods or food constituents on normal functions or biological activities of the body associated with health or performance. They are based on the role that the food or food constituent plays when consumed at levels found in normal dietary patterns.

> There are conditions of use, including minimum levels and content requirements, before a function claim listed as acceptable (i.e. reviewed by Health Canada) can be used on a product label.
> See Chapter 8 of the *Guide to Food Labelling and Advertising* (8.5).
> A function claim may not refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or of their symptoms. It also may not refer directly or indirectly to correcting or restoring abnormal functions or to modifying organic functions beyond the normal physiological effects of food.
> Examples of function claims include:
- *"Consumption of 1 cup of green tea helps to protect blood lipids from oxidation."*
- *"1/4 cup of Product X contains 7 grams of fibre from coarse wheat bran, which promotes regularity."*

Nutrient Function Claims

Nutrient function claims (formerly called biological role claims) describe the well-established roles of energy or known nutrients that are essential for the maintenance of good health or for normal growth and development.

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*). (Canada is a participant on IOM committees.)

> The following two **general** nutrient function claims are acceptable for all nutrients when conditions for their use are followed:
- *"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."*
> Other examples of nutrient function claims include:
- *"Vitamin A aids in the development and maintenance of night vision."*
- *"Calcium aids in the formation and maintenance of bones and teeth."*
- *"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."*
> See Chapter 8 of the *Guide to Food Labelling and Advertising* (8.6).

Probiotic Claims

Food products containing probiotic bacteria can bear function claims in accordance with Health Canada's guidance document, *The Use of Probiotic Microorganisms in Food*. This document sets out the conditions under which health claims about probiotic microorganisms would be considered acceptable. It also outlines the requirements for the safety, quality (stability) and labelling of such food products.

> **Non-strain-specific claims**—Health Canada has accepted a limited number of claims about the nature of probiotic microorganisms. These non-strain-specific claims may be made on food without conducting a detailed review of the scientific basis, when guidance for their use is followed. See Chapter 8 of the *Guide to Food Labelling and Advertising* (8.7).
> **Strain-specific claims**—Health Canada will review these claims on a case-by-case basis and will maintain a list of acceptable strain-specific claims on its Web site.

Like other such health claims, any probiotic claims that promote therapeutic uses must undergo pre-market assessment by Health Canada's Food Directorate, and require an amendment to the FDR to allow their use.

General Health Claims

General health claims promote health through healthy eating or provide dietary guidance. These claims do not refer to a health effect, disease, or health condition.

> See Chapter 8 of the *Guide to Food Labelling and Advertising* for useful information on general health claims as they relate to vitamin and mineral nutrients, body weight, the use of educational material, third-party endorsements and logos, heart symbols, and guidance for healthy eating.
> Statements that imply 'healthy choice' or use a logo or symbol are subject to review and must not be false, misleading or deceptive.
> Acceptable general health claims include:
- *"As part of healthy eating, this food may assist in achieving and maintaining a healthy body weight because it is portion controlled."*
- *"Canada's Food Guide recommends eating at least one dark green and one orange vegetable each day."*

Other Types of Claims Permitted in Canada

Food Ingredient Claims

Claims can be made about the composition, quality, or origin of products—such as "whole grain" or "natural"—as long as they are truthful, not misleading, and in compliance with other regulatory requirements.

> Chapter 4 of the *Guide to Food Labelling and Advertising* provides guidance on their use.

Nutrient Content Claims

Nutrient content claims describe the quantity of energy or a nutrient in a food. The regulations prescribe the reference amount, the unit of measurement for each nutrient, the compositional criteria and the wording for each claim.

> The vitamin or mineral must have an established Recommended Daily Intake, and the food must contain a minimum 5% of the Daily Value (5%DV).
> Specific guidelines govern statements that identify the amount of a nutrient in a food (e.g. "source", "good source", "excellent source"), as well as comparative nutrient content claims (e.g."reduced", "less", "light") based on a regulated standardized reference amount.
> Chapter 7 of the *Guide to Food Labelling and Advertising* provides guidance on the use of nutrient content claims.

