

**COMPREHENSIVE SUMMARY OF CANADIAN FEDERAL STATUTES
AND REGULATIONS GOVERNING PRE-MARKET EVALUATION,
LABELLING, ADVERTISING AND HEALTH CLAIMS FOR
FUNCTIONAL FOODS IN THE CANADIAN MARKET**

**Prepared for the Office of Science and Innovation, Agriculture Policy
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Preface

Manufacturers and importer/distributors of foods and beverages in Canada have long held an interest in being permitted under Canada's regulatory system to incorporate health claims for foods within product labelling and advertising. This interest has been shared with manufacturers and importer/distributors of specially formulated food products and products positioned and sold as natural health products in Canada but as dietary supplements in markets other than Canada.

Between 1995 and 2007, industry interest in gaining approval and/or removing regulatory impediments to health claims has intensified. This has contributed to considerable debate as to the legitimacy and societal merit of health claims as well as to the scientific evidence required to support health claims for foods and beverages. However, the legislative and regulatory context for this debate and Health Canada's public consultations on the issue of health claims for foods is extremely complex. The complexity of the regulatory environment continues to make it very difficult to undertake informed discussion about health claims and for parties engaged in the discussion to gain and maintain a shared understanding of the relevant regulatory requirements.

This document and its various appendices and references are intended to serve as a reference manual for all stakeholders with an interest in health claims for foods and related regulatory requirements. The authors have undertaken to 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 assist readers in examining aspects of Canada's food and natural health product regulatory system in greater detail.

Although every attempt has been made to present a factual explanation and illustrations of the Canadian regulatory environment, there are a number of opinions expressed in this document that are solely those of the authors. These opinions are offered to provide readers with comparisons of requirements within the scope of Canada's federal regulation and to draw attention to principles and precedents within regulations that apply to foods and natural health products where these may be particularly useful in examining options for modernization of regulation pertaining to health claims.

The authors wish to thank Agriculture and Agri-Food Canada for the opportunity to undertake this study and for the department's support in the completion of this report.

Complete drafts of this report were provided to Health Products and Food Branch and Canadian Food Inspection Agency offices for review and comment in late August, 2007. This final report incorporates comments received. The contributions of time and advice from officers of Health Canada and the Canadian Food Inspection Agency are gratefully acknowledged.

Executive Summary

The complexity of the regulatory environment has made it very difficult for individuals in both the private and public sectors to engage in informed dialogue on health claims for foods with a shared understanding of regulatory principles and requirements. This document and its various appendices and references are intended to serve as a reference manual for all stakeholders with an interest in health claims for foods and Canada's regulatory requirements for pre-market evaluation, labelling, advertising of foods with demonstrated health benefits and related health claims. Such foods are often referred to as "functional foods".

Canada's two principal federal government organizations responsible for regulation of foods are Health Canada and the Canadian Food Inspection Agency. By mid-2007, both organizations had launched regulatory modernization initiatives intended to ultimately replace the existing Food and Drugs Act with a Health Protection Act and to extensively overhaul current regulations that apply to foods found within the Food and Drug Regulations.

One of the major stated policy goals of Health Canada's regulatory modernization Blueprint for Renewal II consultation document released in April 2007 is:

"promoting regulatory responsiveness to food innovation and promoting consumer access to foods with assessed health benefits, in particular, the development of a comprehensive approach for the management of food with health claims and completion of a policy on the discretionary fortification of foods;"

At the time of completion of this report in October, 2007, Health Canada's Natural Health Products Directorate has initiated a review of the Natural Health Product Regulations that will in part, clarify the regulatory definition of a natural health product, differentiated from the regulatory definition of food.

Blueprint for Renewal II also promised a re-examination of consumer product categories. That process has not been completed. Nor have there been any recent revisions to the Food and Drugs Act. As a consequence, **the Food and Drugs Act still provides for only two categories of products – "food" and "drug"**.

With this product categorization still residing within the Food and Drugs Act, there are four important facts to be noted in order to understand the current status of the regulation of foods with health claims. These are:

1. Functional foods are not recognized in law or regulation in Canada;

However, there is a policy that requires that foods with health claims (functional) are deemed to be drugs and required to undergo a pre-market evaluation to demonstrate safety and the validity of the claim.

2. Nutraceuticals are not recognized in law or regulation in Canada;

Substances and products considered in other countries to be nutraceuticals are captured by Canada's regulatory definition of “natural health product”.

3. Natural health products are recognized in the Natural Health Product Regulations as a sub-category of drugs; and,

Natural health products must undergo pre-market evaluation and receive product licenses in order to be marketed in Canada.

4. All foods (including foods with health claims), natural health products and drugs are extensively regulated in Canada under federal laws and regulations.

Any product sold for human consumption as a food, beverage, dietary supplement or non-prescription (over the counter) medicine is subject to regulation in Canada whether manufactured in Canada or imported and distributed.

Point 4 above portrays Canada’s federal regulation of foods as being extensive. That is not to say that manufacturers of foods and beverages do not have the right and opportunity to formulate new products or reformulate and label accordingly. Readers should note however that:

▪ **There are significant restrictions on the use of food additives.**

Food additives must undergo pre-market evaluation for safety and efficacy in intended use. Permitted uses and addition rates are listed in the Food and Drug Regulations.

▪ **There are significant restrictions on the addition of vitamins and minerals to foods.**

Permitted addition of vitamins and minerals is also specified in the Food and Drug Regulations.

▪ **The addition to foods of substances typically used as ingredients in natural health products has not been permitted to date and is not provided for within regulations that apply to foods.**

In recent years, manufacturers have sought access to the Canadian market for such products under either regulations within the Food and Drug Regulations that apply to drugs or under the provisions of the Natural Health Product Regulations. Both avenues require pre-market submissions and evaluation.

- **Health claims for foods are generally prohibited under Section 3, Schedule A of the Food and Drugs Act.**

The only health claims currently permitted are specifically exempted from Section 3, Schedule A.

It is also very important to note that Canada’s regulatory requirements for foods, foods with health claims and natural health products (including dietary supplements) are substantially different than those of the USA and other industrialized countries. For example, there is a substantially larger number of health claims permitted for foods in the U.S. In addition, U.S. legislation and regulation does not require that dietary supplements undergo pre-market evaluation and product licensing as is the case in Canada under the Natural Health Product Regulations. In fact, Canada’s Natural Health Product Regulations are unique in the global regulatory context.

Current Policy - Health Claims for Foods

Canada’s federal policy and regulatory environment for foods with health claims has been developed in a relatively short period of time since 1995. Two important policy principles were adopted by Health Canada’s Food Directorate in 1998 and still apply. These are:

- 1. risk reduction and structure/function claims foods should be permitted**
- 2. any health claim for a food or food ingredient that claimed to cure, treat, mitigate or prevent a disease would require that the food or food ingredient would be considered to be and be regulated as a drug. This meant that such products would require pre-market evaluation (before being sold in Canada) to demonstrate safety and efficacy.**

Defined by the Food and Drugs Act and Regulations as Drugs	Defined by Health Canada Policy as Drugs	Defined by the Food and Drugs Act and Regulations as Foods
Non-prescription drugs intended for self-care or use on the advice of a pharmacist or health care practitioner without prescription	Foods with health claims	Whole foods or single ingredient foods, including novel foods that have undergone pre-market evaluation
Natural health products, also intended for self-care or use on the advice of a pharmacist, health care practitioner or nutrition advisor without prescription	Foods containing vitamins, minerals and bioactive substances not specifically permitted and/or present at levels outside of the range permitted in the Food and Drug Regulations	Food additives, permitted for uses and amounts specified in the food additive tables, Division 16, Section B of the Food and Drug Regulations

Health Canada's pre-market evaluation policy and process that still apply were published in 2002 as the *Interim Guidance Document – Preparing a Submission for Foods with Health Claims incorporating Standards of Evidence for Evaluating Foods with Health Claims*. This policy still considers foods with health claims to be defined as drugs and therefore subject to the provisions of the Food and Drug Regulations that apply to drugs and Section 3, Schedule A of the Food and Drugs Act. Foods with claims may not be sold until such foods and the related claims are exempted from drug regulatory requirements and Section 3, Schedule A. Such an exemption requires an amendment to the Food and Drug Regulations and would be made only after a pre-market evaluation of the food for which the approval of the health claim is being sought.

Health Canada considers the adoption of a health claim for a food to present varying degrees of risk to consumers. The pre-market evaluation requirements for foods with health claims are therefore substantial. Applicants for approval of a food with a health claim must demonstrate the safety of the food when consumed as predicted and the causality of the food in achieving the expected health benefit. The applicant must also demonstrate that the expected health benefit is sustained and not temporary. The combination of these information requirements for pre-market evaluation is essentially comparable to or greater than the information requirements for any of a food additive, novel food or natural health product as set out in regulations and guidance documents for these other product sub-categories.

