Canadian Food Health Claim Roadmap

A BUSINESS MANAGEMENT TOOL

March 2011

FOOD REGULATORY ISSUES DIVISION
MARKET AND INDUSTRY SERVICES BRANCH
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**Canadian Food Health Claim Roadmap: A Business Management Tool**

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1 Introduction

1.1 Background

The Canadian Food Health Claim Roadmap (Roadmap) was designed\(^1\) to help Canada’s agri-food industry become more competitive. The Roadmap identifies the knowledge required to function in Canada’s regulatory environment and to take advantage of market opportunities. This capacity building will advance innovation in the Canadian food manufacturing sector and accelerate the successful development and market entry of new food products with added health benefits, while ensuring safety and efficacy.

1.2 Purpose and Objectives

The Roadmap provides a business management tool for industry, business development specialists, trade associations and others involved in new product development or marketing food and food ingredients in Canada. The tool is designed to manage the numerous decisions and activities that relate to putting a nutrient or health claim statement on a food product label in Canada.

The Roadmap contains three key parts to the business management tool:

- a one-page flow chart that outlines strategies and decisions that companies should consider en route to pursuing a nutrient and/or health claim;
- a detailed decision model that leads businesses through a decision-making process based on the regulatory framework and the parallel implications for scientific efficacy, market opportunity and business planning; and
- information to guide activities, analysis and decision making when considering whether a nutrient and/or health claim is appropriate.

The Roadmap is designed for businesses that:

- have products currently in the market (and have marketing and business plans for this product and market); and
- are considering a nutrient and/or health claim for either existing product or new product. (Even for the existing product, significant changes may be required in manufacturing processes, ingredients, markets, business strategies, etc., thus requiring new marketing and business plans.)

Companies need to be thorough and deliberate in accessing, reviewing and acting on the available regulations, guidance documents and various resource materials. The Roadmap is designed to assist with this process.

\(^1\) Agriculture and Agri-Food Canada (AAFC) would like to acknowledge Shambrock Consulting Group Inc., Kelwin Management Consulting, The Pathfinders Research and Management Ltd., and Baytek Systems for their assistance in developing this resource.
It is common for companies and industry associations to use a variety of external resources when developing a nutrient and/or health claim, especially a new food health claim that requires pre-market approval. The cost and scientific substantiation required are usually significant.

The types of external resources used include:

- university researchers;
- food scientists and process engineers;
- provincial government specialists;
- NRC – IRAP representatives;
- centres of excellence in functional foods and natural health products;
- federal and provincial food technology centres;
- business management consultants; and
- regulatory specialists.

1.3 Structure of the Roadmap

This document is organized into the following sections:

- **Section 1: Introduction**
  Section 1 provides the background and purpose of the tool and explains its structure.

- **Section 2: Health Claim Regulatory Landscape in Canada**
  This section explains the various types of nutrient claims and health claims available in Canada based on the current regulations. Section 2 also provides an overview of the federal departments and agencies involved with the development and enforcement of regulations. Other regulatory pathways and frameworks (novel foods, novel fibres, food additives, foods with added vitamins and minerals, and natural health products [NHP]) that may provide an alternative route to market are summarized.

- **Section 3: Introduction to the Health Claim Decision Model for Canadian Food Products**
  The Health Claim Decision Model (decision model) in this resource is introduced by a preliminary discussion of the decision-making process that is used. Section 3 concludes with the decision model presented in an overview format.

- **Section 4: Health Claim Decision Model for Canadian Food Products**
  Section 4 contains the full version of the decision model. It is presented with its detailed activity lists, analytical steps and decision points laid out in sequential order. The suggested decision process is explained for each Step. Each Step’s Go/No Go decision options are outlined and explained. To conclude section 4, a brief overview is provided of the next steps to be taken by companies and industry associations, once the decision to pursue a nutrient and/or health claim is made.
• **Appendix 1: Definitions and Terminology**
  This reference table provides definitions for current and previously used terms that are a part of the regulatory framework. A source and link are provided for all current terms.
  To clearly understand these terms, the reader may wish to first read Appendix 1 before embarking on any activities involved in putting a nutrient or health claim statement on a food product in Canada.

• **Appendix 2: Important Resource Documents**
  Numerous documents are available to companies and industry associations on Health Canada, AAFC, Canadian Food Inspection Agency (CFIA) and Department of Justice websites. A summary reference table is provided that also includes a link to each document.

• **Appendix 3: Health Claims in Australia/New Zealand, Canada, European Union, Japan and United States**
  Two tables are provided for Canada and key export markets: Table 1 presents a brief overview of the status of health claims; Table 2 lists approved disease risk reduction and therapeutic claims.

• **Appendix 4: Sample Matrix to Evaluate Options Against Comparative Criteria**
  In working through the decision model, section 4 describes the use of a matrix to capture ratings of health claim options against specific criteria. A sample matrix is provided for companies and industry associations to use as a reference in creating their own matrix.

• **Appendix 5: Food Science, Nutrition and Technology Centres in Canada**
  A brief description and contact information is provided for provincial and federal technology expertise and facilities across Canada.

• **Appendices 6 and 7: Market Track and Business Track—References**
  These two appendices contain a list of external resources to assist companies in preparing their initial marketing and/or business plans.

• **Appendix 8: Additional Considerations and Cost Implications**
  This appendix suggests activities to consider when updating marketing and/or business plans to include products with health claims, and the associated costs.

• **Appendix 9: Index to the Canadian Food and Drug Regulations**
  The Food and Drug Regulations document is more than 1,200 pages. Appendix 9 provides a quick reference to titles and corresponding page numbers of sections and subsections relevant to food products with health benefits.

### 1.4 How to Use the Roadmap

For companies and industry associations already experienced with the regulatory processes for using or obtaining approvals for Canadian nutrient and health claims, it is possible to briefly review sections 1 and 2 and then go directly to sections 3 and 4. For those less familiar, it is

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2 Note: All links to websites and other sources/resources were operational as of February 1, 2011.
recommended that sections 1 and 2 be reviewed in more detail, as well as the appendices on definitions and terminology and important resource documents.

Complementary resources to this document include a handout of the Nutrient Claim / Health Claim Flow Chart, an interactive electronic tool and a supplemental tool that outlines resource considerations.³

1.5 Description of the Nutrient Claim / Health Claim Flow Chart

Figure 1 provides a simple visual overview to help readers understand the options that exist under the regulations for making nutrient or health claims. It displays the path in a one-page flow chart, including options and decisions that most companies will need to follow.

The decision path focuses first on the nutrient statements that are easier to use, and moves to more onerous nutrient or health claims. The decisions are described in more detail in sections 3 and 4.

³ Available from the Food Regulatory Issues Division, Agriculture and Agri-Food Canada.
Figure 1  Nutrient Claim / Health Claim Flow Chart

STEP 1
Whole Food / Food Product / Food Constituent

Yes
Nutrient / Health Claim Potential

No
Exit

STEP 2
Natural Health Product Regulatory Stream

Food Regulatory Stream

NHP Health Claims

Exit

STEP 3

Food with Added Vitamins and Minerals

Food Additive

Not Novel

Novel Fibre

Novel Food

STEP 4
Whole Food / Food Product / Food Constituent

Nutrition Labelling and Nutrient Claim Options

- Nutrition Facts Table
  Mandatory on most prepackaged food and triggered by the use of a claim or declaration.

- Nutrient Content Claim
  Quantitative statements or expressions that describe, directly or indirectly, the level of a recognized nutrient in a food or a group of foods.

- Quantitative Declaration of Non-Nutrients
  Quantitative statements or expressions about food constituents that are not recognized nutrients.

- Nutrient Function Claim
  Claims about established roles for energy or recognized nutrients essential for maintenance of good health or for normal growth and development.

Food Health Claim Options

- General Health Claim
  Broad claims that promote health through healthy eating, or provide dietary guidance.

- Function Claim
  Claims (including probiotic claims) about maintaining or supporting body functions associated with the maintenance of good health or performance.

- Disease Risk Reduction Claim
  Claims that link a food or food constituent to reducing risk of a diet-related disease or condition.

- Therapeutic Claim
  Claims about treatment or mitigation of a disease or health-related condition, or restoring/correcting a body function.
1.6 Description of the Health Claim Decision Model for Canadian Food Products

The decision model incorporates the separate Steps (shown in Table 1) that a company or industry association must systematically progress through as it investigates the various regulations and their implications for market success and the available resources, for each nutrient claim or health claim option. The four Steps are:

- Step 1: Nutrient/Health Claim Potential—Preliminary Review
- Step 2: Food or Natural Health Product (NHP) Regulatory Stream Assessment
- Step 3: Assessment of Status as Novel Food, Food with Added Vitamins and Minerals, and Food Additive
- Step 4: Nutrient Claim and Food Health Claim Option Assessment

The first three Steps are a filtering process to ensure that the appropriate regulatory framework is selected, before taking the final Step of selecting the best nutrient and/or health claims to pursue.

Within the overall decision process outlined in Table 1, each Step is separated into four Tracks. Each Track is a group of activities and tasks under a common theme or discipline:

1. Regulatory Track
2. Scientific Track
3. Market Track
4. Business Planning Track

When the Steps of the flow chart (Figure 1) are combined with the four Tracks, the following Health Claim Decision Model for Canadian Food Products: Outline Version is created. (See sections 3 and 4 for a full description.)

Table 1  Health Claim Decision Model for Canadian Food Products: Outline Version

<table>
<thead>
<tr>
<th>REGULATORY TRACK</th>
<th>SCIENTIFIC TRACK</th>
<th>MARKET TRACK</th>
<th>BUSINESS PLANNING TRACK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong>: Nutrient / Health Claim Potential – Preliminary Review</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong>: Food or NHP Regulatory Stream Assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong>: Assessment of Status as Novel Food, Food with Added Vitamins and Minerals, and Food Additive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 4</strong>: Nutrient Claim and Food Health Claim Option Assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GO/NO GO DECISION MADE WHETHER TO PURSUE SELECTED NUTRIENT AND/OR HEALTH CLAIM OPTION(S)
In general, the decision model:

- provides a framework that organizes the overall decision process into a coordinated set of **Steps** that are manageable. This framework also addresses the different categories of information needed (i.e. four parallel activity **Tracks** for regulatory, scientific, market and business issues). Each Track must have the appropriate work and activities done at each Step, in a coordinated manner. This improves the quality of decisions and reduces risk.
- identifies needed information appropriate to each Step of the decision process;
- outlines approaches and identifies resources that are sources of information;
- facilitates the collection, review and analysis of collected information and data; and
- outlines a methodology to make strategic decisions based on results and conclusions from the information review process that are appropriate to each Step in the decision process (i.e. the decision to “not pursue a health claim” versus “pursue a health claim”). The decision must also consider “are we confident in the information we have to date to make the Go/No Go decision? Or, should we obtain more detailed information that will make us more confident in the next set of decisions?”

The decision at the end of each Step must use the information from the work in all four Tracks. For example, the Market Track information will often change which regulatory path is viewed as the most appropriate to use for a claim.

There are several important aspects of the decision model, and important assumptions that underpin the model:

- This resource tool is intended for businesses that have a defined product and are seeking to pursue a Canadian nutrient and/or health claim. The regulatory decision pathway (Regulatory Track) includes assessing all regulatory options for communicating nutrient content, nutrient function and health claims in Canada. It also assesses product form options from the regulatory perspectives that include food, ingredients, novel foods, novel fibres, food with added vitamins and minerals, food additives, and natural health products.
- The scientific decision pathway (Scientific Track) follows the guiding principles outlined in Health Canada’s guidance documents.
- The market decision pathway (Market Track) focuses on Canadian markets but also provides some linkages to U.S. and other export market information so companies can see if a similar health claim already exists in other countries and assess whether or not a Canadian health claim would assist in developing markets in other countries.
- The business development pathway (Business Planning Track) helps companies to assess the risks and benefits of pursuing a nutrient and/or health claim.
- The Tracks start from the nutrient and/or health claim “idea” step and proceed to the “yes, we will start the process to complete a Canadian health claim submission” or “no, we will not pursue a Canadian health claim submission.”
- Detailed information on the activities beyond the “yes, we will start the process to complete a Canadian health claim submission” are not within the scope of this decision model. The scope of the resource tool is sufficient for industry to complete the process to the “yes” decision. Health Canada’s *Guidance Document for Preparing a Submission*
for Food Health Claims shows the steps that must be followed to complete a health claim submission.

- Steps beyond the “no, we will not pursue a Canadian health claim submission” decision are limited to providing links to other potential regulatory pathways for communicating nutritional information or nutrient content when appropriate.

The regulatory framework for health claims in Canada is complex. The specific regulations are evolving, as are the classifications of claim types, the terminology to describe them and the pathways for approval. Therefore, it is important to check that the documents used are the most current.

It is also important to understand that there are significant scientific requirements for health claim substantiation in Canada, as there are in most other developed countries. Scientific requirements for health claim substantiation address three main areas: efficacy, quality assurance, and safety. All three areas are important.

Companies and industry associations need to be prepared to put emphasis on safety when dealing with the federal government on health claims. The decision model was designed to help businesses deal with the requirements of regulatory approval while satisfying their need to be market-oriented and profit-driven.
2 Food Regulatory Landscape in Canada

2.1 Food, Drugs and Health Claims

In Canada, the *Food and Drugs Act* provides legal definitions for a variety of terms. A “food” is defined to be:

“Any article manufactured, sold or represented for use as a food or drink for human beings, including chewing gum, and any ingredients that may be mixed with food for any purpose whatever.”

“Drugs” are defined as:

“Any substance or mixture of substances 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 human beings or animals,

(b) restoring, correcting or modifying organic functions in human beings or animals,

(c) disinfection in premises in which food is manufactured, prepared or kept.”

The term “health claim” is not formally defined in food regulations in Canada. Health Canada uses the Codex Alimentarius Commission (1997) definition:

“A health claim for foods means any representation in food labelling and advertising that states, suggests or implies that a relationship exists between a food category, a food, or a food constituent and health.”

A health claim for food is evaluated for its appropriateness in the context of the total diet. By this definition, health claims encompass a range of relationships and modes of representation. The relationships may be specific or general, and may be stated explicitly with words or represented implicitly (implied) through slogans, graphics, logos, symbols or other means such as a name, trademark or seal of approval, or through association (e.g. a hyperlink to a website of a third party or a website sponsored by the manufacturer, or a juxtaposition of “educational” material with advertisements for specific products having the characteristics referred to in the former).

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2.1.1 Health Claim Substantiation

There is a growing recognition of the linkage between food and health among consumers, regulatory authorities, the food industry and the scientific community. This awareness has driven development of new products, stimulated consumer interest in learning about food–health relationships, and intensified the need for regulations to protect the consumer and create fair competition.

In response to these developments, regulatory bodies in several countries, including Canada, Australia/New Zealand, European Union, Japan and the United States, have revised, or are in the process of revising, scientific requirements and regulatory frameworks for the management of health claims for foods. Although each jurisdiction has its own definition of a health claim, most countries generally use a variation of the Codex Alimentarius Commission (1997) definition stated above.

Canada’s approach to health claim substantiation places significant importance on safety and scientific substantiation of claim validity. Safety is also a primary concern in other regulatory routes to the market, including the novel food, novel fibre and food additive regulatory frameworks. Scientific requirements for health claim substantiation vary among different jurisdictions but all are based on the premise that the statement must be “truthful and not misleading.”

2.2 Canadian Government Regulatory Organizations

Health Canada is the federal government department responsible for protecting the health and safety of Canadians. Under the authority of the Food and Drugs Act and Food and Drug Regulations, Health Canada is responsible for establishing policies, setting standards, and providing advice and information on the safety and nutritional value of food. The Food Directorate within the Health Products and Food Branch is the point of contact for most policy issues related to nutrition and health issues impacting food companies and industry associations.

Within the Food Directorate, the Nutrition Evaluation Division of the Bureau of Nutritional Sciences oversees the evaluation of food health claim submissions.7

The Health Products and Food Branch of Health Canada also includes the Natural Health Products Directorate (NHPD). Parallel to the Food Directorate, NHPD regulates natural health products and monitors compliance with the Natural Health Products Regulations (2004).8

The Canadian Food Inspection Agency (CFIA) is the federal authority delegated with responsibility for the enforcement of the Food and Drugs Act and Food and Drug Regulations for food as well as the establishment of policies, regulations and standards for non-health and safety issues and their subsequent implementation and enforcement.9 CFIA publishes the Guide

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to *Food Labelling and Advertising*, an important resource to help industry comply with food labelling and advertising regulations. The decision model references various chapters throughout the model.

With respect to health claims, CFIA’s compliance approach is based on risk. Instances of non-compliance are assessed (case-by-case) in the context of the product’s label and package, and all forms of advertising associated with the product. Correction of non-compliance is normally achieved through development and implementation of corrective action plans by the regulated party, based on reasonable time frames consistent with other similar violations.

Enforcement measures are based on factual information related to potential harm, compliance history and due diligence expected. Several enforcement measures are available to CFIA: information letters, letter of non-compliance, seizure/detention, and ultimately prosecution.¹¹

### 2.3 Important Legislation

Five important pieces of legislation deal with food and drugs (including natural health products):

1. *Food and Drugs Act*
2. Food and Drug Regulations
3. Natural Health Products Regulations
4. *Consumer Packaging and Labelling Act*, and
5. Consumer Packaging and Labelling Regulations.

The *Food and Drugs Act* (FDA) was developed to protect the consumer from adulterated products and fraudulent practices affecting the safety and quality of food. The FDA specifically forbids the labelling or advertising of food in a manner that is “false, misleading or deceptive or likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.”

The Act contains definitions for “food” and “drugs,” which have implications for health claims. Only a drug can be represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms; or restoring, correcting or modifying organic functions. Section 3 of the FDA makes it an offence to advertise or sell a food to the general public as a treatment, preventative or cure for any disease or condition referred to in Schedule A of the Act. Table 2 identifies the Schedule A diseases.

Section 3 and Schedule A of the FDA have been the stumbling block for certain types of diet-related health messages on packaging and in advertising of foods as they cause the product to fall within the definition of a drug. Under the Food and Drug Regulations (FDR), a food may be exempted from any or all provisions of the Act with a regulatory amendment.¹² However, this

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exemption, published in the *Canada Gazette* (and used to allow the existing five disease risk reduction claims in Canada) adds significant time to the approval process. It is recommended that the food industry consider easier alternatives before pursuing such a claim.

**Table 2**  **Schedule A Diseases from the Food and Drugs Act [section 3]**

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

2.4 Nutrition Labelling and Nutrient Claim Options

The decision model starts with options that are easier to implement and moves to those that are increasingly onerous and costly to pursue. It is recommended that businesses and industry associations consider each option in the order presented, to see if they can achieve the desired marketing and other objectives while systematically assessing the costs and risks versus the benefits of each option. Note that more than one claim can be made as long as each claim is truthful and not misleading. For example, a nutrient content claim (section 2.4.2) and a nutrient function claim (section 2.4.4) could be used together: “Product x is an excellent source of vitamin D,” along with “Vitamin D is a factor in the formation and maintenance of bones and teeth.”

2.4.1 Nutrition Facts Table and Ingredient List

The following is a list of basic food labelling requirements in Canada:

- common name;
- net quantity declaration;
- name and address of the manufacturer or importer;
- list of ingredients;
- Nutrition Facts table; and
- durable life date.

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The CFIA Guide to Food Labelling and Advertising provides a detailed description of these requirements and related exemptions for all foods manufactured and distributed in Canada.\textsuperscript{14} Canada’s nutrition labelling regulations provide information about the nutrient content of food in a standardized format, which facilitates product comparison at the point of purchase. The Nutrition Facts table provides information on energy (calories) and 13 nutrients, based on a stated serving size. The Nutrition Facts table must appear on the label in a prescribed manner. The Guide to Food Labelling and Advertising contains detailed information on the presentation of the Nutrition Facts table.\textsuperscript{15}

With few exceptions, almost all prepackaged multi-ingredient foods require an ingredient list in Canada. (See Appendix 1, “List of Ingredients,” for a more complete definition and explanation.) In general, ingredients must be listed in descending order of proportion by weight, as determined before they are combined to make the food.

The Nutrition Facts table and the ingredient list provide the most basic level of information to consumers about food constituents in the food product. The table and the list must be present before more detailed information about the product’s nutritional and potentially beneficial health properties can be communicated.

2.4.2 Nutrient Content Claims

Nutrient content claims are the simplest statement to make as they describe the amount (quantity) of nutrients in a food. The regulations prescribe the unit of measurement for each nutrient, the compositional criteria for each claim and any related additional labelling requirements. The reference amounts are derived from the average quantities of foods consumed at a single eating occasion. Nutrient content claims may be made only for nutrients for which recommended daily intakes (RDIs) have been established by the Institute of Medicine of the National Academies, Washington, DC. A minimum of 5% of the RDI per serving of stated reference size must be present before the vitamin or mineral may be subject to a “source” claim. The regulations define when descriptors such as “good source” and “excellent source” may be used for each nutrient.

In addition to statements identifying the amount of a nutrient found in a food, comparative nutrient content claims (e.g. “reduced,” “less,” “light”) based on a regulated standardized reference amount are allowed. Again, specific rules exist that dictate how or when a comparison can be made between similar foods. Typically, the content of energy or a nutrient must be altered by a minimum of 25% before it can be compared with a similar product. (See Guide to Food Labelling and Advertising for detailed information.\textsuperscript{16})


2.4.3 Quantitative Declaration of Non-Nutrients

Information on the amounts of nutrients or food constituents (i.e. non-nutrients) not permitted within the Nutrition Facts table may be displayed providing it appears on any part of the label other than within the Nutrition Facts table, and is declared, in grams per serving of stated size. Non-nutrients are other constituents of food that are not defined as nutrients, but are demonstrated or purported to have a favourable effect on health.\(^\text{17}\)

Examples of nutrients not permitted within the Nutrition Facts table include other minerals and individually named fatty acids or amino acids. Examples of non-nutrients not permitted in the Nutrition Facts table include isoflavones, lycopene and plant sterols. Quantitative declarations of the levels of non-nutrients and nutrients not included in the Nutrition Facts table provide food manufacturers with an opportunity to inform consumers about amounts of nutrients and other constituents of emerging importance. However, content claims such as “source of/high in/rich in” cannot be made. See Appendix 1, “Non-Nutrient Declarations,” for more details.

2.4.4 Nutrient Function Claims

Nutrient function claims are prescribed statements about the biological role or function of a nutrient required for maintenance of good health and normal growth and development. While nutrient function claims are a subset of function claims (see section 2.5.2), they have been available for use in Canada for years because the role of nutrients has been widely recognized in science. Quantitative information by serving size must also accompany the claim. Table 3 reproduces the list of acceptable nutrient function claims from the *Guide to Food Labelling and Advertising*. Other nutrient function claims may also be acceptable and will be evaluated by Health Canada on a case-by-case basis.

### Table 3  Summary of Acceptable Nutrient Function Claims (updated May 2009)\(^\text{18}\)

<table>
<thead>
<tr>
<th>NUTRIENT</th>
<th>ACCEPTABLE NUTRIENT FUNCTION CLAIMS(^\text{1})</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROTEIN</td>
<td>• helps build and repair body tissues</td>
</tr>
<tr>
<td></td>
<td>• helps build antibodies</td>
</tr>
<tr>
<td>FAT</td>
<td>• supplies energy</td>
</tr>
<tr>
<td></td>
<td>• aids in the absorption of fat-soluble vitamins</td>
</tr>
<tr>
<td>DHA</td>
<td>• 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(^\text{2})</td>
</tr>
<tr>
<td>ARA</td>
<td>• ARA, an omega-6 fatty acid, supports the normal physical development of the brain, eyes and nerves primarily in children under two years of age(^\text{2})</td>
</tr>
<tr>
<td>CARBOHYDRATE</td>
<td>• supplies energy</td>
</tr>
<tr>
<td></td>
<td>• assists in the utilization of fats</td>
</tr>
<tr>
<td>VITAMIN A</td>
<td>• aids normal bone and tooth development</td>
</tr>
<tr>
<td></td>
<td>• aids in the development and maintenance of night vision</td>
</tr>
<tr>
<td></td>
<td>• aids in maintaining the health of the skin and membranes</td>
</tr>
<tr>
<td>VITAMIN D</td>
<td>• factor in the formation and maintenance of bones and teeth</td>
</tr>
<tr>
<td></td>
<td>• enhances calcium and phosphorus absorption and utilization</td>
</tr>
<tr>
<td>VITAMIN E</td>
<td>• a dietary antioxidant</td>
</tr>
<tr>
<td></td>
<td>• a dietary antioxidant that protects the fat in body tissues from oxidation</td>
</tr>
<tr>
<td>VITAMIN C</td>
<td>• a factor in the development and maintenance of bones, cartilage, teeth and gums</td>
</tr>
<tr>
<td></td>
<td>• a dietary antioxidant</td>
</tr>
<tr>
<td></td>
<td>• a dietary antioxidant that significantly decreases the adverse effects of free radicals on normal physiological functions</td>
</tr>
<tr>
<td></td>
<td>• a dietary antioxidant that helps to reduce free radicals and lipid oxidation in body tissues</td>
</tr>
<tr>
<td>THIAMINE (VITAMIN B(_{1}))</td>
<td>• releases energy from carbohydrate</td>
</tr>
<tr>
<td></td>
<td>• aids normal growth</td>
</tr>
<tr>
<td>RIBOFLAVIN (VITAMIN B(_{2}))</td>
<td>• factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td>NIACIN</td>
<td>• aids in normal growth and development</td>
</tr>
<tr>
<td></td>
<td>• factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td>VITAMIN B(_{6})</td>
<td>• factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td>FOLATE</td>
<td>• aids in red blood cell formation</td>
</tr>
<tr>
<td></td>
<td>• a factor in normal early fetal development(^\text{3})</td>
</tr>
<tr>
<td></td>
<td>• a factor in the normal early development of the fetal brain and spinal cord(^\text{3})</td>
</tr>
<tr>
<td>VITAMIN B(_{12})</td>
<td>• aids in red blood cell formation</td>
</tr>
<tr>
<td>PANTOTHENIC ACID</td>
<td>• factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td>CALCIUM</td>
<td>• aids in the formation and maintenance of bones and teeth</td>
</tr>
<tr>
<td>PHOSPHORUS</td>
<td>• factor in the formation and maintenance of bones and teeth</td>
</tr>
<tr>
<td>MAGNESIUM</td>
<td>• factor in energy metabolism, tissue formation and bone development</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRON</th>
<th>• factor in red blood cell formation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZINC</td>
<td>• factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td>IODINE</td>
<td>• factor in the normal function of the thyroid gland</td>
</tr>
<tr>
<td>SELENIUM</td>
<td>• a dietary antioxidant involved in the formation of a protein that defends against oxidative stress</td>
</tr>
</tbody>
</table>

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

2Note that this claim is a change from the claim previously allowed for DHA. This claim is based on available scientific evidence indicating that the development of the brain, eyes and nerves in the human infant takes places very early starting in late pregnancy and up to two years of age. The Institute of Medicine in its 2005 report* stated that "The developing brain accumulates large amounts of DHA during the pre- and postnatal development and this accumulation continues throughout the first two years after birth." *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, DC: National Academies Press, 2005, pp. 444-45.

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

2.5 Food Health Claim Options

The classification and terminology of health claims in Canada has been evolving over the last few years. While all health claims must be truthful and based on science, the category of health claim determines the level of scientific substantiation required, the conditions of use and whether a regulatory amendment is necessary prior to its use. While the term “health claim” is not formally defined in food regulations in Canada, health claims are grouped into several categories: general health claims; function claims; disease risk reduction claims; and therapeutic claims.

Table 4 outlines the Canadian system for categorizing health claims and provides key features of each type of claim. The classification of claims with the current approach separates health claims into a “general” and a “specific” category. The specific health claims are further categorized into function claims, disease risk reduction claims, and therapeutic claims.
Table 4  Canadian Food Health Claims\(^{19}\)

<table>
<thead>
<tr>
<th>General Feature</th>
<th>General Health Claim</th>
<th>Function Claims</th>
<th>Disease Risk Reduction Claim</th>
<th>Therapeutic Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promote healthy eating and refer to dietary guidance. Do not refer to a specific health effect, disease or health condition.</td>
<td>Refer to a specific health effect, disease or health condition.</td>
<td>About maintenance of body functions necessary for maintenance of health/normal growth and development.</td>
<td>Link consumption of food or food constituents to a reduced risk of disease in context of total diet.(^{2})</td>
<td>Refer to the prevention, treatment, management, or mitigation of a disease, disorder, abnormal physical state or their symptoms.(^{2})</td>
</tr>
<tr>
<td>Type of Claim</td>
<td>Specific Feature</td>
<td>Nutrient Function(^{1})</td>
<td>Other Function</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Promote overall health, healthy eating or provide dietary guidance.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^{1}\) Nutrient function claims (see section 2.4.4) are a subset of function claims.

\(^{2}\) Regulatory amendments are required before these claims can be used to exempt claims from: a) provisions of the Act and Regulations pertaining to drugs; and b) provisions of the Act pertaining to Schedule A. Health Canada also requires a pre-market assessment.

Details regarding each type of claim and examples of the health claim statements are provided in sections 2.5.1 through 2.5.4.

The use of health claims may impact the legal status of foods and the way they are regulated. Certain health claims, if applied to foods, would cause the product to be deemed a drug in Canada, as drugs are defined according to their effect and how they are represented for use. A food product deemed to meet the definition of a drug would be subject to the drug-related sections (Part C) of the FDR. Therefore, to permit certain health claims, provisions have been included in the FDR (B.01.601) to exempt food products with these claims (e.g. disease risk reduction claims) from the regulations governing drugs, as well as from section 3 of the Act.

This ensures the continued and consistent application of the food regulations and standards for food products.\(^{20}\)

New claims and the conditions for their use can be added to the table in the Food and Drug Regulations (FDR: B.01.601) through regulatory amendments following a review of the submission and adoption of the amendments by the federal government. Any organization, including industry, academic, public health organizations or alliances among these types of organizations, may make submissions for new claims in this category. Regulatory amendment to permit the use of new health claims of this type is contingent on the submission of sufficient and acceptable scientific evidence to support the claimed effect in the dietary context.

### 2.5.1 General Health Claims

General health claims are broad statements that promote health through healthy eating or that provide dietary guidance. No specific regulations govern the use of general “healthy choice” claims on foods. However, like all claims, they are subject to subsection 5(1) of the Act: they must not be false, misleading or deceptive. Also, no standardized nutritional criteria have been established for foods to be able to carry these types of claims. However, the CFIA and Health Canada have jointly developed guidelines to support the appropriate use of these claims and limit misleading claims.\(^{21}\) Guidance is provided for a range of representations: advertising and educational material, third-party endorsements, logos and seals of approval, and statements related to healthy eating or dietary guidance.\(^{22}\)

### 2.5.2 Function Claims

Function claims link a food component to an essential function or biological role associated with normal growth and development or the maintenance of good health. In addition to nutrient function claims discussed in section 2.4.4, industry may pursue function claims for probiotic and other food constituents as they relate to maintaining or supporting body functions associated with the maintenance of good health or performance.

The manufacturer is responsible under the Act for ensuring that the claim is truthful and not misleading, and for meeting an acceptable level of substantiation based on scientific evidence. It is strongly recommended that industry obtain a letter of no objection for new function claims from Health Canada before marketing a product.

### 2.5.3 Disease Risk Reduction Claims

Disease risk reduction claims are statements that link a food or a food constituent to lowering the risk of developing a diet-related disease or condition (e.g. osteoporosis, cancer, hypertension) in the context of the total diet.\(^{23}\) These claims were previously referred to as

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diet-related health claims. They correspond to health claims in the table following B.01.603 in the Canadian FDR. These claims are allowed on food only where specifically permitted by the FDR. Specific claims for the following diet–health relationships are approved for use in Canada (as a result of regulatory amendments):

- 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
- maximal fermentable carbohydrates in gum, hard candy or breath-freshening products, and the reduced risk of dental caries.

