

Welcome to Nutri-Net Canada Regulatory Portal

Companies interested in developing, producing and marketing foods with health claims and natural health products in Canada face a number of regulations when introducing new products to the Canadian and US marketplace. This portal is designed to quickly determine what category a product falls under, what claims may be allowed and what regulations must be followed to sell a product to consumers. The Canadian and US regulation differ in a number of ways. This must be taken into consideration when developing labelling and marketing material.

To use this guide, read through each description and follow the links (or titles) to the specific information and regulations pertaining to that category.

All consumer products are also subject to labelling and advertising regulations as outlined in [General Food Regulations](#) section of this portal.

Regulations in Canada

Background

All food products sold in Canada must comply with the [Food and Drugs Act](#) and the [Consumer Packaging and Labelling Act](#). The acts are enforced by the [Canadian Food Inspection Agency](#) through regulations and policies.

Under the food and drug act, a product is treated as either a food or a drug according to the definitions. A food is treated as a drug when claims are made regarding the food's affect on the human body. It is important to know that when considering making health related claims, the Food and Drug Act (Section 3) "prohibits the sale or advertisement to the general public of any food, drug, cosmetic or device which indicates a treatment, cure or preventive role for diseases or disorders referred to in **Schedule A** which include, but is not limited to, heart disease, diabetes, cancer, hypertension, obesity and arthritis."

This policy applies to food with health claims, natural health products and drugs. Check [Schedule A](#) for a complete listing of conditions. More information can be found on the [Fact Sheet for Schedule A Health Claims for Natural Health Products](#).

The terms **Functional Foods** and **Nutraceuticals** are not defined terms in the Food and Drug Act or any other legislation.

"Foods with Health Claims" is the term used to describe functional foods.

"Natural Health Products" is the term used to describe nutraceutical type products.

Categories of allowable health claims

1) [Diet Related Health Claims](#)

Found in Chapter 8 of the CFIA **Guide to Food Labelling and Advertising**

The *Food and Drug Regulations* allow some diet-related health claims on foods. The claims must be based on sound scientific evidence that has established a relationship between certain elements of healthy diets and reduction of risk of certain diseases.

a) **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;
- **minimal fermentable carbohydrates** in gum, hard candy or breath-freshening products, and the reduction of risk of dental caries.

b) Biological Role Claims

Biological claims pertain to the **function** of the energy value or a specific nutrient in relation to its affect on the body's normal growth, development, or maintenance of health.

e.g. DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves.
(Product name) is a source of DHA.

The emphasis of the claim is on the **nutrient**, rather than the food or the product.

2) Nutrient Content Claim

Nutrient content claims refer to the **quantity** of a nutrient in the food. Food manufacturers may claim the nutrient content on food labels if the food meets the criteria (i.e. the required quantity to make a claim) as described by the Canadian Food Inspection Agency.

e.g. "high source of fibre" pertains to a product that contains 4 grams or more of fibre per serving.

3) Food for Special Dietary Use

Food that has been specially processed or formulated to meet the particular requirements of a person:

- a. in whom a physical or physiological condition exists as a result of a disease, disorder or injury;
or
- b. for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods.

These foods include:

- a formulated liquid diet
- a meal replacement
- a nutritional supplement
- a gluten-free food
- a food represented as
 - a protein-restricted diet,
 - a low-amino acid diet, or
 - a very low-energy diet

These regulations are fully described in Chapter 9, [Section 9.9](#) of the CFIA Guide to Food Labelling and Advertising.

4) Novel Foods

A food product may be deemed a novel food if it is derived from one of the following:

- 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.

Examples may include, but are not limited to:

- Genetically modified canola
- Enhancing lutein content of chicken eggs through the bird's diet.
- Enhancing omega 3 fatty acids of chicken eggs and meat through the bird's diet.

5) [Novel Fibres](#)

A novel fibre (or a novel fibre source) is a food that has been manufactured to be a source of dietary fibre, and:

- has not traditionally been used for human consumption to any significant extent; or
- has been chemically processed (e.g., oxidized) or physically processed (e.g., very finely ground) so as to modify the properties of the fibre; or
- has been highly concentrated from its plant source.