Canada's complete federal regulatory requirements for foods reside in a number of Acts in addition to Food and Drugs Act and Regulations. The interpretation of these other Acts is set out in many Regulations that have the force of law and could also apply to foods with health claims.

Within these additional Acts and Regulations are a number of compositional standards (standards that dictate the composition of the food by various characteristics) for foods that will likely present an impediment to modification of such standardized foods by the addition of bioactive substances demonstrated to result in a health benefit. This suggests that health claims for foods that must currently comply with federal compositional standards will not be permitted without enabling amendments to the compositional standards. However, certain "biological role" claims are currently permitted for foods, although limited in number and language.

Natural Health Product Regulations - 2004

Canada's Natural Health Product (NHP) Regulations, also pursuant to the Food and Drugs Act, came into force in January of 2004. These regulations were drafted to take into account a large number of recommendations of the House of Commons Standing Committee on Health accepted by the Minister of Health when the recommendations were published. The Natural Health Product Regulations define NHPs as sub-category drugs, available at a consumer's discretion without prescription. This classification permits the sale of NHPs in a broad range of retail establishments including retail grocery stores retail health food stores. NHPs may also be dispensed by direct sellers and complementary health care practitioners.

The NHP Regulations not only permit but essentially require health claims for each NHP in the market in the form of a statement as to the purpose of use on product labels. The standards of evidence for such claims for safety and for demonstrating the causality of the NHP or active ingredient could be considered to be broader than those that apply to foods with health claims. The NHP pre-market evaluation framework places greater weight on history of safe use in Canada and other countries. The NHP framework also recognizes “traditional use” for specific indications. These and other principles inherent within the NHP Regulations and related guidance documents may serve as examples in the modernization of regulations and guidance documents that apply to foods with health claims.

Also of potential relevance to modernization of the regulatory system for foods with health claims is the concept of “progressive licensing” that Health Canada is proposing to incorporate into the regulatory system for drugs. If applied to pre-market evaluation of foods with health claims, “progressive licensing” might permit the de-coupling of safety and efficacy in pre-market evaluation. Such a de-coupling might in turn permit applicants to go to market without claims (sell the foods without claims or with qualifying statements) having demonstrated safety and to gather information demonstrating the causality (legitimacy of health claim) through real world experience. In a limited number of instances, the Food Directorate has granted Temporary Marketing Authorizations in order to facilitate the gathering of information under actual market circumstances.

Federal Regulatory Directive - 2007

The Government of Canada issued a revised regulatory policy in April of 2007. This document, entitled the *Cabinet Directive on Streamlining Regulation* should also have significant influence on the modernization of regulations that apply to foods, including foods with health claims. The new policy, in keeping with its predecessor, requires that regulatory intervention and regulatory measures employed be proportionate to risk. In practice, this principle should lead to pre-market evaluation scientific information requirements being lower for health claims for foods whose safety is well established.

The federal regulatory policy also requires that federal regulatory departments and agencies conduct cost and benefit assessments of proposed regulations and amendments. Assessing costs and benefits of pre-market evaluation of foods with health claims will not be an easy task since there is to date, a very limited amount of post-market (real world) experience in Canada since only 5 claims are currently allowed.

The new federal regulatory policy should also contribute to streamlining Canada’s regulatory amendment process. In recent years, a food regulatory amendment has typically required 12 to 24 months to complete. In light of these delays, Health Canada has sought and received authority to issue Interim Marketing Authorizations to permit use of food additives during the period of time required for a formal (legal) regulatory amendment. However, the IMA process has not to date been applied to foods with health claims.

New Developments - Expected Health Claim Public Consultations in 2007/2008

Readers of this report should note that Canada's regulatory provisions that apply to foods, foods with health claims and natural health products are not static. Rather, changes are in process, if not always apparent or publicly anticipated. A most recent example is the September, 2007 policy decision of the Health Products and Food Branch to delegate responsibility for pre-market evaluation of natural health products that resemble foods to the Branch's Food Directorate. Although the NHP Regulations will apply to such products, Food Directorate will hold primary responsibility for their pre-market evaluation. This step should be seen as an interim measure to deal with foods and beverages containing bio-active substances and/or NHP ingredients that are not permitted under the Food and Drug Regulations as they apply to foods. The announcement of this policy was accompanied by a statement of intent that foresees such products ultimately being brought under a modernized food regulatory framework.

As at end of October, 2007, Health Canada's Food Directorate was preparing to launch a new round of public consultations on health claims for foods. Based on limited information in the public domain, it is widely expected that these consultations will contemplate a broader range of permissible biological role, structure/function and health claims in future.

I INTRODUCTION

Canada's regulatory environment for foods and beverages is extremely complex; a mix of civil and criminal statutes (laws), regulations authorized by the statutes and guidance documents that have been developed to interpret the statutes and regulations. The complexity of the regulatory environment has made it very difficult for individuals in both the private and public sectors to engage in informed dialogue on health claims for foods with a shared understanding of regulatory principles and requirements.

This document and its various appendices and references are intended to serve as a reference manual for all stakeholders with an interest in health claims for foods and Canada's regulatory requirements for pre-market evaluation, labelling, advertising of foods with demonstrated health benefits and related health claims.

Federal Regulatory Departments and Agencies Responsible for Foods and Natural Health Products

Health Canada and the Canadian Food Inspection Agency are the two federal organizations that hold legislative authority to regulate all products that are ingested by humans and animals, including foods, beverages, natural health products and other products (drug products) consumed in dosage form for any purpose. At the time of preparation of this reference manual, both Health Canada and the Canadian Food Inspection Agency (CFIA) are undertaking a number of initiatives to modernize Canada's federal regulatory system for foods and beverages

Health Canada has consulted extensively in recent years on the need for new legislation to consolidate laws under its authority into a new enabling piece of legislation, including the Food and Drugs Act, that is proposed to be called the Health Protection Act. However, in the second half of 2006, the department launched a new consultation process, *Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food*. Following an initial round of consultations, Health Products and Food Branch (HPFB) published an updated consultation document, *Blueprint for Renewal II*. These documents are available to readers on the HPFB web site (www.hc-sc.gc.ca Health Products and Food Branch). The department's own assessment of the current regulatory system is worth noting, set out as what are described as:

“five major challenges that must be addressed to ensure continued, timely access by Canadians to ensure continued, timely access by Canadians to safe and effective health products and a safe and nutritious food supply:

- **an outdated regulatory toolkit that is increasingly limited and inflexible in responding to today's health products and food environment;**
- **the regulatory system's incapacity to consider a given product through its entire life cycle, from discovery through to examining the “real-world” benefits and risks of a health product or a food on the market;**

- **the impact of social and economic changes, such as accelerating scientific and technological advances, the rise of transborder health and environmental threats, and a more informed and engaged citizenry;**
- **a regulatory system that currently works in isolation from the activities and policies at the research and development stage, and those of the broader health care system; and,**
- **a regulatory system with insufficient resources for long-term efficiency and sustainability.**

Blueprint for Renewal II (April 2007) elaborates on 10 objectives. Four of these are particularly pertinent to development, commercialization and sale of foods with health claims.

- The first is described as **“moving to a product life-cycle approach”**, meaning the department wishes to extend its regulatory involvement and authority over “all stages of development and use”. The focus of this objective is actually pharmaceuticals and biologic drugs. However, one aspect of this approach is to adopt a “progressive licensing framework”. How this concept might apply to foods with health claims is examined in some detail in Section IV of this report.
- The second objective is described as **“moving to regulatory interventions proportional to risk”**. This is actually embedded in Canada’s new federal regulatory policy that came into effect in April of 2007. The department notes that it must address “inconsistent approaches across regulatory frameworks for standards of evidence, health claims and risk-based regulatory responses”. HPFB has already adopted a tiered risk (products categorized by level of risk) approach for natural health products and medical devices.
- The fourth objective stated in *Blueprint for Renewal II* is **“moving to a modernized regulatory approach for food safety and nutrition”** which refers to a Regulatory Modernization Strategy of Food and Nutrition (RMSFN). Among the policy goals of RMSFN is: **“promoting regulatory responsiveness to food innovation and promoting consumer access to foods with assessed health benefits, in particular, the development of a comprehensive approach for the management of food with health claims and completion of a policy on the discretionary fortification of foods”**.
- The sixth objective stated is also potentially pertinent to foods with health claims, **“moving to a stronger post-market surveillance system”**. Although presented in reference to drugs and natural health products, this objective further recognizes that understanding of product benefits and risks can change with the benefit of experience in Canada’s consumer-driven market. Better understanding can in turn contribute to more appropriate regulation at a generic and product-specific level.