### 2.5.4 Therapeutic Claims

Therapeutic health claims clearly move food into the definition of a drug because they describe the link between a diet, food or food constituent and the treatment or mitigation of a disease or health-related condition, or restoring, correcting or modifying body functions. Health Canada has approved blood cholesterol-lowering claims for certain food products with added plant sterols and for oat products. See Appendix 1, “Therapeutic Health Claims.”

Table 5 summarizes the food health claim requirements in Canada.

#### Table 5  Food Health Claim Requirements in Canada

<table>
<thead>
<tr>
<th>TYPE OF HEALTH CLAIM</th>
<th>MUST BE TRUTHFUL AND NOT MISLEADING</th>
<th>BRINGS FOOD UNDER DRUG REGULATIONS (UNLESS SPECIFICALLY PERMITTED IN FOOD REGULATIONS)</th>
<th>PRE-MARKET ASSESSMENT REQUIRED</th>
<th>REGULATORY AMENDMENT REQUIRED</th>
<th>GUIDANCE DOCUMENT PROVIDED</th>
<th>CONDITIONS FOR TYPE OF FOOD THAT CAN CARRY CLAIMS SET OUT IN FDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>yes (on specific topics)</td>
<td>no</td>
</tr>
<tr>
<td>Function</td>
<td>yes</td>
<td>no</td>
<td>no (strongly recommended)</td>
<td>no</td>
<td>yes</td>
<td>yes (guidance)</td>
</tr>
<tr>
<td>Nutrient function</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>yes (regulated)</td>
</tr>
<tr>
<td>Disease risk reduction</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Therapeutic</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

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2.6 Natural Health Products in Food Form

Natural health products (NHPs) became a subcategory of drugs with the coming into force of the Natural Health Products Regulations (2004). The definition of NHPs, like the definition of drugs, does not explicitly exclude foods or food constituents. Unlike drugs, the definition for NHPs expands on the term “modifying organic function” so that it encompasses uses associated with the maintenance and promotion of health not generally recognized as a primary purpose of drugs. However, like drugs, NHPs are required to provide information on dosage and use. As a result, some products in food form have been regulated under the NHP framework, which allowed the use of a disease risk reduction or therapeutic health claim on the label.

NHPs in food form are subject to the NHP regulations and required to seek manufacturing site and product licences. However, these products are not subject to any of the food-related regulations and standards, including those aimed at protecting health and safety. Recognizing the difficulties with food-like products being regulated as NHPs, in 2009 Health Canada released the guidance document *Classification of Products at the Food–Natural Health Products Interface: Products in Food Formats.*[^25] The document provides criteria by which to exclude food-like products from the purview of the NHP regulations to ensure that such products are safe if consumed as foods and their representation is consistent with that for foods.

2.7 Food Additives

Companies that would like to introduce new food constituents to the industry may wish to consider the food additive route (see Appendix 1, “Food Additive”). Food additives must be listed in Part B, Division 16 of the FDR to be used. The regulations include 15 tables with 250 additive listings. Food processors must use additives as prescribed in the FDR, and not exceed the maximum amounts specified. Food additives not listed in the FDR must be assessed for safety and added to the approved list before being marketed. New uses of currently listed additives must also be approved before marketing, through amendment of an existing listing.

2.8 Foods with Added Vitamins and Minerals (Fortified Foods)

The addition of vitamins and minerals to food in Canada is controlled by the Food and Drug Regulations (Part D). The Regulations specify which foods may contain added vitamins and mineral nutrients, which vitamins and mineral nutrients may be added, as well as their levels in the food.[^26]

The current Food and Drug Regulations permit the addition of vitamins and minerals to foods to:

- replace vitamins and mineral nutrients lost in the manufacturing process;
- act as a public health intervention to prevent or correct demonstrated deficiencies of vitamins or mineral nutrients in the population or a segment of it;
- ensure the nutritional equivalence of substitute foods; or


• ensure the appropriate vitamin and mineral nutrient composition of foods for special dietary purposes.

In 1998, Health Canada initiated a review of the policy to examine how to support public health goals and continue to prevent harm to the health of consumers while acknowledging both the interests of the food industry to have greater flexibility to develop new food products and the desire of consumers for broader choice of fortified foods. The review included a series of consultations with health and disease interest groups, health professionals, consumers, industry, academia and government bodies, as well as a detailed risk assessment using statistical modelling of vitamin and mineral nutrient intakes. A draft policy was proposed in 2005, which was expected to continue to protect consumers while addressing industry concerns that the present policy is restrictive and inhibits innovation.

The proposed policy (2005) retained current fortification practices to prevent and correct nutritional problems, such as requiring the addition of vitamin D to milk to combat the childhood disease of rickets and the addition of folic acid to flour to reduce certain birth defects. As well, fortification of foods to restore vitamins and minerals lost through processing would continue, current requirements for addition of vitamins and mineral nutrients to meal replacements and nutritional supplements would be updated based on recent scientific evidence, and provision would be made for more special-purpose foods and for vitamin and mineral nutrient addition to more specific foods. The proposed policy also considered a new regulatory framework for the addition of vitamins and mineral nutrients to more foods at the discretion of the manufacturer (discretionary or voluntary addition or fortification) without a specific nutritional rationale.

Currently, Health Canada is proceeding with the amendments pertaining to foods already sold under the Interim Marketing Authorization (IMA) process and will be prioritizing other items in the 2005 draft policy. However, at this time Health Canada has decided not to proceed with the implementation of “discretionary” additions of vitamins and minerals to food.

Manufacturers can request an amendment to the Food and Drug Regulations to provide for the addition of vitamins, minerals or amino acids to foods where not currently permitted. In this regard, manufacturers can consider the IMA process (section B.01.056 FDR) if they have sufficient data to support a rationale as required for a regulatory amendment or they can request a Temporary Marketing Authorization Letter (TMAL) (section B.01.054 FDR) if they need to generate additional information to support a rationale for a regulatory amendment.

2.9 Novel Foods

The Food Directorate of Health Canada conducts novel food safety assessments. Division 28 of Part B of the FDR sets out the definition of novel foods (B.28.001) as well as the procedures for pre-market notification (B.28.002) and the responsibilities of the Food Directorate in responding to a pre-market notification (B.28.003). (See Appendix 1, “Novel Food” and “Novel Fibre” [which has specific additional regulatory requirements].) See Appendix 2 for Guidelines for the Safety Assessment of Novel Foods, June 2006, and Guideline Concerning the Safety and

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Physiological Effects of Novel Fibre Sources and Food Products Containing Them, November 1997.

Under the FDR, novel food (and novel fibre) marketing is prohibited without pre-market notification to Health Canada and approval from Health Canada. Marketing approval involves Health Canada conducting a pre-market assessment of the safety of the novel food for consumption, based on the information provided by the applicant. If the provided information is not sufficient to establish safety of the novel food, Health Canada requires that the applicant provide further information regarding the novel food.

A pre-market notification must include the following:

(a) The common name under which the novel food will be sold;

(b) The name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;

(c) A description of the novel food, together with:
   (i) Information respecting its development,
   (ii) Details of how it is manufactured, prepared, preserved, packaged and stored,
   (iii) Details of the major change, if any,
   (iv) Information respecting its intended use and directions for its preparation,
   (v) Information respecting history of food use in a country outside Canada, if applicable, and
   (vi) Information relied on to establish that the novel food is safe for consumption;

(d) Information respecting the estimated levels of consumption by consumers of the novel food;

(e) The text of all labels to be used in connection with the novel food.\(^{28}\)

The novel food section of the FDR specifies that Health Canada will review a pre-market notification within 45 days of receipt of the application. If additional information is required, the regulations specify that, within 90 days of its receipt, Health Canada will review and assess this additional information and, “if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.”\(^{29}\) The manufacturer must receive a letter of no objection before the novel food may be marketed.

### 2.10 Pre-Market Approval

In Canada, new disease risk reduction claims and therapeutic claims are subject to pre-market approval. However, all health claims must be substantiated before they appear on food product labels and in advertising. As has been indicated in previous sections, in the case of 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. Also as indicated previously, novel foods and food additives as well as new uses of approved food additives


\(^{29}\) Division 28 of the Food and Drug Regulations, Appendix 1.
require pre-market approval in Canada. To support efficiency, all pre-market approval submissions are to be made through a single point of entry, Health Canada’s Submission Management and Information Unit (SMIU).

Table 6 provides a summary of pre-market approval information for novel foods, food additives and new health claims in Canada. It has been adapted from an AAFC information document that was released in March 2010.

Table 6  Summary of Pre-Market Approval Requirements for Novel Foods, Food Additives and New Health Claims in Canada

<table>
<thead>
<tr>
<th>PRODUCT CATEGORY OR TYPE OF CLAIM</th>
<th>PRE-MARKET APPROVAL</th>
<th>SCIENTIFIC SUBSTANTIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novel Foods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Foods resulting from a process not previously used for food</td>
<td>• Mandatory pre-market notification for all novel foods</td>
<td>• Consult Guidelines for the Safety Assessment of Novel Foods</td>
</tr>
<tr>
<td>• Products that do not have a history of safe use as a food</td>
<td>• Health Canada maintains a list of recent approvals</td>
<td>o assists in preparing a novel food notification and explains what information is considered sufficient for a safety assessment</td>
</tr>
<tr>
<td>• Foods that have been modified by genetic manipulation; also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods</td>
<td></td>
<td>o applies to all novel foods derived from plant or microbial sources, whether whole foods, food products or food ingredients</td>
</tr>
<tr>
<td>Food Additives</td>
<td>Required for:</td>
<td></td>
</tr>
<tr>
<td>• 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)</td>
<td>• new food additive not already regulated in FDR</td>
<td>• Consult A Guide for the Preparation of Submissions on Food Additives</td>
</tr>
<tr>
<td></td>
<td>• new uses of approved food additives</td>
<td>• A Submission Checklist is also available</td>
</tr>
<tr>
<td>All Health Claims</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 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</td>
<td>• Required for new disease risk reduction claims and claims that are therapeutic in nature</td>
<td>• For a health claim to be considered not misleading, prior to its use there should be scientific evidence that substantiates the claimed health effect</td>
</tr>
<tr>
<td></td>
<td>• Recommended for other new claims</td>
<td>• The Guidance Document for Preparing a Submission for Food Health Claims provides guidance on how to prepare a submission</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Function Claims</th>
<th>Nutrient Function Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 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</td>
<td>• A subset of function claims</td>
</tr>
<tr>
<td>• Based on the role that the food or the food constituent plays when consumed at levels consistent with normal dietary patterns</td>
<td>• 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</td>
</tr>
<tr>
<td>• Recommended for new function claims</td>
<td>• Formerly known as biological role claims</td>
</tr>
<tr>
<td>• Evidence should be available upon request</td>
<td>• List of acceptable nutrient function claims and conditions for their use is maintained in Chapter 8 of the Guide to Food Labelling and Advertising (section 8.6)</td>
</tr>
<tr>
<td>• List of acceptable claims (those that have been reviewed by Health Canada) and conditions for their use is maintained in Chapter 8 of the Guide to Food Labelling and Advertising (section 8.5)</td>
<td>• Two general claims can be made for any nutrient when conditions for their use are followed</td>
</tr>
<tr>
<td>• Consult the Guidance Document for Preparing a Submission for Food Health Claims</td>
<td>• Such claims may be made only for the energy value or recognized nutrients in a food</td>
</tr>
<tr>
<td>• Claims should be supported by acceptable standards of evidence</td>
<td>• New nutrient function claims will be considered only for nutrients with established recommended intakes and if the function reflects consensus among authoritative scientific bodies</td>
</tr>
</tbody>
</table>

- May be stated explicitly with words, or implied through symbols, graphics, logos or other means such as a name, trademark or seal of approval for review by the Food Directorate of Health Canada for all new claims, other than for nutrient function claims.
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)

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

Therapeutic Claims
- Statements that link a food or food constituent to treatment or mitigation of a disease or health-related condition; or restoring/correcting a body function

<table>
<thead>
<tr>
<th>Probiotic Claims</th>
<th>Disease Risk Reduction Claims</th>
<th>Therapeutic Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Recommended for new probiotic claims</td>
<td>• Required if not on the list of permitted claims</td>
<td>• Must demonstrate that it is scientifically substantiated</td>
</tr>
<tr>
<td>• 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 Guide to Food Labelling and Advertising (section 8.7)</td>
<td>• Regulatory amendment is needed to exempt the product from section 3 of the FDA, 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</td>
<td>• Follow the Guidance Document for Preparing a Submission for Food Health Claims</td>
</tr>
<tr>
<td>• List of acceptable strain-specific claims will be maintained by Health Canada as reviewed and accepted</td>
<td>• Regulatory amendment is also needed to confirm that the product is exempt from requirements applicable to drugs</td>
<td>o systematic scientific literature review with emphasis on randomized clinical trials and observational studies in humans</td>
</tr>
<tr>
<td>• General information about evidence requirements applicable to health claims of all types, including function claims, also apply to probiotic claims</td>
<td>• Permitted claims can be used without seeking pre-market approval, provided all other requirements are met</td>
<td>o the amount required to achieve the intended effect</td>
</tr>
<tr>
<td>• Consult the Guidance Document— The Use of Probiotic Microorganisms in Food</td>
<td>• 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 (section 8.4)</td>
<td>o the likelihood of consuming adequate amounts based on Canadian consumption patterns</td>
</tr>
<tr>
<td>o sets out the conditions under which health claims about probiotics would be considered acceptable</td>
<td></td>
<td>o safety data</td>
</tr>
<tr>
<td>o provides guidance on the safety, quality (stability) and labelling aspects of such food products</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.11 Health Claims in Major Export Markets

The decision model is meant to be used by Canadian food companies and industry associations interested in pursuing a nutrient and/or health claim for a product to be marketed in Canada. Many Canadian food manufacturers sell into export markets. Canadian products must comply with the export markets’ regulations governing all aspects of packaging and labelling, health claims, non-nutrient declarations and nutrient claims.

It is beyond the scope of the Roadmap to provide a comprehensive analysis of the regulatory frameworks for health claims in other jurisdictions. However, Appendix 3 contains two summary tables of information that will be useful to those considering exporting products to Australia/New Zealand, European Union, Japan and the United States.

Table A3.1 outlines the classification of health claims in key export markets in Australia/New Zealand, Canada, European Union, Japan and the United States. Table A3.2 provides a summary of the status of disease risk reduction health claims in Australia/New Zealand, Canada, European Union, Japan and the United States. Information from the Canadian system is provided for comparison in both tables. Readers who require more detailed information on the regulatory frameworks for health claims, novel foods, addition of vitamins and minerals to foods, and food additives, and the agencies responsible in the four other countries, are referred to other publications.31,32

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3 Introduction to the Health Claim Decision Model for Canadian Food Products

The decision model builds on previous work with Wellness West\textsuperscript{33} and the resource Pathways to Market (the Commercialization Roadmap).\textsuperscript{34} 

The decision model is designed for use by a business that already has at least one food product being sold in the marketplace. It focuses on a business’s activities and decisions related to pursuing Canadian nutrient and/or health claims, as they are impacted by regulatory requirements. Businesses should recognize that the overall process for new product development includes strategic activities and decisions beyond the scope of the Roadmap.

3.1 Differences Between Government Regulatory Agency and Business Perspectives on Health Claims

Canadian government regulatory agencies have significant scientific requirements for health claim substantiation. This is also the case in most other developed countries. Scientific requirements for health claim substantiation address three main areas: efficacy, quality assurance and safety. All three areas are important.

The decision model was designed to help a business comply with the government’s requirements for health claim substantiation, and also address its need to be market-oriented and profit-driven.

3.2 The Fundamental Decisions Relating to Nutrient Claims and Health Claims

For most companies, the key decisions regarding nutrient and health claims are best approached in the sequential order presented in Figure 1.

- The flow chart identifies six fundamental decisions regarding the use of a nutrient and/or health claim in Canada:
  1. whether or not there is a health relationship with respect to the food (or ingredient or component) that could justify the use of a nutrient or health claim, in the packaging and marketing of the product;
  2. whether Health Canada would consider the product an NHP and therefore it would come under the NHP regulatory stream, or if the material would be considered a food regulated by the FDR;

\textsuperscript{33} Wellness West is a Western Canadian collaboration of provincial and federal government departments and agencies dedicated to developing an economically viable functional foods and natural health products industry in Canada.

3. whether or not there is any aspect of the food material’s history, composition or production process that would cause it to be a novel food or novel fibre in Canada;
4. whether or not the food product should consider Canada’s regulations that deal with the addition of vitamins and minerals to foods;
5. whether or not the food product should consider Canada’s food additive regulations;
6. whether individual or a combination of nutrient claims and health claims should be pursued.

- There are several exit points in the decision-making process leading to a variety of suitable strategies that do not include the use of a nutrient or health claim.

### 3.3 Information Requirements for Making Decisions

Although the decisions listed above are straightforward, the activities that need to be performed and the analysis of results from these activities are complex and time consuming. The decision model is designed to organize these activities, the review of the findings and the decisions that follow into a logical step-by-step process that can be managed and controlled. This greatly reduces the risk of making suboptimal or poorly timed decisions.

The fully developed decision model (section 4) is a comprehensive series of activity lists and decision steps that cover many pages. The Overview shown in section 3.7 (Table 7) introduces the full model and explains how it is structured and how it is to be used.

As shown in Figure 1 and even more clearly in Table 1, the decision model incorporates four separate Steps and four Tracks.

The Overview of the decision model in section 3.7 (Table 7) further demonstrates that within each Step, and within each of the four parallel Tracks, there are specific activities that are appropriate. This sequence of Steps and activities has typically proven effective, based on experiences of working with companies that have gone through the process. However, the order of some of the activities may vary, given the specific circumstances of each individual situation.

Specific activities to take place within each Step are listed and organized under one of the four Tracks. These activities involve researching issues and accessing information by reviewing documents, interviewing knowledgeable individuals, etc.

The work in all four Tracks will occur before making any decision at the end of each Step.

### 3.4 The Decision-Making Process

As shown in section 3.7 (Table 7), a review and decision process is required at the end of each Step. The review and analysis of the Step’s activities and results are where companies or industry associations make decisions to pursue a claim further, or not.

At the end of each Step, the decision model outlines the different decisions that can occur. Companies or industry associations are required to develop specific criteria that will help them make an informed decision at the end of each Step. This Go/No Go decision cannot be made until all the research and information-gathering activities for that Step have been completed, in all four Tracks, and the results analyzed.
The criteria are then used to decide if:

- the appropriate regulatory/claim strategy has been identified for the product and business;
- further investigations into the regulations and claim options should continue (i.e. proceed to the next Step);
- a challenge exists that shows previous work needs to be redone (i.e. the review of information from the current Step indicates the need to revisit one or more of the previous Steps to revise the work, get new or more detailed information, and review the decision). In some cases, it may make sense to redo the current Step with more information. In others, it may be advisable to go back one or more Steps to figure out how to overcome the problem that has been identified; or
- further investigations should be halted and the business will not proceed with a nutrient or health claim for the product under consideration. The decision to stop pursuing the development of a claim is appropriate where the probability of claim approval, or of success in the market, is not sufficient to justify investing time and money in the next Step.

3.5 Decision Criteria

The decision model uses criteria to help make Go/No Go decisions at the end of each Step. The specific criteria that help make sound decisions vary widely. They depend on the specific product/market opportunity (e.g. health benefit, regulatory framework, product form, target user, distribution channel) that is being considered. From the business’s perspective, the most important criteria are ones that reflect either the:

- greatest financial risk (whether in direct costs, such as the investment in clinical trials to confirm efficacy, or in indirect costs, such as damage to reputation or brand if the product fails and diminishes the sales of other products already in the marketplace);
- greatest uncertainties (i.e. those aspects for which there is the least information, such as a new bioactive compound for which no history-of-use information is available); or
- profitability in the longer term as well as short term (e.g. if the payoff is significant, more risk may be acceptable than if the payoff is modest).

The review and analysis required by the decision model to make the Go/No Go decision at the end of each Step is the key to reducing risk. By formalizing this decision-making process, companies can reduce the chance of spending money on activities that should not be done. These unnecessary activities can be avoided if the appropriate Go/No Go decision is to halt work on pursuing a nutrient or health claim.

The process and criteria should aim to ensure that if the final decision is to be No Go, the decision is made as early as possible to avoid wasting time and money. Another type of risk is not pursuing a new claim that holds potential. A thorough process, as provided by the decision model, is required to reduce both types of risk. The criteria appropriate for use in making this Go/No Go decision are those that indicate whether it is wise to spend the time and resources
on the next Step. This Go/No Go decision is not about whether to proceed all the way in pursuing a claim, but specifically whether to proceed and expend the resources required to conduct the work and activities in the next Step.

Two types of criteria need to be developed to analyze the Step results and make the Go/No Go decision. The first is a checklist of veto criteria (Yes/No criteria), which if not met, prevent the project from being acceptable or cause a decision leading to exit of the model. The second type is comparative criteria.

3.5.1 Veto Criteria

Examples of these veto criteria include:

- acceptable strategic fit with the company’s core business strategy;
- identifiable market;
- availability of sufficient scientific evidence to establish the health benefit linkage to the product for regulatory approval;
- reasonable likelihood of profit; and
- acceptable levels of risk.

If a veto criterion is not met—regardless of whether other aspects look favourable—the claim should not be pursued (i.e. if the following criterion is not met, “Availability of sufficient scientific evidence to establish the health benefit linkage to the product, for regulatory approval,” development risks and costs are not justified).

3.5.2 Comparative Criteria

The comparative criteria reflect the ability of each option to add to the company or industry association’s competitive advantage. Each one of the comparative criteria can be met to varying degrees, but nutrient or health claim options that meet these criteria to the greatest degree have the most potential for success. Comparative criteria are specific to the option being evaluated.

To deal with the comparative criteria systematically and efficiently, they can be listed in a matrix, typically a spreadsheet. The product/regulatory framework/market option is assessed against each criterion, one at a time. They are usually scored on a simple 1 to 10 system with 10, the highest score, indicating the most favourable results. The matrix is structured to provide total scores or averages as may be required by the company or industry association. Appendix 4 contains a sample evaluation matrix.

Several reviewers who are knowledgeable about the product, regulations, market and business should score the nutrient or health claim option against each criterion and total the results. The total score must meet or exceed a predetermined threshold in order for the Step Decision to be a “Go” (i.e. to proceed to the next Step). Similarly, if the total score is below a predetermined threshold, the decision might be “No Go,” the project is halted and no claim option is pursued.

If the score is somewhere in between these two cut-off points, the decision may be to try a new strategy (such as targeting a different nutrient or health claim), and then repeat some of the activities in this Step (or a previous Step). Then the Go/No Go decision should again be made.
3.6 Financial Analysis for Sound Decisions

The financial impact of a nutrient and/or health claim must be the primary basis for business decisions at the end of each Step. Three key types of financial analysis are required, as well as a number of specific considerations:

1. **Risk analysis:** Can the risks be managed at an acceptable level? The financial impact of a new health claim product failure can be very serious.

   The decision model is especially valuable to those who need to manage financial risks. By considering the risks for each of the Tracks at the end of each Step, a business can halt investment in pursuing a health claim that is too risky before it has invested too much money. The key is to identify when to abandon a health claim option at the earliest possible Step, so that minimal investment is wasted.

2. **Potential profits:** Is there a realistic probability of sufficient profits to justify the risks?

3. **Ability to finance:** Can the whole nutrient or health claim process be financed? For many smaller companies, financing is a great challenge—even when profits and risk appear acceptable (e.g. a food health claim that requires a full set of clinical trials to confirm efficacy and safety can be well beyond the resources of many small companies).

3.7 The Health Claim Decision Model in Overview Format

Table 7, displayed on the following pages, is the *Decision Model for Canadian Food Products: Overview*. It contains the four Steps and four activity Tracks that were described earlier. For each of the activity tracks, the set of activities appropriate to the Step is described in general terms. The purpose of these activities is also outlined. At the end of each Step in the diagram the Step’s Go/No Go decision options are laid out.

While the overview version of the decision model is not sufficiently detailed to be of use in guiding a company or industry association through the process of deciding which (if any) nutrient and/or health claim options to pursue, it does provide insight to the processes used within the model and the results that can be expected. The full version of the model, developed in section 4, is formatted to be directly usable by a business considering a Canadian nutrient and/or health claim strategy.
### Table 7  Health Claim Decision Model for Canadian Food Products: Overview

<table>
<thead>
<tr>
<th>Step 1: Nutrient/Health Claim Potential—Preliminary Review</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Track</strong></td>
</tr>
<tr>
<td>Purpose is to determine which regulations apply to the product of interest and, in concert with results of other Tracks, select (or prioritize) the regulatory streams with the most market potential.</td>
</tr>
<tr>
<td>Product/Regulatory options: • Natural health product • Food/food ingredient • Food additive • Food with added vitamins and minerals • Novel food • Novel fibre</td>
</tr>
<tr>
<td>Nutrient claim options: • Nutrient content • Non-nutrient declaration • Nutrient function</td>
</tr>
<tr>
<td>Health claim options: • General • Specific o Function o Disease risk reduction o Therapeutic</td>
</tr>
<tr>
<td>Note: If export markets are being considered, each country’s regulatory framework must be investigated.</td>
</tr>
<tr>
<td>1) Potential for a claim: Proceed to Step 2</td>
</tr>
<tr>
<td>2) Uncertain potential for non-nutrient declaration, nutrient and/or health claims and/or NHP claim: Redo Current Step</td>
</tr>
<tr>
<td>3) No potential for any non-nutrient declaration, nutrient and/or food health claim or NHP claim: Exit Model</td>
</tr>
</tbody>
</table>
**Step 2: Food or NHP Regulatory Stream Assessment**

<table>
<thead>
<tr>
<th>Regulatory Track</th>
<th>Scientific Track</th>
<th>Market Track</th>
<th>Business Planning Track</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Purpose is to gain an understanding of the breadth and depth of scientific information available to support an NHP submission or designation of the target material as a food. Activities concentrate on assessing the intended use, product form and potential claim of ingredient or bioactive under review, including an extensive review of product quality, safety and efficacy. This is an in-depth investigation into the body of knowledge that exists for the target materials.</td>
<td>Purpose is to create a preliminary estimate of the size and attractiveness of each option (i.e. NHP and food). These market snapshots are matched with the output of the Scientific and Regulatory Tracks to demonstrate the relative attractiveness of each product/regulatory framework/market combination. The key analysis compares the NHP option to the alternative nutrient and/or health claim option. Activities are focused on market research to identify potential target market segments for each product/regulatory framework/market option. Each segment’s market size and competitive position (for the material of interest if it was to be manufactured and distributed as an NHP, and alternatively, as a food product) are researched. Specific attention is given to assessing the alternative product form characteristics for each market segment.</td>
<td>Purpose is to create a framework to compare each option to the resource requirements for the NHP/regulatory framework/distribution channel option versus the food product/food regulations/distribution channel option. Activities are focused on assessing the fit of: 1) an NHP manufacturing/distribution channel business model; versus 2) a food product manufacturing/distribution business model into the existing business strategy.</td>
</tr>
<tr>
<td><strong>Activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Purpose is to identify if target material is an NHP or a food additive, food ingredient or food:  
- If NHP, determine activities and information required to comply with NHP regulations and related guidance documents.  
- If clearly determined to be a food, move to next Step.  
- If determination is unclear, assess the specific criteria that Health Canada uses to determine whether the material of interest will be accepted as an NHP or if it will be classified as a food/food ingredient.  
- If still unclear, contact Health Canada.  
Activities are focused on reviewing definitions and requirements of NHP regulations with specific attention to policy/guidance documents from Health Canada that relate to food regulations. | | |

**Step 2 Go/No Go Decision Options:**

1) NHP: Proceed as NHP: (1) Initiate NHP process (2) Exit Model
2) Food: Proceed to Step 3
3) NHP/Food status uncertain: Redo Current or Previous Step
4) No non-nutrient declaration, nutrient and/or health claim: Exit Model
### Step 3: Assessment of Status as Novel Food, Food with Added Vitamins and Minerals, and Food Additive

<table>
<thead>
<tr>
<th>Regulatory Track</th>
<th>Scientific Track</th>
<th>Market Track</th>
<th>Business Planning Track</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purposes:</strong></td>
<td><strong>Purposes:</strong></td>
<td><strong>Purpose is to create estimates of the size and attractiveness of each market option. These market snapshots are matched with the output of the Scientific and Regulatory Tracks to demonstrate the relative attractiveness of pursuing:</strong></td>
<td><strong>Purposes:</strong></td>
</tr>
<tr>
<td>1. Whether or not any of the novel food or novel fibre regulations apply.</td>
<td>1. Evaluate whether or not the food material is a novel food. If a novel food, the review will also identify any gaps in information required to meet the novel food regulations and guidelines in order to complete a submission to Health Canada.</td>
<td>the novel food/novel fibre regulatory framework;</td>
<td>1. To create a framework to compare the option to the resource outlay requirements for the novel food regulatory framework vs. other possible options that will not require the novel food approval.</td>
</tr>
<tr>
<td>2. Whether or not any of the food with added vitamins and minerals regulations apply.</td>
<td>2. Identify gaps in the available evidence needed to support the approval of a food with added vitamins or minerals.</td>
<td>food with added vitamins and minerals applications and regulations; or</td>
<td>2. To create the business case that will guide the pursuit of a food with added vitamins and minerals or a food additive R&amp;D/manufacturing/distribution strategy for the business.</td>
</tr>
<tr>
<td>3. Whether or not any of the food additive regulations apply.</td>
<td>3. Determine the level of scientific evidence available and identify information gaps so that a food additive petition can be submitted.</td>
<td>the food additive submission process.</td>
<td></td>
</tr>
<tr>
<td><strong>Activities are focused on the review, interpretation and understanding of:</strong></td>
<td>4. In combination with the output of the Regulatory Track, develop a research plan to address any data shortages to support the food additive submission.</td>
<td><strong>Activities are focused on:</strong></td>
<td><strong>Activities are focused on:</strong></td>
</tr>
<tr>
<td>• Part B Division 28 of the Food and Drug Regulations (Novel Food Regulations);</td>
<td>Activities create a comprehensive review of evidence related to the food ingredient or bioactive, for both the raw material and finished product. This includes evaluating history of use; dietary exposure; nutritional, toxicological and microbiological safety; genetic history; manufacture; packaging; and intended use.</td>
<td>• assessing the company or industry association’s ability to comply and cope with the novel food pre-market notification process; and assessing the fit of the novel food, food with added vitamins and minerals, or food additive manufacturing/testing/distribution strategy into the existing business strategy.</td>
<td>• assessing the company or industry association’s ability to comply and cope with the novel food pre-market notification process; and assessing the fit of the novel food, food with added vitamins and minerals, or food additive manufacturing/testing/distribution strategy into the existing business strategy.</td>
</tr>
<tr>
<td>• Part B Division 16 (Additives);</td>
<td>Activities for food with added vitamins and minerals concentrate on reviewing manufacturing process and controls, safety (allergenicity, toxicity, chemical and nutritional) and bioactivity of the vitamin or mineral of interest in specific foods.</td>
<td><strong>Activities are focused on:</strong></td>
<td></td>
</tr>
<tr>
<td>• Part D (Vitamins, Minerals and Amino Acids); and</td>
<td>Activities for food with added vitamins and minerals focus on reviewing and evaluating information regarding the composition; methods of manufacture and testing; chemical and physical properties; technical effects in food; residue limits; and safety of the food additive under conditions of intended use. Will also require information on any potential health</td>
<td>• assessing the company or industry association’s ability to comply and cope with the novel food pre-market notification process; and assessing the fit of the novel food, food with added vitamins and minerals, or food additive manufacturing/testing/distribution strategy into the existing business strategy.</td>
<td></td>
</tr>
<tr>
<td>• guidance documents from Health Canada that relate to the definition and safety assessment of novel foods, foods with added vitamins and minerals, and food additives.</td>
<td>Activities for food additives focus on reviewing and evaluating information regarding the composition; methods of manufacture and testing; chemical and physical properties; technical effects in food; residue limits; and safety of the food additive under conditions of intended use. Will also require information on any potential health</td>
<td></td>
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</tr>
</tbody>
</table>
benefits associated with its consumption.