Examples of approved novel fibres include: oat hull fibre, psyllium seed husk, rice bran, soy cotyledon fibre, sugar beet fibre and fine wheat bran (less than 0.5mm in particle size) and inulin.

6) [Natural Health Products](#)

Natural Health Products (NHPs) are defined as those substances (medicinal ingredient in a natural health product) that are 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.

These include:

- Vitamins and minerals
- Herbal remedies
- Homeopathic medicines
- Traditional medicines such as traditional Chinese medicines
- Probiotics, and
- Other products like amino acids and essential fatty acids

Natural Health Products in food form are currently being reviewed by the Food Directorate and the Natural Health Products Directorate.

[Additional Resources - Canada](#)

General Food Regulations

All food products must comply with the standard format and requirements for the labelling of food products in Canada. A list of the acts and regulations associated with food production and sale are found under [Canadian Food Inspection Agency - Acts and Regulations](#).

Acts that cover Food Labelling

1. The [Food and Drugs Act](#)

“prohibits the labelling, packaging, treating, processing, selling or advertising of any food (at all levels of trade) in a manner that is false, misleading or deceptive to consumers or is likely to create an erroneous message regarding the character, value, quantity, composition, merit or safety of the product. Subsections 3(1) and (2) prohibit health claims that might suggest that a food is a treatment, preventative or cure for specified diseases or health conditions, **unless provided for in the regulations.**”

2. [The Consumer Packaging and Labelling Act](#)

“provides for a uniform method of labelling and packaging of prepackaged consumer goods (products sold at retail). It contains provisions regarding prevention of fraud and provides for mandatory label information with which consumers can make informed choices. It also requires the use of metric units of measurement and bilingual labelling.”

<http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/reg/index-eng.php>

Main Resource for Nutritional Labelling Requirements

- o [2003 CFIA Guide to Food Labelling and Advertising](#) and [the Amendments](#).
- o Food and Drug Regulations for Nutritional Labels - [Examples of acceptable nutritional label formats](#)
- o [Nutrition Labelling Toolkit](#)
- o Allowable serving sizes are established in Table 6-3 of the Guide to Food Labelling and Advertising - [Reference Amounts \[Schedule M\] and Serving Sizes](#).

Enforcement of the Food Labelling Regulations by the Canadian Food Inspection Agency

CFIA's [Nutrition Labelling Compliance Test](#) is the system for ensuring the accuracy of nutrient information in Canada. It included information on acceptable laboratory and nutritional database analysis. A tolerance of 20% is allowed between the claimed amount and the true lot average. This is to take into account the variability of food manufacturing.

Food Production - Food Safety

Manufacturing of food and natural health products is regulated by a variety of organizations depending on the type of food, the geographic location and the distribution of the food.

CFIA registered food manufacturing plants are required to follow the food safety principles outlined in [Hazard Analysis Critical Control Points / Food Safety Enhancement Program](#).

Good Manufacturing Practices for Natural Health Products are also outlined in Health Canada's [Good Manufacturing Practices Guidance Document](#).

Non- federally registered food manufacturing facilities require a municipal license and must adhere to provincial Public Health Acts

Diet Related Health Claims

Nutritional analysis may be required if linking a food's nutritional properties to a diet related health claim. More information related to nutrient content can be found under the [Nutrient Content Claims](#) section of the CFIA's Guide to Food Labelling and Advertising.

1. **Permitted Diet Related Health Claims** regulations are described in Chapter 8, [Section 8.4](#) of the CFIA Guide to Food Labelling and Advertising

The wording described in the Guide cannot be modified. It must not be separated or reordered and must be displayed in equal prominence with no part highlighted.

Example of an allowable claim:

"A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Name of the food) is free of (or low in) saturated and trans fats."

2. **Biological Role Claims** regulations are described in Chapter 8, [Section 8.5](#) of the CFIA Guide to Food Labelling and Advertising.

Specific biological role claims that are allowed, and are outlined in [Table 8-2 Summary Table of Biological Role Claims](#). The Regulations also permit biological role claims to be made about other nutrients not listed in the table if a quantitative statement of the nutrient(s) in grams per serving appears on the label or in the advertisement for the food.