Health Canada is already proceeding in 2007 to refine and clarify the recently implemented (2004) Natural Health Product (NHP) Regulations and related guidance documents. The Natural Health Products Directorate has outlined 7 products to be undertaken. However, none are

expected to substantially alter the NHP Regulations, site licensing or product licensing pre-market evaluation requirements.

CFIA (www.inspection.gc.ca) is an active partner in HPFB's regulatory modernization, working closely with Health Canada's Food Directorate. Reporting to Parliament through the Minister of Agriculture and Agri-Food, CFIA is responsible for compliance and enforcement of the Food and Drug Regulations and for the administration of several additional federal laws corresponding regulations pertaining to foods.

Regulatory Status of Functional Foods in Canada

As context for the examination of the current regulatory and policy framework that applies to functional foods, it is important to recognize that Canada's food regulatory system is highly prescriptive, affecting all aspects of the manufacture, packaging and labelling of foods.

- **There are significant restrictions on the use of food additives.**

Food additives must undergo pre-market evaluation for safety and efficacy in intended use. Permitted uses and addition rates are listed in the Food and Drug Regulations.

- **There are significant restrictions on the addition of vitamins and minerals to foods.**

Permitted addition of vitamins and minerals is also specified in the Food and Drug Regulations.

- **The addition to foods of substances typically used as ingredients in natural health products has not been permitted to date and is not yet provided for within regulations that apply to foods.**

There are four important facts that readers need to take into account in order to understand the current status of the regulation of "functional foods: (food with health claims) in Canada. These are explained below.

1. Functional Foods are not recognized in law or regulation in Canada.

As later sections of this manual will illustrate in greater detail, **there is no regulation in Canada that applies specifically to "functional foods"**. Functional foods are not defined in any federal legislation or regulations that apply to foods and beverages. As a consequence, foods that are considered to be "functional" by those who manufacture and sell them and by consumers are subject to the same regulatory requirements that apply to foods that are consumed as part of any consumer's diet. Under Canada's Food and Drugs Act, food is defined as:

"food" includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever;

Although there is no regulatory definition for functional foods, Health Canada has adopted and published a working definition. This working definition (for discussion purposes) is:

A functional food is similar in appearance to, or may be, a conventional food that is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions, i.e. they contain bioactive compound.

2. Nutraceuticals are not recognized in law or regulation in Canada

Similarly there is no regulatory definition for the term “nutraceutical” that is widely used in some countries. Health Canada’s working definition is:

A nutraceutical is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with foods. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease.

However, it is important to note that from a regulatory perspective, the term “nutraceutical” is no longer relevant in Canada. That is because Health Canada’s definition of “natural health product” that resides in Canada’s Natural Health Product Regulations (NHP Regulations) is very broad and encompasses the working definition of nutraceutical.

3. Natural Health Products are recognized in regulation as a sub-category of drugs.

The definition of “natural health product” is:

“natural health product” means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

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

Although the Natural Health Products Regulations are in force, the Food and Drugs Act was not amended to include the definition of “natural health product”. As noted earlier in this section, there is within the Act a definition of “food” and there is within the Act a definition of a “drug”. Because the above regulatory definition for natural health products does not fall within the Act’s definition of a food, **natural health products are by default and pursuant to the Act, a sub-category of drug.**

This “drug status” for NHP was the intent of Health Canada in the development of the NHP Regulations as it allowed the new regulations to be drafted and brought into force without the need to substantially amend the Food and Drugs Act with the approval of Canada’s Parliament.

4. All foods (including foods with health claims), natural health products and drugs are extensively regulated in Canada under federal laws and regulations.

There is no product or product category that is sold and ingested by humans within Canada’s international borders that is not subject to Canadian federal regulatory requirements. To be legally sold in Canada, a product that is ingested must comply with one of:

- The sections of the Food and Drug Regulations that apply to foods
- The sections of the Food and Drug Regulations that apply to drugs
- The Natural Health Product Regulations

It is important to note the word “sold” in the preceding sentence. Natural health products, other over-the-counter (OTC) medicines that are purchased in other countries by individual consumers and imported for personal use are not required to comply with Canadian regulation unless they contain “controlled substances” such as certain narcotics.

Readers should also note that Health Canada’s Health Products and Food Branch initially determined that products not intended for sale in dosage form, typically resembling foods but altered by the addition of bio-active substances are not eligible for NHP product licenses. This was an administrative decision designed in part to limit pre-market evaluation of NHPs to those that clearly fall within the NHP definition. More recently (September, 2007) the Branch deemed NHPs that resemble foods eligible for NHP product licenses, subject to pre-market evaluation by the HPFB Food Directorate.

Figure 1 on the following page illustrates the categorization of products under Canada’s Food and Drugs Act and Regulations and policies of Health Canada. As noted earlier, foods with health claims are deemed to be drugs.

Figure 1: Categories of Foods and Drugs Defined by the Food and Drugs Act and Regulations and by Health Canada Policy

Defined by the Food and Drugs Act and Regulations as Drugs	Defined by Health Canada Policy as Drugs	Defined by the Food and Drugs Act and Regulations as Foods
Non-prescription drugs intended for self-care or use on the advice of a pharmacist or health care practitioner without prescription	Foods with health claims	Whole foods or single ingredient foods, including novel foods that have undergone pre-market evaluation
Natural health products, also intended for self-care or use on the advice of a pharmacist, health care practitioner or nutrition advisor without prescription	Foods containing vitamins, minerals and bioactive substances not specifically permitted and/or present at levels outside of the range permitted in the Food and Drug Regulations	Food additives, permitted for uses and amounts specified in the food additive tables, Division 16, Section B of the Food and Drug Regulations
Schedule C drugs (drugs listed in Schedule C of the Food and Drugs Act)		Foods for Special Dietary Use, Division 24 of Food and Drug Regulations
Schedule D or biologic drugs including vaccines		Infant Foods, Infant Formula, Division 25 of the Food and Drug Regulations
Schedule F or drugs available by prescription only		Irradiated foods permitted under Division 26 of the Food and Drug Regulations
New Drugs as defined in Division 8 of the Food and Drug Regulations		Novel Foods as defined and meeting the requirements of Division 28 of the Food and Drug Regulations
Other drugs as defined in Divisions 5,6,10 and Parts G and J of the Food and Drug Regulations		
Drugs intended for veterinary use (essentially subject to new drug provisions of the regulations)		

Brief History of Health Canada’s Approach to Regulation of Functional Foods and Related Health Claims

The chronology of Health Canada’s approach to the regulation of functional foods and related health claims is relatively short, spanning the period of 1995 to date. Although industry interest in health claims predated 1995, the publication by Agriculture and Agri-Food Canada in that year of an international comparative analysis of regulation of functional foods served as a catalyst for industry/government and interdepartmental discussion on health claims for foods. At the time of completion of the aforementioned 1995 study, a number of generic health claims for

foods had been approved in the United States by the U.S. Food and Drug Administration (USFDA). A larger number of product-specific health claims for foods had been approved in Japan. This study was updated in 2004.

Health Canada's Food Directorate prepared and released its first consultation document on health claims for foods in 1996. Food Directorate subsequently published a policy regarding health claims for foods in November of 1998. This policy document is entitled ***Policy Paper on Nutraceuticals/Functional Foods and Health Claims for Foods***. That policy document included two key policy decisions:

- 1. risk reduction and structure/function claims foods should be permitted**
- 2. any health claim for a food or food ingredient that claimed to cure, treat, mitigate or prevent a disease would require that the food or food ingredient would be considered to be and be regulated as a drug. This meant that such products would require pre-market (before being sold in Canada) evaluation to demonstrate safety and efficacy.**

In subsequent years, responding to representations from a number of interested parties, Health Canada undertook to evaluate the generic claims approved in the U.S. to determine whether the evidence for these claims was sufficient to warrant the adoption of the claims in Canada. In the absence of an established framework for evaluation of health claims for foods (standards of evidence), Health Canada's Food Directorate opted to use a peer review model for this project. Food Directorate selected teams of 3 scientists, one team per claim, to conduct a comprehensive review of the claim and the supporting evidence. Of the 11 claims that were approved in the U.S., one (folic acid) was deemed to be subject to Health Canada's pending policy on fortification of foods and was therefore set aside for consideration separately. The remaining 10 claims were evaluated. Of these 10, **five health claims were formally approved in amendments to the Food and Drug Regulations that accompanied the nutrition labelling regulations in January of 2003.**

Meanwhile, Health Canada also began work on a framework for evaluation of health claims for foods to be applied regardless of the approval status of claims in other jurisdictions. The draft ***Standards of Evidence for Evaluation of Foods with Health Claims*** was published in 2000 and formal public consultations on this document were undertaken by Food Directorate on this discussion document. The document remains available on Health Canada's web site (www.hc-sc.gc.ca)

Food Directorate subsequently addressed the question of health claims that would apply to individual food products with the October 2001 consultation document entitled ***Product-Specific Authorization of Health Claims for Foods – A Proposed Regulatory Framework***, also still available on Health Canada's web site.