<table>
<thead>
<tr>
<th>Step 3 Go/No Go Decision Options:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Novel fibre with potential for nutrient claim: Proceed to Step 4</td>
</tr>
<tr>
<td>2) Novel food with or without potential as a food with added vitamins and minerals, with potential for non-nutrient declaration, nutrient claim and/or health claim: Proceed to Step 4</td>
</tr>
<tr>
<td>3) Not novel, food with added vitamins and minerals with potential for non-nutrient declaration, nutrient claim and/or health claim: Proceed to Step 4</td>
</tr>
<tr>
<td>4) Not novel with potential for non-nutrient declaration, nutrient claim and/or health claim: Proceed to Step 4</td>
</tr>
<tr>
<td>5) Potential as a food additive: (1) Pursue food additive submission process; (2) Exit Model</td>
</tr>
<tr>
<td>6) Status as novel, food with added vitamins and minerals, or food additive uncertain: Redo Current or Previous Step</td>
</tr>
<tr>
<td>7) No non-nutrient declaration, nutrient claim or health claim: Exit Model</td>
</tr>
</tbody>
</table>
### Step 4: Nutrient Claim and Food Health Claim Option Assessment

<table>
<thead>
<tr>
<th>Regulatory Track</th>
<th>Scientific Track</th>
<th>Market Track</th>
<th>Business Planning Track</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Purpose is to determine the breadth and depth of scientific information available and identify gaps (if any) to be filled in order to substantiate the desired nutrient and/or health claim.</td>
<td>Purpose is to create detailed estimates of the size and attractiveness of each product/regulatory framework/market option.</td>
<td>Purpose is to create a framework to compare the option to the resource outlay requirements for each product/regulatory framework/market combination.</td>
</tr>
<tr>
<td><strong>Nutrient claim options:</strong></td>
<td>If the output of the Regulatory Track determines that a new food health claim application is required, a research plan is developed to address any data shortages.</td>
<td>The impact of using each type of health claim on sales and market share estimates needs to be assessed individually. These market snapshots are matched with the output of the Scientific and Regulatory Tracks to demonstrate relative attractiveness of each product/regulatory framework/market option.</td>
<td>Less desirable options are systematically eliminated and more desirable options area advanced for more in-depth study.</td>
</tr>
<tr>
<td>• nutrient content</td>
<td>Activities specifically focus on evaluation of product manufacture and process controls for both raw bioactive and finished product, and product quality, safety and efficacy as it relates to the type of nutrient and/or health claim being proposed.</td>
<td>Activities are focused on market research to identify potential customers, market size and high-volume user groups for each product/regulatory framework/market option being considered. For ingredients, specific attention is given to assessing the alternative product form characteristics for each application by food processor customers.</td>
<td>Ultimately, the purpose is to create new product development plans, business plans and other management planning/monitoring tools that will guide the pursuit of a food ingredient or a food R&amp;D/manufacturing/distribution strategy for the business.</td>
</tr>
<tr>
<td>• non-nutrient declaration</td>
<td>This is an in-depth investigation into the body of knowledge that exists for the target food material.</td>
<td>Need to identify and substantiate:</td>
<td></td>
</tr>
<tr>
<td>• nutrient function</td>
<td></td>
<td>• food and health or disease relationship and disease risk;</td>
<td></td>
</tr>
<tr>
<td><strong>Health claim options:</strong></td>
<td></td>
<td>• biomarkers in the causal relationship;</td>
<td></td>
</tr>
<tr>
<td>• general</td>
<td></td>
<td>• history of use;</td>
<td></td>
</tr>
<tr>
<td>• specific</td>
<td></td>
<td>• safety (allergenicity, toxicity, chemical and nutritional);</td>
<td></td>
</tr>
<tr>
<td>o function</td>
<td></td>
<td>• intended use and product applications;</td>
<td></td>
</tr>
<tr>
<td>o disease risk reduction</td>
<td></td>
<td>• dietary use and product applications;</td>
<td></td>
</tr>
<tr>
<td>o therapeutic</td>
<td></td>
<td>• product quality.</td>
<td></td>
</tr>
<tr>
<td><strong>Activities:</strong></td>
<td>Human clinical trials using the finished product of interest are absolutely necessary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After addressing regulatory impact of the relevant Food and Drugs Act and Food and Drug Regulations for a specific food form, proponents are ready to focus on the specific regulations, guidelines and policies impacting the approval of a nutrient/health claim for a food or food ingredient.</td>
<td></td>
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</tbody>
</table>

### Step 4 Go/No Go Decision Options:

1. Food, food ingredient or food with added vitamins and minerals with selected nutrient claim: Pursue Nutrient Claim Process
2. Food, food ingredient or food with added vitamins and minerals with selected food health claim: Pursue Health Claim Submission
3. Optimal non-nutrient declaration/nutrient claim/health claim strategy not clear: Redo Current or a Previous Step
4. Food, food ingredient or food with added vitamins and minerals with no non-nutrient declaration, nutrient claim and/or health claim: Exit Model
4 The Health Claim Decision Model for Canadian Food Products

This section of the Roadmap provides the detailed tables that make up the decision model. It has the same format as the overview version in the previous section; however, it includes a much more detailed description of:

- the appropriate activities at each Step, on each Track;
- the process to review each Step’s results;
- the Decision Criteria;
- use of an assessment matrix for each Step’s decision process; and
- the Go/No Go decision options at the end of each Step.

4.1 General Introduction

As described previously, the activities are organized via four Steps and four Tracks. A company or industry association may want to change the order. In some cases, some activities can be eliminated and others may need to be modified. The four Tracks are described in the following sections.

4.1.1 Regulatory Track

The Regulatory Track begins each Step by identifying the key documents that must be reviewed to understand the Step’s activities and processes. The referenced guidance documents provide the detail needed for many of the Step’s activities. The referenced documents are described and sourced for the reader in Appendix 2 of the Roadmap.

4.1.2 Scientific Track

The Scientific Track provides the list of activities and questions that guide the business through the technical aspects of nutrient/health claim substantiation. The regulations and guidance documents are referenced to provide the context for what information is to be researched, or what results are to be generated, from the activity. In many places a series of questions is provided. Answering these questions guides the user to the next section of the Track, or suggests which activities can be eliminated or modified because of individual circumstances.

The Scientific Track in Step 3: Assessment of Status as Novel Food, Food with Added Vitamins and Minerals, and Food Additive is particularly complex. This is due to the amount of detailed work required to assess each product category and to the complexity of the regulations. To assist the reader, the Supplementary Table: Step 3 Scientific Track Assessment of Product Categories is provided, immediately following the Step 3 table. At several points in the Step 3 Scientific Track, the reader is directed to the Supplementary Table where the detailed tasks are organized under the product categories being considered: novel foods, novel fibres, foods with added vitamins and minerals, and food additives.
4.1.3 Market Track

The decision model is designed for use by a business that already has at least one food product being sold in the marketplace and therefore already has a marketing plan in place. For businesses that are preparing their initial marketing plan, see Appendix 6 for an overview of marketing plans and a list with links to external resources.

The Market Track focuses on a business’s activities and decisions related to incorporating a Canadian nutrient and/or health claim and the impact of regulations, by either:

- making adjustments to the marketing plan; or
- developing a new marketing plan for a new product, or for the same product shifting to new target markets.

The Market Track helps a business to identify the related marketing decisions, at each Step in the process, that need to be considered as a result of the requirements of the Canadian regulatory framework on making a nutrient and/or health claim. A list of items to consider and their cost implications is provided in Appendix 8.

4.1.3.1 Food or Food Ingredient

The decision whether to market a product as a food, or as a food ingredient, is generally based on marketing and/or business strategy reasons.

The nature of the product also plays a role in determining which option is feasible. In this document, “ingredient” is defined as a food product that is sold to another food-processing business to incorporate into its product(s). An example is oatmeal. It can be packaged for consumer-ready sale as a food, or it can be bulk shipped to a cookie manufacturer to use as an ingredient.

A business may decide to sell the food material as an ingredient to expand its markets or to sell it only as an ingredient to avoid the risks, time and costs (e.g. label, package, consumer testing, building market awareness, point of sale material, promotional campaign) of developing a consumer-ready product. Often, a business’s product is not suited for sale directly to consumers, and thus must be sold to further processors as an ingredient.

4.1.4 Business Planning Track

As noted at the beginning of section 3, additional information for overall development of a health-oriented new food product can be found elsewhere. The decision model’s Business Planning Track focuses on the financial and business strategy activities and decisions of a business that is dealing with the Canadian food-related regulations for nutrient and/or health claims.

For businesses preparing their initial business plan, see Appendix 7 for an overview of business plans and a list with links to external resources. For businesses updating their business plans to include a health claim, a list of items to consider and their cost implications is provided in Appendix 8.
4.2 Company / Industry Association Objectives

Whether using the decision model or some other less structured approach to deciding if a nutrient and/or health claim should be part of the business strategy, the decision process has to be driven by, and be consistent with, overall corporate objectives. As a business is starting to prepare its plan for nutrient and/or health claims, it is important to have all managers who will work on the decision model review the overall objectives of the company or industry association (i.e. the strategic long- and medium-term vision as it relates to developing and positioning products in specific markets). These objectives need to be formalized in a short written document or statement, with wording that all agree on. This should be communicated to all managers who will work on the decision model.

In addition to the formal statement of the company or industry association objectives, a specific statement of the business’s product and nutrient/health claim objectives is needed. All managers involved in the nutrient/health claim determination process need to understand this statement fully, so there is a common vision of what objectives exist for all products, including the specific one under review. This is important to prevent managers in one functional business area, working on a Track in the decision model, making decisions about the nutrient/health claim based on assumptions that differ from other managers in the business who are working on other Tracks.

The benefit of ensuring all managers are familiar with corporate objectives and basing decisions according to a shared vision is illustrated by the following example. If the company or industry association has decided that its objective for new products includes supporting the corporate brand image of being a high-technology industry leader that delivers unique health and wellness benefits and has stated as part of its product and nutrient/health claim objectives that all new products will support this, it will impact nutrient/health claim option decisions. A Marketing Track decision about whether to incur higher costs in targeting customers with a specific health concern or to use a more generic lower-cost positioning message that will still create some level of awareness in the distribution channel could be heavily influenced by the product and nutrient/health claim objectives in this case.

4.3 Management Structure for Health Claim Decisions

Like all important functions in a company or industry association, the nutrient/health claim decision process needs to be effectively managed, if it is to be successful.

Health claim decision management starts with organizational structure (i.e. who is in charge and driving the process). The CEO or president is usually the one ultimately in charge. However, the complete nutrient/health claim decision reporting structure (i.e. who reports on this specific nutrient/health claim project to whom) needs to be clarified, as does who has authority to make what types of decisions (i.e. such as who can make changes to the budget, human resource allocation). All of this information needs to be clarified up front.
The Health Claim Decision Team will likely consist of the four people (could be fewer and typically will be one person in small companies)\(^{35}\) who are responsible for the four Tracks within the decision model (i.e. the Track managers). The Team will also likely include corporate managers, and perhaps external business advisors, consultants or technical specialists including regulatory specialists.

The Health Claim Decision Team needs to decide how communications will take place among Team members and to senior management to ensure there is coordination between the functional areas of the business. This will ensure that, for example, marketing staff and R&D staff agree on how, what and when communication will take place. This is an important part of the nutrient/health claim decision process. Ignoring communications and coordination will lead to serious problems and cost overruns when one part of the Team is going in a different direction from the rest of the Team.

Poor communication is such a common problem that the decision model has been developed with built-in requirements for communication and coordination across the Tracks. Before moving forward, each Step of the model requires that:

- activities in all four functional business areas (all four Tracks) must be addressed; and
- the appropriate information needed to make the formal decision at the end of each Step is available from all four Tracks and analyzed.

This requirement for coordination of all four Tracks is a critical concept in the decision model that overcomes the tendency to proceed too far on one Track without getting appropriate information on the other Tracks, usually a result of poor or no communication.

### 4.4 Step 1: Nutrient / Health Claim Potential—Preliminary Review

Step 1 has several purposes. They are to:

- determine which regulations apply to the product of interest and, in concert with results of other Tracks, select (or prioritize) the regulatory streams with the most potential for a commercially successful nutrient and/or health claim;
- gain an understanding of the breadth and depth of scientific information available, identify information gaps (if any) compared with what will be needed to support a nutrient/health claim or pursue other market or regulatory options, and collect an appropriate amount of information related to health and wellness potential (in vitro, in vivo, animal, human studies);
- create a preliminary estimate of the size and attractiveness of each product/regulatory framework/market option. These market snapshots are matched with the output of the Scientific and Regulatory Tracks to demonstrate relative attractiveness of option; and

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\(^{35}\) In smaller companies, it is possible that only one or two people will be tasked with determining the optimal health claim strategy for the product(s) in question. Given the complexities of the tasks and the multidisciplinary skills that are required, it is recommended that the company enhance its management capacity for this work by bringing onboard outside assistance—private sector advisors and/or regulatory and government sector specialists who can work with individual companies.
create a framework to compare the market opportunity with the resource requirements to pursue each product/regulatory framework/market option. Less desirable options are eliminated and more desirable options are advanced for more in-depth study.

With these purposes in mind, the Health Claim Decision Team should proceed to the activities and tasks listed below in Table 8.
Table 8  Decision Model: Step 1 Activities Organized by Track Focus

<table>
<thead>
<tr>
<th>Step 1: Nutrient/Health Claim Potential—Preliminary Review</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Track</strong></td>
</tr>
</tbody>
</table>
| 1. Review the following documents, which are described and referenced in Appendix 2. Note: The Guide to Food Labelling and Advertising and the Guidance Document for Preparing a Submission for Food Health Claims are critical documents to consult.  
   - Food and Drugs Act (FDA): Part 1  
   - Food and Drug Regulations (FDR), Part A and Part B (Foods)  
   - FDR, Part D (Vitamins, Minerals and Amino Acids)  
   - Guide to Food Labelling and Advertising (CFIA)  
   - Guidance Document for Preparing a Submission for Food Health Claims (March 2009)  
   - Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them (1997)  
   - Guidelines for the Safety Assessment of Novel Foods (June 2006)  
   - A Guide for the Preparation of Submissions on | 1. Describe product and its intended use in detail by considering the following questions:  
   - Is it a whole food, a food product or a food constituent?  
   - Is it a vitamin, mineral or amino acid?  
   - Is it a substance that could be a natural health product?  
   - Is it a substance with a specific technical function in a food (e.g. enzyme, preservative)?  
   - Is it novel? Never consumed before, or a new process or has it been genetically modified?  
   - Is it a novel dietary fibre?  
   2. Decide if desirable to state, suggest or imply that a relationship exists between the product and health.  
   - If YES, continue with this model.  
   - If NO, exit the model.  
   - If unsure, continue with the model.  
   A number of opportunities exist for different products to make health-related claims, including:  
   For foods  
   - nutrient content claims  
   - non-nutrient declaration  
   - nutrient function claims  
   - general health claims  
   - function claims  
   - disease risk reduction claims  
   - therapeutic claims | 1. Define the target market segments that have potential for each of the different nutrient and/or health claims that the Regulatory Track and Scientific Track show might be made.  
   2. Conduct literature review, executive interview and other types of preliminary secondary and primary market research. Locate data on sales trends of similar products.  
   3. Identify potential customer characteristics, competition (both direct and substitute products), and competitive advantages, and estimate market size for each option* being considered.  
   4. Identify any potential competitors in each market (defined by claim option type, distribution channel and other market segmentation parameters that are relevant to the company or industry association). Evaluate the relative strength of each competitor (both products and companies).  
   5. Through critical evaluation, identify the optimal nutrient/health claim strategy for the business, considering all business factors.  
   6. Complete an initial business case analysis related to the potential nutrient and/or health claims. This will be at a | 1. Assess the fit of each option* for the various nutrient and/or health claims into the existing business strategy.  
   2. Determine the financial and human resources required to complete the claim process compared with what the business has available. This should be done using a budget that includes appropriate line items for all expenses that can be identified.  
   3. Identify the risks to the business in pursuing each type of claim, including financial and others such as loss of reputation in the event of failure in key market segments.  
   4. Estimate the potential profits and benefits (e.g. strengthened reputation or competitive advantage) of a successful claim.  
   5. Through critical evaluation, identify the optimal nutrient/health claim strategy for the business, considering all business factors.  
   6. Complete an initial business case analysis related to the potential nutrient and/or health claims. This will be at a |
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2. Understand the major difference between nutrition labelling requirements and a nutrient content claim option, vs. a food health claim option.

3. List the potential health-related benefits of consumption of the particular product or nutrient under consideration.

4. Gather as much information as possible regarding the proposed health relationship(s), including:
   - characterization of food, food product or food constituent conferring the proposed health benefit (e.g. source, composition, processing, product specifications, stability);
   - efficacy of the material; and
   - characterization of product composition, form and history of use.

5. Based on the information gathered so far, make a preliminary determination about the type of claim that might be possible:
   - (a) Nutrient or non-nutrient information and nutrient content claim or non-nutrient declaration
   - (b) Nutrient function claim—referring to a nutrient that is essential for the maintenance of good health or for normal growth and development
   - (c) General health claim—referring to healthy eating or providing dietary guidance
   - (d) Function claim—referring to the positive contribution to health and the maintenance of a physiological function

6. Prepare a preliminary budget of marketing and product launch costs for each product/health claim/distribution channel option under consideration.

7. Estimate the impact of each type of nutrient/health claim on sales and market share of each option*. 

8. Estimate the relative attractiveness of each option*.

9. Match the above estimates with the output of the Scientific and Regulatory Tracks to identify the optimal nutrient/health claim strategy for the company or industry association.

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* Where “option” means each product/regulatory framework/market segment/distribution channel combination.

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5. Estimate the amount of education that will be required to inform customers about the benefits of the product. See CFIA Guide 8.12 for distinction between education and advertising.

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7. Using the information developed during this Step, prepare a pre-feasibility study that addresses the greatest risks and greatest uncertainties, and provides a preliminary estimated indication of the viability of developing the nutrient and/or health claims.
or to physical or mental performance

(e) *Disease risk reduction or therapeutic claims*—referring directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or of their symptoms, or claim to restore or correct abnormal functions of the body or modify body functions beyond the normal physiological effects of food

(f) Be considered for a new *nutrient function* claim where the nutrient is one for which a Recommended Dietary Allowance (RDA), Adequate Intake (AI), or Acceptable Macronutrient Distribution Range (AMDR) has been established by the Institute of Medicine of the U.S. National Academies, **AND** the function reflects consensus in the scientific community and has been published by an authoritative scientific body

(g) Be considered as a new *nutrient function* claim where the nutrient does not have an RDA, AI or AMDR, or authoritative statement for support

(h) Be considered as a *natural health product* based on the product’s composition, representation and format as well as public perception and history of use
### Process to Review Step 1 Results

1. The Regulatory Track manager ensures the activities listed above are completed, and then analyzes and summarizes the key data, findings and observations. Focus on the differences among the types of nutrient and health claims allowed by regulations, and how they relate to the product in question. Emphasize any unexpected findings or areas where further research is warranted. The implications of the relevant regulations should be summarized. The Steps Key Results for this Track, in the form of key information, analyses and implications, are to be brought forward to the Step Decision.

2. The Scientific Track manager ensures the activities listed above are completed, and then analyzes and summarizes the key data, findings and observations. Focus on the amount of product testing needed to support the relevant nutrient/health claim application(s). Emphasize any unexpected findings or areas where further research is warranted. Note the implications of the analyses. The Steps Key Results for this Track, in the form of the analyses and implications, are to be brought forward to the Step Decision.

3. The Market Track manager ensures the activities listed above are completed, and then analyzes and summarizes the key data, findings and observations. Focus on the market with respect to its overall attractiveness and the degree to which it can be accessed and protected. Do this for each target market segment—matched to each nutrient claim or health claim option. Emphasize any unexpected findings or areas where further research is warranted. Note the implications of the analyses. The Steps Key Results for this Track, in the form of the analyses and implications, are to be brought forward to the Step Decision.

4. The Business Planning Track manager ensures the activities listed above are completed, and then analyzes and summarizes the key data, findings and observations. Focus on the overall suitability of the product/claim/market in terms of how it fits in with the core business and the Vision. Emphasize any unexpected findings or areas where further research is warranted. Note the implications of the analyses. The Steps Key Results for this Track, the related analyses and the implications are to be brought forward to the Step Decision.

5. The purpose of summarizing the results from the work in each Track (for this Step) is to:
   - make the information more useful and meaningful to each of the other Track managers and other members of the Health Claim Decision Team; and
   - prepare the data for use in the Step Go/No Go decision.

6. Each Track manager will review the Step Key Results from the other Tracks and identify the implications for his/her Track.

7. All Health Claim Decision Team members will review all Step Key Results for implications for the company or industry association as a whole and for all external stakeholders.

8. A meeting of the Health Claim Decision Team is held to discuss all available information. This meeting is a creative thinking and brainstorming session to:
   - jointly review Step Key Results for all Tracks and identify further implications for any functional area of the business (i.e. the four Tracks);
   - identify any implications for each product/regulatory framework/market segment/distribution channel option. Specific attention is paid to any trade-offs that need to be considered or factored into future planning (e.g. selling price vs. benefits and the cost to incorporate those benefits);
   - identify any implications of Step Key Results for all Tracks to the company or industry association; and
   - summarize the challenges yet to be overcome and the opportunities not yet fully seized. Note the modifications to the product needed in light of this summary.
### Step 1 Decision Criteria

The Step 1 Decision Criteria consist of veto and comparative criteria as described previously. The criteria come from two sources.

The first is the company or industry association strategy and values. Companies will typically have an overall set of requirements for all new business ventures (e.g. the new product must fit within the strategy for high-technology products, or must target markets with growth rates of greater than 12% per year).

The other source of Decision Criteria is the Track managers. They are the best qualified to determine the criteria that should be used to assess that functional area of the business (i.e. the Track they are responsible for). In practice, each Track manager would prepare an initial list of three to five criteria that is submitted to the rest of the Health Claim Decision Team. These, along with any corporate Decision Criteria, are put together into one list and then summarized/fine tuned.

The Step 1 veto and comparative criteria listed below are provided as examples only. The Track managers must develop the specific criteria that are appropriate for the product, its likely manufacturing technology, specific markets, and the company or industry association objectives (at both the manufacturing business unit level and the corporate level).

#### Sample Veto Criteria:

- It appears sufficient scientific evidence is available, or can be developed, to establish the safety and health benefit linkage of the product for regulatory approval.
- The product/regulatory framework/market option is an acceptable strategic fit with the company or industry association objectives.
- There is a potential market of sufficient size to likely allow sufficient sales volume to generate profits.
- The resources required to pursue a health claim may be available.
- Risk levels are acceptable.

#### Sample Comparative Criteria:

- There are lower risks related to regulatory approval.
- The R&D, testing protocols and other related costs of complying with regulations are lower.
- The Intellectual Property Rights (IPR) associated with the regulatory process can be better protected.
- The market is more familiar with the product/regulatory framework/market option, and the market places more value on related health benefits.
- The market is larger and/or has the potential for more rapid growth.
- There is potential for a competitive advantage versus competitors.
- There is greater potential for profit.
Assessment Matrix for the Step 1 Decision Process

The Health Claim Decision Team performs the assessment of each nutrient/health claim opportunity against the Step Decision Criteria. It is suggested that a matrix such as the sample provided in Appendix 4 be used during this process. The Step Decision process follows these basic steps:

1. The veto criteria are dealt with first. The product/regulatory framework/market option is assessed against each criterion, one at a time. They are usually scored on a simple Yes/No or Pass/Fail system. The process starts with all individuals on the Team indicating how they score the new product idea against a criterion. The veto criteria are listed in a matrix that is projected on a screen, and the scores from all participants are shown on separate rows. Team members discuss their views and reasons why they prefer different scores. It is during this discussion that significant insights are gained and the project areas with the greatest uncertainty (i.e. the highest levels of risk) are identified. After all Team members have expressed their views, the group comes to a consensus on the score and moves on to the next criterion. After all veto criteria have been considered, the scoring is reviewed. If a product/regulatory framework/market option has passed against all veto criteria, the Health Claim Decision Team moves on to the comparative criteria. If there is one or more failing scores, the Team must decide how to proceed.

If it is clear that the veto criteria cannot be met by the product/regulatory framework/market option, the project work should halt immediately and there is no reason to deal with the comparative criteria (i.e. the Team moves on to the next option). If there is some uncertainty about the failing score or the degree of impact these criteria may have on the overall project, the Team has an option to investigate further into the issues and factors that created a failing score on the veto criteria. The Team may choose to postpone scoring the option with the comparative criteria until this new information is brought back to the Team and a decision is reached.

2. When the Health Claim Decision Team is ready to deal with the comparative criteria, these criteria are also listed in a matrix, typically a spreadsheet. The product/regulatory framework/market option is assessed against each criterion, one at a time. They are usually scored on a simple 1 to 10 system with 10, the highest score, indicating the most favourable results. The process starts with everyone indicating how they score the new product idea against a criterion. The comparative criteria matrix is projected on a screen, and the scores from all participants are shown on separate rows. Team members discuss their views and reasons why they prefer different scores. While it may at first seem quite trivial to have people negotiating whether a "5" or a "6" is the appropriate score, it is during this discussion that:

- significant insights are often attained;
- creativity is generated by the managers’ interaction, often leading to new ideas;
- the information gathered from each of the four Tracks comes together to create a clearer image of the product/regulatory framework/market option. This enhanced definition, shared by all the Health Claim Decision Team members, is critical for proceeding further; and
- this scoring approach ultimately drives objectivity into what otherwise tends to be a subjective situation.

After all Team members have expressed their views, the group comes to consensus on the score and moves on to the next criterion. Often, as the Team moves through the criteria, new information is presented that creates a different perspective on the discussion and scoring of previous criteria. This might cause the Team to go back to previous criteria and change the score. This is quite acceptable and shows the process is working well. It also tends to ensure that a more consistent approach is used throughout the scoring.

3. As noted in the summary below, in general there are four potential outcomes of the decision process for each option:

- Go: Proceed to the next Step because the decision results have indicated a nutrient claim/product/market option is sufficiently positive to merit further development in the next Step.
- Go: Proceed to the next Step because the decision results have indicated a health claim/product/market option is sufficiently positive to merit further development in the next Step.

- Redo the current Step: The decision results have produced a middle-of-the-road result that suggests the claim/product/market option should not be advanced with what is known now, but may hold potential if current Step activities were redone with new sources, focusing on aspects where there is the greatest uncertainty; and this produced different results that are more positive, or more negative, so a decision could be finalized.

- No Go: Stop all work on the process immediately because the decision process results are sufficiently negative and there appears to be no merit in pursuing any identified Canadian food-related nutrient and/or health claim.

(Note: A business may decide to pursue food-related health claims in other countries, or to pursue non-food claims, such as in the pet food market.)

One method for making the Step Decision is to assess each claim/product/market option against all criteria and total the results. The total score must meet or exceed a predetermined threshold in order for the Step Decision to be a Go (i.e. proceed to the next Step). Similarly, if the total score is below a predetermined threshold, the decision is No Go and the project is halted. For example, if there are 10 criteria and a 1–10 scoring system is used, the theoretical maximum score attainable is \(10 \times 10 = 100\). An upper threshold score of 85 could be established, meaning that with any score of 85 or more the claim/product/market option advances to the next Step. Similarly, a lower threshold of 50 could be adopted, so that options scoring 49 or less are stopped immediately and no further work is done. If the score is somewhere in between these two thresholds (i.e. 50–84), the Health Claim Decision Team decides which Track activities should be redone for the Step. The Redo Decision is made when the claim/product/market option has some problems in its present state that may limit the product’s chances of being commercially successful in the marketplace, or limit the chances of the health claim being approved. The approach may be to select a new bioactive compound or a new market segment and then redo some of the activities in this Step.

**Step 1 Go/No Go Decision Options:**

1. Potential for a claim: Proceed to Step 2
2. Uncertain potential for non-nutrient declaration, nutrient and/or health claims and/or NHP claim: Redo Current Step
3. No potential for any non-nutrient declaration, nutrient and/or food health claim or NHP claim: Exit Model
4.5 Step 2: Food or NHP Regulatory Stream Assessment

The purposes of the second Step are to:

- identify if the target material is an NHP or if it is a food additive or a food/food ingredient;
- gain an understanding of the breadth and depth of scientific information available to support an NHP submission or to support a nutrient and/or health claim for the material as a food;
- create a preliminary estimate of the size and attractiveness of each product/regulatory framework/market option (i.e. NHP and food). These market snapshots are matched with the output of the Scientific and Regulatory Tracks to demonstrate the relative attractiveness of each option; and
- create a framework to compare each option to the resource requirements for the NHP/regulatory framework/distribution channel option versus the food product/food regulations/distribution channel option.

With these objectives in mind, the Health Claim Decision Team should proceed to the activities and tasks in Table 9.
Table 9  Decision Model: Step 2 Activities Organized by Track Focus

<table>
<thead>
<tr>
<th>Step 2: Food or NHP Regulatory Stream Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Track</strong></td>
</tr>
<tr>
<td>1. Review the following documents, which are described and referenced in Appendix 2:</td>
</tr>
<tr>
<td>a. FDA, Part 1, Definitions of Food and Drug, advertise, sell, etc.</td>
</tr>
<tr>
<td>b. FDR, Part B, Division 1, General (and other Divisions)</td>
</tr>
<tr>
<td>c. FDR—Natural Health Product (NHP) Regulations</td>
</tr>
<tr>
<td>d. Guidance documents for pre-market approval of NHPs—site and product licensing (on Natural Health Products Database website)</td>
</tr>
<tr>
<td>e. Classification of Products at the Food—Natural Health Products Interface: Products in Food Formats (March 2009)</td>
</tr>
<tr>
<td>2. Review definitions of a food and NHP or food products deemed as NHPs.</td>
</tr>
<tr>
<td>a. Food: means any article manufactured, sold or represented for use as a food or drink for human beings, including chewing gum, and any ingredients that may be mixed with food for any purpose whatever (section 2, FDA).</td>
</tr>
<tr>
<td>b. Natural health product: means a substance set out in Schedule 1 of the Natural Health Product Regulations (NHPR) or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1 (see below), a homeopathic medicine or a traditional medicine, that is</td>
</tr>
<tr>
<td>2. The Food—NHP Classification Committee of Health Canada, on a case-by-case basis, evaluates...</td>
</tr>
</tbody>
</table>
and determines whether a product in food format should be designated a food or an NHP. Review the criteria that follow and determine the implications for the product in question.

Criteria for Evaluation

1. **Product Composition**
   - Determine if the food or ingredient is present solely to provide nourishment, nutrition or hydration, to satisfy hunger, thirst or a desire for taste, texture or flavour. If yes, this indicates the product is a food, even if it contains any of the substances listed in Schedule 1 of the NHPR.
   - If the product is or contains an added ingredient with no known food purpose, but has only a therapeutic use, this is an indication the product is an NHP.
   - Also a product that is, or contains a substance with a known food purpose, but which is present at a level incompatible with its use as a food and is consistent only with a therapeutic use, would likely be classified as an NHP.