Prohibited claims are listed in Chapter 8.5.1.

Additional information:

[Managing Health Claims for Foods in Canada: Towards a Modernized Framework](#)

[Health Canada's Interim Guidance Document - Preparing a Submission for Foods with Health Claims: Incorporating Standards of Evidence for Evaluating Foods with Health Claims](#)

Nutritional Analysis Laboratories can be located in your local yellow pages under:
Laboratories – Testing or at the following: [Canadian Council of Independent Laboratories](#)

Nutrient Content Claims

Nutrient Content Claims regulations are described in [Chapter 7](#) of the CFIA Guide to Food Labelling and Advertising.

“Nutrient content claims are statements or expressions which describe, directly or indirectly, the level of a nutrient in a food or a group of foods.” Food manufacturers may claim the nutrient content of specific nutrients if the food meets criteria described by the CFIA regulations.

The Food and Drug Regulations stipulate minimum levels for claims pertaining to protein, vitamins and mineral nutrients. Nutrients not included on the [Nutrition Facts Table](#) can be quantified per serving size and stated outside the table.

[Section 7.5](#) discusses the general requirements of a nutrient content claim including placement of the wording and letter size while the remaining sections (7.6 through 7.25) delve into the specifics of the nutrient content claims. The fastest way to find information on a specific claim is to look through the [Table of Contents](#) of the Guide to Food Labelling and Advertising, Chapter 7.

Allowable serving size are established in Table 6-3 of the Guide to Food Labelling and Advertising - [Reference Amounts \[Schedule M\] and Serving Sizes](#).

Examples of Nutrient Content Claims can be found at http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/educat/te_background-le_point-08-table1-eng.php

Additional Information

Health Canada's [Guide to Developing Accurate Nutrient Values](#)

Nutritional Analysis Laboratories can be located in your local yellow pages under: Laboratories – Testing or at the following: [Canadian Council of Independent Laboratories](#)

In addition to laboratories, many food research facilities and universities have Nutritional Analysis Software that may give an estimate of the nutrient content.

Novel Foods

Health Canada controls the sale of novel foods through a mandatory pre-market notification conducted by its Health Products and Food Branch.

[Guideline for Submission of a Novel Food Application](#)

Regulations

Interpretation of Novel Foods Regulations including full definition of a [Novel Food](#)
[Division 28 of Food and Drug Regulations](#)

Companies are encouraged to contact the Food Directorate if they are unsure if their product is considered a novel food. The Food Directorate is also available to discuss data requirements to develop the safety assessment package. Safety assessments include the following information:

- History of use
- Dietary exposure
- Detail of novel process
- History of organism(s)
- Characterization of derived line/strain
- Genetic modification considerations
- Nutritional considerations
- Toxicology considerations
- Allergenicity considerations
- Chemical considerations
- Microbiological considerations

Contact for Novel Food Pre-Market Notification/Submission

Health Canada
Novel Food Notification
Food Program
Food Directorate
Health Canada
4th Floor West
Sir Frederick G. Banting Research Center
251 Sir Fredrick Banting Driveway
Tunney's Pasture, PL 2204A1
Ottawa, Ontario K1A 0K9
e: novelfood_alimentnouveau@hc-sc.gc.ca

[Guidelines for Safety Assessment of Novel Foods](#) (including pre-market notification)

Manufacturer or importers are required to notify the Food Directorate in writing of their intention to sell or advertise for sale a novel food. The following link is a detailed guideline of the submission requirements.

[Submission Examples and Approved Novel Foods](#)

Resources related to Novel Foods.

- [BioPortal – Canadian Government](#)
- [Safety Assessment FAQ](#)
- [FAQ related to GM and Biotechnology foods](#)

- [Health Canada's Role in the Regulation of Products from Biotechnology](#)

Novel Fibres

Health Canada controls the sale of novel fibres for use as ingredients in Canadian foods through a mandatory pre-market notification conducted by its Health Products and Food Branch.

[Guideline for Submission of a Novel Food \(Fibre\) Application](#)

Manufacturers or importers are required to submit information to Health Canada regarding the product in question so that a determination can be made with respect to the product's safety prior to sale.