In 2002, Food Directorate published a guidance document entitled ***Interim Guidance Document-Preparing a Submission for Foods with Health Claims incorporating Standards of Evidence for Evaluating Foods with Health Claims***. The document provides advice on submission

format and content as well as the weighting of evidence of safety and efficacy in the evaluation of submissions. This guidance document is included for ease of reference as Appendix 1 to this report.

Between 1996 and 2004, Health Products and Food Branch was also intensively engaged with industry and other stakeholders on the need for development of a regulatory framework for “natural health products” (dietary supplements, traditional alternative medicines, etc.). This issue was examined by a non-government advisory committee to the Minister of Health and subsequently by the House of Commons Standing Committee on Health. The Standing Committee’s report included 53 recommendations, many of which, touched upon health claims, standards of evidence for claims and consumers’ needs for information about product intended use and potential health benefits.

As the Natural Health Product (NHP) Regulations were developed and then implemented (came into force) in January of 2004, it had become very apparent that existing provisions of the Food and Drugs Act (Act) remained as an impediment to the full implementation of the NHP Regulations with respect to claims. Specifically, Schedule A to the Act pursuant to Section 3, then stood and remains as a prohibition against health claims for diseases and disease states listed in Schedule A. This prohibition applies to all products whether foods, drugs or natural health products.

Health Products and Food Branch (HPFB) took the initiative of appointing an External Working Group in February of 2003 to examine Section 3, Schedule A. That External Working Group submitted its recommendations in a report to the Minister of Health in January, 2004. The executive summary of the report is contained in Appendix 2 to this report. The external advisory committee included parties holding and interest in each of foods, NHPs and OTC drug products.

HPFB is responding to these recommendations in 2007 through a project entitled Project 1539 (Schedule A revision and claims) being led by HPFB Therapeutic Products Directorate. However, the intent of this project is to address Section 3, Schedule A impediments for non-prescription drugs and NHPs only and where such products have undergone pre-market evaluation and received authorization (approval) of the product-specific health claims proposed by the applicant (party filing the pre-market evaluation submission). The outcome of the project will be a reduction in the number of diseases and disease states and the adoption of criteria governing the inclusions of diseases and disease states in future.

Readers should note that this project was not intended specifically to remove impediments to health claims for foods. Rather, the revised Schedule A will continue to apply to Health claims for foods will still require pre-market evaluation and formal approval in the form of an amendment to the Food and Drug Regulations. The currently proposed amendments to Schedule A were published in Canada Gazette Part I on June 16, 2007 and are attached to this report as Appendix 3.

Food Directorate published a consultation paper in December of 2006 entitled *Position Paper on Five US Health Claims Considered for Use in Canada* (www.hc-sc.gc.ca/fn-an/label-etiquet/claims=reclam/position_paper-enonce_position). This document proposes the adoption of four additional generic health claims previously approved in the U.S. The paper also provides discussion on three additional health claims already approved in the U.S. but not being proposed for adoption in Canada. Readers should note that this consultation document affirms two critically important aspects of Health Canada's approach to the regulation of health claims for foods. These are:

- **The 2001 Interim Guidance Document – Preparing a Submission for Foods with Health Claims: Incorporating Standards of Evidence for Evaluating Foods With Health Claims remains in effect.**

The primary significance of continuing this approach is that pre-market evaluation of health claims for foods requires what is essentially a complete safety and nutrition assessment of the food for which the claim is being proposed, regardless of whether a history of safe consumption of the food in an ad libitum (unrestricted choice of foods and amounts of foods) diet enjoyed by the Canadian population.

- **Statements or claims linking a food to a reduction in risk of a disease are deemed to bring the food within the definition of a drug in the *Foods and Drugs Act*.**

The implication of this position is that risk reduction health claims for foods will not be permitted for use in labelling in advertising unless specifically exempted by regulatory amendment from the provisions of the *Food and Drugs Act and Regulations* that apply to drugs. Considering that natural health products are defined by the NHP Regulations be a sub-category of drugs, it would appear likely that disease risk reduction claims for foods will also require, by regulatory amendment, an exemption from the provisions of the NHP Regulations.

In summary, as at the time of preparation of this reference manual in mid-2007, Health Canada's approach to the regulation of health claims for foods is:

- Proposed health claims (generic and product-specific) for foods must undergo a pre-market evaluation by the Food Directorate of Health Products and Food Branch. This pre-market evaluation includes an evaluation of the possible risks from a chemical (toxicological, interaction) and nutritional perspective that could arise from significant changes in dietary intake that could occur as a consequence of the claim. Evidence and information requirements for product-specific claims are more rigorous than for generic claims.
- Health claims for foods that have been approved (successfully undergone pre-market evaluation to remove objection to the use of the claim) are not permitted under the existing policy (foods with claims are deemed to be drugs) for use in labelling and advertising until specifically exempted by regulatory amendment from the provisions of the *Food and Drugs Act and Regulations* that prohibit use of claims (Section 3, Schedule A, provisions of the regulations that apply to drugs).

Health Canada's pre-market evaluation requirements for foods with health claims/health claims for foods are examined in greater detail in Section III of this document.

II Canadian Federal Regulatory Framework that Applies to Foods, Foods With Health Claims and Natural Health Products

This section of the report has been developed to provide a brief overview of laws and regulations that apply to foods (including foods considered to be functional, with or without health claims) and natural health products.

Federal Versus Other Jurisdictions Within Canada

The title of this section includes “federal regulatory framework” to describe the laws, regulations and interpretive guidance documents that fall under the authority of the government of Canada as opposed to laws, regulations and guidelines that are in place under the authority of governments of Canada’s provinces, territories and municipalities.

Provincial and municipal laws apply only within those respective jurisdictions and not at the national level. The majority of provincial regulation that applies to foods pertains to production, processing, inspection and marketing of dairy, poultry, meat and other agricultural products subject in some provinces to “natural products” acts and regulations. These various provincial laws and regulations are largely intended to ensure product safety, product integrity (required composition and appropriate labelling) and orderly marketing of products under supply-management regimes and agencies to whom provincial governments have delegated marketing and licensing powers. A large percentage of provincial laws and regulations that apply to foods either replicate or incorporate by reference, provisions of federal acts and regulations, including compositional standards.

However, provincial laws and regulations that pertain to foods apply only if the food is produced and sold within the same province or territory. All foods that are transported across any provincial or territorial boundary and/or imported into Canada and destined for sale in Canada are subject to the federal government regulatory framework (laws and regulations) that applies to foods.

This reference manual has been prepared to deal only with Canada’s federal laws, regulations and guidance documents that apply to foods, foods with health claims and natural health products.

A “law” is a piece of legislation that has been approved by Canada’s Parliament otherwise known as an “Act” of Parliament. Some Acts of Parliament confer upon the Minister responsible for the Act, authority to make regulations through a formal regulatory development and amendment process described in Appendix 4 to this report.

A “regulation” is an interpretation of and is pursuant to an Act of Parliament. Regulations have the force of law and are therefore legally binding.

A “guidance document” is usually developed as a further interpretation and explanation of regulatory requirements, an explanation of a federal policy or a procedure such as applying for pre-market approval of a health claim for foods, novel food or food additive. Guidance documents do not have the force of law and are not in the strict sense, legally binding. Legal obligations and federal powers reside within laws and regulations.

Food and Drugs Act

The current federal *Food and Drugs Act* (the Food and Drugs Act) is the principal and most comprehensive piece of federal legislation that applies to foods. When the amended Food and Drugs Act came into force in 1953, it had already been developed approximately 20 years prior to:

- **provide for the safety and integrity (acceptable quality) of foods, drugs, cosmetics and medical devices offered for sale in Canada; and**
- **ensure that products falling under the authority of the act would not be represented and/or sold in a manner that is fraudulent or misleading.**

The Food and Drugs Act has undergone very little modification since 1953. The specific provisions of the Food and Drugs Act that apply to food composition, quality, safety, packaging, labelling and advertising are found in Part I, sections 2, 3, 4, 5, 6 and 7 described briefly below.