2. **Product Representation**
   - If the product is represented or sold as a product having therapeutic uses, and is not based upon the use of the product as a food, it may be deemed an NHP.

3. Research and analyze the implications of each of the following points as it relates to the product in question:
   - Products that are foods as defined in the FDA are subject to the FDA as it applies to food and to Parts A, B and D of the FDR.
   - Products that meet the definition “natural health product” in the Natural Health Product Regulations (NHPR) are subject to the FDA as it applies to a drug and to the NHPR.
   - A product that is both an NHP and a food is subject to the NHPR but is exempted from the FDA as it applies to a food.
   - NHPs must be safe for consideration as over-the-counter products and not require a prescription to be sold.

4. Identify any potential competitors in each market (defined by claim option type, distribution channel and other market segmentation parameters that are relevant to the company or industry association). Evaluate the relative strength of each competitor (both products and companies).

5. Estimate the amount of education that will be required to inform customers about the benefits of the product.

6. Prepare a preliminary budget of marketing and product launch costs if marketed as an NHP.

7. Estimate the impact of each type of nutrient/health claim on sales and market share.

8. Estimate the relative attractiveness of each regulatory framework/market option.

9. Match the above estimates with the output of the Scientific and Regulatory Tracks to identify the overall attractiveness of an NHP market entry strategy.

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<table>
<thead>
<tr>
<th>1. <strong>Product Composition</strong></th>
<th>2. <strong>Product Representation</strong></th>
<th>3. Research and analyze the implications of each of the following points as it relates to the product in question:</th>
<th>4. Identify any potential competitors in each market (defined by claim option type, distribution channel and other market segmentation parameters that are relevant to the company or industry association). Evaluate the relative strength of each competitor (both products and companies).</th>
<th>5. Estimate the amount of education that will be required to inform customers about the benefits of the product.</th>
<th>6. Prepare a preliminary budget of marketing and product launch costs if marketed as an NHP.</th>
<th>7. Estimate the impact of each type of nutrient/health claim on sales and market share.</th>
<th>8. Evaluate the relative attractiveness of each regulatory framework/market option.</th>
<th>9. Match the above estimates with the output of the Scientific and Regulatory Tracks to identify the overall attractiveness of an NHP market entry strategy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine if the food or ingredient is present solely to provide nourishment, nutrition or hydration, to satisfy hunger, thirst or a desire for taste, texture or flavour. If yes, this indicates the product is a food, even if it contains any of the substances listed in Schedule 1 of the NHPR.</td>
<td>If the product is or contains an added ingredient with no known food purpose, but has only a therapeutic use, this is an indication the product is an NHP. Also a product that is, or contains a substance with a known food purpose, but which is present at a level incompatible with its use as a food and is consistent only with a therapeutic use, would likely be classified as an NHP.</td>
<td>Products that are foods as defined in the FDA are subject to the FDA as it applies to food and to Parts A, B and D of the FDR. Products that meet the definition “natural health product” in the Natural Health Product Regulations (NHPR) are subject to the FDA as it applies to a drug and to the NHPR. A product that is both an NHP and a food is subject to the NHPR but is exempted from the FDA as it applies to a food. NHPs must be safe for consideration as over-the-counter products and not require a prescription to be sold. A product in food format (see Appendix 2) would be considered an NHP if it: contains a substance listed in Schedule 1 of the NHPR at a level not permitted for use in a food under the food provisions of the FDR; or makes a claim for a therapeutic use that</td>
<td>Identify any potential competitors in each market (defined by claim option type, distribution channel and other market segmentation parameters that are relevant to the company or industry association). Evaluate the relative strength of each competitor (both products and companies).</td>
<td>Estimate the amount of education that will be required to inform customers about the benefits of the product.</td>
<td>Prepare a preliminary budget of marketing and product launch costs if marketed as an NHP.</td>
<td>Estimate the impact of each type of nutrient/health claim on sales and market share.</td>
<td>Evaluate the relative attractiveness of each regulatory framework/market option.</td>
<td>Match the above estimates with the output of the Scientific and Regulatory Tracks to identify the overall attractiveness of an NHP market entry strategy.</td>
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<td>Schedule 1:</td>
<td>3. Product Form</td>
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<td>1. a plant or a plant material, an alga, a bacterium, a fungus or a non-</td>
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<td>human animal material</td>
<td>• Typically, NHPs are sold in a format that allows them to be consumed in</td>
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<td>2. an extract or isolate of a substance described in item 1, the</td>
<td>measured or controlled amounts (doses) (e.g. capsules, pills, tablets, liquids or</td>
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<td>primary molecular structure of which is identical to that which it had</td>
<td>bulk form).</td>
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<td>prior to its extraction or isolation</td>
<td>• However, a product sold in a particular food format (e.g. beverage, gums or</td>
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<td>3. any of the following vitamins: biotin, folate, niacin,</td>
<td>bars) that lends itself to dosing could be considered an NHP.</td>
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<td>pantothenic acid, riboflavin, thiamine, vitamin A, B6, B12, C, D, E,</td>
<td>4. Public Perception and History of Use</td>
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<td>K1, K2</td>
<td>• If the public perceives the product as a food, this is a good indication that</td>
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<td>4. an amino acid</td>
<td>it is a food. If the public perceives the product as having a therapeutic use,</td>
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<td>5. an essential fatty acid</td>
<td>it is likely an NHP.</td>
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<td>6. a synthetic duplicate of a substance described in any of items 2 to 5</td>
<td>• The Committee also considers the nature of and risks associated with the</td>
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<td>7. a mineral</td>
<td>health effects and a product’s representation of therapeutic effects.</td>
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<td>8. a probiotic</td>
<td>Determine the impact this would have on the product in question.</td>
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</table>

**Process to Review Step 2 Results**

1. The Regulatory Track manager uses the same general process outlined in Step 1. In Step 2, focus on the aspects of the product that will determine food or NHP status and how they relate to the product in question. Emphasize any unexpected findings or areas where further research is warranted.

2. The Scientific Track manager uses the same process outlined in Step 1. Focus on the results of the assessment of the product against the factors that determine food or NHP status.

3. The Market Track manager uses the same process outlined in Step 1. Focus on the NHP market segments versus food market segments with respect to overall attractiveness and the degree to which each can be accessed and protected.

4. The Business Planning Track manager uses the same process outlined in Step 1. Focus on the overall suitability of the NHP market in terms of how it fits in with the core business. Compare this to a nutrient/health claim business model.
5. The purpose of summarizing the results from each Track is to:
   - make the information more useful and meaningful to each of the other Track managers and other members of the Health Claim Decision Team; and
   - prepare the data for use in the Step Go/No Go decision.

6. Each Track manager will review the Step Key Results from the other Tracks and identify the implications for his/her Track.

7. All Health Claim Decision Team members will review all Step Key Results for implications for the business as a whole and for all external stakeholders.

8. A meeting of the Health Claim Decision Team is held to discuss all available information, as described in Step 1.

### Step 2 Decision Criteria

The Step 2 Decision Criteria consist of veto and comparative criteria. As in Step 1, the criteria come from two sources: the company or industry association strategy and values, and the Track managers. All criteria are put together into one list and then summarized and fine tuned.

The Step 2 veto and comparative criteria listed below are provided as examples only. Track managers must develop the specific criteria appropriate for both the NHP and food product, their respective manufacturing technologies and specific markets, and the company or industry association objectives (at both the manufacturing business unit level and the corporate level).

In Step 2, the veto criteria are ones that either cause the project to no longer be acceptable or lead to a decision to exit the model (e.g. pursue an NHP option).

**Sample Veto Criteria:**
- Step 2 results show that the veto criteria from Step 1 are no longer met.
- The product meets the criteria used by Health Canada to determine NHP status and this is the preferred option.

**Sample Comparative Criteria:**
- There are lower risks related to regulatory approval.
- The R&D, testing protocols and other related costs of complying with regulations are lower.
- The IPR associated with the regulatory process can be better protected.
- The market is more familiar with the product/regulatory framework/market option, and the market places more value on related health benefits.
- The market is larger and/or has the potential for more rapid growth.
- There is potential for a competitive advantage versus competitors.
- There is greater potential for profit.
Assessment Matrix for the Step 2 Decision Process

The Health Claim Decision Team performs the assessment of the NHP versus food regulatory determination against the Step Decision Criteria (see Appendix 4 for a sample assessment matrix) and ultimately drives the Step Decision with a process that follows the same basic steps outlined in Step 1.

As noted in the summary below, in general there are four potential outcomes of the decision process for Step 2:

- **No Go:** There is potential as an NHP and other market and business factors support this direction for the company or industry association. The NHP process is beyond the scope of the decision model; therefore, exit the model and initiate the NHP approval process.

- **Go:** Proceed to the next Step because the decision results have indicated the product is a food and there is a market opportunity for a nutrient and/or health claim option that merits further development in the next Step.

- **Redo the current or previous Steps:** The decision results have produced a middle-of-the-road result that suggests the overall decision process should not be advanced with what is known now, but an NHP or nutrient/health claim option may hold potential if current Step activities were redone in more detail and produced different results that were more positive, or more negative, so a decision could be finalized.

- **No Go:** Stop all work on the pursuit of a nutrient/health claim immediately because the decision process results are sufficiently negative.

The method described in Step 1 for making the Decision by assessing each product/regulatory framework/market option against all criteria and totalling the results also applies in Step 2.

**Step 2 Go/No Go Decision Options:**

1) NHP: Proceed as NHP: (1) Initiate NHP process (2) Exit Model
2) Food: Proceed to Step 3
3) NHP/Food status uncertain: Redo Current or Previous Step
4) No non-nutrient declaration, nutrient and/or health claim: Exit Model
4.6 Step 3: Assessment of Status as Novel Food, Food with Added Vitamins and Minerals, and Food Additive

The purposes of the third Step are:

• to determine whether or not the food additive, food/food ingredient or food constituent falls under the novel food or novel fibre regulations;
• if determined to be a novel food or ingredient, or a food additive, to understand the requirements to comply with the regulations and complete a submission for regulatory approval under appropriate regulations;
• if a novel food, to identify any gaps in information required to meet the novel food regulations and guidelines in order to complete a submission to Health Canada;
• if food with added vitamin and minerals (food fortification) regulations apply, to determine the type and level of the vitamin or mineral that can be added to specific foods and the claims that can be made;
• if a food with added vitamins and minerals, to identify gaps in the available evidence needed to support the approval;
• if a food additive, to determine the level of scientific evidence available and identify information gaps so that a food additive petition can be submitted;
• to develop a research plan to address any data shortages to support the novel food or food additive submission;
• to create estimates of the size and attractiveness of each market option. These market snapshots are matched with the output of the Scientific and Regulatory Tracks to demonstrate the relative attractiveness of pursuing:
  o the novel food / novel fibre regulatory framework;
  o food with added vitamins and minerals applications and regulations; or
  o the food additive submission process.
• to create a framework to compare the market opportunity to the resource requirements for the novel food regulatory framework versus other possible formulation options that will not require the novel food pre-market notification; and
• to create the business case that will guide the pursuit of a food with added vitamins and minerals or food additive R&D/manufacturing/distribution strategy for the business.

With these objectives in mind, the Health Claim Decision Team should proceed to the activities and tasks listed below in Table 10.
### Table 10  Decision Model: Step 3 Activities Organized by Track Focus

<table>
<thead>
<tr>
<th>Regulatory Track</th>
<th>Scientific Track</th>
<th>Market Track</th>
<th>Business Planning Track</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 3: Assessment of Status as Novel Food,</strong>&lt;br&gt;<strong>Food with Added Vitamins and Minerals, and Food Additive</strong></td>
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</tr>
<tr>
<td>1. Review the following documents, which are described and referenced in Appendix 2:</td>
<td>Some food categories, food products and/or food constituents require regulatory approval before they can be used in foods to be marketed or sold in Canada. This includes new novel foods, novel fibres, foods with added vitamins and minerals, and food additives. Regulatory approval is also required before a new health claim can be made.</td>
<td>1. Analyze the market impacts of the results of the Regulatory Track work identifying the product as a novel food, a food with added vitamins and minerals, or a food additive.</td>
<td>1. Assess the strategic business fit of each of a novel food, novel fibre, food with added vitamins and minerals, or food additive to the company or industry association’s operating model.</td>
</tr>
<tr>
<td>- FDR, Part B, Division 1, General</td>
<td><strong>Note:</strong> The Step 3 Scientific Track list of activities and issues for consideration is lengthy. To assist the reader in making this Step more manageable, a <strong>Supplementary Table:</strong> <strong>Step 3 Scientific Track Assessment of Product Categories</strong> is provided. It is found immediately after this Step 3 table. The discussion below will direct the reader to the supplementary table when appropriate.</td>
<td>2. Identify the appropriate target market segments.</td>
<td>2. Assess the risks of each type of regulatory approval process.</td>
</tr>
<tr>
<td>- FDR, Part B, Division 16, Food Additives</td>
<td>1. Definitions determine the appropriate regulations to consult and the information required by regulatory authorities to evaluate the safety and/or efficacy of new foods or food constituents. Determine the appropriate regulations for the product in question by answering the following questions:</td>
<td>3. Conduct literature review, executive interview and other types of preliminary secondary and primary market research. Locate data on sales trends of similar novel, fortified or food additive products.</td>
<td>3. Assess the resource requirements for obtaining a regulatory approval as a novel food, novel fibre or food additive, and for complying with food fortification regulations.</td>
</tr>
<tr>
<td>- FDR, Part B, Division 28, Novel Foods</td>
<td>- Is the substance a food additive as defined in B.01.001 FDR? If yes, refer to B.16.002 (a). (Go to Supplementary Table—Food Additives Column.)</td>
<td>4. Identify potential customer characteristics, competition (both direct and substitute products), potential competitive advantages, and estimate market size for each option* being considered.</td>
<td>4. Assess the company or industry association’s ability to comply and cope with the regulatory requirements, especially the novel food pre-market notification process.</td>
</tr>
<tr>
<td>- FDR, Part D, Vitamins, Minerals and Amino Acids (Food Fortification)</td>
<td>- Is the substance intended to be a new fibre or dietary fibre</td>
<td>5. Identify any potential competitors in each market (as a novel food, a food with added vitamins and minerals and/or food additive). Evaluate the relative strength of each competitor (both products and companies).</td>
<td>5. Assess the profit potential and benefits of the novel food, food with added vitamins and minerals, or food additive strategy.</td>
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<tr>
<td>- Guidelines for the Safety Assessment of Novel Foods (June 2006)</td>
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<tr>
<td>- Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them (1997)</td>
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<tr>
<td>- A Guide for the Preparation of Submissions on Food Additives (December 2007)</td>
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<tr>
<td>- Guide to Food Labelling and Advertising</td>
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</table>
source? If yes, refer to novel fibre guidelines. (Go to Supplementary Table—Novel Fibre Column.)

- Is the substance a vitamin, mineral or nutrient that can be added to certain foods or food categories? If yes, refer to Part D, FDR. (Go to Supplementary Table—Food Fortification Column.)

- Is this food category, food product or food ingredient considered novel? (Go to Supplementary Table—Novel Food Column.) Novel status must be considered if yes is answered to any one of the three questions below:
  - Is this a food produced by, and/or containing an organism (to the species level) not previously used in food in Canada?
  - Is the source organism from which the food is derived, genetically modified (as per B.28.001)?
  - Is the food the result of a process not previously used on that food and has this process resulted in a major change to the food (B.28.001)?

2. Review the available options:
   - If the whole food, food product or food constituent is none of the above (i.e. not a novel food or novel fibre), and not a food with added vitamins and minerals, or a food additive, the full range of nutrient/health claim options discussed in Step 4 are possible.

6. Assess the competitive position and the positive or negative pricing and sales impacts due to beneficial characteristics of the novel food, or benefits of a food with added vitamins and minerals, or unique applications of a food additive.

7. Prepare a preliminary budget of marketing and product launch costs for each option* under consideration.

8. Estimate the relative attractiveness of each option*.

9. Match the above estimates with the output of the Scientific and Regulatory Tracks to identify the optimal nutrient and/or health claim strategy.

* Where “option” means each product/regulatory framework/market segment/distribution channel option.
- If the food constituent is considered to be a food additive, no nutrient or health claims are possible.
- If the food product or food constituent is considered to be a novel fibre, certain nutrient/health claims are possible.
- If the food product or food constituent is considered novel, the full range of nutrient/health claim options discussed in Step 4 is possible.

3. For each of the above options, review the information requirements in the relevant regulations and/or guidance documents (as suggested in the relevant column of the Supplementary Table) to determine gaps in information.

4. Develop a research plan to acquire the missing information.

Process to Review Step 3 Results

1. The Regulatory Track manager uses the same general process outlined in Step 1. In Step 3, focus on the aspects of the regulations that will determine status as novel food, food with added vitamins and minerals, or food additive and how they relate to the product in question.

2. The Scientific Track manager uses the same process outlined in Step 1. Focus on the results of the assessment of the product against the factors that determine status as novel food, novel fibre, food with added vitamins and minerals, or food additive.

3. The Market Track manager uses the same process outlined in Step 1. Focus on the market opportunities for each product option (food, food with added vitamins and minerals, food additive) with respect to overall attractiveness and the degree to which each can be accessed and protected. Assess the impact a determination of novel status will have, if any, on these market estimates.

4. The Business Planning Track manager uses the same process outlined in Step 1. Focus on the overall suitability of each of the product/regulatory framework/market options in terms of how it fits in with the core business.

5. The purpose of summarizing the results from each Track is to:
   - make the information more useful and meaningful to each of the other Track managers and other members of the Health Claim Decision Team; and
   - prepare the data for use in the Step Go/No Go decision.

6. Each Track manager will review the Step’s Key Results from the other Tracks and identify the implications for his/her Track.
7. All Health Claim Decision Team members will review all Step Key Results for implications for the business as a whole and for all external stakeholders.

8. A meeting of the Health Claim Decision Team is held to discuss all available information, as described in Step 1.

**Step 3 Decision Criteria**

The Step 3 Decision Criteria consist of veto and comparative criteria as described previously.

The Step 3 veto and comparative criteria listed below are provided as examples only. Track managers must develop the specific criteria that are appropriate to assess all the product/regulatory framework/market options evaluated in Step 3 (novel food, novel fibre, food, food with added vitamins and minerals, and food additive), their respective manufacturing technologies and specific markets, and the company or industry association objectives (at both the manufacturing business unit level and the corporate level).

In Step 3, the veto criteria are ones that either cause the project to no longer be acceptable or lead to a decision to exit the model (e.g. pursue a food additive option).

**Sample Veto Criteria:**

- Based on the new Step 3 information, the Step 1 veto criteria are no longer met.
- It appears the regulations will not consider the product a food additive.

**Sample Comparative Criteria:**

- There is, or can be, more scientific evidence to support a novel food or novel fibre pre-market submission process.
- There is more scientific evidence to support the product falling under the regulations for food with added vitamins and minerals.
- There are lower risks related to regulatory approval.
- The market is larger and/or has the potential for more rapid growth.
- The market is more familiar with the product/regulatory framework/market option, and the market places more value on related health benefits.
- The product/regulatory framework/market option is a strategic fit with the company or industry association.
- The resources required to pursue a regulatory stream are lower.
- There is likelihood of greater profit.
- Risk levels are lower.
- The IPR associated with the regulatory process can be better protected.
- There is potential for a competitive advantage versus competitors.

**Assessment Matrix for the Step 3 Decision Process**

The Health Claim Decision Team performs the assessment of status as a novel food or novel fibre and the status as a food with added vitamins and minerals, and a food additive against the Step Decision Criteria (see Appendix 4 for a sample assessment matrix) and ultimately drives the Step Decision with the process described in Step 1.

As noted in the summary below, in general there are seven potential outcomes of the decision process for Step 3:

1. **Go:** Proceed to the next Step because the decision results have indicated the product is a novel fibre and there is a market opportunity for a nutrient claim option that merits further development in the next Step.
2. Go: Proceed to the next Step because the decision results have indicated the product is a novel food, which may or may not be a food with added vitamins and minerals, and there is a market opportunity for a non-nutrient declaration, nutrient claim and/or health claim option that merits further development in the next Step.

3. Go: Proceed to the next Step because the decision results have indicated the product is a food with added vitamins and minerals and there is a market opportunity for a non-nutrient declaration, nutrient claim and/or health claim option that merits further development in the next Step.

4. Go: Proceed to the next Step because the decision results have indicated the product is a food and there is a market opportunity for a non-nutrient declaration, nutrient claim and/or health claim option that merits further development in the next Step.

5. No Go: There is potential as a food additive and other market and business factors support this direction for the company or industry association. Food additives, by regulation, cannot use a non-nutrient declaration, nutrient claim or health claim; therefore, exit the model and initiate the food additive submission process.

6. Redo the current or previous Steps: The decision results have produced a middle-of-the-road result that suggests the overall decision process should not be advanced with what is known now, but a non-nutrient declaration, nutrient claim and/or health claim option may hold potential if current Step activities were redone in more detail and produced different results that were more positive, or more negative, so a decision could be finalized.

7. No Go: Stop all work on the pursuit of a nutrient/health claim immediately because the decision process results are sufficiently negative.

The method described in Step 1 for making the decision by assessing each product/regulatory framework/market option against all criteria and totalling the results also applies in Step 3.

**Step 3 Go/No Go Decision Options:**

1) Novel fibre with potential for nutrient claim: Proceed to Step 4
2) Novel food with or without potential as a food with added vitamins and minerals, with potential for non-nutrient declaration, nutrient claim and/or health claim: Proceed to Step 4
3) Not novel, food with added vitamins and minerals with potential for non-nutrient declaration, nutrient claim and/or health claim: Proceed to Step 4
4) Not novel with potential for non-nutrient declaration, nutrient claim and/or health claim: Proceed to Step 4
5) Potential as a food additive: (1) Pursue food additive submission process; (2) Exit Model
6) Status as novel, food with added vitamins and minerals, or food additive uncertain: Redo Current or Previous Step
7) No non-nutrient declaration, nutrient claim or health claim: Exit Model
### Supplementary Table: Step 3 Scientific Track Assessment of Product Categories

#### NOVEL FOODS REQUIREMENTS

1. **Review these key documents:**
   - FDR, Division 28, Novel Foods; and

   These documents detail the information required to prepare the novel food notification and complete the safety assessment.

2. **At a minimum, the following information is required in the notification package; determine what information is in place and what needs to be researched:**
   - common name;
   - name and address of manufacturer or importer; and
   - description of the novel food, including:
     - how it was developed;
     - methods of manufacture, preparation, preservation, packaging and storage;
     - details of the major change;
     - intended use and directions for preparation;
     - history of safe use in Canada or elsewhere;
     - evidence to show food is safe to consume;
     - estimated levels of consumption by consumers of novel food;
     - text of all labels used with novel food; and
     - name and signature of authorizing person.

   Health Canada will review the notification package and determine if the information is adequate to make a decision. If not, additional data for supporting the safety of the food is required.

3. **The safety assessment data package contains a comprehensive review of established evidence or experimental data for the following factors (determine what information is available and what needs to be obtained, such as history of use [e.g. consumption patterns, adverse effects, methods of preparation, cultivation]):**
   - dietary exposure (quantity and frequency of consumption and role in diet);
   - detail of novel process (if applicable);
   - history of organisms;
   - characterization of derived line/strain (if applicable);
   - genetic modification considerations (if applicable);
   - nutritional considerations (nutritional quality of food: nutrient composition, nutrient bioavailability, presence of anti-nutrients, bioactives);
   - toxicology considerations (may include chronic toxicity, developmental toxicity, genotoxicity or carcinogenicity);
   - allergenicity considerations (assessing the allergenic potential of a food); and
   - chemical considerations (chemical contaminants including inorganic [e.g. heavy metals], organic [e.g. pesticides], natural [e.g. mycotoxins].

4. **The amount and type of information necessary for safety assessments varies widely, depending on the novel food and its source (plant, animal or microorganism). Consult with the Food Directorate of Health Canada to determine the appropriate data requirements.**

5. **Return to Step 3 Scientific Track.**
### NOVEL FIBRE REQUIREMENTS

1. Review these key documents:
   - FDR, Part B, Division 1, General
   - *Guide to Food Labelling and Advertising*, Dietary Fibre (Chapter 6.8.1)
   - *Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them* (1997), including:
     - Appendix 1: Proposed Guidelines for Clinical Studies
     - Appendix 2: Guidelines for Planning and Statistical Review of Clinical Laxation Studies for Dietary Fibre

2. The petitioner must demonstrate safety and physiological efficacy of the food by scientific evidence. Of the following required information list, determine what is available and what would need to be obtained for the product in question.

   **Required Information:**
   - **a)** Form, manufacture and intended use
     - origin and physical form
     - method of manufacture, particularly any processes affecting properties or nutritional value
     - potential applications and levels of intended use in products
   - **b)** Physico-chemical specifications
     - nutrient composition: dietary fibre (total and constituents), protein, fat, carbohydrate, ash, energy value, vitamins and minerals
     - properties: particle size, hydratability
     - chemical analysis: presence of natural toxins, anti-nutritive components and contaminants including toxic metals, pesticide or solvent residues
   - **c)** Functional properties in foods
   - **d)** Microbiological specifications (for safety)
   - **e)** Physiological efficacy evaluation
     - must demonstrate one of three physiological effects following procedures outlined in Appendix 1 or 2 of the novel fibre guidelines
       - laxation
       - normalization of blood lipid levels
       - attenuation of blood glucose responses
     - Animal experiments to provide information on in vivo properties of novel fibre source (e.g. apparent digestibility, fecal volume)
     - Clinical studies to assess acceptability and tolerance, and monitor possible adverse effects

3. Return to Step 3 Scientific Track.
## FOOD WITH ADDED VITAMINS AND MINERALS REQUIREMENTS

1. Review these key documents:
   - FDR, Part D, Vitamins, Minerals and Amino Acids, Divisions 1, 2 and 3 with reference to Schedules K (Reasonable Daily Intake for Various Foods) and Schedule M (Reference Amounts)
   - *Guide to Food Labelling and Advertising* (sections 7.2.5 and 7.7)
   - *Guide to Food Labelling and Advertising* (section 8.6.4. Summary Table of Acceptable Nutrient Function Claims)
   - Nutrition Labelling Compliance Test

2. Manufacturers must follow the current prescribed regulations. Legislation to permit discretionary fortification of foods has not been amended. Fortification of foods continues on a case-by case approval basis by Health Canada. Determine if the product in question will comply with regulations.

3. Determine the suitability for the product in question of the claims available for vitamins and minerals in a food:
   - is a factor in the maintenance of good health
   - is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development

4. Claims may be made only for vitamins or mineral nutrients for which recommended daily intakes (RDIs) have been established. A minimum of 5% of the RDI per serving of stated size must be present for the vitamin or mineral that is the subject of the claim. Assess whether the product in question will comply.

5. Some vitamins and minerals in some foods are eligible for nutrient function claims. Determine which claims are of interest.

6. Manufacturers are advised to review the Health Canada policy on IMA and TMAL with regard to discretionary fortification.

7. Return to Step 3 Scientific Track.
## FOOD ADDITIVE REQUIREMENTS

1. Review these key documents:
   - FDR, Part B, Division 1 (B.01.001)
   - FDR, Part B, Division 1, sections B.01.042 to B.01.045
   - FDR, Part B, Division 16, Food Additives and accompanying tables
   - A Guide for the Preparation of Submissions on Food Additives (December 2007)

2. Determine which of the data requirements for a food additive submission to Health Canada are available:
   - description of the food additive, including chemical name and use name, method of manufacture, chemical and physical properties, composition and specifications
   - amount, purpose, directions, recommendations and suggestions for use
   - acceptable methods of analysis for determining amount of food additive and any substance resulting from its use
   - efficacy data demonstrating the technical effect
   - safety data (see details below)
   - residue data
   - proposed maximum limits of use
   - labelling samples
   - sample of food additive, sample of active ingredient, and sample of finished product (if requested)

   The guide provides more detailed information for each of the statutory requirements listed above.

   The guide also provides detailed information on the safety assessment requirements, a key component of the submission.

3. Determine which comprehensive scientific data addressing the following topics are available for the safety assessment:
   - food intake data
   - toxicological data (may include pharmacokinetic studies or human clinical studies where the extent of testing depends on chemical structure and properties, disposition, toxicity and exposure)
   - nutritional considerations: effects of the food additive on nutritional quality and safety of the food for the general population and vulnerable sub-groups (children, elderly)
   - microbiological considerations for food additives derived from microorganisms or genetically modified organisms, to test efficacy of preservatives or to ensure that any changes to physicochemical properties of the food due to the food additive do not compromise the safety of that food.

4. Prepare a summary of consumer benefits and effect on overall food quality of the additive to be included with the petition.

5. Return to Step 3 Scientific Track.
4.7 Step 4: Nutrient Claim and Food Health Claim Option Assessment

The purposes of the fourth Step are:

- to confirm or determine:
  - novel food or novel fibre status,
  - permissible food applications,
  - manufacturing guidelines,
  - ingredient classification (i.e. food additive, fibre), and
  - the type and level of nutrient and/or health claim to be pursued.
- to determine the breadth and depth of scientific information available and identify gaps (if any) to be filled in order to substantiate the desired nutrient and/or health claim;
- in combination with the output of the Regulatory Track, to develop a research plan to address any data shortages to complete the nutrient/health claim application;
- to create detailed estimates of the size and attractiveness of each market option;
- to create a framework to compare the market opportunity to the resource requirements for each product/regulatory framework/market option; and
- to create business plans and other management planning/monitoring tools that will guide the pursuit of a nutrient/health claim R&D/manufacturing/marketing/distribution strategy for the business.