[Guidelines Specific to the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Novel Fibres](#)

Companies are encouraged to contact the Food Directorate if they are unsure if their product is considered a novel fibre. The Food Directorate is also available to discuss data requirements to develop the safety assessment package. Safety assessments include the following information:

- History of use
- Dietary exposure
- Detail of novel process
- History of organism(s)
- Characterization of derived line/strain
- Genetic modification considerations
- Nutritional considerations
- Toxicology considerations
- Allergenicity considerations
- Chemical considerations
- Microbiological considerations

The physiological efficacy of novel fibre sources as dietary fibre must also be established before they may be claimed to be a source of dietary fibre in foods. If the novel fibre source has not been tested (and proven) for efficacy, it is considered an unproven novel fibre. If safe, it may be used in foods but it cannot be claimed to be a source of dietary fibre.

[Proposed Guidelines for Clinical Studies](#)

[Guideline for Planning and Statistical Review of Clinical Laxation Studies for Dietary Fibre](#)

This system is unique in that Health Canada approves applications on a case-by-case basis, granting approvals to individual companies to use their particular brands of a fibre as ingredients, as opposed to approving the ingredient itself. Each company must seek approval for its own brand of fibre.

Some examples of novel fibres not currently recognized in Canada as food ingredients or fibre sources include:

- fibre that has not traditionally been used for human consumption to any significant extent, such as cane sugar stalks, cocoa bean hulls, oat hulls, mucopolysaccharides (e.g., chitin) from shells of shellfish, and wheat straw;
- fibre that has been chemically processed, (e.g., oxidized), or physically processed (e.g., very finely ground), so as to modify the properties of the fibre, such as bleached oat hulls, finely ground wheat bran, bleached pea hulls (seed coats), and bleached wheat straw; and
- fibre that has been highly concentrated from its plant source, such as beta-glucans from barley and oats.

Ingredients such as resistant starches and fructooligosaccharides have become embroiled in the controversy over the definition of dietary fibre. Although many of these products are permitted for use in Canada, they are not considered dietary fibre under the current definition and thus can not be labeled as “fibre”. Nutrition labeling poses a special problem for these products.

Natural Health Products

Natural Health Products (NHPs) are treated as a sub-category of drugs under the Food and Drug Act and are typically sold in dosage form as either a pill, liquid or powdered product. Compliant products are issued a product licence and corresponding Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) only when the products are approved and supported by sufficient evidence and deemed to be safe, effective and of high quality. The NPN or DIN-HM must appear on the product label as proof that Health Canada has authorized the sale of the product.

Regulations pertaining to NHPs in food form are currently under review.

Foods fortified with vitamins and minerals are not evaluated as natural health products unless the food meets the NHP definition and is prescribed in dosage form.

Natural Health Products

Natural Health Products are regulated under the [Natural Health Product Regulations](#) of the Food and Drug Act. Compliance to these regulations is outlined in the [Compliance Policy for Natural Health Products](#).

Health Canada provides background information on NHP for industry and consumers under the main page of the [Natural Health Products](#) website. Under this section of the Health Canada site, industry can find [Guidance Documents](#) and [Product Licensing Forms & Templates](#). Of particular interest is the [Product Licensing Guidance Document](#) which walks a NHP manufacturer or marketer through the steps of the application process. Companies can also access a list of approved products through the [Licensed Natural Health Products Database](#).

In addition to a product license, a company must also apply for a site license if the company manufactures, packages, labels and/or imports a NHP for sale in Canada. For more information regarding who is required to obtain a site licence and how to apply, see Health Canada's [Site Licensing Guidance Document](#).

Natural Health Products in Food Form

There are currently no regulations in place to deal with Natural Health Products in food form. i.e foods that have an recommended dosage amount. e.g. “eat one bar per day to ease menopausal symptoms”

Food Directorate is now collaborating with NHPD to review applications for “food-like NHPS”

An interim document has been prepared to guide companies through the submission process for Foods with Health Claims.

[Interim Guidance Document - Preparing a Submission for Foods with Health Claims: Incorporating Standards of Evidence for Evaluating Foods with Health Claims](#)