Section 2 provides the legal definition of “food” and the important definitions for “advertisement”, “sell”, “package”, “label” and “unsanitary conditions” found in subsequent sections of the act and sections of the Food and Drug Regulations that apply to food.

Section 3 prohibits the advertising of any food to the general public (consumers) “as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A” (to the Food and Drugs Act). It is this section of the Food and Drugs Act that remains as the legal impediment to health claims for foods. **Health claims for foods are not permitted unless specifically identified within the Food and Drug Regulations as being exempt from the Section 3, Schedule A general prohibition.**

Section 4 prohibits the sale of food that unsafe (contains a poisonous or harmful substance), unfit for human consumption (by any standard, including containing unwholesome ingredients or being adulterated with foreign material) or food manufactured under “unsanitary conditions”. This section of the act has provided the legal foundation for Canada’s food safety requirements, including pre-market evaluation of food additives, novel foods, pest control products and food irradiation.

Section 5 is in two parts. The purpose of section 5 is to deal with packaging and labelling of foods, principally from the perspective of preventing fraud and providing

information to consumers. Part 2 of Section 5 further clarifies that food must be packaged and labelled in accordance with the regulations (regulations are broadly defined elsewhere in the Food and Drugs Act) and that foods that do not comply with the packaging and labelling requirements set out in regulations are automatically (deemed to be) in contravention of the Food and Drugs Act. Part 2 is therefore the legal underpinning of Health Canada and/or the Canadian Food Inspection Agency authority to exercise enforcement of the requirements as set out in the regulations and/or prosecute in the Federal Court system, persons who are responsible for the sale of the non-compliant products.

Section 6 was amended in 1985 as a consequence of a Supreme Court decision in 1979. The effect of the amendment is that standardized foods produced and sold exclusively within a single province are exempt from meeting the requirements of federal compositional standards for foods. However, federal jurisdiction over food health and safety was not altered by this amendment and still applies.

Section 7 prohibits the manufacturing, preparation, preservation, packaging or storage of food “under unsanitary conditions”.

“Unsanitary conditions” are defined under Section 2 of the Food and Drugs Act as “such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health, a food, drug or cosmetic”.

Food and Drug Regulations

Although Sections 2 to 7 of the Food and Drugs Act are very brief, in contrast, the Food and Drug Regulations are not. There have been hundreds of “regulatory amendments” that apply to food within the scope of the Food and Drug Regulations made since 1953. The authority to impose, modify or remove regulations governing foods resides within Section 30 of the Food and Drugs Act, sub-section (1) clauses a, b, c, d, e, f, g, I, j, k, l, m and n. The scope of regulations provided for in these sections is consistent with the comprehensive scope of Section 3 to 7 of the Food and Drugs Act. The Governor in Council (please refer to Appendix A – Federal Regulatory Process) “may make regulations for carrying the purposes and provisions of the Act into effect, and, in particular....may make regulations”

- determining what constitutes an adulterated food
- requirements for food packaging and labelling
- use of substances as ingredients
- prescribing standards (composition, strength, potency, purity, quality or other property)
- importation
- methods of manufacture, storage and testing
- retention of manufacturing and analytical records
- cooperation with inspectors
- prescribing administrative forms to be used in compliance with the Food and Drugs Act and Regulations

- conditions for release into the environment
- exempting food, drugs, cosmetics and medical devices from provisions of the Food and Drugs Act for various purposes
- adding and deleting items from Schedules to the Food and Drugs Act and Regulations

The requirements for **pre-market evaluation (safety assessment) of “novel foods”** reside within Division 28 of Part B of the Food and Drug Regulations (attached as Appendix 6 to this report). These are examined and contrasted with pre-market evaluation requirements for foods in **Section III of this reference manual**.

Food Inspection, Analysis, Compliance and Enforcement

The provisions of the Food and Drugs Act that provide the federal government (Health Canada and the CFIA Canadian Food Inspection Agency) with authority to inspect, seize, analyze and in some circumstances retain or destroy foods are set out in sections 22 to 29, contained in Part II, Administration and Enforcement of the Food and Drugs Act. . Additional authority is provided or interpreted under the Canadian Food Inspection Agency Act and additional federal laws and regulations under the authority of the Minister of Agriculture and Agri-Food sub-delegated (assigned to) the CFIA.

Punishment for Contravention of the Food and Drug Act and Regulations

Readers should note that the Food and Drugs Act and Regulations fall within the scope of Canada's Constitution as criminal law. Persons who contravene any provision of the act and regulations are deemed under Sections 31 and 31.1 to be guilty of a criminal offence and on summary conviction punishable by fines (convicted party must pay monetary penalties to the government of Canada and/or imprisonment of up to six months. If found guilty and convicted by indictment of an offence pertaining to food, the maximum fine per offence is \$250,000 and the maximum term of imprisonment for offence is three years (both fines and imprisonment may be imposed).

Fines and/or imprisonment can be imposed under Section 32.(1) at any time up to two years from the time the “subject matter of the prosecution” (not the date of the offence) becomes known to the Minister. In the case of an offence pertaining to food, the responsible Minister is the Minister of Agriculture and Agri-Food.

Natural Health Product Regulations

Canada’s Natural Health Product Regulations (NHP Regulations) came into force in January of 2004. As noted in Section 1 of this reference manual, the NHP Regulations are also pursuant to the federal Food and Drugs Act. However, the NHP Regulations do not apply to products that meet the legal definition of a food (as per Section 2 of the Food and Drugs Act) but only to products that meet the legal definition of a natural health product contained within Section 1.(1) of the NHP Regulations.

Canada's Natural Health Product Regulations and related guidance documents are examined in greater detail in Section IV of this reference manual from the perspective of offering a possible model for health claims for foods.

An overview of the principal federal regulatory requirements and related guidance documents for foods and natural health products is provided in tabular form in tables 1.A, 1.B and 2 below.

Table 1.A: Summary of Federal Regulatory Requirements for Foods and Natural Health Products

REGULATORY REQUIREMENT	Food, including whole foods and prepared and processed packaged foods	Food additives	Foods for Special Dietary Use	Infant Foods	Novel Food	Natural Health Products	Regulatory changes pending as of August, 2007
Definition found in:	F&D Act, Section 2, Interpretation	F&D Regs, Division 1, B.01.001	F&D Regs, Division 24, B.24.001		F&D Regs., Division 28, B.28.001	Natural Health Product Regulations, Section 1, Interpretation	Definition of NHP will be amended and included in proposed Health Protection Act
Principal regulatory requirements found in:	F&D Division 1 of Regs, Sections B.01 to	F&D Regs., Division 16	F&D Regs., Division 24	F&D Regs., Division 25	F&D Regs., Division 28	Natural Health Product Regulations	NHP regulations are under review
Principal guidance documents that apply ,listed numerically in table 1.B	1,5,6,7	2	5	5	3	8,9,10,11,12, 13,14,15,16,	
General labelling requirements	F&D Regs., Sections B.01.003 to B.01.35	F&D Regs., Sections B.01.003 to B.01.35	F&D Regs., Sections B.01.003 to B.01.35	F&D Regs., Sections B.01.003 to B.01.35	F&D Regs., Sections B.01.003 to B.01.35	Natural Health Product Regulations	
Specific labelling requirements	F&D regs., various divisions according to		F&D Regs., Division 24	F&D Regs., Division 25	None, other than provision of proposed labelling in	Natural Health Product Regulations, Part 5, Sections	

	food types and standards				pre-market evaluation	75 to 94 apply to both inner and outer labels	
REGULATORY REQUIREMENT	Food, including whole foods and prepared and processed packaged foods	Food additives	Foods for Special Dietary Use	Infant Foods	Novel Food	Natural Health Products	Regulatory changes pending as of August, 2007
Pre-market notification required	No	Yes	No	Yes	Yes	Yes	
Pre-market evaluation required	No, unless a health claim is intended or the food is considered novel or is prepared using a novel process	Yes	No	No	Yes	Yes	
Product may be sold in dosage form	No, but single serving packages are permitted	Does not apply	No, but single serving packages are permitted	No, but single serving packages are permitted	No, but single serving packages are permitted	Yes, recommended dosage is mandatory	
Product license is issued	No	Letter of notification of intent to amend the regulations to permit the proposed use is sent to applicant	No	No	No, but letter of notification that pre-market submission information is “sufficient” must be issued	Yes, specific to each product formulation in each dosage strength, Part 1, NHP Regulations	