With these objectives in mind, the Health Claim Decision Team should proceed to the activities and tasks listed below in Table 11.
Table 11  Decision Model: Step 4 Activities Organized by Track Focus

<table>
<thead>
<tr>
<th>Step 4: Nutrient Claim and Food Health Claim Option Assessment</th>
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<tbody>
<tr>
<td><strong>Regulatory Track</strong></td>
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</table>
| 1. Review the following key documents, which are described and referenced in Appendix 2: | 1. A number of claim options are available for food categories, food products or food constituents. The decision is what type of claim will be pursued, what conditions apply to the claim and what information is required to substantiate claims. Work through the following questions to make the determination. Decision Questions:  
1. Do you only want to convey nutrition information about the product (e.g. quantity of fats, protein, carbohydrates, vitamins or minerals) present per serving size of stated food, OR make a claim about the nutrient content (e.g. “low fat,” “cholesterol free,” “source of fibre,” “natural,” “organic,” etc.)? If yes, options include:  
   - Nutrition Facts table and ingredients list  
   - nutrient content claims  
   - non-nutrient declarations  
   These options are not health claims. Consult CFIA’s Guide to Food Labelling and Advertising for guidance.  
2. Do you want to make nutrient and/or health claims already permitted in Canada? These include:  
   - nutrient function claims  
   - general health claims  
   - function claims  
   - disease risk reduction claims | 1. Define the target market segments for each of the different potential nutrient and/or health claims.  
2. Conduct secondary and primary market research on each option* under review.  
3. Identify key trends in the market that influence sales and buyer behaviour.  
4. Identify specific competitors, study their strengths and project their likely response to a new market entrant.  
5. Analyze the competitive position for each potential nutrient and/or health claim and perform a benefits analysis of the claim vs. competitors’ claims.  
6. Review the business’s marketing strengths, position in the market and resource capacity to introduce the new claim/product and build market share.  
7. Identify detailed potential customer characteristics and competition (both direct and substitute products).  
8. Identify key aspects of pricing structures for | 1. Assess the strategic fit into the business of each type of nutrient and/or health claim.  
2. Estimate the financial and human resource requirements for each type of claim.  
3. Determine the manufacturing capacity and raw material supplies needed for success.  
4. Outline the risks, including the company or industry association’s ability to comply with the regulatory requirements for approval of each type of claim.  
5. Compare the relative profits and benefits of each type of claim. |

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*Note: The asterisk (*) indicates that further details or notes are required for each option.
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| 2. Review the definitions and guidance documents discussing nutrient and health claim options not requiring pre-market approval or regulatory amendment: | If yes, FDR (Part B, Division 1) and the *Guide to Food Labelling and Advertising* describe the currently permitted claims and the conditions for using the claims.  
   3. Do you want to make a new health claim (nutrient function, function, disease risk reduction or therapeutic claims)?  
      If yes, consult the *Guidance Document for Preparing a Submission for Food Health Claims* for the list of evidence required to ensure the claim can be substantiated. |
|   |   |
|   | 2. Health claims not requiring pre-market approval or regulatory amendment include general health claims, function claims and nutrient function claims. Determine if the following conditions that apply to these types of claims are suitable to the company or industry association:  
      - Claim must be truthful and not misleading.  
      - Manufacturers are expected to have evidence (in-house) to substantiate the health claim should they be questioned by enforcement agencies.  
      - Manufacturers are advised to follow the *Guidance Document for Preparing a Submission for Food Health Claims* to ensure the claim is properly substantiated and/or to provide a voluntary submission to Health Canada.  
      - Consult with Health Canada before marketing the food product.  
   3. New disease risk reduction claims and therapeutic claims must have pre-market approval by Health Canada and require regulatory amendment.  
      Follow the *Guidance Document* all potential competing products.  
   10. Assess factors such as buyer power and potentially dominant competitors that will become barriers to market entry.  
   11. Identify distribution channels and assess advantages and costs of each option.  
   12. Estimate the sales potential for each product with each potential claim.  
   13. Estimate the relative attractiveness of each product/regulatory framework/market option.  
   14. Match the above estimates with the output of the Scientific and Regulatory Tracks to identify the optimal nutrient/health claim strategy.  
   15. Assess the potential sales increases, or reduced costs for packaging and market development, of an ingredient sales strategy (i.e. products being sold to further processors), rather than a consumer-ready product form.  
   * Where “option” means each product/regulatory framework/market segment/distribution channel option.
for Preparing a Submission for Food Health Claims to ensure all evidence is available and could be submitted for assessment.

The main requirements of the petition include:
- petitioner’s contact information
- details pertaining to the health claim
- status of health claim in other jurisdictions
- characterization of the food: composition and manufacturing meet quality standards
- characterization of the health effect
- evaluation of the claim validity
- checklist for submission
- references

4. Consult the Guidance Document for Preparing a Submission for Food Health Claims for more detailed information on what is required to complete a submission. Working through the guidance document will identify any information gaps. The degree to which there are information deficiencies will provide some indication as to whether or not a new health claim should be pursued.

5. If the decision to pursue a health claim is positive, develop a research plan to address the information deficiencies and/or prepare the submission.

Process to Review Step 4 Results

1. The Regulatory Track manager uses the same general process outlined in Step 1. In Step 4, the focus is on the differences among the types of nutrient claims and health claims and how they relate to the product in question. Specific attention also needs to be paid to the differences between the claims that require pre-market approval and those that do not. The Step 4 review is similar to but more focused than Step 1, given the work done in Steps 1–3 and the clarity this will provide regarding the benefits of each type of claim to the company or industry association’s chosen market and the relative costs in pursuing each type of claim.

2. The Scientific Track manager uses the same process outlined in Step 1. By working through the Track questions and research activities, a clearer understanding should be attainable about the optimal nutrient and/or health claim option to pursue and the work plan that will be required to pursue it.

3. The Market Track manager uses the same process outlined in Step 1. However, much more precision is brought to market estimates because the additional work in previous Steps will provide a greater level
of understanding of market dynamics and greater confidence in all projections. Focus on the market with respect to its overall attractiveness and the current and potential competitors. This is done for each market as matched to each nutrient claim or health claim option.

4. The Business Planning Track manager uses the same process outlined in Step 1. Focus on the overall profit potential of each claim type in each market segment under consideration.

5. The purpose of summarizing the results from each Track is to:
   - make the information more useful and meaningful to each of the other Track managers and other members of the Health Claim Decision Team; and
   - prepare the data for use in the Step Go/No Go decision.

6. Each Track manager will review the Step’s Key Results from the other Tracks and identify the implications for his/her Track.

7. All Health Claim Decision Team members will review all Step Key Results for implications for the business as a whole and for all external stakeholders.

8. A meeting of the Health Claim Decision Team is held to discuss all available information, as described in Step 1.

### Step 4 Decision Criteria

The Step 4 Decision Criteria consist of veto and comparative criteria as described for Steps 1 through 3. The criteria for Step 4 are similar to those of Step 1. However, they are much more detailed and precise, as they are based on the specific circumstances of the individual company or industry association. Work in the previous three Steps should have prepared the Health Claim Decision Team to look at the company or industry association’s capabilities, constraints and objectives critically. The Decision Criteria are fine tuned accordingly.

The veto and comparative criteria from Step 1 are listed below (with some modifications) for ease of reference. The Track managers must rework these criteria with sufficient detail and precision to enable confidence in the final set of decisions to be made.

#### Sample Veto Criteria:

- It appears sufficient scientific evidence is available, or can be developed, to establish the safety and health benefit linkage of the product for regulatory approval.
- The product/regulatory framework/market option is an acceptable strategic fit with the company or industry association objectives.
- There is a potential market of sufficient size to likely allow sufficient sales volume to generate profits.
- The resources required to pursue a health claim may be available.
- Risk levels are acceptable.

#### Sample Comparative Criteria:

- There is, or can be, more scientific evidence to support an approval under the regulatory process for the selected option.
- The R&D, testing protocols and other related costs of complying with regulations are lower.
- The IPR associated with the regulatory process can be better protected.
- The market is more familiar with the product/regulatory framework/market option, and the market places more value on related health benefits.
- The market is larger and/or has the potential for more rapid growth.
- There is potential for a competitive advantage versus competitors.
- There is greater potential for profit.
- The product/regulatory framework/market option is a strategic fit with the company or industry association.

Assessment Matrix for the Step 4 Decision Process

The Health Claim Decision Team performs the assessment of each product/regulatory framework/market option against the Step Decision Criteria (see Appendix 4 for a sample assessment matrix) and ultimately drives the Step Decision with a process that follows the same basic steps outlined in Step 1.

As noted in the summary below, in general there are four potential outcomes of the decision process for each option:

1. Go: Pursue a nutrient claim process because the decision results have indicated an option (food, ingredient or food with added vitamins and minerals) is sufficiently positive to invest time and resources to follow the requirements of pertinent regulations and guidance documents for claim usage.

2. Go: Pursue a health claim submission because the decision results have indicated an option (food, ingredient or food with added vitamins and minerals) is sufficiently positive to invest time and resources to follow the requirements of pertinent regulations and guidance documents for claim approval and/or usage.

3. Redo the current or previous Steps: The decision results suggest the option should not be advanced with what is known now, but may hold potential if current Step activities were redone in more detail and produced different results that were more positive, or more negative, so a decision could be finalized.

4. No Go: Stop all work on the process immediately because the decision process results are sufficiently negative and there appears to be no merit in pursuing any sort of nutrient or health claim for the food, ingredient or food with added vitamins and minerals.

The method described in Step 1 for making the decision by assessing each product/regulatory framework/market option against all criteria and totalling the results also applies in Step 4.

Step 4 Go/No Go Decision Options:

1) Food, food ingredient, or food with added vitamins and minerals with selected nutrient claim: Pursue Nutrient Claim Process
2) Food, food ingredient, or food with added vitamins and minerals with selected food health claim: Pursue Health Claim Submission
3) Optimal non-nutrient declaration/nutrient claim/health claim strategy not clear: Redo Current or a Previous Step
4) Food, food ingredient or food with added vitamins and minerals with no non-nutrient declaration, nutrient claim and/or health claim: Exit Model
4.8 Next Steps

At the end of Step 4 of the decision model, the company or industry association has decided what nutrient and/or health claim strategy it will pursue. The options can be summarized as follows:

**NHP:** If the work from Step 2 determined the product should follow the NHP regulations, the source of the relevant regulations was identified. It is beyond the scope of the Roadmap to proceed any further with the NHP approval process.

**Novel:** Step 3 of the decision model included a determination of whether or not the product in question was considered to be novel under the Canadian definition of this term. If the decision is that the product is novel, the company or industry association must proceed with a pre-market approval for the novel product under the novel food regulations before proceeding with the nutrient/health claim processes (regardless of whether a pre-market approval for the claim is required). The Roadmap has identified the appropriate regulations to be consulted and the necessary guidance documents that must be followed with the novel food approval process.

**Food with added vitamins and minerals:** If this strategy is deemed optimal, the company or industry association can proceed to market following the regulations that cover the addition of vitamins and minerals to foods and any related claims that these products can make.

**Food additive:** Alternatively, the company or industry association may have decided the appropriate regulatory framework and product form option is that of a food additive. Likewise, the company or industry association is now ready to proceed with the food additive approval process following the guidance documents referenced in the Roadmap.

**Nutrition Facts table and ingredients list, nutrient claims, non-nutrient declarations, nutrient function claims, general health claims or function claims that do not require pre-market approval:** If it is the company or industry association’s strategy to pursue nutrient claims or health claims that do not require pre-market approval, it can proceed to market following the regulations that cover these claims and the products carrying them.

**Disease risk reduction claims or therapeutic claims that do require pre-market approval:** If pre-market approval for a health claim is required, the challenge is to work through the guidance documents that have been referenced throughout the Roadmap to produce the company or industry association’s health claim submission. Any new claim must submit a substantial body of scientific evidence to obtain approval prior to use on a food label.

The overall purpose of the Roadmap is to bring the company or industry association to the point of deciding whether or not to pursue a nutrient and/or health claim. If the decision is not to use a nutrient/health claim, the Roadmap has identified alternative strategies to pursue. If the decision is yes, the appropriate guidance documents have been identified in the decision model for the nutrient and/or health claim. These are the places to start planning the work required for a nutrient or health claim.
It is recommended that the company or industry association prepare a detailed plan that will guide how it will manage the submission process, including the defining of:

- necessary activities needed to drive it;
- person to lead it, and persons to manage the activities for each Track; and
- resources (human, financial and time) to conduct the activities, prepare and submit the applications, and to respond to Health Canada feedback and requests for more information.

Finally, it may be beneficial to contact the Food Regulatory Issues Division of Agriculture and Agri-Food Canada for assistance (see coordinates provided on the copyright page).
## Appendix 1: Definitions and Terminology

In any field, it is important to understand the language and terms that are used. This is particularly true for the regulations and guidance documents that deal with nutrient claims and health claims. Few of the terms have legal definitions (i.e. actually defined in an Act or Regulation). As a result, different authors use different descriptions for a type of health claim and different examples of each type of claim. Health Canada is undertaking an extended review and update of Canada’s food regulatory framework. Extensive consultation with industry, consumer groups and other stakeholders has resulted in a situation where certain terms are being dropped and replaced by newer terms. During this evolutionary period, both older and newer terms are being used interchangeably and the different wording can create confusion when earlier reports are referenced.

The following table lists important terms that need to be understood when considering nutrient or health claims in Canada. For each term, the current definition or explanation of the term is provided along with the source(s) used and a link to the source document. In the case of older terms, they are also listed and defined, and the term that replaces the older one is identified.

<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION/SOURCE</th>
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<tbody>
<tr>
<td><strong>Bioactive Substance</strong></td>
<td>A bioactive substance is one that is demonstrated or purported to have a favourable effect on health. Bioactive substances include nutrients or non-nutrients in foods or other substances with medicinal or pharmacological properties from non-food sources. <em>Examples</em>: vitamins, minerals, isoflavones from soybeans, probiotic cultures, botanical materials (i.e. <em>Hypericum perforatum</em> [St. John’s Wort])</td>
</tr>
<tr>
<td><strong>Biological Role Claims</strong></td>
<td>This term is no longer used. This category of function claim has been renamed “nutrient function claim.” See Nutrient Function Claim.</td>
</tr>
</tbody>
</table>
| **Disease Risk Reduction Claim** | Disease risk reduction claims, previously referred to as diet-related health claims, correspond to health claims in the table following B.01.603 in the Canadian Food and Drug Regulations. These claims are allowed only in food where specifically permitted by Food and Drug Regulations. They are 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 and hypertension) in the context of the total diet. The Regulations provide for claims that 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 |

- maximal fermentable carbohydrates in gum, hard candy or breath-freshening products, and the reduced risk of dental caries.

**Guide to Food Labelling and Advertising, Chapter 8**  

**Drug Claims**  
A drug claim is one that suggests the product has the properties of a drug (e.g. the treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms) or that the product has an effect on the body beyond that normally associated with a food (e.g. restoring, correcting or modifying organic functions in the body). Most disease risk reduction and therapeutic claims are drug claims. Disease risk reduction claims and therapeutic claims are allowed on food only where specifically permitted by the Food and Drug Regulations.

**Guide to Food Labelling and Advertising, Chapter 8**  

**Food**  
Any article manufactured, sold or represented for use as a food or drink for human beings, including chewing gum, and any ingredients that may be mixed with food for any purpose whatever.

**Food and Drugs Act (section 2)**  
[http://laws.justice.gc.ca/eng/F-27/page-1.html#anchorbo:3](http://laws.justice.gc.ca/eng/F-27/page-1.html#anchorbo:3)

**Food Additive**  
Section B.01.001 of Division 1, Part B (Foods) of the Food and Drug Regulations defines “food additive” as follows:

“Food additive means 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, but does not include:

(a) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food,
(b) vitamins, mineral nutrients and amino acids, other than those listed in the tables to Division 16,
(c) spices, seasonings, flavouring preparation, essential oils, oleoresins and natural extractives,
(d) agricultural chemicals, other than those listed in the tables to Division 16,
(e) food packaging materials and components thereof, and
(f) drugs recommended for administration to animals that may be consumed as food.”

**Food and Drug Regulations**  

**Food Exposure and Food Intake**  
These terms are used interchangeably in Health Canada guidance documents. In both experimental and epidemiological studies, the assessment of food intake may be supported by a biomarker of exposure (e.g. intake of lutein from foods may be supported by measurement of blood lutein levels).

**Guidance Document for Preparing a Submission for Food Health Claims**  
### Food Format
A product is in food format if it is sold in a format and serving size consistent with food use. Examples of products in a food format include chewing gums, hard candies, candy bars, tea, juices and beverages. Capsules, pills and tablets are not considered to be food formats.

**Classification of Products at the Food–Natural Health Products Interface: Products in Food Formats**

### Foods with Added Vitamins and Minerals
This term may be used interchangeably with “food fortification” and “fortified foods,” depending on the context. Health Canada has been working through a lengthy review of current policies and has developed, through consultations, a revised policy for Canada relating to the addition of vitamins and minerals to food products. It is not yet in place and the time frame for final approval has not been clarified. The key elements of the revised policy are as follows. Vitamin and mineral addition to foods is permitted under the following broad categories, to help protect consumers from nutrient inadequacies and from excessive nutrient intakes:

- Vitamin and mineral addition is permitted to maintain and improve the nutritional quality of the food supply through (i) restoration and (ii) nutritional equivalence of substitute foods.
- Programs for addition of vitamins and minerals will continue to be employed to correct and/or prevent nutritional problems of public health significance.
- Discretionary addition of any nutrient from a defined list of vitamins and minerals, over defined ranges at the discretion of manufacturers, is expanded to allow for a wider range of products with added vitamins and minerals which would provide for more food sources of nutrients without increased risk to health.
- The special-purpose foods category is broadened to allow the formulation of a greater variety of products designed for people who may require them for special nutritional purposes.

**Addition of Vitamins and Minerals to Foods, 2005: Health Canada’s Proposed Policy and Implementation Plans**

### Food–Health Relationship
Refers to a biologically plausible association between a food and a health outcome.

**Guidance Document for Preparing a Submission for Food Health Claims**

### Food Purpose
Means a purpose that has been established by history of use, or by being regulated, defined or implied by the FDR, or that has been accepted following a novel food notification.

**Classification of Products at the Food–Natural Health Products Interface: Products in Food Formats**
### Function Claims

Food provides energy and the building blocks needed for growth, development and the maintenance of life and health. Function claims relate to the specific beneficial effects that the consumption of a food or a constituent of a food (nutrient or other component) has on the normal functions or biological activities of the body. Such claims relate to a positive contribution to health and the maintenance of a physiological function or to physical or mental performance. Function claims are based on the role that the food or the food constituent plays when consumed at levels consistent with normal dietary patterns. *Example:* Product X promotes regularity. **Nutrient function claims** (previously called **biological role claims**) are considered a subset of function claims. See “Nutrient Function Claims” for more information.

Function claims are about the specific beneficial effects that the consumption of a food or food constituent has on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or performance. A function claim about the physiological effects of food or food constituents must not refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or of their symptoms. Claims about restoring or correcting abnormal functions of the body or modifying body functions beyond the normal physiological effects of food are considered to be therapeutic claims, not function claims. Such claims would require a pre-market review by Health Canada and (if the claim is supported by sufficient scientific evidence) an amendment to the Food and Drug Regulations to permit their use on food.

**Guide to Food Labelling and Advertising, Chapter 8**


### General Health Claim

General health claims are broad claims that promote health through healthy eating or that provide dietary guidance. These claims do not refer to a specific or general health effect, disease, or health condition. *Examples:* “Include low-fat product X as part of healthy eating.” “As part of healthy eating, this food may assist in achieving and maintaining a healthy body weight because it is portion controlled.”

**Guide to Food Labelling and Advertising, Chapter 8**


### Generic Health Claim

The term “generic health claim” is old terminology for claims in which a group of foods or a nutrient or other food constituent is the subject of the claim. Such claims can be generalized to similar foods that meet specified nutritional criteria. *Example:* “A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer.” This type of health claim is now referred to as “Disease Risk Reduction Claim.”

### Health Effect and Health Outcome

The terms “health effect” and “health outcome” are used interchangeably. Both terms refer to a body function, health condition or disease risk, or mental or physical performance. With regard to disease risk, it refers to an effect on a true disease endpoint, such as heart disease mortality, or to an effect on a recognized surrogate marker of disease or a disease risk factor, such as blood LDL cholesterol. With regard to normal physiological function, or mental or physical performance, it refers to an effect associated with the maintenance or enhancement of health (e.g. promotes regularity, builds and repairs muscles), and not to a therapeutic effect (e.g. relieves constipation, restores mental alertness).
### Guidance Document for Preparing a Submission for Food Health Claims


### Health Claim

A health claim for foods means any representation in food labelling and advertising that states, suggests or implies that a relationship exists between a food category, a food, or a food constituent and health (Codex Alimentarius Commission, 1997) (e.g. disease risk reduction claims, function claims and general health claims).


### Implied Health Claim

An implied health claim is any representation of a health claim without explicitly stating that a relationship exists between a food category, a food, or a food constituent and health. Examples of this include the use of a logo, symbol, name, trade mark, seal of approval, or by association (e.g. hyperlink to a website, or juxtaposition of “educational” material with advertisements for specific products having the characteristics referred to in the former). Such representation may apply to a general health claim or a specific health claim. **Example:** The use of a heart symbol to imply that the food is heart-healthy or that the food may be part of a diet to reduce the risk of heart disease.


### List of Ingredients

Prepackaged multi-ingredient foods require an ingredient list, with the following exceptions:

- prepackaged products packed from bulk at retail (except for mixed nuts and meat products packed by a retailer which contain phosphate salts and/or water: these products do require an ingredient list);
- prepackaged individual portions of food served with meals or snacks by restaurants, airlines, etc. (e.g. coffee creamers, ketchup);
- prepackaged individual servings of food prepared by commissaries and sold in mobile canteens or vending machines;
- prepackaged meat, poultry and poultry meat by-products barbecued, roasted or broiled on the retail premises; and
- standardized alcoholic beverages and vinegars.

In general, ingredients must be listed in **descending order of proportion by weight**, as determined before they are combined to make the food. The exceptions are spices, seasonings and herbs (except salt), natural and artificial flavours, flavour enhancers, food additives, and vitamin and mineral nutrients and their derivatives or salts, which may be shown at the end of the ingredient list in any order. The ingredient list must be shown in both **English and French** unless otherwise exempted by the Food and Drug Regulations [B.01.012].

**Guide to Food Labelling and Advertising, Chapter 2—Basic Labelling Requirements**

### Natural Health Product

A substance set out in Schedule 1 of the Natural Health Products Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in:

(a) The diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

(b) Restoring or correcting organic functions in humans; or

(c) Modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

**Natural Health Products Regulations**


### Non-Nutrient Declarations

In the context of health claims for foods, non-nutrients are constituents of food that are not known nutrients but are demonstrated or purported to have a favourable effect on health. Non-nutrients cannot be listed in the Nutrition Facts table, whereas nutrients can be listed. Information on the amounts of non-nutrients not permitted within the Nutrition Facts table, such as boron or individually named fatty acids, may be displayed on a **voluntary basis** providing it appears on any part of the label **other** than within the Nutrition Facts table, and is declared, in grams per serving of stated size. **Example:** has X g “non-nutrient” per 100 g serving. Do not use “contains.”

**Guide to Food Labelling and Advertising, Chapter 5, section 5.4.3**

www.inspection.gc.ca/english/fssa/labeti/guide/ch5e.shtml#5.4

**Guide to Food Labelling and Advertising, Chapter 7, section 7.4**

www.inspection.gc.ca/english/fssa/labeti/guide/ch7e.shtml


### Novel Fibre

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.

There are safety considerations unique to novel fibre sources that must be taken into account in the evaluation of their acceptability as foods. 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 0.5 mm in particle size) and inulin.

Note that while approval must be given for novel fibres to be included in foods, a novel fibre does not necessarily mean it is a dietary fibre. Dietary fibres require clinical studies to show a biological effect such as laxation or impact on blood lipids. There can be no nutrient function claim with a novel fibre and it can be listed only in the ingredients list. Dietary fibres, on the other hand, are listed in the ingredients list and in the Nutrition Facts table, and a nutrient content claim can be made.
**Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them**


<table>
<thead>
<tr>
<th>Novel Food</th>
<th>Novel food means:</th>
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<tbody>
<tr>
<td></td>
<td>(a) a substance, including a microorganism, that does not have a history of safe use as a food;</td>
</tr>
<tr>
<td></td>
<td>(b) a food that has been manufactured, prepared, preserved or packaged by a process that:</td>
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<tr>
<td></td>
<td>(i) has not been previously applied to that food, and</td>
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<tr>
<td></td>
<td>(ii) causes the food to undergo a major change*; and</td>
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<tr>
<td></td>
<td>(c) a food that is derived from a plant, animal or microorganism that has been genetically modified** such that</td>
</tr>
<tr>
<td></td>
<td>(i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,</td>
</tr>
<tr>
<td></td>
<td>(ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or</td>
</tr>
<tr>
<td></td>
<td>(iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.</td>
</tr>
<tr>
<td></td>
<td>*“Major change” means, in respect of a food, a change in the food that, based on the manufacturer’s experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to:</td>
</tr>
<tr>
<td></td>
<td>(a) the composition, structure or nutritional quality of the food or its generally recognized physiological effects;</td>
</tr>
<tr>
<td></td>
<td>(b) the manner in which the food is metabolized in the body; or</td>
</tr>
<tr>
<td></td>
<td>(c) the microbiological safety, the chemical safety or the safe use of the food.</td>
</tr>
<tr>
<td></td>
<td><strong>“Genetically modify” means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.</strong></td>
</tr>
</tbody>
</table>

**Division 28 of the Food and Drug Regulations (Novel Foods Regulations)**

*www.hc-sc.gc.ca/fn-an/consult/_novel_foods/consultation_appendix-annexe1-eng.php*

| Nutrient | Nutrients are chemical compounds that are generally recognized to provide energy, or to be required for growth and development and maintenance throughout the life cycle. Essential nutrients are generally regarded as those compounds that are not synthesized in the body at all, or not in sufficient quantities to meet normal requirements, and must be provided by the diet. For the purposes of health claims and nutrition labelling in Canada, known nutrients are those recognized by the Institute of Medicine of the National Academies, Washington, DC, for which recommended intakes have been established (e.g. vitamins, minerals, protein, dietary fibre). |


**Nutrient Content Claim**

Nutrient content claims are statements or expressions that describe, directly or indirectly, the level of a nutrient in a food or a group of foods. They are not health claims. Nutrient content claims are now limited to those that are permitted by the FDR. Only the wording permitted in the Regulations may be used. The Regulations also prescribe the compositional criteria for each claim and any related additional labelling requirements. The compositional criteria for most of the nutrient content claims are based on regulated standardized “reference amounts” for foods as well as the “serving of stated size” for the particular food. Reference amounts are based on average food quantities eaten at a single eating occasion.

*Guide to Food Labelling and Advertising, Chapter 7—Nutrient Content Claims*

www.inspection.gc.ca/english/fssa/labeti/guide/ch7e.shtml

**Nutrient Function Claims**

Nutrient function claims, formerly known as biological role claims, describe the well-established roles of energy or known nutrients that are generally essential for the maintenance of good health or for normal growth and development. Provisions for nutrient function claims are made in B.01.311, D.01.006 and D.02.004 of the FDR. Nutrient function claims are not made for a food per se; they may only be made respecting the energy value or nutrients in a food.

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

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

*Guide to Food Labelling and Advertising, Chapter 8*

www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.shtml

**Nutrition Facts Table**

Canada’s nutrition labelling regulations have been designed to provide a system for conveying information about the nutrient content of food in a standardized format, which allows for comparison among foods at the point of purchase. The Nutrition Facts table provides information on energy (Calories) and 13 nutrients, based on a serving of stated size. The Nutrition Facts table must appear on the label in a prescribed manner. The *Guide to Food Labelling and Advertising* contains detailed information on the presentation of the Nutrition Facts table and those situations where a product is exempt from this requirement.

*Guide to Food Labelling and Advertising, Chapter 5*

www.inspection.gc.ca/english/fssa/labeti/guide/ch5e.shtml

**Nutritional Criteria**

Nutritional criteria are compositional criteria that determine the eligibility of a food to carry health claims. *Qualifying* nutritional criteria specify the minimum levels of certain nutrients (e.g. some vitamins and mineral nutrients) that should be met for a food to carry health claims. *Disqualifying* nutritional criteria specify maximum levels of specified nutrients (e.g. certain nutrients considered to increase the risk of some chronic diseases) that should not be exceeded for a food to carry health claims.

*Report on Stakeholder Feedback on Modernizing Canada’s Framework for Health Claims on Food, September 2009*

# Probiotic

According to the Expert Consultation (2001) conducted by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), probiotics are: “Live microorganisms which when administered in adequate amounts confer a health benefit on the host.” In the case of foods, the FAO/WHO Expert Consultation limited the scope of the definition to: “Live microorganisms which when consumed in adequate amounts as part of food confer a health benefit on the host.”

According to Health Canada, the term “probiotics” and similar terms or representations (e.g. “with beneficial probiotic cultures”; “contains bacteria that are essential to a healthy system”; and a Latin name of a microbial species modified to suggest a health benefit) in text or graphics on food labels and in advertising that suggest a food confers a health benefit are examples of health claims.

**Guidance Document—The Use of Probiotic Microorganisms in Food**


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## Product-Specific Health Claim

Product-specific health claims apply only to food products for which the evidence supporting a claim specific to a particular product is not generalizable to other similar products. This recognizes that food matrices and processing conditions could have an effect on the physiologic property of foods. However, as there is no example that can be verified at present, Health Canada is not permitting product-specific claims at this time.

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## Special-Purpose Foods

The Codex definition of special-purpose foods is used in Canada (i.e. “foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by the addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use.”) “Food for special dietary use” means food that has been specially processed or formulated to meet the particular requirements of a person:

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

Examples of foods for special dietary uses include formulated liquid diets; meal replacements; nutritional supplements; gluten-free foods; and sodium-reduced foods for sodium-restricted diets.

The current regulations contain detailed nutrient compositional requirements for formulated liquid diets, meal replacements and nutritional supplements.

**Addition of Vitamins and Minerals to Foods, 2005: Health Canada’s Proposed Policy and Implementation Plans**


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## Submission

Means a stand-alone dossier containing all the required information for substantiation of a food–health relationship (i.e. a health claim).

**Guidance Document for Preparing a Submission for Food Health Claims**

### Substitute Foods

The Canadian regulations allow for the addition of vitamins and minerals to foods that are meant to replace certain foods in a person’s diet for specific health or dietary requirements. Examples include:

- fruit-flavoured drinks as a substitute for breakfast drinks of fruit juices;
- simulated meat;
- plant-based beverages as an alternative to milk; and
- fortified vegetable-based or vegetable and milk protein-based products, which resemble cheese.

*Addition of Vitamins and Minerals to Foods, 2005: Health Canada’s Proposed Policy and Implementation Plans*

[www.hc-sc.gc.ca/fn-an/nutrition/vitamin/fortification_final_doc_1-eng.php#c3](http://www.hc-sc.gc.ca/fn-an/nutrition/vitamin/fortification_final_doc_1-eng.php#c3)

### Therapeutic Health Claims

These are health claims that describe the link between the characteristics of a diet, food or food constituent and the treatment or mitigation of a disease or health-related condition, or about restoring, correcting or modifying body functions. Two therapeutic claims have been approved in Canada: for plant sterols (phytosterols) and blood cholesterol lowering, and for oat products and blood cholesterol lowering.

*Guide to Food Labelling and Advertising, Chapter 8*


### Therapeutic Use

Means a product that is used for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans, or restoring or correcting organic functions in humans, or modifying organic functions in humans.

*Classification of Products at the Food–Natural Health Products Interface: Products in Food Formats*

Appendix 2: Important Resource Documents

Numerous discussion papers, guidance documents and regulations are available on Health Canada, AAFC, CFIA and Department of Justice websites. The table below summarizes many of the key documents that should be researched in depth by any company or industry association considering a nutrient claim, non-nutrient declaration or health claim in Canada. The agency or department responsible for each document is identified and a link to each document is provided.