Pre-Market Approval

> **Health claims** must be truthful and not misleading. It is mandatory that health claims be substantiated before they appear on food product labels in Canada. In some cases, such as for disease risk reduction and therapeutic claims, a pre-market assessment of the health claim and the scientific evidence in support of the claim by Health Canada's Food Directorate is required. In other cases, such as with function claims, it is voluntary but encouraged (see Summary Table on page 7).

> For **dietary novel fibres**, see *Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them*.
> **Novel foods** and **food additives** require pre-market approval in Canada (see Summary Table below).
> Submissions are to be made through a single point of entry, Health Canada's Submission Management and Information Unit (SMIU).

SUMMARY—PRE-MARKET APPROVAL OF NOVEL FOODS AND FOOD ADDITIVES IN CANADA

Novel Foods or Food Additives	Pre-Market Approval	Scientific Substantiation
Novel Foods • Foods resulting from a process not previously used for food • Products that do not have a history of safe use as a food • Foods that have been modified by genetic manipulation; also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods	• Mandatory pre-market notification for all novel foods • Health Canada maintains a list of recent approvals	• Consult *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* - assists in preparing a novel food notification and explains what information is considered sufficient for a safety assessment - applies to all novel foods derived from plant or microbial sources, whether whole foods, food products, or food ingredients • Safety assessment criteria for novel foods derived from animal sources are under development
Food Additives • Any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food (specific exclusions outlined in the FDR)	Required for: • new food additive not already regulated in the FDR • extension of the use of an existing food additive	• Consult *A Guide for the Preparation of Submissions on Food Additives* • A Submission Checklist is also available

SUMMARY—ACCEPTABILITY OF NEW HEALTH CLAIMS IN CANADA

Type of Claim	Pre-Market Approval	Scientific Substantiation
All Health Claims • 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 • May be stated explicitly with words, or implied through symbols, graphics, logos or other means such as a name, trademark or seal of approval	• Required for claims that are therapeutic in nature or that are considered "drug" claims • Recommended for other new claims	• For a health claim to be considered not misleading, prior to its use there should be scientific evidence that substantiates the claimed health effect • The *Guidance Document for Preparing a Submission for Food Health Claims* 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
Disease Risk Reduction Claims • 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 • Formerly known as diet-related health claims	• Required • Regulatory amendment is needed to exempt the product from requirements applicable to drugs, as it is 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 of the FDA • The list of permitted claims, including the wording prescribed in the FDR, can be found in Chapter 8 of the *GFLA* (Section 8.4)	• Must demonstrate that it is scientifically substantiated • Follow the *Guidance Document for Preparing a Submission for Food Health Claims* - systematic scientific literature review with emphasis on randomized clinical trials and observational studies in humans - the dose required to achieve the intended effect - the likelihood of consuming adequate amounts based on Canadian consumption patterns - safety data
Function Claims • Statements based on the specific beneficial effects that the consumption of a food or a food constituent has on the normal functions or biological activities of the body • Based on the role that the food or the food constituent plays when consumed at levels consistent with normal dietary patterns	• Recommended for new function claims • Evidence should be available upon request • List of acceptable claims (those that have been reviewed by Health Canada) and conditions for their use is maintained in Chapter 8 of the *GFLA* (Section 8.5)	• Consult the *Guidance Document for Preparing a Submission for Food Health Claims* • Claims should be supported by acceptable standards of evidence • Claims should clearly state a specific and scientifically supported physiological effect associated with good health or performance
Nutrient Function Claims • A subset of function claims • Describe the well-established roles of energy or known nutrients that are essential for the maintenance of good health or for normal growth and development • Formerly known as biological role claims	• Recommended for new nutrient function claims • Evidence should be available upon request • List of acceptable nutrient function claims and conditions for their use is maintained in Chapter 8 of the *GFLA* (Section 8.6) • Two general claims can be made for any nutrient when conditions for their use are followed	• Such claims may only be made for the energy value or recognized nutrients in a food • New nutrient function claims will be considered only for nutrients with established recommended intakes and if the function reflects consensus among authoritative scientific bodies
Probiotic Claims • Claims about the benefits of probiotic microorganisms • Includes 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)	• Recommended for new probiotic claims • List of acceptable claims about the nature of probiotics (non-strain-specific claims) and the eligible species for the claims, along with guidance for their use, is maintained in Chapter 8 of the *GFLA* (Section 8.7) • List of acceptable strain-specific claims will be maintained by Health Canada as reviewed and accepted	• General information about evidence requirements applicable to health claims of all types, including function claims, also apply to probiotic claims • Consult the *Guidance Document – The Use of Probiotic Microorganisms in Food* - sets out the conditions under which health claims about probiotics would be considered acceptable - provides guidance on the safety, quality (stability) and labelling aspects of such food products
General Health Claims • Broad claims that promote health through healthy eating or that provide dietary guidance • Do not refer to a health effect, disease, or health condition	• Pre-market approval is not normally required • A general statement is only permissible if no linkage is made to a specific product or to a health effect, disease or health condition • Use with caution to avoid positioning a food as a drug, or giving the impression that the food may help prevent, treat or cure diseases	• Consult Chapter 8 of the *GFLA*: - vitamin and mineral nutrients - body weight - the use of educational material - third-party endorsements and logos - heart symbols - guidance for healthy eating