Addition of vitamins and minerals permitted	Yes, as per Part D, F&D Regulations	Does not apply	Yes, as per Part D, F&D Regulations and in compliance with Division 24, Part B, F&D Regulations	Yes, as per Part D, F&D Regulations and in compliance with Division 24, Part B, F&D Regulations	Yes, as per part D, F&D Regulations	Yes, as per NHP Regulations	New policy on voluntary addition of vitamins and minerals to foods is under development
Nutrition labelling required	Yes	Does not apply	Yes	Yes	Yes	No	

REGULATORY REQUIREMENT	Food, including whole foods and prepared and processed packaged foods	Food additives	Foods for Special Dietary Use	Infant Foods	Novel Food	Natural Health Products	Regulatory changes pending as of August, 2007
Nutrient content claims permitted	Yes	Not relevant to food additives	Yes	Yes	Yes	Required for vitamin and mineral ingredients	
Biological role claims permitted	Yes, but restricted to those that are permitted in F&D Regs., B.01.311, B01.312, D.01.006	Does not apply	Yes but restricted to those that are permitted in F&D Regs., B.01.311, B01.312, D.01.006	Yes but restricted to those that are permitted in F&D Regs., B.01.311, B01.312, D.01.006	Yes but restricted to those that are permitted in F&D Regs., B.01.311, B01.312, D.01.006	Recommended use is required in labelling content	
Health claims permitted	No, except where specifically exempted from drug regulations	Not relevant to food additives.	No, except where specifically exempted from drug regulations	No, except where specifically exempted from drug regulations	No, except where specifically exempted from drug regulations	Mandatory, recommended use is required in labelling content. Section 3 Schedule A claims not permitted	Proposed Revisions to Section 3, Schedule A published June, 2007 to apply to Drugs and NHPs
Advertising to general public permitted	Yes	Does not apply	Yes	Yes	Yes	Yes	

Table 1.B – List of Principal Guidance Documents That Apply to Food, Natural Health Products

Guidance Document Number Referenced in Table A.1	Guidance Document Title	Responsible Health Canada or Canadian Food Inspection Agency Office
Foods		
1.	Interim, Guidance Document – Preparing a Submission for Foods With Health Claims Incorporating Standards of Evidence for Evaluating Foods with Health Claims	HPFB – Food Directorate, Nutrition Evaluation Division
2.	Guide for Preparation of Submissions on Food Additives	HPFB – Food Directorate, Bureau of Chemical Safety
3.	Guidelines for the Safety Assessment of Novel Foods	HPFB – Food Directorate, Novel Foods Directorate
4.	Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Foods Containing Them	HPFB – Food Directorate
5.	Guide to Food Labelling and Advertising	CFIA – Food Safety Directorate
6.	Nutrition Labelling Compliance Test	CFIA – Food Safety Directorate
7.	Nutrition Labelling Toolkit	CFIA – Food Safety Directorate
Natural Health Products		
8.	Compliance Guide for Natural Health Products	HPFB – Natural Health Products Directorate
9.	Product Licensing	HPFB – Natural Health Products Directorate
10.	Compendium of Monographs	HPFB – Natural Health Products Directorate
11.	List of Acceptable Non-medicinal Ingredients	HPFB – Natural Health Products Directorate
12.	Evidence for Safety and Efficacy of Finished Natural Health Products	HPFB – Natural Health Products Directorate
13.	Master File Procedures	HPFB – Natural Health Products Directorate
14.	Labelling	HPFB – Natural Health Products Directorate
15.	Site Licensing	HPFB – Natural Health Products Directorate
16.	Good Manufacturing Procedures	HPFB – Natural Health Products Directorate

Table 2: Regulatory References for Important Definitions that Pertain to Regulation of Foods and Foods With Health Claims

Term	Definition is found in:
Food	F&D Act, Section 2, Interpretation
Natural health product	Natural Health Product Regulations, Section 1
Drug	F&D Act, Section 2, Interpretation
Label	F&D Act, Section 2, Interpretation
Package	F&D Act, Section 2, Interpretation
Sell	F&D Act, Section 2, Interpretation
Advertisement	F&D Act, Section 2, Interpretation
Unsanitary conditions	F&D Act, Section 2, Interpretation
Adulteration : of a food	F&D Regulations, B.15.001
Foods for special dietary use	F&D Regulations, B.24.001
Formulated liquid diet	F&D Regulations, B.24.001
Infant food	F&D Regulations, B.25.001

Other Federal Acts and Regulations That Apply to Foods

There are a number of federal laws and regulations developed pursuant to these laws that apply to foods in Canada. In the interest of being brief and for ease of reference, these are listed and described in tabular form in Appendix 5.

III Pre-market Evaluation Requirements for Foods With Health Claims

Section I of this reference manual briefly explains that foods with health claims are by Health Canada's policy (although not specifically required by regulation), subject to pre-market evaluation for safety. Pre-market evaluation submissions to Health Canada must also conclusively demonstrate the causal relationship between the food and the anticipated health benefit associated with consumption of the food. Put in other terms, foods with health claims must be demonstrated to be safe and effective in achieving the health outcome claimed.

The brief explanation of pre-market evaluation requirements for foods with health claims which follows is derived from information contained in Health Canada's guidance document entitled *Preparing a Submission for Foods With Health Claims: incorporating Standards of Evidence for Evaluating Foods With Health Claims* (Appendix 1 www.hc-sc.gc.ca Food and Nutrition).

What is a claim?

A claim is a statement of representation in product labelling or advertising regarding the character, value, quantity, composition, merit or safety of the product.

What is a health claim for a food?

A health claim for a food is a claim that relates primarily to paragraphs (a) or (b) of the definition of "drug" found in Section 2 of the Food and Drugs Act. That definition is:

"drug" includes any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

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

Health claims for foods include:

Structure/function claims: that relate primarily to paragraph (b) of the definition of "drug" with respect to modifying, restoring or correcting an organic function or body structure of human beings, beyond normal growth and development or maintenance of good health.

Readers should note that some structure/function claims for specific nutrients relating to normal growth and development or maintenance of good health are already permitted for foods as "biological role claims". These can be found in Sections B.01.311, D.01.006 and D.02.004 of the Food and Drug Regulations. These are elaborated upon in CFIA's Guide to Labelling and Advertising.

Risk reduction claims: that relate primarily to paragraph (a) of the definition of “drug” with respect to significantly altering a major risk factor(s) for a disease or adverse health condition.

Readers should note that there are currently four risk reduction claims permitted for foods pursuant to amendments made to the Food and Drug Regulations that came into force in January of 2003 (B.01.600). The claims are permitted by way of being exempted from provisions of the Food and Drugs Act that apply to drugs and the general prohibition of claims found in Section 3, Schedule A.

Therapeutic claims: that relate primarily to paragraph (a) of the definition of “drug” with respect to treatment, mitigation, or prevention of a disease, disorder, abnormal physical state, or its symptoms in humans.

Readers should note for the purposes of health claims for foods, the word “treatment” should be interpreted to mean “management” of the disease, disorder, abnormal physical state, or its symptoms in humans. This is referred to in the guidance document as “dietary management” for which a number of criteria are provided. There are currently no generic or product-specific therapeutic claims permitted for foods.

Why is pre-market evaluation required for foods with health claims?

The underlying principle for requiring pre-market evaluation for foods with health claims is that as a consequence of the claim being permitted in labelling and advertising, dietary intake of consumers is likely to change sufficiently to present a health risk.

This underlying principle has profound implications for the quantity and types of evidence required for pre-market evaluation. Applicants seeking a health claim for a food must present evidence that extends beyond the causal relationship (relationship between food consumption and the health outcome) to include evidence of safety that is equal to or greater than the evidence of safety required for pre-market evaluation of novel foods without claims and food additives without claims.

A second reason for pre-market evaluation of health claims is to ensure that health benefits from the intake of the food for which a claim is permitted are sustainable and not temporary.

In addition, pre-market evaluation is required to protect consumers against fraudulent claims.

What are the health risks associated with health claims for foods?

The possible health risks associated with foods with health claims are identified by Health Canada as being “adverse nutritional, toxicological or microbiological effects”.

The health risks associated with generic health claims for foods are presented somewhat differently than those identified for product-specific health claims.