<table>
<thead>
<tr>
<th>TITLE</th>
<th>DESCRIPTION/SOURCE</th>
</tr>
</thead>
</table>
| A Guide for the Preparation of Submissions on Food Additives—December 2007 | The purpose of this guide is to assist food manufacturers and distributors in the preparation of food additive submissions. Information is also provided on irradiated food submissions and on requests for opinions on substances not regulated as food additives. This guide is not legally binding but merely represents an interpretation and elaboration of the provisions of section B.16.002 of the Food and Drug Regulations.  
Health Canada  
| Addition of Vitamins and Minerals to Foods, 2005: Health Canada’s Proposed Policy and Implementation Plans | Health Canada initiated a comprehensive policy review on the addition of vitamins and minerals to foods in January 1998. Stakeholders indicated that the major issues regarding fortification were those in the areas of public health, safety, consumer choice and availability, and trade and competitiveness. The revised policy would retain current fortification practices to prevent and correct nutritional problems, such as requiring the addition of vitamin D to milk to combat the childhood disease of rickets and the addition of folic acid to flour to reduce birth defects. Fortifying foods to restore vitamins and minerals lost through processing would also continue. The policy examined the possibility of a new provision for food fortification done at the “discretion” of the manufacturer (within defined limits set by Health Canada) to meet a market demand as well as the possible expansion of the product category of special-purpose foods. The proposal remains on Health Canada’s website but there has been no decision on whether to alter the existing policy at this time.  
Health Canada  
www.hc-sc.gc.ca/fn-an/nutrition/vitamin/fortification_final_doc_1-eng.php                                                                                       |
| Classification of Products at the Food–Natural Health Products Interface: Products in Food Formats—March 2009 | This guidance document outlines the principles and considerations to be applied in determining if a product in a food format is an NHP. “It has been created and published with a view to achieving greater consistency, transparency and quality of classification decisions relating to products in food format.” It is intended to be used in conjunction with other existing guidance documents and policies. Health Canada, Natural Health Products Directorate and Food Directorate [www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php) |
| Consumer Packaging and Labelling Act and Regulations | This is the legal document that covers the packaging, labelling, sale, importation and advertising of prepackaged and certain other products in Canada. All food products and natural health products must comply with this legislation and associated regulations. Department of Justice [http://laws.justice.gc.ca/PDF/Statute/C/C-38.pdf](http://laws.justice.gc.ca/PDF/Statute/C/C-38.pdf) |
| Comprehensive Summary of Canadian Federal Statutes and Regulations Governing Pre-Market Evaluation, Labelling, Advertising and Health Claims for Functional Foods in the Canadian Market—2007 | This document and its various appendices and references are intended as a reference manual for all stakeholders with an interest in health claims for foods and related regulatory requirements. The authors provide readers with a factual overview of statutes and regulations pertinent to pre-market evaluation of health claims. Also provided are a number of appendices and references to help readers examine aspects of Canada’s food and natural health product regulatory system in greater detail. Inter/Sect Alliance Inc. [http://admin.nutrinetcanada-nnc.ca/useredits/files/premarket_evaluation.pdf](http://admin.nutrinetcanada-nnc.ca/useredits/files/premarket_evaluation.pdf) |
| Draft Guidance Document: Management of Pre-Market Submissions—2007 Consultation | This document describes the Food Directorate’s proposed management of pre-market submissions for food additives, novel foods and infant formulas pursuant to requirements of the Food and Drug Regulations. It provides information on activities and timelines related to the management of submissions, and is intended to improve the predictability and transparency of the process. By adhering to this process, submission deficiencies, omissions or inadequacies will be identified early in the process and procedures will be in place to address any such gaps, thus reducing the overall submission review time. Note: This document is in draft form and is not complete. Health Canada, Health Products and Food Branch, Food Directorate [www.hc-sc.gc.ca/fn-an/consult/blueprint_food-plan_aliments/pre_mark_sub-dem_pre-eng.php](http://www.hc-sc.gc.ca/fn-an/consult/blueprint_food-plan_aliments/pre_mark_sub-dem_pre-eng.php) |
### Food and Drugs Act

This is the legal document that covers the manufacture and sale of food, drug, cosmetic and therapeutic products in Canada.

**Department of Justice**


### Food and Drug Regulations

These are the Regulations that provide the details for enforcement of the *Food and Drugs Act*. The Regulations, where applicable, prescribe the standards of composition, strength, potency, purity, quality or other property of the food or drug to which they refer.

**Department of Justice**


### Food Fortification in Canada: Updating the Policy

In 1998, Canada began a review of its food fortification policy. The review responded to concerns that the current policy and practices are too restrictive and that they limit the development of new products, as well as Canadians’ access to fortified foods available in other countries. Health Canada responded by re-visiting the underlying reasons that guide current food fortification regulations and reviewing the latest scientific information. The proposed policy is outlined in the document, *Addition of Vitamins and Minerals to Food, 2005: Health Canada's Proposed Policy and Implementation Plans*. This document provides an overview of the policy and its key principles.

**Health Canada**


### Guidance Document for Preparing a Submission for Food Health Claims—March 2009

This document updates the *Interim Guidance Document—Preparing a Submission for Foods with Health Claims: Incorporating Standards of Evidence for Evaluating Foods with Health Claims*, which has been available since 2002. Its purpose is to ensure that health claims for foods are substantiated in a systematic, comprehensive and transparent manner. When petitioners are preparing submissions for the use of new health claims on food products, **they are required to follow the format set out in this guidance document**. A common submission format among petitioners will ensure a comprehensive and well-organized submission and improved efficiency in the review process.

**Health Canada, Bureau of Nutritional Sciences, Food Directorate, Health Products and Food Branch**

### Guidance Document: The Use of Probiotic Microorganisms in Food—April 2009

The purpose of this guidance document is to clarify the acceptable use of health claims about microorganisms represented as “probiotics” on food labels and in advertising. It also provides guidance on the safety, quality (stability) and labelling aspects of food products containing probiotic microorganisms. The Canadian Food Inspection Agency will use this guidance document to administer and assess compliance of food products containing probiotic microorganisms with the *Food and Drugs Act* and with the food provisions of the Food and Drug Regulations.

Health Canada, Food Directorate, Health Products and Food Branch

### Guide to Developing Accurate Nutrient Values—2007

The guide’s purpose is to help users develop accurate nutrient values and understand some of the factors that cause nutrient values to vary in a food. As nutrient data are used for a variety of applications, the guide can help choose the appropriate approach or approaches for generating nutrient values that will be suitable for the intended purpose. It describes the advantages and disadvantages of three approaches to generating nutrient values:

1. a direct approach: laboratory analysis of appropriately selected samples;
2. an indirect approach: calculations based on nutrient data on specific ingredients (with or without laboratory validation); and
3. an indirect approach: calculations based on generic values from reference databases.

However, this guide is not designed to give a precise step-by-step blueprint on how to develop nutrient values for products.

Health Canada

### Guide to Food Labelling and Advertising

The guide provides information on food labelling and advertising requirements as well as policies that apply to statements and claims made for foods, including alcoholic beverages. As such, it is an important tool to assist industry to be in compliance with legislation and consumer protection. Food claims that adhere to the guidelines set out in this document are considered to comply with the provisions set out in the *Food and Drugs Act* and the Food and Drug Regulations, the *Consumer Packaging and Labelling Act* and Consumer Packaging and Labelling Regulations and other relevant legislation. With respect to health claims, the following chapters are the most relevant:

Chapter 5—Nutrition Labelling
Chapter 6—The Elements Within the Nutrition Facts Table
Chapter 7—Nutrient Content Claims
Chapter 8—Health Claims
Note: The framework set out in this guide for the labelling and advertising of food specifically applies to foods imported into, manufactured in and/or sold in Canada. The policies do not apply to foods destined solely for export unless otherwise indicated.

Canadian Food Inspection Agency
[link](www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml)

### Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them—1997

This guideline explains the policy outlined in Information Letter (I.L.) No. 736, Dietary Fibre, with respect to new or novel fibre sources. There are safety considerations unique to novel fibre sources that must be taken into account in the evaluation of their acceptability as foods. Also, since knowledge of the physio-chemical nature of the dietary fibre in a food cannot reliably predict the potential benefit of that food, the physiological efficacy of the food must be demonstrated by scientific evidence. This guideline has been developed to assist manufacturers in identifying the procedures to verify the safety and physiological efficacy of new products they wish to represent as dietary fibre sources and dietary fibre-containing food products. It is primarily intended to provide basic direction and rationale than to specify procedural details.

Health Canada

### Guidelines for the Safety Assessment of Novel Foods—June 2006

These guidelines are intended to assist the petitioner in preparing a novel food notification and to ensure that the information is sufficient for a safety assessment. This document encompasses novel foods, whether whole foods, food products or food ingredients, that are derived from plant or microbial sources. Novel food safety assessments are conducted by the Food Directorate, Health Products and Food Branch of Health Canada. The guidelines are not intended to define explicitly all the data that might be required in a safety assessment. Further data requirements may be identified on a case-by-case basis during the process.

Health Canada, Health Products and Food Branch, Food Directorate
[link](www.hc-sc.gc.ca/fn-an/legislation/guide-lgd/nf-an/guidelines-lignesdirectrices-eng.php#2)

### Health Canada’s Regulatory Modernization Strategy for Food and Nutrition—December 2008

This document summarizes Health Canada’s strategy to modernize its way of regulating the industry as based on feedback from industry and consumers. The Strategy’s five goals are:

1. improving Predictability, Effectiveness, Efficiency, and Transparency in Health Canada’s Food Regulatory System
2. promoting Regulatory Responsiveness to Food Innovation and Promoting Consumer Access to Foods with Assessed Health Benefits
3. modernizing the Regulatory Toolkit to Address “Food Contributors” to Chronic Disease
4. improving Health Canada’s Responsiveness to Acute Food Safety Health Risks—Responding to New Threats While Managing Ongoing Risks  
5. promoting a Sustainable and Integrated System for Food Safety and Nutrition

Health Canada  
[Link to Health Canada's website]

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<tr>
<td>This report outlines and critically compares the scientific requirements in health claim applications among five jurisdictions (Australia/New Zealand, Canada, European Union, Japan and the United States) and regulatory processes that guide the review of health claim applications. Recommendations for Canada to improve its health claim application process are also discussed.</td>
</tr>
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</table>
| Cantox Health Sciences International  
[Link to Cantox Health Sciences International website]

<table>
<thead>
<tr>
<th>International Market Trends Analysis for the Functional Foods and Natural Health Products Industry in the United States, Australia, the United Kingdom and Japan—March 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>This report summarizes the market opportunities that exist for the Canadian agri-food industries from improved regulation. Several information sources were used to analyze selected foreign markets for functional foods and natural health products (FFNHP). The data are presented to provide a point of comparison with the Canadian market for FFNHPs, and to assist in identifying opportunities for growth and advancement of Canada’s FFNHP sector.</td>
</tr>
</tbody>
</table>
| George Morris Centre  
[Link to George Morris Centre website]

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<tr>
<td>Nutri-Net Canada funded Cantox Health Sciences International to:</td>
</tr>
</tbody>
</table>
| • apply Canada’s revised guidance document for food health claim submissions to a food–health relationship (specifically walnuts and coronary heart disease with blood cholesterol as a surrogate marker); and  
| • provide feedback and recommendations on the comprehensibility and ease of use of the guidance document. |
| Note: This is an excellent resource to use as an example of how a submission should be prepared and organized. |
| Cantox Health Sciences International  
[Link to Cantox Health Sciences International website]
This discussion document was available to stakeholders throughout Canada to solicit feedback as Health Canada set out to review the current regulatory framework for management of health claims on foods. Issues discussed include:

**Efficient and Transparent Processes**
- Business improvements for increased efficiency
- Increased openness and transparency

**Sound Evidence for Consistent, Credible Claims**
- Scientific substantiation of claims
- Supporting good-quality submissions

**Clear Policies for Today and Tomorrow**
- Functional foods and the food–natural health product interface
- Managing a broader range of function claims
- Managing diverse front-of-package claims
- Eligibility criteria for foods to carry claims

**Supporting Informed Consumer Choice**
- Improving consumer understanding of health claims
- Monitoring the impact of health claims on the food supply and consumer choice

Health Canada

**Natural Health Products Regulations/Guidance Documents and Related Forms/Licensed Product Database/Site Licensing Guidance Document**

These are the regulations that deal with the licensing, manufacture and sale of natural health products in Canada.

Department of Justice

Numerous guidance documents are available to assist with preparing an NHP licence application. They are available on the Health Canada website.

Health Canada

Particular attention should be paid to the Product Licensing Guidance Document. The required forms are also available on the Health Canada website as templates.

Health Canada

Companies can also access a list of approved products through the Licensed Natural Health Products Database.

Health Canada  

In addition to a product licence, a business must also apply for a site licence if it manufactures, packages, labels and/or imports an NHP for sale in Canada. For more information on who is required to obtain a site licence and how to apply, see Health Canada’s Site Licensing Guidance Document.

Health Canada  

<table>
<thead>
<tr>
<th><strong>Nutrition Labelling Compliance Test</strong></th>
<th>The purpose of the Nutrition Labelling Compliance Test (Compliance Test) is to provide a transparent, science-based system for assessing the accuracy of nutrient information for food in Canada. The Compliance Test outlines the Canadian Food Inspection Agency’s procedure for assessing the accuracy of nutrient values on food labels and in advertising via laboratory analysis. The test applies to a nutrient, including an added vitamin or mineral nutrient, that is declared in the Nutrition Facts table or is the subject of a nutrient content claim or a disease risk reduction claim. The Compliance Test also assesses whether a food bearing a nutrient content claim or health claim meets the nutrient content criteria for the claim set out in the Food and Drug Regulations.</th>
</tr>
</thead>
</table>
| **Nutrition Labelling, Nutrient Content Claims and Health Claims: CFIA Compliance Test to Assess the Accuracy of Nutrient Values** | Canadian Food Inspection Agency  
www.inspection.gc.ca/english/fssa/labeti/nutricone.shtml |

<table>
<thead>
<tr>
<th><strong>Nutrition Labelling Toolkit</strong></th>
<th>This Nutrition Labelling Toolkit is intended to be a practical aid to the interpretation of the nutrition labelling provisions of the Food and Drug Regulations. While the Toolkit was originally designed for CFIA inspectors, it is also useful to food manufacturers. The Toolkit should answer key questions:</th>
</tr>
</thead>
</table>
| | - Which products require a Nutrition Facts table and which are exempt?  
- What are the requirements of the Nutrition Facts table? What is acceptable and what is not?  
- When do the Regulations come into force?  
- What are the technical and graphic requirements of Nutrition Facts tables? |
| **Nutrition Labelling Toolkit** | Canadian Food Inspection Agency  
www.inspection.gc.ca/english/fssa/labeti/nutrikite/nutrikite.shtml |
<table>
<thead>
<tr>
<th>Opportunities for the Canadian Agri-Food Industries in Functional Foods and Natural Health Products—March 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>This report provides evidence of the market opportunities that exist for agri-food industries from modernized functional food and NHP regulation. This was accomplished by an analysis of the functional food and NHP industry potential in Canada. The report describes the current FFNHP industries in Canada and outlines the opportunities for the Canadian agri-food industries and the distribution of benefits through the value chain from improved FFNHP regulation.</td>
</tr>
<tr>
<td>George Morris Centre</td>
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<tr>
<td>This reference manual is intended as an introduction to the requirements for health claim substantiation in Canada. The main body of the document is written in question and answer format, and is divided into the following four major sections:</td>
</tr>
<tr>
<td>1. General Considerations</td>
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<tr>
<td>2. Substantiating Safety</td>
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<tr>
<td>3. Substantiating Quality Assurance</td>
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<tr>
<td>4. Substantiating Efficacy</td>
</tr>
<tr>
<td>Cantox Health Sciences International</td>
</tr>
<tr>
<td>Note: This is an internal Agriculture and Agri-Food Canada document. For more information, please contact: <a href="mailto:info.FRID-DERA@agr.gc.ca">info.FRID-DERA@agr.gc.ca</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Towards a Regulatory Modernization Strategy for Food and Nutrition—2007</th>
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</thead>
<tbody>
<tr>
<td>The purpose of this document is to provide a basis for a discussion between Health Canada, regulatees and Canadians about the direction of Health Canada’s efforts to modernize its food regulatory system. This document is intended to lead to the completion of a Regulatory Modernization Strategy for Food and Nutrition which will provide strategic direction for Health Canada planning and program activity, and will be consistent with the principles, priorities and relevant objectives of the Blueprint for Renewal. This document provides a good overview of Canada’s food regulatory system.</td>
</tr>
<tr>
<td>Health Canada, Health Products and Foods Branch</td>
</tr>
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</table>
## Appendix 3: Health Claims in Australia/New Zealand, Canada, European Union, Japan and United States

<table>
<thead>
<tr>
<th>COUNTRY/REGION</th>
<th>TABLE A3.1: HEALTH CLAIM OVERVIEW</th>
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<tbody>
<tr>
<td>Australia/New Zealand</td>
<td>Currently, the regulatory body (FSANZ—Food Standards Australia New Zealand) is consulting industry about a new framework for the regulation of nutrition, health and related claims. The proposed framework includes provisions for the following:</td>
</tr>
<tr>
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<td><strong>Classified as health claims:</strong></td>
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<td></td>
<td>• general-level claims that refer to the presence of a nutrient or substance in a food and to its effect on a health function (e.g. “Calcium is good for strong bones and teeth, when consumed as part of a healthy diet containing a variety of foods”)</td>
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<td></td>
<td>• high-level claim—directly or indirectly refers to a serious disease or a biomarker (e.g. “This food is high in calcium. Healthy diets high in calcium may increase bone mineral density, which has particular importance for women.”)</td>
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<tr>
<td></td>
<td><strong>Not classified as health claims:</strong></td>
</tr>
<tr>
<td></td>
<td>• nutrient content claim—a statement about the amount of a nutrient, energy or a biologically active substance in the food</td>
</tr>
<tr>
<td>Canada</td>
<td><strong>Classified as health claims:</strong></td>
</tr>
<tr>
<td></td>
<td>• function claims—relate to modifying, restoring or correcting a body structure or function beyond what is normal and required for the maintenance of good health</td>
</tr>
<tr>
<td></td>
<td>• nutrient function claims—refer to the generally/scientifically recognized nutritional function of energy or nutrients in maintaining good health and normal growth and development</td>
</tr>
<tr>
<td></td>
<td>• 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 in the context of the total diet</td>
</tr>
<tr>
<td></td>
<td>• therapeutic claims—refer to the prevention, treatment, management or mitigation of a disease, disorder, abnormal physical state or their symptoms</td>
</tr>
<tr>
<td></td>
<td><strong>Not classified as health claims:</strong></td>
</tr>
<tr>
<td></td>
<td>• nutrient content claims (statements or expressions) outside the Nutrition Facts table, which directly or indirectly describe the level of a nutrient in a food (e.g. “0 g fat”)</td>
</tr>
<tr>
<td>European Union</td>
<td>A new regulation for nutrition and health claims on foods (Reg. (EC) No. 1924/ (2006)) came into force January 2007. It is intended to harmonize laws across member states. EFSA (European Food Safety Authority) is the independent risk-assessing agency funded by the EU that will evaluate health claims.</td>
</tr>
</tbody>
</table>
Canadian Food Health Claim Roadmap

March 2011

Food Regulatory Issues Division, Agriculture and Agri-Food Canada

Page 97

Classified as health claims:

- Article 13 claims that refer to the role of a nutrient or substance in growth, development, body functions, psychological or behavioural functions, weight control or loss. Each member state has its own health claim provisions. A unified list of claims was announced in January 2010. A confirmed list of Article 13 claims was announced amid considerable controversy. Article 13 claims are currently under review and revision.

- Article 14 claims that relate to disease risk reduction or children’s development and health

Not classified as health claims:

- nutrient claims that refer to the amount of Calories of a nutrient or a substance

Japan

The Ministry of Health, Labour and Welfare (MHLW) provides standards and regulations for foods. Health foods are not regulated.

Types of foods classified with health claims:

Foods with nutrient function claims (FNFC):

- structure/function claims—function of nutrients
- prohibited from making exaggerated, misleading claims, and claims that are not substantiated by evidence
- pre-approved claims

Foods for specific health uses (FOSHU):

- refer to the function of nutrients or other food ingredients
- structure/function claims or disease-reduction claims
- approved by MHLW through a standard, qualified or individual route of approval.

United States

The Office of Nutritional Products, Labeling and Dietary Supplements receives and evaluates health claim petitions. The Nutrition Labelling Education Act (NLEA) was designed to make available scientifically valid information, to consumers, about the foods they eat. Among other provisions, NLEA authorized the FDA to allow statements (i.e. health claims that describe the relationship between a nutrient and a disease- or health-related condition on foods and dietary supplements).

Classified as health claims:

- authorized health claims
- qualified health claims

Not classified as health claims:

- structure/function claims
- nutrient content claims
<table>
<thead>
<tr>
<th>COUNTRY/REGION</th>
<th>TABLE A3.2: APPROVED DISEASE RISK REDUCTION AND THERAPEUTIC HEALTH CLAIMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia/New Zealand</td>
<td>Currently available for use:</td>
</tr>
<tr>
<td></td>
<td>Folic acid and neural tube defects</td>
</tr>
<tr>
<td></td>
<td>High-level health claims that will be available for use once</td>
</tr>
<tr>
<td></td>
<td>Standard 1.2.7 comes into effect:</td>
</tr>
<tr>
<td></td>
<td>• calcium (with or without vitamin D) and osteoporosis</td>
</tr>
<tr>
<td></td>
<td>• sodium (with or without potassium) and hypertension</td>
</tr>
<tr>
<td></td>
<td>• saturated fat and/or trans fat and elevated serum cholesterol or heart disease</td>
</tr>
<tr>
<td></td>
<td>• fruit and vegetables and coronary heart disease</td>
</tr>
<tr>
<td>Canada</td>
<td>Approved:</td>
</tr>
<tr>
<td></td>
<td>• sodium and high blood pressure, a risk factor for stroke and heart disease</td>
</tr>
<tr>
<td></td>
<td>• calcium and vitamin D, and regular physical activity, and osteoporosis</td>
</tr>
<tr>
<td></td>
<td>• saturated and trans fats and heart disease</td>
</tr>
<tr>
<td></td>
<td>• vegetables and fruit and some types of cancer</td>
</tr>
<tr>
<td></td>
<td>• fermentable carbohydrates and dental caries</td>
</tr>
<tr>
<td></td>
<td>• plant sterols (phytosterols) and blood cholesterol lowering</td>
</tr>
<tr>
<td></td>
<td>• oat products and blood cholesterol lowering</td>
</tr>
<tr>
<td>European Union</td>
<td>Article 14 claims include reduction of disease risk claims or claims</td>
</tr>
<tr>
<td></td>
<td>referring to children's development and health.</td>
</tr>
<tr>
<td></td>
<td>Disease risk reduction claim:</td>
</tr>
<tr>
<td></td>
<td>• any health claim that states, suggests or implies that the consumption of a food category, a food or its constituents significantly reduces a risk factor in the development of a human disease</td>
</tr>
<tr>
<td></td>
<td>Children’s claims:</td>
</tr>
<tr>
<td></td>
<td>• no legal definition provided</td>
</tr>
<tr>
<td></td>
<td>Timelines for approval of Article 14 claims not clear.</td>
</tr>
<tr>
<td>Japan</td>
<td>• calcium and osteoporosis</td>
</tr>
<tr>
<td></td>
<td>• folic acid and neural tube defects</td>
</tr>
<tr>
<td>United States</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td></td>
</tr>
<tr>
<td><strong>Authorized claims:</strong></td>
<td></td>
</tr>
<tr>
<td>• calcium and osteoporosis</td>
<td></td>
</tr>
<tr>
<td>• sodium and hypertension</td>
<td></td>
</tr>
<tr>
<td>• dietary fat and cancer</td>
<td></td>
</tr>
<tr>
<td>• dietary saturated fat and cholesterol and risk of coronary heart disease</td>
<td></td>
</tr>
<tr>
<td>• fibre-containing grain products, fruits and vegetables and cancer</td>
<td></td>
</tr>
<tr>
<td>• fruits, vegetables and grain products that contain fibre, particularly soluble fibre, and risk of coronary heart disease</td>
<td></td>
</tr>
<tr>
<td>• fruits and vegetables and cancer</td>
<td></td>
</tr>
<tr>
<td>• folate and neural tube defects</td>
<td></td>
</tr>
<tr>
<td>• dietary sugar alcohol and dental caries</td>
<td></td>
</tr>
<tr>
<td>• soluble fibre from certain foods and risk of coronary heart disease</td>
<td></td>
</tr>
<tr>
<td>• soy protein and risk of coronary heart disease</td>
<td></td>
</tr>
<tr>
<td>• plant sterol/stanol esters and risk of coronary heart disease</td>
<td></td>
</tr>
<tr>
<td>• whole grain foods and risk of heart disease and certain cancers*</td>
<td></td>
</tr>
<tr>
<td>• potassium and the risk of high blood pressure and stroke*</td>
<td></td>
</tr>
<tr>
<td>• fluoride and risk of dental caries*</td>
<td></td>
</tr>
<tr>
<td>• saturated fat, cholesterol and trans fat and risk of heart disease*</td>
<td></td>
</tr>
<tr>
<td>• substitution of saturated fat with unsaturated fatty acids and risk of heart disease*</td>
<td></td>
</tr>
<tr>
<td>*authorization based on authoritative statements by federal scientific bodies</td>
<td></td>
</tr>
</tbody>
</table>

**Qualified claims (not based on significant scientific substantiation):**

• specific foods approved for six health categories: cancer, cardiovascular disease, cognitive function, diabetes, hypertension, neural tube defects
Appendix 4: Sample Matrix to Evaluate Options Against Comparative Criteria

<table>
<thead>
<tr>
<th>Product/Claim/Market Option</th>
<th>Criteria</th>
<th>Overall Average</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option #</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Ingredient strategy in Canada with non-nutrient claim</td>
<td>8 10 9 8 10 9 9 *</td>
<td>9.0 1</td>
<td></td>
</tr>
<tr>
<td>2 Pursue ingredient strategy in Canada with no claim</td>
<td>7 8 6 10 10 10 10</td>
<td>8.7 2</td>
<td></td>
</tr>
<tr>
<td>3 Pursue an ingredient strategy under U.S. GRAS process</td>
<td>8 10 10 10 8 6 8</td>
<td>8.6 3</td>
<td></td>
</tr>
<tr>
<td>4 Consumer product with disease risk reduction claim</td>
<td>7 7 6 10 6 9 8</td>
<td>7.6 8</td>
<td></td>
</tr>
<tr>
<td>5 Consumer product with nutrient content claim</td>
<td>8 8 7 9 9 8 8</td>
<td>8.3 5</td>
<td></td>
</tr>
<tr>
<td>6 Consumer product with nutrient function claim</td>
<td>8 8 7 7 8 8 8</td>
<td>7.9 6</td>
<td></td>
</tr>
<tr>
<td>7 Consumer product with other function claim</td>
<td>9 9 8 9 8 7</td>
<td>8.4 4</td>
<td></td>
</tr>
<tr>
<td>8 Consumer product with therapeutic claim</td>
<td>9 8 7 6 8 7 7</td>
<td>7.4 9</td>
<td></td>
</tr>
<tr>
<td>9 Pursue approval under Canadian food additive regulations</td>
<td>7 8 9 7 9 6 8</td>
<td>7.7 7</td>
<td></td>
</tr>
<tr>
<td>10 Pursue NHP regulatory framework for Canada-wide sales</td>
<td>5 6 6 7 5 8 6</td>
<td>6.1 12</td>
<td></td>
</tr>
<tr>
<td>11 Joint fortified food/nutrient content claim strategy</td>
<td>2 2 6 3 2 1 4</td>
<td>2.9 13</td>
<td></td>
</tr>
<tr>
<td>12 Global sales of ingredients with no claims</td>
<td>8 7 7 7 5 8 8</td>
<td>7.1 11</td>
<td></td>
</tr>
<tr>
<td>13 Global sales of vitamins to further processors</td>
<td>5 8 9 8 5 8 8</td>
<td>7.3 10</td>
<td></td>
</tr>
</tbody>
</table>

Notes
- Each option is rated on a scale of 1 (not favourable) to 10 (very favourable) for each criterion. The rank order is determined by the average score for each option.
- A Veto can be used for a rating where the analysis shows that the option is sufficiently unacceptable on that criterion that even if the option rated high on all other criteria, the option still would not be acceptable.

Criteria
1. There are lower risks related to regulatory approval relative to other options.
2. The R&D, testing protocols and other related costs of complying with regulations are lower.
3. The IPR associated with the regulatory process can be better protected.
4. The market is more familiar with the product/regulatory framework/market option, and places more value on related health benefits.
5. The market is larger and/or has the potential for more rapid growth.
6. There is potential for a competitive advantage versus Competitors.
7. There is greater potential for profit.
### Appendix 5: Food Science, Nutrition and Technology Centres in Canada

<table>
<thead>
<tr>
<th>FACILITY/PROGRAM TYPE</th>
<th>DESCRIPTION AND CONTACT INFORMATION</th>
</tr>
</thead>
</table>
| University Food Science Programs | **University of British Columbia**  
Faculty of Land and Food Systems  
2357 Main Mall  
Vancouver, BC  
Phone: 604-796-2221  
Website: [www.landfood.ubc.ca](http://www.landfood.ubc.ca)  

The Food Science department has research laboratories with modern analytical instrumentation, including analytical ultracentrifuge, scintillation counter, electrophoretic analysis and imaging instrumentation, chromatography systems including FPLC, HPLC, and GC, UV-visible spectrophotometers, spectrofluorometers, Raman spectrometer, circular dichroism spectropolarimeter, microtitre plate readers, PCR equipment, gene chip Fluidic station and hybridization oven, rheometry and texture analyzers, Hunterlab colorimeter, fermenters and incubators. Specialized facilities include computerized sensory evaluation facilities, kitchens and pilot plant equipment for food preparation and processing, and biohazard (level 3) facilities. |
| | **University of Alberta**  
Department of Agricultural, Food and Nutritional Science  
410 Agriculture/Forestry Centre  
Edmonton, AB T6G 2P5  
Phone: 780-492-3239  
Fax: 780-492-4265  
Website: [www.ales.ualberta.ca/afns/ContactUs.aspx](http://www.ales.ualberta.ca/afns/ContactUs.aspx)  

The Department integrates many disciplines to meet growing demands for safe and nutritious foods, bioproducts and healthy human environments. The focus is on cutting-edge research to improve the health and quality of life, from primary production and biotechnology in plant and animal sciences, to innovative food and agri-food products, and human nutrition and wellness. |
| | **University of Saskatchewan**  
Department of Food and Bioproduct Sciences  
Saskatoon, SK  
Phone: 306-966-4343  

This department provides the agri-food and bioresources industries with highly trained graduates and innovative research solutions for exploiting existing and emerging opportunities for the agriculture sector. The interdisciplinary teaching approach provides Canadian and international students with the advanced knowledge and understanding of agricultural outputs and by- and co-products (proteins, carbohydrates/fibre and lipids), processing, genetic engineering and microbial biotechnology that can then be tailored to the areas of food science and technology, biomaterials, biotechnology and bio-energy. Researchers are at the forefront of food and bioproducts research in Canada, and are recognized internationally for their specialties in food for health, food chemistry, processing, microbial biotechnology, authenticity, nanotechnology, meat science and bio-energy. The department provides a research continuum from traditional agriculture sciences to value-added industrial technologies. |
<table>
<thead>
<tr>
<th>University of Manitoba</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Food Science</td>
</tr>
<tr>
<td>Faculty of Agricultural and Food Sciences</td>
</tr>
<tr>
<td>250 Ellis Building</td>
</tr>
<tr>
<td>University of Manitoba</td>
</tr>
<tr>
<td>Winnipeg, MB R3T 2N2</td>
</tr>
<tr>
<td>Phone: 204-474-9621</td>
</tr>
<tr>
<td>Fax: 204-474-7630</td>
</tr>
<tr>
<td>Website: <a href="http://umanitoba.ca/faculties/afs/food_science/info/overview.shtml">http://umanitoba.ca/faculties/afs/food_science/info/overview.shtml</a></td>
</tr>
<tr>
<td>Food Science is the study of food and food components in relation to their utilization and safety through use of the biological, chemical and physical sciences. The faculty has expertise in the basic sciences, food science and food technology. They conduct research on the processing, functional quality and safety of foods, apply the resulting knowledge in education and training of students and provide technical information and assistance to the food industry, consumers and government. Food Science is presently housed in two buildings located on the Fort Garry Campus. Research laboratories for food chemistry, cereal chemistry, food proteins, food carbohydrates, food biotechnology, food processing and food microbiology are housed in the Ellis Building. The Dairy Building houses departmental efforts pertaining to dairy science. Each building contains a pilot plant. Both buildings are used for research as well as classroom and laboratory instruction.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>University of Guelph</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Science Department</td>
</tr>
<tr>
<td>50 Stone Road East</td>
</tr>
<tr>
<td>Guelph, ON N1G 2W1</td>
</tr>
<tr>
<td>Phone: 519-824-4120</td>
</tr>
<tr>
<td>Website: <a href="http://www.uoguelph.ca/foodscience/">www.uoguelph.ca/foodscience/</a></td>
</tr>
<tr>
<td>The Department of Food Science offers diverse and highly rated educational programs, including a Distance Education Certificate, Short Courses in Dairy and Meat Processing, and undergraduate and graduate programs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>McGill University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Food Science and Agricultural Chemistry</td>
</tr>
<tr>
<td>Macdonald Campus, McGill University</td>
</tr>
<tr>
<td>21, 111 Lakeshore</td>
</tr>
<tr>
<td>Ste Anne de Bellevue, QC H9X 3V9</td>
</tr>
<tr>
<td>Phone: 514-398-7898</td>
</tr>
<tr>
<td>Fax: 514-398-7977</td>
</tr>
<tr>
<td>McGill University is establishing a reputation in evolving scientific disciplines such as Food Science through a professionally accredited Food Science program designed to supply Canada with highly qualified food scientists for the food industry, government and academia. McGill’s Food Science undergraduate program has been designed to combine the basic sciences with specialty courses that are directly related to the discipline, with Food Chemistry, Food Science and Food Industry Options.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laval University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty of Agriculture and Food Sciences</td>
</tr>
<tr>
<td>Bureau 1104</td>
</tr>
<tr>
<td>2425, rue de l’Agriculture</td>
</tr>
<tr>
<td>Québec, QC G1V 0A6</td>
</tr>
<tr>
<td>Phone: 418-656-3145</td>
</tr>
<tr>
<td>Fax: 418-656-7806</td>
</tr>
</tbody>
</table>
The Department offers seven Bachelor’s programs, six of which are the only French-language programs of their kind in North America. These include Bachelor’s degrees in agronomy, agri-food economics and management, agroenvironmental engineering, food engineering, consumer sciences, food technology and nutrition. The Department also offers nearly 20 Master’s and PhD programs.