GFLA = Guide to Food Labelling and Advertising

Resources

Health Canada Food Directorate Guidance Documents Web page

www.hc-sc.gc.ca/fn-an/legislation/guide-ld/index-eng.php

Guidance documents prepared to assist in the interpretation of policies and governing statutes and regulations, and to assist in preparing submissions when seeking approval from Health Canada's Food Directorate for food products, processes and packaging materials.

Food Additives

- A Guide for the Preparation of Submissions on Food Additives
- Food Additive Submission Checklist

Health Claims, including Probiotics

- Guidance Document for Preparing a Submission for Food Health Claims (2009)
- Guidance Document – The Use of Probiotic Microorganisms in Food (2009)

Management of Pre-Market Submissions

- Announcement: Food Directorate's New Process for the Management of Pre-Market Submissions for Food Additives, Infant Formulas, and Novel Foods

Novel Fibre Sources

- Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them (1997)

Novel Foods

- Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms (2006)

Additional Information on Novel Foods

www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php

- Information on Health Canada's regulations
- A list of recent Health Canada approvals of novel foods
- Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms

Foods vs. Natural Health Products

- Classification of Products at the Food–Natural Health Product Interface: Products in Food Formats *www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php*

CFIA Guide to Food Labelling and Advertising

- *www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml*
  The *Guide* provides information on food labelling and advertising requirements as well as policies that apply to statements and claims made for foods. As such, it is a tool to assist industry in ensuring compliance with legal requirements.

CFIA and Health Canada Information on Labelling of Food Allergens

- Questions and Answers Regarding the Labelling of Food Allergens
  A guidance document to assist food manufacturers and importers in following the recommendations *www.inspection.gc.ca/english/fssa/labeti/allerg/allergee.shtml*
- Food Allergen Labelling *www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/index-eng.php*

Email notification lists

- NUTSCI: *www.hc-sc.gc.ca/fn-an/res-rech/res-prog/nutri/nustci_mailing_list-liste_correspondant_nutsci-eng.php*
- Nutrition Bulletin: *www.hc-sc.gc.ca/fn-an/nutrition/listserv-eng.php*
- Food Allergies: *www.hc-sc.gc.ca/fn-an/securit/allerg/fa-aa/allergen_e-notice_avis-eng.php*
- Labelling: *www.inspection.gc.ca/english/util/listserv/listcsube.shtml?LABETI-DEC*

Health Canada Submission Management and Information Unit (SMIU)

- *www.hc-sc.gc.ca/fn-an/legislation/guide-ld/smiu_qa-qr-eng.php*
  Phone: (613) 960-0552; Fax: (613) 946-4590; Email: smiu-ugdi@hc-sc.gc.ca

To learn more about Canada's functional food and natural health products industry, visit: **www.agr.gc.ca**

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