As outlined in Section 4.2 of the guidance document, in the case of generic claims, the potential risks are:

- **exceeding safe and tolerable intakes of any biologically active substance(s) of concern in the food(s)**
- **dietary, nutrition or metabolic imbalance**

In the case of product-specific claims, the identified risks are similar but presented as being more acute as a consequence of the potential for high dietary intake of the food for which the claim is permitted. The more acute risks identified include

- **effects that may be indistinguishable from the effects of some drugs**
- **drug interaction and**
- **increased potential for other adverse effects among individuals and/or population sub-groups.**

This more acute risk is expected to arise from the food product being a “novel food” as defined in the Food and Drug Regulations or an “altered food”. **The guidance document defines “altered food” as one characterized by:**

“the addition of a bioactive substance to the food, or other modification in the food, including modifying the level and/or bioavailability of a bioactive substance naturally occurring in the food in order to achieve the claimed effect”

The inclusion of this definition within the pre-market evaluation policy ensures that all foods (whether whole foods, single ingredient foods or multiple ingredient foods) that are demonstrated to have characteristics for which a causal relationship can be demonstrated will be subject to pre-market evaluation, even if not meeting the regulatory definition of “novel food”.

How does pre-market evaluation of foods with health claims compare to other pre-market evaluation requirements?

Similar or like foods without health claims (whether whole foods, single ingredient foods or multi-ingredient foods) are not required to undergo pre-market evaluation unless they fall within the regulatory definition of a “food additive” or a “novel food”, in which case, extensive pre-market evaluation is required.

The definition of “food additive” is not included in the Food and Drugs Act but only in the Food and Drug Regulations, rendering food additive a sub-category of “food”. The regulatory definition of “food additive” found in Section B.01.001, Part I, Division B of the Food and Drug Regulations is:

"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 preparations, 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;

The pre-market evaluation submission for a food additive must also demonstrate that the food additive is safe and effective for the proposed use. At the time of preparation of this report, Food Directorate is nearing completion and publication of a new guidance document **entitled *Guide for Preparation of Submissions on Food Additives***. The contents of Table 3 are derived in part from a draft of the new guidance document provided to the authors by the HPFB Food Directorate.

“Novel food” is defined in Section B.28.001, Division 28 of the Food and Drug Regulations (attached to this report as Appendix 5) as:

- (a) a substance, including a microorganism, that does not have a history of safe use as a food;
- (b) a food that has been manufactured, prepared, preserved or packaged by a process that
 - i) has not been previously applied to that food, and
 - ii) causes the food to undergo a major change; and
- (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
 - (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
 - (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
 - (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. (aliment nouveau)

The pre-market notification and safety assessment data package that is required for pre-market evaluation of a novel food is limited to safety, unless a health claim is proposed for the novel

food, in which case both the novel food and health claim pre-market evaluation requirements will apply.

Novel foods are also required to undergo an assessment of environmental safety (impact on the environment and potential for indirect human health implications). If the novel food is a plant variety with a novel trait, it must undergo evaluation for environmental safety pursuant to the Seeds Act. If the novel food or processing waste from the novel food is intended for use as an animal feed ingredient, there are additional safety evaluation requirements pursuant to the Feeds Act and Regulations. For the purposes of comparison in Table 3 below, the pre-market submission requirements identified for novel foods are limited to those required for safety as food (not livestock feeds and not a new plant variety intended for cultivation in Canada).

Although pre-market evaluation is also required for food irradiation applications and infant formula, these are not included in Table 3 for comparative purposes.

Table 3.
Comparison of Pre-market Evaluation Submission Requirements for Foods with Health Claims, Food Additives, Novel Foods and Natural Health Products

Notification and Submission Requirement	Foods With Health Claims	Food Additives	Novel Foods	Natural Health Products
Pre-market notification required	Yes (by policy) *	Yes (pursuant to regulation)	Yes (pursuant to regulation)	Yes (pursuant to regulation)
Pre-market sub-mission required	Yes (by policy)	Yes (pursuant to regulation)	Yes (pursuant to regulation)	Yes (pursuant to regulation)
Safety assessment required	Yes, basic evaluation mandatory with further evaluation required at discretion of Food Directorate	Yes	Yes	Yes
Efficacy assessment required	Yes, causal relationship between intake of food and health outcome must be demonstrated	Yes, additive must be demonstrated to have the intended effect in the food.	No	Yes, totality of evidence including health outcomes associated with traditional use
Sustainability of health outcome in target population must be demonstrated	Yes	No	No	No
Controlled human experimental studies required	Yes	No	May be required.	May be applicable.
Projected dietary exposure data required	Yes	Yes	Yes	No, but recommended dosage and duration of use are required
Identification of population sub-groups potentially at risk is required	Yes	Yes	Yes	Labelling statements may be required
History of safe use required	Yes	If available from use in other countries	If available from use in other countries	Yes
Identification of physiological role and metabolic fate are required	Yes	Yes	No	No
Information on nutritional quality is required- presence of bioactive substances	Yes	No	Yes	Yes
Nutrient bioavailability assessment required	No	No	Yes, if a novel process or altered nutrient	No
Nutritional analysis is required	Yes	No	Yes	No, except for selected products containing vitamins and minerals only

Summary of Canadian Federal Statutes and Regulations Government Pre-market Evaluation, Labelling, Advertising and Health Claims for Functional Foods in the Canadian Market

Expected interaction with nutrients must be established	Yes	Yes	Yes	No, unless evidence exists to suggest a possible adverse effect
Expected effect on nutrient uptake and metabolization must be described	Yes	Yes	Yes	No
Allergenicity considerations required	May be a requirement	No	Yes	No
Expected interaction with drugs described	Yes	Yes	May be a requirement	Yes
Toxicology data required	Yes, animal, in vitro and human studies	Yes, acute, short-term, long-term, oncogenicity, neurotoxicity, genotoxicity and developmental toxicity	Yes.	Yes, publicly available data.
Nutritional safety data	Yes	Yes	Yes	No
Microbiological safety data	Yes	Yes	Yes	May be required.
Method of manufacture, QA practices declared	Yes	Yes	Yes, if a novel process.	No, except in compliance with NHP guidance documents and site licensing requirements
Specification of analytical methods is required	Yes, if methods not previously established	No	No	No. Generally accepted analytical methods or use of HC approved analytical methods.
Specifications of identity and purity required	Yes, B.16.002	No	Yes	Yes
Raw material specification required	May be a requirement	No	No	Yes, but by declaration of active and source ingredients
Recommended maximum level of dietary intake	No, not provided in regulation but policy provides for possibility of labelling statements required by Food Directorate as a condition of approval	No, assumed safe for a lifetime of use in prepared foods when used in compliance with Division 16, Part B, F&D Regulations	No, not provided in regulation	Maximum dose rate may be required on product labels.
Recommended maximum level of use by manufacturers in food processing	No	Yes, to specified limits or at discretion of manufacturer in using good manufacturing practices	No	Not relevant
Use of attestable monographs permitted	No, but permitted generic claims may apply	No	No	Yes, monographs published by NHPD & approved by NHPD

IV Natural Health Product Regulations as a Model for Regulation of Foods With Health Claims

The observations contained in this section should not be interpreted by readers as criticisms of existing and/or proposed regulation of foods with health claims in Canada. Rather, the observations are provided to:

- **provide readers who may have limited understanding of Health Canada’s regulatory framework for natural health products with some additional background on the development of the NHP Regulations and related guidance documents; and,**
- **illustrate not only opportunities but limitations in applying the approach taken for NHPs to the regulation of health claims and foods with health claims**

In comparison with the Food and Drug Regulations that have expanded and evolved through a period of over 50 years, the Natural Health Product Regulations (NHP Regulations) were developed and implemented within a time frame of approximately 6 years between 1998 and 2004. Guidance documents interpreting the NHP Regulations have been largely drafted and amended between 2003 and 2007. Considering the intensity of effort, consultation and industry/government cooperation that has permitted this rapid implementation of a new regulatory framework, it may be the case that the NHP Regulations and their implementation could serve in part as a model for a regulatory framework for health claims for foods.

In considering this possibility, it is important to note that the NHP Regulations arose as a consequence of intensive and sustained representation to the government of Canada by industry and complementary health care interest groups to not regulate natural health products (vitamin, mineral, herbal, botanical and homeopathic preparations) as “drugs” under the Food and Drug Regulations. As written, the Food and Drug Act and Regulations would not in 1998 and in 2007 accommodate (permit access to market) for the majority of products that now fall within the scope of the definition of “natural health product” set out in the NHP Regulations.

Since such products did not and still do not meet the definition of food in the Food and Drugs Act, they were defined by default as drugs. Since the majority of such products were not deemed to be old drugs (not new drugs) brought to market under older provisions of the Food and Drugs Act and Regulations, the products were subject to the pre-market evaluation and post-market requirements for “new drugs”. Pre-market evaluation of “new drugs” requires demonstration of safety and efficacy based on a strong body of evidence generated through extensive research, including clinical studies. The cost of such research is generally prohibitive when measured against historical and potential revenues from individual natural health products within the relatively small Canadian market of 31 million consumers.