Through its Institute and 25 research centres, chairs and groups, the Faculty’s research projects and activities touch every aspect of the bio-food chain, from production and industrial processing to marketing and final consumption.

<table>
<thead>
<tr>
<th>University Food/Nutrition Programs</th>
<th>University of British Columbia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty of Agricultural Studies</td>
<td>Food, Nutrition and Health</td>
</tr>
<tr>
<td>240 - 2205 East Mall</td>
<td>Faculty of Agricultural Studies</td>
</tr>
<tr>
<td>Vancouver, BC V6T 1Z4</td>
<td>240 - 2205 East Mall</td>
</tr>
<tr>
<td>Phone: 604-827-5046</td>
<td>Phone: 604-827-5046</td>
</tr>
<tr>
<td>Fax: 604-822-5143</td>
<td>Fax: 604-822-5143</td>
</tr>
<tr>
<td>Website: <a href="http://www.landfood.ubc.ca/undergraduate/program/fnh/major/dietetics">www.landfood.ubc.ca/undergraduate/program/fnh/major/dietetics</a></td>
<td>Website: <a href="http://www.landfood.ubc.ca/undergraduate/program/fnh/major/dietetics">www.landfood.ubc.ca/undergraduate/program/fnh/major/dietetics</a></td>
</tr>
</tbody>
</table>

Researchers are addressing critical global issues around human health, a sustainable food supply, and land and water resources. Researchers have attracted research funding from sources including Genome Canada, the Canadian Institutes of Health Research (CIHR), the Michael Smith Scholar, the Canadian Foundation for Innovation (CFI), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC).

<table>
<thead>
<tr>
<th>University Food/Nutrition Programs</th>
<th>University of Alberta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dept. of Agricultural, Food and Nutritional Science</td>
<td>Dept. of Agricultural, Food and Nutritional Science</td>
</tr>
<tr>
<td>Faculty of Agriculture, Forestry and Home Economics</td>
<td>Faculty of Agriculture, Forestry and Home Economics</td>
</tr>
<tr>
<td>4-10 Agriculture Forestry Building</td>
<td>4-10 Agriculture Forestry Building</td>
</tr>
<tr>
<td>Edmonton, AB T6G 2P5</td>
<td>Edmonton, AB T6G 2P5</td>
</tr>
<tr>
<td>Phone: 780-492-9287</td>
<td>Phone: 780-492-9287</td>
</tr>
<tr>
<td>Fax: 780-492-4265</td>
<td>Fax: 780-492-4265</td>
</tr>
<tr>
<td>Website: <a href="http://www.afns.ualberta.ca">www.afns.ualberta.ca</a></td>
<td>Website: <a href="http://www.afns.ualberta.ca">www.afns.ualberta.ca</a></td>
</tr>
</tbody>
</table>

The Department integrates many disciplines to meet growing demands for safe and nutritious foods, bioproducts and healthy human environments. The focus is on cutting-edge research to improve the health and quality of life, from primary production and biotechnology in plant and animal sciences, to innovative food and agri-food products, and human nutrition and wellness.

<table>
<thead>
<tr>
<th>University Food/Nutrition Programs</th>
<th>University of Saskatchewan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division of Nutrition and Dietetics</td>
<td>Division of Nutrition and Dietetics</td>
</tr>
<tr>
<td>College of Pharmacy and Nutrition</td>
<td>College of Pharmacy and Nutrition</td>
</tr>
<tr>
<td>110 Science Place</td>
<td>110 Science Place</td>
</tr>
<tr>
<td>Saskatoon, SK S7N 5C9</td>
<td>Saskatoon, SK S7N 5C9</td>
</tr>
<tr>
<td>Phone: 306-966-5837</td>
<td>Phone: 306-966-5837</td>
</tr>
<tr>
<td>Fax: 306-966-6377</td>
<td>Fax: 306-966-6377</td>
</tr>
<tr>
<td>Website: <a href="http://www.usask.ca/pharmacy-nutrition/">www.usask.ca/pharmacy-nutrition/</a></td>
<td>Website: <a href="http://www.usask.ca/pharmacy-nutrition/">www.usask.ca/pharmacy-nutrition/</a></td>
</tr>
</tbody>
</table>

Pharmacy and Nutrition are dynamic, challenging disciplines, committed to the promotion of health and the treatment of disease. The programs provide students with the essential knowledge and skills to be leaders, discoverers and contributors in their professions. The joining of the two health science disciplines—Pharmacy and Nutrition—is unique in Canada, and provides excellent opportunities for collaboration in teaching, research and outreach.
University of Manitoba
Department of Human Nutritional Sciences
Faculty of Human Ecology
Room 204, Human Ecology Building
Winnipeg, MB R3T 2N2
Phone: 204-474-8207
Fax: 204-788-8417
Website: www.umanitoba.ca/faculties/human_ecology/

The Faculty’s mission is to sustain, develop and transmit knowledge that supports individuals and their interactions in families and communities as they enhance their quality of life and improve their physical and social environments. Teaching and research integrate both basic and applied sciences, incorporating innovative technologies and emergent areas of knowledge. The Department believes in delivering outstanding research and education that promote optimum health and quality of life. The goal is to contribute to the public policy debate by being a leading provider both of scientifically based food, health and social policy information and of professionals who can generate and apply this information.

The University of Western Ontario
Department of Food and Nutritional Sciences
Brescia University College
1285 Western Road
London, ON N6G 1H2
Phone: 519-432-8353 ext. 28254
Fax: 519-858-5137
Website: www.uwo.ca/brescia

This program has received national and international recognition. The Master of Science in Foods and Nutrition (Internship Stream) is a professional program and is accredited by Dietitians of Canada. The majority of Brescia’s faculty members are Registered Professional Home Economists and/or Registered Dietitians. They conduct research in such areas as obesity prevention programs and services for children. They are also experts in national food and nutrition policies.

University of Guelph
Department of Family Relations and Applied Nutrition
Guelph, ON N1G 2W1
Phone: 519-824-4120 ext. 54831
Fax: 519-766-0691
Website: www.family.uoguelph.ca/

The Department is an interdisciplinary academic unit focused on the enhancement of the quality of human development in diverse communities. The Department is interdisciplinary in pursuit of its mandate to respond to the evolution of contemporary issues affecting families in their social contexts. Through continuing development as an academic unit of provincial, national and international stature, the faculty promotes excellence in education, research and service. The emphasis on both theoretical and basic/applied research continues to have impact on professional practice, social and health policy, family relationships, human development and aging, and health and human nutrition. The faculty focuses on preparation of leaders in the fields of interventions and preventive strategies.

Ryerson University
School of Nutrition
350 Victoria Street
Toronto, ON M5B 2K3
Phone: 416-979-5074
Fax: 416-979-5204
Website: www.ryerson.ca/foodandnutrition/

The Mission of the School of Nutrition is to provide a diverse learning environment that prepares nutrition and food graduates for professional careers, reflective practice and responsible citizenship informed by their engagement in research and scholarship.
<table>
<thead>
<tr>
<th>University of Toronto</th>
<th>McGill University</th>
<th>University of Montréal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Department of Nutritional Sciences</strong>&lt;br&gt;Faculty of Medicine&lt;br&gt;FitzGerald Building, 150 College Street&lt;br&gt;Toronto, ON M5S 3E2&lt;br&gt;Phone: 416-978-2747&lt;br&gt;Fax: 416-978-5882&lt;br&gt;Website: <a href="http://www.utoronto.ca/nutrisci/dns.html">www.utoronto.ca/nutrisci/dns.html</a></td>
<td><strong>Professional Practice in Dietetics</strong>&lt;br&gt;<strong>School of Dietetics and Human Nutrition</strong>&lt;br&gt;<strong>Macdonald Campus</strong>&lt;br&gt;21, 111 Lakeshore&lt;br&gt;Ste Anne de Bellevue, QC H9X 3V9&lt;br&gt;Phone: 514-398-7982&lt;br&gt;Fax: 514-398-7631&lt;br&gt;Website: <a href="http://www.mcgill.ca/dietetics">www.mcgill.ca/dietetics</a></td>
<td><strong>Department of Nutrition</strong>&lt;br&gt;C.P. 6128, Succursale Centreville&lt;br&gt;Montréal, QC H3C 3J7&lt;br&gt;Phone: 514-343-6403&lt;br&gt;Fax: 514-343-7395&lt;br&gt;Website: <a href="http://www.mdnut.umontreal.ca/">www.mdnut.umontreal.ca/</a></td>
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The Department is one of a few in North America situated in a Faculty of Medicine. Its activities include not only basic science but also clinical and community aspects of nutrition. The Department offers BSc, MSc and PhD degree programs. Jointly with the Department of Public Health Sciences, it also offers a professional Master’s degree (Master of Health Sciences) in Community Nutrition. Research programs focus on basic and clinical nutrition related to human health and chronic diseases including cancer, obesity, diabetes, cardiovascular disease, neurodegenerative disease and osteoporosis, as well as community and public health nutrition. Approaches range from the basic such as nutrigenomics and nutrigenetics and studies in molecular biology and biochemical metabolism, to clinical trials and qualitative research. The location within the Faculty of Medicine enables investigators to draw on the strengths of other basic science departments as well as the public health and clinical departments to explore fully the relationships between nutrition and human health and disease and to influence public health programs and clinical practice.

The School is the oldest teaching and research institution in Human Nutrition in Canada. The primary mission is to improve human health during the entire life span by training future leaders in the role of macro- and micronutrients in health and disease. Research expertise includes maternal and child nutrition, Indigenous peoples’ nutrition and food safety, nutritional status and food security in developing countries, nutritional interventions to minimize chronic diseases such as obesity, diabetes, osteoporosis, interaction of diet and genes with nutrient metabolism, and clinical applications of nutritional interventions in hospitalized patients. Research is conducted in on-site research laboratories, the Centre for Indigenous Peoples’ Nutrition and Environment (CINE), the Mary Emily Clinical Nutrition Research unit, and the MUHC Teaching Hospitals. The School offers programs leading to BSc, MSc, MSc (Applied) and PhD degrees in Dietetics or Human Nutrition.

The Department has a threefold mission:
- research and training in basic, clinical and preventive public nutrition research;
- training of professional dietitians and other categories of professional nutrition training connected to the field of health; and
- support the clinical departments and hospitals in the field of nutrition.
The Department contributes research to advance knowledge in (metabolic) basic nutrition and applied (clinic, preventive and public) nutrition, as well as in applied sciences which are the basis for the professional practice of nutrition and dietetics.

Through advanced nutrition training, the Department also contributes to the implementation of this knowledge by the professional health specialists of this discipline—nutritionist-dietitians. In addition, it contributes to improving health in the general population through the advancement, application and dissemination of knowledge.

**Laval University**
Département des sciences des aliments et de nutrition
1312 Pavillon Comtois
Sainte-Foy, QC G1K 7P4
Phone: 418-656-2131
Fax: 418-656-3353
Website: [www.ulaval.ca/sg/PR/C1/1.438.91.html](http://www.ulaval.ca/sg/PR/C1/1.438.91.html)

The individual, food and health are the three major components of the Bachelor’s degree in nutrition program. The program trains students in nutrition to meet the nutritional needs of individuals and groups.

**University of Prince Edward Island**
Department of Family and Nutritional Sciences
550 University Avenue
Charlottetown, PE C1A 4P3
Phone: 902-566-0521
Fax: 902-628-4367
Website: [www.upei.ca/~famnut](http://www.upei.ca/~famnut)

The educational focus of the Department draws from a broad academic base: the biological, physical and social sciences; humanities; and professional studies. The Department offers three distinct programs in Foods and Nutrition, Family Science, and Child and Family Studies. The curriculum reflects current scientific knowledge in these disciplines concerned with improving the life conditions of families, individuals and communities.

**Mount St. Vincent University**
Department of Applied Human Nutrition
166 Bedford Highway
Halifax, NS B3M 2J6
Phone: 902-457-6248
Fax: 902-457-6134

The Department’s mission is focused on developing understanding and responsibility for food, nutrition and health issues in social, political, and economic contexts, through integration of classroom and community learning.

** Acadia University**
School of Nutrition and Dietetics
Wolfville, NS B4P 2R6
Phone: 902-585-1366
Fax: 902-585-1637
Website: [http://nutrition.acadiau.ca/](http://nutrition.acadiau.ca/)

Since 1928, the School has been graduating individuals with education in the art and science of nutrition who either obtain work in the dietetic profession or continue their studies in graduate school, education
or the health professions, such as medicine, physiotherapy, nursing and dentistry. Students in this program build on a foundation of food and develop an appreciation for current issues in nutrition and dietetics. Nutrition students gain solid knowledge in biology and chemistry which is applied to studies of food and nutrient metabolism. This background, combined with courses in areas such as communications, nutrition education, psychology and statistics, prepares students to work effectively with individuals, families and communities to plan, develop and manage relevant nutrition programs. A joint program developed with the School of Recreation Management and Kinesiology allows Nutrition students to pursue Kinesiology courses in the Nutrition/Kinesiology option. This is ideal for those students interested in nutrition as a part of fitness and athletics and supports an overall healthy lifestyle.

### St. Francis Xavier University

**Department of Human Nutrition**  
P.O. Box 5000  
Antigonish, NS B2G 2W5  
Phone: 902-867-3877  
Fax: 902-867-2389  
Website: [www.stfx.ca/academic/human-nutrition/](http://www.stfx.ca/academic/human-nutrition/)

The goal of the University's Integrated Dietetic Internship (IDI) is to enable students enrolled in the Human Nutrition Program to attain Dietitian of Canada standards for competency in preparation for entry into dietetic practice. Human Nutrition faculty members have background and expertise in areas reflecting multiple facets of human nutrition, such as food science, metabolic aspects of nutrition, dietetic practice, community health and development, communications, and policy development. Faculty members are active researchers and contribute within their respective communities and fields of practice. Members have participated in a number of local, provincial and national nutrition and health policy initiatives.

### University of Moncton

**École de nutrition et d'études familiales**  
Moncton, NB E1A 3E9  
Phone: 506-858-3762  
Fax: 506-858-4283  
Website: [www.umoncton.ca/umcm-fsssc-esanef/](http://www.umoncton.ca/umcm-fsssc-esanef/)

The Bachelor of Science Nutrition prepares professionals to guide people in their food choices for nutritional and therapeutic purposes during different life cycles to enable them to achieve and maintain optimal health. In addition, the program allows students to develop skills in food service management. The program also includes the study of nutrients and the physiological processes through which the body absorbs and uses them. The Nutrition program includes practical training courses recognized by Dietitians of Canada.

### Food Technology Centres

**BC Agri-Food Centre**  
c/o British Columbia Institute of Technology  
Burnaby Campus  
3700 Willingdon Avenue  
Burnaby, BC V5G 3H2  
Tel: 604-432-8948  
Fax: 604-433-7879

The Agri-Food Centre is not a formal centre per se, but a partnership of academic institutions and industry associations representing the needs of micro, small, medium and large BC agri-food companies. This “virtual” network offers the agri-food value chain access to expertise and technology, as well as physical resources such as pilot plants and equipment, with the intent that a single food technology centre may evolve. Currently, the network helps companies access a wide variety of support and services for new product development, prototype development and pilot processing for food, natural health and bio-based products and ingredients. Additionally, members of the network provide support services, such as food safety/HACCP training as well as other business services, such as market access.
**Food Processing Development Centre**
Leduc, AB T9E 7C5
Phone: 780-980-4873
Fax: 780-986-5138
Website: [www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/fpdc5012](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/fpdc5012)

Leduc’s Food Processing Development Centre is a modern, fully equipped pilot plant and product development facility. It is staffed with experienced food scientists, engineers and technologists. Services are designed to strengthen and expand the capability of food processors to meet the challenges of the marketplace through application of new technology and the development of new or improved products and processes. The Centre also houses the Agrivalue Processing Business Incubator. The incubator is a multi-tenant CFIA-approved facility dedicated to new food processors, enabling them to scale up and commercialize new products, which can be nationally and internationally marketed.

**Core services**
- Product development
- Pilot plant/process development
- Analytical services
- Sensory evaluation
- Food Science and Technology Centre (Brooks, AB)

**Facilities**
- Federally inspected pilot plant areas and product development kitchens
- Sensory and consumer product testing centres (in Leduc and Edmonton)
- Agrivalue Processing Business Incubator: eight fully serviced processing bays with centralized shipping and receiving and shared cold storage, staff welfare areas and reception.

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**Saskatchewan Industry Food Development Centre Inc.**
117-105 North Road
Saskatoon, SK S7N 4L5
Phone: 306-933-7555
Fax: 306-933-7208
Website: [www.foodcentre.sk.ca/](http://www.foodcentre.sk.ca/)

The Saskatchewan Food Industry Development Centre Inc. offers one-stop, full service assistance to food processors wanting to add value to their products for domestic and/or international markets. The Food Centre is a partnership of the Saskatchewan Ministry of Agriculture, the Saskatchewan Food Processors Association and the University of Saskatchewan. The range of expertise that each partner brings to the table enables the Food Centre to provide processors with information and technical assistance needed to manufacture a product, get it to market, and maintain a viable operation.

**Core services**
- Product development
- Extrusion technology
- Interim processing: Commercial Kitchen and Pilot Plant
- Technology transfer
- Quality assurance
- Training

**Facilities**
- Commercial Kitchen (CK): The CK is public health inspected. Products manufactured in the CK can be sold in Saskatchewan and may be sold out of province (unless the product is regulated by CFIA).
- Federal Processing Pilot Plant Facility: Innovative products can be manufactured for test marketing or market penetration at this state-of-the-art facility. The pilot plant can be used as an interim processing facility for meat, dairy and processed foods. The facility’s federal inspection status can provide processors with new export capabilities.
POS Bio-Sciences
118 Veterinary Road
Saskatoon, SK S7N 2R4
Phone: 306-978-2800
Toll-free: 1-800-230-2751
Fax: 306-975-3766
Website: www.pos.ca

POS Pilot Plant is a confidential contract research, toll processing, and analytical services organization. POS specializes in extraction, fractionation, purification and modification of bio-based materials. It conducts a wide range of confidential, applied R&D projects relating to bioprocessing industries, such as food ingredients, nutraceuticals, biofuels, functional foods, skin care, industrial bioproducts, agricultural biotechnology, forestry, marine, and more. The 54,000 sq. ft. facility has 5 pilot plant processing areas, 11 laboratories, warehousing and quarantine areas, library, client rooms and administrative areas.

Core services
- Process and product development
- Toll processing/small-scale specialty manufacturing
- Analytical services

Facilities
- Dedicated pilot plant processing areas for primary, solvent, oils and secondary processing
- 11 fully equipped laboratories carrying out a wide variety of bioprocessing operations
- Warehouse with quarantine area, coolers, freezers, flammable pallet storage
- Four functional client rooms with modem hook-ups, direct telephone lines, work areas

Food Development Centre
810 Phillips Street
Portage la Prairie, MB R1N 3J9
Phone: 204-239-3150
Toll-free: 1-800-870-1044
Fax: 204-239-3180
Website: www.manitoba.ca/agriculture/fdc

The Food Development Centre (FDC) can help steer a product through every stage of development, from initial research through product testing and scale-up, to marketing. FDC scientists and food engineers can help clients achieve high standards of food safety, quality and efficiency as they develop and modify products. FDC can help evaluate the consumer appeal and safety of a product using trained professionals and unbiased panelists.

Core services
- Product development/process development
- Food safety and regulatory support
- Sensory evaluation and shelf-life testing
- Nutrition labelling
- Education, training and library services
- Off-site plant trouble shooting

Facilities
- Pilot plant
- Liquid food processing specialization

Richardson Centre for Functional Foods and Nutraceuticals
196 Innovation Drive, SmartPark
University of Manitoba
Winnipeg, MB R3T 2N2
Phone: 204-474-9787
Fax: 204-474-7552
Website: www.rcffn.ca/home
Located in SmartPark Research and Technology Park, University of Manitoba, the Centre is dedicated to the discussion, discovery and development of functional foods and nutraceuticals, with a focus on the crops of the Canadian Prairies.

Core services
- Animal model research
- Clinical research
  - An advanced metabolic kitchen facility that permits careful preparation of fixed diets where nutrients and foods are specifically controlled to several dozen individuals simultaneously
  - Clinical office for physical examination
  - Blood collection facility; specific blood tests including cardiovascular, immunological, hormonal, other measurements
  - Pulse-oximeter
  - Electrocardiogram
  - Respiratory metabolic unit for energy expenditure
  - Dual x-ray emission absorptiometry for bone density and body composition analysis
  - Retinography
- Bioprocessing
  - Extrusion, blending and filling
  - Encapsulating, tableting and coating capabilities for dosage development

Facilities
- Nutrigenomics Lab
- Protein Characterization Lab
- Pathology and Toxicology Lab
- Microbiology Lab
- Cell/Tissue Culture Lab
- Quality Control (QC) Lab
- Growth and Stability Chamber Unit

**Canadian International Grains Institute**
1000-303 Main Street
Winnipeg, MB R3C 3G7
Phone: 204-983-5344
Fax: 204-983-2642
Website: [www.cigi.ca](http://www.cigi.ca)

Incorporated in 1972 as a non-profit market development organization, the Canadian International Grains Institute (CIGI) is dedicated to promoting Canada’s field crop industries in international and domestic markets through educational programming and technical activities. CIGI’s technical staff are specialists in a wide range of disciplines, sharing their commercial knowledge and technical expertise through programs, applied research and customer service activities. CIGI’s commodity-based technology facilities provide access to a large variety of processing equipment in one location. Pilot facilities are designed to optimize the value of Canadian field crops to customers.

Core services
- Baking technology
- Feed technology
- Milling technology
- Noodle and Asian products technology
- Pasta technology
- Pulse processing and specialty milling
- Biofuels technology
- Analytical services
- Food quality testing
- Education and training
Facilities

- Pilot flour mill
- Pulse processing and specialty milling facility
- Commercial-scale pilot bakery
- Test bakery
- Pilot noodle plant
- Pilot pasta plant
- Analytical services and food quality testing laboratories
- Portable biodiesel plant housed in an 8- x 20-foot trailer
- Fully equipped seminar rooms and library

Guelph Food Technology Centre
88 McGilvray Street
Guelph, Ontario N1G 2W1
Phone: 519-821-1246
Fax: 519-836-1281
Website: www.gftc.ca

The Guelph Food Technology Centre (GFTC) is a global leader in food safety, training, quality and technical solutions. It is an independent, industry-driven, not-for-profit organization focused on helping clients improve their competitiveness and profitability.

Core services

- Product research
- Regulatory review
- Formula development
- Package selection
- Shelf-life studies
- Ingredient performance evaluation
- Troubleshooting
- Food safety consulting services
- Audit and certification services
- Training services
- Sustainability services

Guelph Food Technology Centre
88 McGilvray Street
Guelph, Ontario N1G 2W1
Phone: 519-821-1246
Fax: 519-836-1281
Website: www.gftc.ca

Cintech agroalimentaire
3224, rue Sicotte
Saint-Hyacinthe, QC J2S 2M2
Phone: 450-771-4393
Fax: 450-771-0832
Website: www.cintech-aa.qc.ca

Cintech is a not-for-profit agri-food technology innovation centre, providing solutions for food and bioproduct companies. Cintech offers full services from concept to commercialization, including R&D, product development, processing support (laboratory and pilot scale), sensory evaluation and analysis. High-tech equipment to evaluate texture, colour and starch behaviour is also available. Vacuum microwave and press dryers, an extruder, a pilot fermenter as well as supercritical CO₂ extraction and purification units are also available for use by industry.

Core services

- R&D and technology transfer
- Product development and feasibility studies
- Reformulation for cost and quality optimization
• Technical solutions
• Process improvements and scale-up
• Sensory evaluation
• Package identification and evaluation; label compliance
• Equipment identification and evaluation
• Production process establishment and optimization
• Assess feasibility and recommend novel technologies (i.e. ohmic heating)
• Scale up from bench-top to pilot plant to processing line
• By-product assessments
• Food safety and quality support
• Training
• Marketing and business support
• Nutrition/marketing

Facilities
• 12,000 sq. ft. pilot plant
• Laboratories

Merinov
Centre d’innovation de l’aquaculture et des pêches du Québec
96, montée Sandy Beach
bureau 1.07
Gaspé, QC G4X 2V6
Phone: 418-368-7653
Fax: 418-360-8514
Website: www.merinov.ca

Merinov, Quebec’s aquaculture and fisheries innovation centre, is an organization that provides innovative services to Quebec’s fisheries and aquaculture industry. Formed by the merger of the Department of Agriculture, Fisheries and Food research centres, a Cégep de la Gaspésie et des Îles research centre and the Université du Québec à Rimouski research teams, it brings together most of the experts dedicated to innovation in Quebec’s fisheries and aquaculture industry. The Centre carries out applied research, experimental development and technology transfer activities to generate new knowledge and technologies that benefit the aquatic biomass production and conversion industry. It provides technical assistance to companies across Quebec and is involved in the monitoring and dissemination of strategic information. Merinov boasts four coastal research centres equipped with basin rooms, pilot plants and multi-purpose equipment laboratories and has boats and measurement equipment for sea and lagoon operations.

Core services
• Development of food products from aquatic biomass, and supporting processes
• Improvement of plant productivity and efficiency with a focus on sustainability
• Quality and preservation of marine products
• Development of co-products (from by-products of processing)
• Applied research in marine bioactivities
• Research leading to commercialization
• Optimization and establishment of new processes
• Support for industrial scale-up
• Technical trouble-shooting
• Loan and assessment of equipment
• Further development of novel species
• General technical and processing information
• Analytical laboratory services
• Sensory analysis and consumer test panels

Facilities
• Multi-purpose pilot plant for product and process development
• Secure area for confidential pre-commercial production
- Product development laboratory for prototype development
- Fractioning platform for extraction, separation and purification of biomolecules
- Three analytical laboratories

**PEI Food Technology Centre**
101 Belvedere Avenue
Charlottetown, PE C1A 7N8
Phone: 902-368-5548
Toll-free in North America: 1-877-368-5548
Fax: 902-368-5549
Website: [www.gov.pe.ca/ftc/](http://www.gov.pe.ca/ftc/)

The PEI Food Technology Centre (FTC) is dedicated to the development of new and improved food products and processes on behalf of international, regional and local clients. FTC offers a broad range of services to the food processing and bioresource industry. Bioresource upgrading is the new wave of development in the food industry, and FTC is on the leading edge in the development of new uses from primary resources. Training programs in HACCP implementation, sensory analysis, and laboratory management are conducted both internationally and regionally. From concept to commercialization, and everything in between, FTC will take its clients and their products through every stage of development, including scale-up, quality and safety testing, sensory analysis and packaging.

Core services
- Innovative applied research, comprehensive analysis and testing
- Product development/process engineering and development
- Pilot plant
- Natural products (bioresource) extraction
- Food safety and sanitation training and systems implementation
- Information retrieval service and interpretation of scientific information
- Trouble-shooting expertise
- Public-private partnering arrangements with corporations leading to commercialization
- Technology transfer and innovation systems and activities
- Analysis (chemical, physical and microbial analysis)
- Equipment assessment and testing
- Nutrition labelling, sensory analysis and shelf-life testing

Facilities
- Natural products processing (5,000 sq. ft. laboratory and two processing suites)
- Two pilot plants (1,200 & 600 sq. ft.) can be connected into one continuous plant

**Canadian Institute of Fisheries Technology**
1360 Barrington Street
P.O. Box 1000
Halifax, NS B3J 2X4
Phone: 902-494-6030
Fax: 902-420-0219
Website: [http://cift.engineering.dal.ca/index.php](http://cift.engineering.dal.ca/index.php)

The Canadian Institute of Fisheries Technology (CIFT) at Dalhousie University was established in 1979 as a specialized resource centre of advanced technology for research in food science and process engineering with an emphasis on seafood. It promotes technology transfer and the development of advanced technologies aimed at more effective commercial use of marine resources in Canada and throughout the world. Major areas of emphasis include aquaculture development, biotechnology, fish/food process engineering, marine oils and nutrition, physical properties of foods, process chemical science, seafood biochemistry and toxicology.

Core services
- Product and process developments
- Sensory evaluation, with emphasis on seafood sensory
- Optimal process design, particularly in regards to improved quality for frozen seafood
- Biochemical, toxicological, sensory and physical analysis
- Interim processing facilities
- Training and auditing: seafood technology short courses
- Assessment of technology (local, new and/or imported)
- By-product utilization
- Packaging technology
- Product evaluation and quality confirmation

Facilities
- Product development kitchen
- Rheology and texture laboratory
- Pilot plant, fully equipped with computerized retort system
- Computer-controlled cold storage area
- Laboratories for chemistry, microbiology, marine oils, proteins and enzymes and product development evaluations

New Brunswick Research and Productivity Council
921 College Hill Road
Fredericton, NB E3B 6Z9
Phone: 506-452-1212
Toll-free: 1-800-563-0844
Fax: 506-452-1395
Website: [www.rpc.ca/english/servfood.html](http://www.rpc.ca/english/servfood.html)

The Research and Productivity Council (RPC) has served the food industry for over 40 years, providing technical expertise across many food product categories. It specializes in developing innovative new products, designing improvements to existing products, and assisting clients in finding ways to reduce production costs through ingredient, processing and/or packaging alterations. Members of the team also undertake in-plant problem solving, process line development, QA/QC program development, and production equipment modification and commissioning.

Core services
- Food safety
- New product development
- Lean manufacturing
- Heat processing and validation services
- Shelf-life studies
- Pilot plant processing
- Nutritional testing

Facilities
- Experimental kitchen
- Licensed food/seafood pilot plant
- Food microbiology laboratories
- Spice product development laboratory

Centre for Aquaculture and Seafood Development
Fisheries and Marine Institute
Memorial University of Newfoundland and Labrador
P.O. Box 4920
St. John’s, NL A1C 5R3
Phone: 709-778-0532
Toll-free: 1-800-563-5799
Fax: 709-778-0670
Website: [www.mi.mun.ca/casd](http://www.mi.mun.ca/casd)

The Marine Institute’s Centre for Aquaculture and Seafood Development (C-ASD) offers a complete range of services for seafood processing and aquaculture industries in the areas of applied research, product development, and process optimization.
and process development, technology transfer, advisory services, and education and training. From single-person owner/operator start-up companies to large, national corporations, C-ASD can play an integral role. C-ASD provides a suite of technical capabilities expertise for addressing industry needs and participates in R&D efforts for future growth and diversification. Clients can access C-ASD’s modern aquaculture research facility and two food pilot plant facilities. The Marine Institute plant is provincially and federally registered, and has an approved QMP program in place. Clients also benefit from C-ASD’s attention to quality assurance that comes with the Institute’s ISO-9001™ (2000 standards) registration.

Core services
- New food product and process development
- Equipment design and evaluation
- Product analysis
- HACCP assistance
- Post-harvest technologies
- Fishery by-products utilization
- Workshop, development and delivery

Facilities
- Pilot plant
- Aquaculture facilities

**Pacific Agri-Food Research Centre**
4200 Highway #97, South
Summerland, BC V0H 1Z0
Phone: 250-494-7711 Fax: 250-494-0755
Website: [www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1180620561099&lang=eng](http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1180620561099&lang=eng)

The Pacific Agri-Food Research Centre in British Columbia is one of 19 research centres in Agriculture and Agri-Food Canada’s national network. It has two research sites (the location in Agassiz) and a separate facility in Summerland, including the Kamloops Range Research Unit. Research at both sites addresses national agricultural priorities in the areas of horticultural and field crop production and protection including tree fruits, small fruits, greenhouse vegetables, special crops, and forages; advanced processing, utilization, quality and safety of plant products; the cellular and molecular biology of plant pathogens; soil resource conservation and land evaluation; poultry production and genetic resources; and dairy cattle behaviour and welfare.

Core services (Summerland)
- Discovering ways to enhance the quality of tree fruits and specialty crops, and more efficient ways to produce and store them
- Controlling plant virus diseases through the use of natural products
- Identifying and using components from Canadian crops and by-products from food industries to develop foods that promote health beyond their basic nutrients (functional food and nutraceuticals; investigating these food ingredients to determine antioxidant and anti-inflammatory properties)
- Developing new separation techniques such as extraction/fractionation to obtain various components from crops that can be converted and processed into higher-value end products
- Evaluating fruit and vegetable products for taste, texture, appearance and smell (sensory evaluation)
- Distinguishing new and existing cultivars of grapes; profiling the character of Canadian wines; assessing the quality of fruits and vegetables where preservation techniques (such as modified atmosphere packaging) are used to prolong the freshness of the product

Facilities
- Summerland location consists of 320-hectare site, with approximately 90 hectares irrigated and available for research
- Food research pilot plant; sensory evaluation laboratory
- Extraction and fractionation laboratory pilot plant
- Electron microscope and confocal microscope
Guelph Food Research Centre
93 Stone Road West
Guelph, ON N1G 5C9
Phone: 519-829-2400
Fax: 519-829-2602
Website: [www.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1180620168432&lang=eng](http://www.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1180620168432&lang=eng)

The Guelph Food Research Centre specializes in food safety, quality and nutrition, and is committed to ensuring that food produced in Canada continues to be among the safest and of the highest quality in the world. Research covers all aspects of food production, from the field to the fork. In addition to its focus on food quality and safety, much of the Centre’s work is exploring the potential for conventional foods to offer nutritional and other therapeutic benefits. Scientists are also developing innovative methods to reduce food-borne biological and chemical hazards that may be present in farm commodities, fresh market and processed foods. The Guelph Centre is a partner in many collaborative projects with industry, farm groups and the University of Guelph in the areas of product development, packaging, shelf life, food safety and the improvement of food quality and productivity.

Core services:
- Conducting research on novel bioprocesses for separating and modifying agricultural and agri-food products that will have enhanced properties and commercial potential
- Characterizing and identifying agricultural bioproducts for human, animal and industrial applications
- Methods for preventing food-borne hazards through the use of innovative natural controls and strategies
- Exploring technologies to control toxins in foods and livestock feeds
- Finding ways to preserve safety, quality and nutrition of processed and packaged foods
- Identifying food-borne bacteria and viruses that cause illness in humans and animals
- Preserving the functional and nutraceutical properties of foods before, during and after processing
- Investigating the potential of natural antioxidants and other health-enhancing nutrients as anti-cancer agents
- Conducting research on bioactive elements and the bio-availabilities of phytochemicals (plant chemicals with potential disease-preventing compounds) and natural health products from Canadian crops and plants

Facilities
- Molecular Biology Research Unit with equipment and expertise for studying food DNA, and the monitoring and tracking of harmful food-borne bacteria
- Food processing pilot plant with traditional and novel processing equipment (high pressure, temperature, ultraviolet, ozone) used to study food processing and product safety
Food Research and Development Centre
3600 Casavant Boulevard West
Saint-Hyacinthe, QC J2S 8E3
Phone: 450-773-1105
Fax: 450-773-8461
Website: www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1180639333520&lang=eng

The Centre focuses on conducting research and developing methods to preserve food and maintain its quality, and to process food safely and efficiently. Research is also conducted on food ingredients having health and other benefits beyond basic nutritional values. Food safety is also a major area of research, and in doing this work, the Centre collaborates with the University of Montreal’s Faculty of Veterinary Medicine and the CFIA. Through the Centre’s Industrial Program, pilot plants are leased to agri-food companies in support of their small-scale food-processing and testing needs. In addition, the Centre also provides extensive information retrieval and analysis services.

Core services:
- Studying the process of combining organic acids (lactic and propionic acids) to stabilize and preserve plant-derived food products
- Researching yeast extracts and bacteria, and their effects on processing food safely
- Conducting research on more effective ways to detect and control disease-producing microorganisms, including viruses, which are believed to cause 80% of food-borne illnesses
- Research to identify, characterize and control food allergens, and ensure operational traceability and the safety of fresh products. Designing projects to improve the energy efficiency of food production processes, and that preserve and improve the quality of food
- Conducting research on foods for taste, smell and texture as well as their health properties
- Studying the expectations of consumers regarding food quality and convenience, including storage
- Other areas of study: recombinant enzymes and bioactive molecules, dairy ingredients, biopolymers, spectral analysis and the structure–property relationship of biomolecules

Facilities
- 8,030 square meter building with 3,200 square meters of pilot plants for food processing
- Crossroads for Food Innovation Technology facility comprising four laboratories, four pilot plants and associated offices

Atlantic Food and Horticultural Research Centre
32 Main Street
Kentville, NS B4N 1J5
Phone: 902-679-5333
Fax: 902-679-2311
Website: www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1180623750202&lang=eng

Located in Kentville, in western Nova Scotia’s Annapolis Valley, the Centre’s programs are unique in addressing problems throughout the Canadian horticultural and food system, but with a focus on the regional needs of Atlantic Canada. In its field and laboratory, work is conducted on primary production, crop protection, soil and water evaluation, post-harvest storage, food quality assessment, pilot plant processing of food and consumer safety. There is multidisciplinary research at all levels, from the field to the consumer. In addition to its main office/laboratory in Kentville, the Centre manages the Nappan Research Farm, near Amherst, and a satellite research field site at Sheffield. The Nappan Research Farm is mainly involved with beef research for the Atlantic region, along with some forage and soils work. The Centre is also responsible for scientists co-located at the Nova Scotia Agricultural College working in poultry, forage breeding and soil science.

Core services
- Breeding strawberries, raspberries, blackberries and grapes; evaluating their properties and the quality of hybrids such as apples and pears
- Examining technologies for producing and managing tree fruits, berries and vegetables, including organic fruit; commercializing superior plants
- Extracting and characterizing bioactive components of fruits and vegetables
- Conducting research on technologies to enhance the storage of horticultural crops
- Finding new processes for handling and producing processed (or minimally processed) fruits and vegetables and analyzing the effects of processing on food microbes
- Evaluating handling operations for perishable foods during each step of the cold chain (e.g. storage, transportation, retailing) and their effect on the quality and safety of food
- Assessing the chemical, structural, nutritional, physical and sensory properties of food
- Conducting research on the molecular properties of food to improve quality
- Research on food fermentation techniques to improve nutritional value

### Facilities

- Specialized laboratories and facilities, including:
  - Small and large lab-scale food storage chambers with individual control and monitoring of modified atmosphere food storage conditions
  - Pilot plant (550 square metres) for fruit and vegetable processing
  - Laboratory robotics equipment
  - Electron and light microscopes
  - Quantitative Digital Image Analysis
  - Chemical analysis and identification of bio-active and other selected components using chromatographic, selective detectors, immunoassay and biochemical techniques
  - Geographic Information Systems Analysis (Arc-View)
- Growth cabinets
- Sensory testing facility equipped with computerized data collection
Appendix 6: Market Track – References

When developing plans for the marketing aspects of a business, managers will often start with an initial **market overview** to gain a high-level understanding of elements such as market segments, competitors and trends.

As the business proceeds further with its planning activities, the usual key business management tool used is a **marketing plan**.

A marketing plan is both:

- a written document; and
- a process for coordinating all the planning activities of defining pricing, promotion and distribution of a company’s products (whether an existing business adding a significant new product or a new start-up business).

The written marketing plan document, when complete, describes the plan for the business’s marketing strategy and the tactics of how the strategy will be executed. It explains:

- the product description, specifications and performance features, and the nutrient and/or health claim that will be made for the product;
- most importantly, the benefits it provides to the customer, from the customer’s perspective, noting what the customer values most;
- the overall marketing strategy that will create a competitive advantage for the product in the marketplace;
- the selected target market segments;
- who the competitors are and how they will likely respond to the new product;
- positioning strategies to convey the core of why the product exists and why customers should purchase it;
- target markets in terms of location, size and scope;
- customer profiles;
- pricing strategies and distribution channels (e.g. agents, brokers, distributors, retailers);
- promotional and advertising programs to stimulate trial use and repeat purchases of the product;
- timelines for running key initiatives and the attainment of sales targets; and
- budgets (both in terms of money and people) for all marketing-related activities.

The process for coordinating the development of the marketing plan occurs by bringing together information from all parts of the marketing function. This includes both internal and external resources such as sales, packaging/labelling design, logistics, promotional programs and advertising in order to ensure consistency.

This process of ensuring consistency occurs when the marketing plan becomes a written document. The completed marketing plan will allow the actual launch of the new product to be lower risk and more readily controlled.
Following is a list of web-based resources to help businesses prepare a marketing plan (found near the beginning of the list) and those that provide market research information (found later in the list):

<table>
<thead>
<tr>
<th>REFERENCE</th>
<th>DESCRIPTION AND CONTACT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BANKS</strong></td>
<td></td>
</tr>
<tr>
<td>Business Development Bank of Canada</td>
<td>The BDC website provides a five-step process for preparing a marketing plan. <a href="http://www.bdc.ca/en/advice_centre/articles/Pages/marketing_plan.aspx">www.bdc.ca/en/advice_centre/articles/Pages/marketing_plan.aspx</a></td>
</tr>
<tr>
<td>Canadian Imperial Bank of Commerce</td>
<td>CIBC has a marketing plan downloadable template. <a href="http://www.cibc.com/ca/pdf/small-business-planningguide-part-B-1.pdf">www.cibc.com/ca/pdf/small-business-planningguide-part-B-1.pdf</a></td>
</tr>
<tr>
<td>Royal Bank of Canada</td>
<td>RBC’s marketing plan information includes Target Market, Services/Products, Pricing Strategy, Sales/Distribution Plan and Advertising and Promotions Plan. <a href="http://www.rbcroyalbank.com/RBC:RYsbAY71ABYAAaSwWa/sme/bigidea/marketing.html">www.rbcroyalbank.com/RBC:RYsbAY71ABYAAaSwWa/sme/bigidea/marketing.html</a></td>
</tr>
<tr>
<td>Scotiabank</td>
<td>Scotiabank’s website offers an interactive planning tool to help create a business plan. <a href="http://www.scotiabank.com/cda/content/0,1608,CID10328_LIDen,00.html">www.scotiabank.com/cda/content/0,1608,CID10328_LIDen,00.html</a></td>
</tr>
<tr>
<td>TD Canada Trust</td>
<td>TD Canada Trust offers downloadable business planning software. <a href="http://www.tdcanadatrust.com/smallbusiness/busplan.jsp">www.tdcanadatrust.com/smallbusiness/busplan.jsp</a></td>
</tr>
<tr>
<td><strong>GOVERNMENT OF CANADA</strong></td>
<td></td>
</tr>
<tr>
<td>Agriculture and Agri-Food Canada</td>
<td>Agriculture and Agri-Food Canada provide profiles of 14 sub-sectors of the processed food and beverages industry. <a href="http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1171292241348&amp;lang=eng">www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1171292241348&amp;lang=eng</a></td>
</tr>
</tbody>
</table>
| Canada Business | Canada Business is a service for entrepreneurs provided by the Government of Canada. It includes a useful site titled “Developing a Marketing Plan.” [www.canadabusiness.ca/eng/guide/2533/](http://www.canadabusiness.ca/eng/guide/2533/)  
This site addresses the relevant topics in a marketing plan:  
1. Why develop a marketing plan?  
2. Before writing a marketing plan—Market Research  
   • Designing a Questionnaire [www.canadabusiness.ca/eng/guide/2780/](http://www.canadabusiness.ca/eng/guide/2780/)  
   Gives advice on how to design a survey questionnaire in order to gather market research data.  
   Shows how market research can help a business succeed and shows how to conduct a variety of market research activities.  
   • Market Research Approaches [www.canadabusiness.ca/eng/guide/2126/](http://www.canadabusiness.ca/eng/guide/2126/)  
   Shows research approaches that can support market research efforts.  
   Gives tips/guidelines on the design and implementation of web-based surveys.  
   • Types of Survey Questions [www.canadabusiness.ca/eng/guide/3132/](http://www.canadabusiness.ca/eng/guide/3132/)  
   Shows different kinds of closed and open-ended questions that can be used in surveys. |
3. Sections of a marketing plan
- Executive summary
- Business description—including business's vision and mission statement
- Product or service—what need is being met and why is it better than competitors
- Target market—identify customers
- Competitors—including SWOT analysis
- Distribution channels
- Marketing strategy and activities—including marketing challenges and how they will be overcome
- Prices and pricing strategy
- Sales projections—including one-, three- and five-year targets

This site also offers a wide variety of market research data.
www.canadabusiness.ca/eng/88/
It includes:
- Labour and employment data
- Demographics
- Industry sector data
- Canadian economy
- International markets
- Importing and exporting
- Environment
- Science and technology
- General research and statistics

Industry Canada
Industry Canada’s "Strategis" is a significant source of industry market and economic information. It offers information by industry sector, company directories (including company directories by industrial sector), economic and market research statistics, and a variety of types of information and statistics. www.strategis.gc.ca.

Statistics Canada
Statistics Canada information can be accessed in a variety of ways, including:
- Demographic data www.canadabusiness.ca/eng/88/191/
- Labour and employment data www.canadabusiness.ca/eng/88/190/
- Provincial government searchable databases (e.g. the Ontario Business Directory is a directory and search engine for businesses, companies, services, organizations, tourist information, estate listings, entertainment, news, events calendars, and other information about Ontario). www.ontario-directory.com/

OTHERS
Carnegie Library of Pittsburg
This site includes a substantial index listing most types of small businesses and a corresponding sample business plan, profile or book about the business with sources provided after each entry. www.carnegielibrary.org/research/business/bplansindex.html

GDSourcing
GDSourcing is a directory designed for market research. It has many Canadian references and links to a wide variety of useful Canadian sources of market information. www.gdsourcing.com/SiteMap.htm

KnowThis.com
KnowThis.com is a leading information and resource website for those involved in marketing, market research, advertising, selling, promotion and other marketing-related areas. There are tutorials for doing market research and others on how to prepare a market study. www.knowthis.com
| Natural Foods Merchandiser magazine | The *Natural Foods Merchandiser* magazine website has information on a wide variety of:
- Conferences, tradeshows and webinars (e.g. it has summaries and video coverage of events like the Natural Products Expo East)
- Food, beverages and related new technology
- Market trends and related topics
[www.naturalfoodsmerchandiser.com](http://www.naturalfoodsmerchandiser.com) |
| Newsletters | Food- and nutrition-related electronic newsletters offer useful market information. Those with free subscriptions include:
- [www.foodnavigator.com](http://www.foodnavigator.com) — food and beverage development globally
- [www.foodnavigator-usa.com](http://www.foodnavigator-usa.com) — food and beverage development in the U.S.
- [www.nutraingredients.com](http://www.nutraingredients.com) — nutrition and related health-oriented products globally
- [www.nutraingredients-usa.com](http://www.nutraingredients-usa.com) — nutrition and related health-oriented products in the U.S.
All of these also offer market research reports that are for sale at high prices. |
| Reports for sale | A large number of private sector for-profit market research businesses offer an assortment of reports, often at high prices. An example of one that has many reports on the Canadian food industry is “Food/Beverage Market Research Reports Portal” by Global Information, Inc. [www.foodandbeveragereports.com/cgi-bin/product_list.cgi?country=NA02](http://www.foodandbeveragereports.com/cgi-bin/product_list.cgi?country=NA02) |
| TD Canada Trust releases | A variety of financial institutions, professional accounting/consulting firms, and others maintain a steady stream of releases of economic outlook and market information. For example, the TD Canada Trust site has “Information for Small Business.” [www.tdcanadatrust.com/smallbusiness/economics.jsp](http://www.tdcanadatrust.com/smallbusiness/economics.jsp) |
The highlights include:
- Canadian and international regulatory updates
- Market information on trends, functional foods, supplements, organics, etc.
- Research updates
- An updated WCFN and events section
For a free subscription contact Mira Laza at [mlaza@wcfn.ca](mailto:mlaza@wcfn.ca) |

### DIRECTORIES

| Economic Development Departments | Economic development departments of cities, regions and provinces offer a wide variety of detailed market information that can be sourced for specific regions. |
| Frasers Directories | Frasers Directories describes itself as “Canada’s On-Line Industrial Directory.” It offers a comprehensive directory and search tool, providing information on Canadian industrial wholesalers, manufacturers, distributors and their products and services. It also lists international companies that supply goods and services to the Canadian marketplace. Searches can be conducted in several ways:
- Search database by company, product or brand name.
- Find a specific item on any of listed company websites by selecting the Industrial Search.
| Scott’s Directories | Scott’s Directories offers listings of government, business, association and other types of organizations, for a fee. [www.scottsdirectories.com/new/](http://www.scottsdirectories.com/new/) |
Appendix 7: Business Track – References

A business plan is one of the key management tools used for planning the development of a business, whether it is to plan all the changes to the business needed to successfully develop a significant new product with a nutrient and/or health claim, or whether it is to start a new business.

What Is a Business Plan?

A business plan is both:

- a written document; and
- a process.

The process of creating or updating a business plan requires identifying and then coordinating all the work activities of developing the business. The research to document all aspects of the business and obtain that documentation (e.g. cost quotes for new processing technology/equipment) often requires significant resources (both management time and money).

The business plan is both detailed and comprehensive. It describes the future plan for the business. It explains the business concept, summarizes the objectives of the business, identifies the financial and human resources that will be needed by the business, describes how those resources will be obtained, and tells the reader why the business will succeed by explaining how it has a competitive advantage. It also describes location, timeline for getting under way, and risks and how they will be overcome, and projects the financial returns expected.

What Is the Process?

The business planning process uses the document to bring together all aspects of the business in one place and ensure all are coordinated, and optimized, before spending the money and time to actually implement the plan.

The business planning process is a creative process, using the strategic skills of management and the resources they can bring to the business (e.g. consultants, management team meetings) to create a better future for the business than would otherwise occur. Because the business plan encompasses all aspects of the business, the planning process is very comprehensive. All the specific functional areas of the business (product, regulatory claims, production technology, marketing, human resources, finance) must have their key information described and documented.

Consistency

The business plan document must be a story, with supporting documentation of all key business aspects that are consistent. The regulatory, marketing and manufacturing sections must be consistent, when studied, with the regulatory section describing the permitted nutrient/health claims, the marketing section describing how customers will perceive a value
from the health aspect of the product, and the manufacturing section describing how the healthy attribute will be included in the product.

Creating this consistency in management’s plans for the business creates value for the business. This value is the primary reason for preparing a business plan.

There is also considerable value in forcing the information to be written down and brought together in one document, because gaps in information will highlight where more work is needed in developing the business (e.g. if the sourcing of financing is falling behind where it should be relative to the marketing and manufacturing areas).

Thus, the work on developing the business plan can be much more efficient and the risk of “going too far” in making commitments in one area can be managed by identifying the progress in development of each functional area of the business, and knowing when it is appropriate to make firm commitments.

Why Prepare a Business Plan?

There are a number of benefits and reasons for preparing a business plan.

- It lowers risk and increases efficiency as the business proceeds to implement its plans.
- The process of developing the business plan forces managers to think about the business and its opportunities, focusing on what will create competitive advantage. It includes such activities as researching options for better ways to seize the opportunities, and identifying risks and mitigation strategies.
- A business plan identifies the future financing needs of the business.
- A business plan is required to obtain financing from bankers and from investors. The business plan provides the information about the proposed venture to lenders, investors and suppliers to demonstrate how their money will be used, and to establish a basis for the business’s credibility. Every source of financing will expect a business plan to be included in an application for financing.
- The business plan is used to describe the business’s plans and strategies to employees, investors and others.
- Once the business is operating, the business plan provides a benchmark against which to compare the progress and performance of the business, and is a business management tool to use when business decisions are required.

Where Business Plans Fit into the Overall Business Planning Processes

Six studies and plans are most commonly used by managers as they develop a business that is planning for significant change. If the planned change is modest, then only the appropriate ones from this set will be used.

1. The Market Overview provides an initial brief analysis of potential markets.
2. The Pre-Feasibility Study lays the groundwork with preliminary information appropriate for the early stages of examining if an opportunity is worth pursuing.
3. The Feasibility Study builds on the previous work and adds more details and considerations.
4. The Marketing Plan builds on the previous Market Overview work. (See Appendix 6 for an overview of marketing plans and a list with links to external resources.)
5. The Preliminary Business Plan builds on the previous work to create the first versions of the business plan, while conducting the process of developing the business plan.

6. The Business Plan—as described above.

After each of these steps, managers can make decisions whether or not to proceed with developing the new product and related business capacity. With each succeeding step, the level of detail required increases and thus risk is reduced as more is known. Because each step in the process requires significantly more time and money to be invested, it is wise to reduce risk in this orderly manner, before making the larger investments.

Business Plan References

A number of web-based resources provide general information to help businesses prepare a business plan. While all have differences, many of the fundamental aspects are similar. Some of the most relevant resources are presented in the following table.

<table>
<thead>
<tr>
<th>REFERENCE</th>
<th>DESCRIPTION AND CONTACT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GOVERNMENT AND FINANCIAL INSTITUTIONS</strong></td>
<td></td>
</tr>
<tr>
<td>Government of Canada</td>
<td>The Government of Canada provides advice on how to prepare a business plan.</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.canadabusiness.ca/eng/86/4877/">www.canadabusiness.ca/eng/86/4877/</a></td>
</tr>
<tr>
<td>Business Development Bank of Canada</td>
<td>The BDC website offers a business plan template as well as a template to help with financial planning.</td>
</tr>
<tr>
<td></td>
<td>BDC also offers other business management tools, such as an entrepreneurial self-assessment.</td>
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<tr>
<td></td>
<td><a href="http://www.bdc.ca/EN/advice_centre/tools/Pages/default.aspx">www.bdc.ca/EN/advice_centre/tools/Pages/default.aspx</a></td>
</tr>
<tr>
<td></td>
<td>These tools include processes such as benchmarking tools.</td>
</tr>
<tr>
<td>Canadian Imperial Bank of Commerce</td>
<td>CIBC’s website offers a business plan template.</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.cibc.com/ca/small-business/article-tools/business%E2%80%90plannin%E2%80%8C%E2%80%8Cg.html">www.cibc.com/ca/small-business/article-tools/business‐plannin‌‌g.html</a></td>
</tr>
<tr>
<td>Royal Bank of Canada</td>
<td>RBC offers advice on preparing a business plan.</td>
</tr>
<tr>
<td>Scotia Bank</td>
<td>Scotiabank’s website offers business planning advice.</td>
</tr>
<tr>
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<td><a href="http://www.scotiabank.com/cda/content/0,1608,CID10328_LIDen,00.html">www.scotiabank.com/cda/content/0,1608,CID10328_LIDen,00.html</a></td>
</tr>
<tr>
<td>TD Canada Trust</td>
<td>TD Canada Trust offers a downloadable business planning guide.</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.tdcanadatrust.com/smallbusiness/busplan.jsp">www.tdcanadatrust.com/smallbusiness/busplan.jsp</a></td>
</tr>
</tbody>
</table>
## ECONOMIC AND INDUSTRY DEVELOPMENT ORGANIZATIONS

<table>
<thead>
<tr>
<th>Organization</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bplans.com</td>
<td>Bplans.com offers a collection of free sample business plans. A five-minute video explains how to use a sample business plan.</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.bplans.com/samples/sba.cfm">www.bplans.com/samples/sba.cfm</a></td>
</tr>
<tr>
<td>Community Business Development</td>
<td>CBDC has a web-based application assisting new and aspiring entrepreneurs to prepare a three-year business plan online.</td>
</tr>
<tr>
<td>Corporations</td>
<td><a href="http://obp.cbdc.ca/?lang=0">http://obp.cbdc.ca/?lang=0</a></td>
</tr>
<tr>
<td>Canadian Youth Business Foundation</td>
<td>CYBF is focused on supporting youth entrepreneurship. It has an online Interactive Business Planner tool designed to guide both new and experienced entrepreneurs through the process of writing a comprehensive business plan.</td>
</tr>
<tr>
<td>Entrepreneurship Centre</td>
<td>Entrepreneurship Centre offers “Writing an Effective Business Plan,” a free 55-page how-to guide.</td>
</tr>
<tr>
<td>GDSourcing</td>
<td>GDSourcing has a directory of free statistics and links to relevant websites specifically designed for assisting entrepreneurs. While mostly oriented to doing market research, it has three links to business plan information under the heading of “Research Intro.”</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.gdsourcing.com/SiteMap.htm">www.gdsourcing.com/SiteMap.htm</a></td>
</tr>
<tr>
<td>Harvard Business Review</td>
<td>HBR’s resource, “How to Write a Great Business Plan” (author: William Sahlman), is a brief, low-cost book available through most book stores for about $10. It can be read in an hour or two.</td>
</tr>
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Appendix 8: Additional Considerations and Cost Implications

A) Market Track

Assuming the company or industry association has a basic marketing plan and wants to:

• add a nutrient claim and/or health claim to an existing ingredient/food product, or
• create a new ingredient/food product that qualifies for a nutrient and/or health claim, and

assuming it has:

• reviewed Steps 1, 2 and 3 of the Nutrient Claim / Health Claim Flow Chart (page 9),
• considered nutrient and health claim options outlined in Step 4, and
• selected some of these options for exploration of market value,

additional costs will be incurred to develop the necessary changes to the marketing plan.

In addition to the traditional information gathered to update a marketing plan, companies and industry associations considering adding nutrient and/or health claims to their ingredients and/or products should also consider:

• Current usage of claim(s)
  o Identify companies/products using claim.
  o Estimate market penetration (% products in category using claim).
  o Estimate growth in use of claim in past few years and in the future.
• Consumer
  o Describe existing consumer who is buying products using claim.
  o Obtain studies that measured consumer knowledge of claim.
  o Identify consumer target market segment(s) that will maximize profits, especially including considering the segment(s) that will create the greatest competitive advantage.
• Marketing channels
  o Identify existing marketing/distribution channels used to serve target consumers.
  o Identify new marketing/distribution channels that may create a competitive advantage.
• Claim promotion
  o Identify key sources of promotional information already going to consumers, and what messages might be used to create a competitive advantage.
  o If claim is new, determine whether anyone is conducting an educational program, and what educational activities might be used/supported to create a competitive advantage.
• Pricing
  o Confirm existing pricing.
  o Identify pricing strategy that will maximize profits while creating a competitive advantage.
• Consider the likely reaction from any competitors in the market to a new entrant using a nutrient/health claim and decide what impact this will have on the price that could be used at entry and the periods that follow.

• Company/association strategy
  o Does claim fit with corporate image?

If any of the above is missing, added costs will be incurred for one or more research activities that will need to be conducted to generate the data, such as:

• secondary research (e.g. literature reviews); and/or
• primary research to fill identified gaps that remain after doing secondary research, such as surveys, focus groups, executive interviews, and test marketing.

The additional costs incurred for the above will vary widely, depending upon the:

• Consumer knowledge of the product and claim
  If it is necessary to educate the consumer regarding the product/claim, the costs to develop the market, and the planning to do that will be much higher than if the consumer is already knowledgeable.

• Complexity of the product, claim and market being pursued
  The more complex it is, typically the more challenging it is to effectively communicate the message to consumers, thus requiring more planning and development work.

• Relative “newness” of the product.
  The newer it is, typically the more intensive a communication/promotion campaign is needed to attract attention to the product and then educate consumers about aspects such as its benefits and the claim.

• Size/volume of the market being pursued
  A larger-volume market will typically incur higher costs than pursuing a small target market.

• Variations within the target market:
  o targeting a diverse geographic area will have higher costs for the research and planning to appropriately address these variations between regions; and
  o targeting consumers with differing characteristics (e.g. a product/claim that is beneficial to both older and younger consumers will require added costs to effectively communicate with the two different sets of demographics).

• Marketing strategy:
  o a consumer-ready retail product strategy will require higher costs for the:
    - development of labels, packaging, point-of-sale and related promotional material, advertising/promotion to create consumer awareness;
    - fees to distributors to assist in market development;
    - listing fees with retailers; and
    - other marketing/sales costs.
  o an industrial/ingredient sales strategy will require lower retail strategy costs, as the food processor customers who will use the ingredient in their products will be covering those costs for their finished products.
B) Business Track

Assuming the company or industry association has a basic business plan and wants to expand into ingredient/product(s) with nutrient and/or health claims, review and updating of the business plan will be required.

Additional development costs may be expected in the following areas:

- **Product**
  - quality—if increased standards are needed to meet specifications required by claim
  - safety—if ingredient is not currently approved for intended use
  - efficacy—if claim is not already permitted
- **Marketing**
  - understanding market for claim and if consumer education program is required
- **Production technology and systems** required for new ingredient/product
- **Finance-related aspects**
- **Human resources impacts**
- **Business strategy compatibility or modification**

For the product-related items, individual steps and their associated range of costs are available through a supplemental tool.36

For the marketing-related items, the costs are discussed in the previous notes on additional costs related to updating the marketing plan in part A.

For the other topics, additional costs will vary widely, depending upon the:

- production complexity and whether the technology/process is well established or if it is yet to be commercialized at the scale being pursued. If a laboratory-scale or a pilot-scale initial production system must be created before accessing the full commercial scale, development costs will be higher;
- financing requirements and whether the new undertaking is self-financed by the existing business or whether new financing is required. If new debt and/or equity is required, these arrangements will require more documentation of all new aspects than if self-financed. New equity can add significant development costs if it requires Security Commission approval;
- added development costs to recruit human resources with the needed expertise or experience, especially if they are challenging to obtain; and
- required modifications to the business strategy. For example, if a strategic alliance with another business is identified as the most appropriate way to pursue the new opportunity, the management systems, information systems, and even business culture may need significant change to be successful. All of these will incur added development and planning costs.

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36 Available from the Food Regulatory Issues Division, Agriculture and Agri-Food Canada.
Appendix 9: Index to the Canadian Food and Drug Regulations

How to Use This Quick Reference

The Food and Drug Regulations are divided into parts. Each part contains sections and subsections. This quick reference is intended to show what topic is covered in sections that may be relevant to food products with health benefits. Note that not all sections are included and a topic may be covered under several subsections.

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