The proponents of new regulations for natural health products argued that such products should be regulated neither as foods nor drugs by virtue of NHPs being a “third category” of product deserving a unique set of regulations. As explained in numerous consultation documents pertaining to the NHP Regulations, it was not possible to create a third category without

substantial amendments to the Food and Drugs Act that might have delayed a new regulatory framework indefinitely. Health Canada therefore opted to create the third category as a sub-category of drugs, but with its own unique set of regulations.

The NHP Regulations were drafted with the benefit of a report of a special advisory committee to the Minister of Health (1997) and a report of the House of Commons Standing Committee on Health (1998). The latter contained 53 recommendations that were accepted by the Minister of Health. Although there was not unanimity of thought among the advisory committee and Standing Committee, there was a strong consensus that status quo (regulation of NHPs under the existing Food and Drug Regulations) was no longer an option.

The NHP Regulations were subsequently drafted to incorporate and/or reflect:

- **only the provisions of Canadian drug regulations that were relevant to the NHP category**

The drafters (Department of Justice counsel and NHPD Natural Health Products Directorate staff) recognized that although NHPs would be legally defined as a sub-category of drugs, they recognized that not all provisions of the existing Food and Drug Regulations should apply. In light of this, they developed brief regulatory text to exempt NHPS from the drug regulations except where specifically stated or incorporated by reference in the NHP Regulations. This served to narrow the scope of existing regulations that would apply and to differentiate NHPs from other drug products.

The current approach to regulation of foods with health claims is that all existing provisions of the Food and Drug Regulations and other federal regulations must also apply.

- **industry's (not the regulator's) lead responsibility for compliance with good manufacturing practices, product safety, quality and stewardship in the market**

The drafters recognized that NHPD and/or other Health Canada directorates such as the Inspectorate would not have the resources to audit and pre-qualify all suppliers of NHPs to the Canadian market and their Canadian and foreign facilities. Instead, NHPD made use of existing Canadian drug establishment licenses and a policy of self-certification of compliance with GMPs for NHPs.

In the case of food and beverage processing establishments, compliance with GMPs is already assumed in the regulation of packaged foods, food ingredients, food additives and processing aids. In addition, the QA/QC, GMP and food security audits imposed by buyers at various levels of the food supply chain have all but eliminated the need for an inspection and audit function on the part of the federal regulators except in the case of animal and fishery products.

- **the need for industry (manufacturer, importer/distributor) advice in the development and implementation of the regulations**

The drafters of the NHP Regulations availed themselves of the advice of industry through a formal advisory committee established during the early stages of drafting. This facilitated timely advice while respecting federal regulatory policy requirements for broader public consultation.

- **a requirement to demonstrate both safety and efficacy through pre-market evaluation**

NHP Regulation drafters respected the need to ensure the safety of NHPs but acknowledged the role that NHPs are believed to play in contributing to good health and nutrition through traditional use. NHPD ultimately opted for a broader range of claims supported by a broader range of supporting evidence, providing NHP suppliers with the option of making additional claims where they have the means and the will to develop the additional supporting evidence to demonstrate a causal relationship.

Health Canada's food health claim evidence requirements to demonstrate a causal relationship would appear to be substantially greater than the requirements for NHPs.

- **standards of evidence that favour a totality of evidence (clinical studies, observational studies, product and source ingredient monographs, post-market experience, published literature and traditional use)**

In drafting the NHP Regulations, NHPD was required to address the substantial number (thousands) of "traditional medicines" in widespread use by millions of consumers in the Canadian market. This contributed to the recognition within the NHP regulatory framework that greater emphasis needed to be placed on long-term post-market experience as evidence of safety and efficacy.

In addition, NHPD did not opt to speculate as to whether the addition of a Health Canada product license number (authorization to go to market) to a NHP label would result in significantly higher intake, triggering the need for a new safety evaluation.

In comparison, the existing policy for health claims for foods makes a new safety evaluation (basic evaluation or basic plus further evaluation at Health Canada's discretion) mandatory, regardless of the history of safe use of the food in Canada and/or other countries.

- **mandatory generic or product-specific claims in labelling**

In the interest of informed consumer choice and bringing order to the market, the NHPD regulatory framework requires that

- 1) all medicinal (active) ingredients in NHPs have a reason (declared by the product license applicant) for being included in the product formulation

2) all NHP labels include a “claim” while providing options for a wider range of claims

NHPD has played a leading role in the recent review and current revision of Schedule A that will lead to a wider range of health claims being permitted for NHPs and non-prescription drugs.

The proposed Schedule A revisions are not intended to automatically apply to foods. Rather, Food Directorate’s policy that foods with health claims are “deemed to be drugs” will still apply. Therefore, the mechanism for future approval of health claims is intended to be by regulatory amendment exempting the approved claims from Section 3, Schedule A and the provisions of the Food and Drug Regulations that apply to drugs.

- **a requirement for site licenses for manufacturing, packaging, labelling and importation**

The NHPD regulations require that all suppliers of NHPs to the Canadian market obtain and maintain a valid site license, regardless of whether they are the manufacturers of the product.

- **the need to accommodate many new product formulations over time**

With over 30,000 NHPs already in the Canadian market to be brought into compliance with the NHP Regulations and with industry advice that many new product formulations would be brought forward for evaluation in future, NHPD was required to develop a framework that would ultimately permit many “combination products”. There are few restrictions within the NHP Regulations and related guidance documents on the development of new product formulations. Pre-market evaluation of combination products is available, subject to the product license applicant having the means and the will to satisfy safety and efficacy evidence requirements.

In contrast, Health Canada’s policy for health claims for foods and the (to be completed) policy on fortification of foods with vitamins, minerals and bioactive substances are to date, highly restrictive.

- **histories of safe use of alternative medicines (falling within Canada’s regulatory definition of NHP) in countries other than Canada**

NHPD incorporated history of safe use in other countries as acceptable evidence in the pre-market evaluation of NHPs.

The pre-market evaluation policy for foods with health claims and novel foods does not place as much emphasis (weight in demonstrating safety) on history of safe use in other countries. The history of safe use in other countries does not remove the need for a safety assessment.

- **international regulatory precedent and experience in the regulation of alternative medicines**

Many foreign markets, including a large number that are considered to be industrialized countries, have exhibited greater market penetration and consumer use of products that fall within Canada's regulatory definition of NHP. The experience of regulatory departments and agencies in a number of these countries was taken into account in the drafting of the NHP Regulations and related guidance documents.

- **recognition of the competence of regulators in other industrialized countries**

NHPD made effort to acknowledge best practices of other regulators in the development of Canada's NHP regulatory framework. Similarly, Health Canada's Inspectorate (Inspection Directorate) and Therapeutic Products Directorate purposefully negotiated a mutual recognition agreement with the EU (MRA negotiations with other countries are in process) for drug site and establishment licenses (Health Canada will normally accept an EU license as being adequate to issue a Canadian license).

NHPD is also undertaking to acknowledge NHP product and ingredient monographs recognized in other jurisdictions as being attestable (applicants may reference the monographs in their product license applications as the primary evidence of safety and efficacy).

In comparison, Health Canada has not to date accepted pre-market evaluations of novel foods and food additives performed by foreign regulators as the primary evidence of safety or in the case of health claims approved in other jurisdictions, of efficacy.

- **the objective of providing consumers in Canada with access to a broad range of products available in other regulatory jurisdictions – facilitating access to market for imported products**

The House of Commons Standing Committee and Minister of Health agreed that consumers in Canada should have timely access to NHPs available in other countries.

Health Canada's current pre-market evaluation requirements do not place great emphasis on timely access to market. However, this is reflected as a priority in the HPFB regulatory modernization initiative.

- **the objective of not having the new regulations remove products from the Canadian market that have a history of safe use and are valued by consumers and their health care and nutrition advisors**

The NHPD Regulations were accompanied by a phased implementation schedule (compliance policy) based on a tiered risk approach (various NHP product sub-categories were assigned levels of risk). Under this compliance policy, the product categories deemed

to present the highest level of risk are the first to face mandatory compliance and the lowest risk the last. During the phase-in period, NHPD undertook to not remove products from the market that had a history of importation/distribution and/or manufacture, sale and safe use prior to the coming into force of the NHP Regulations (January 1, 2004). Since that date, interventions on the part of the Inspectorate (HPFB Inspection Directorate) and Canada Border Agency have been risk-based and selective in the interest of facilitating continued access to the Canadian market.

Blueprint for Renewal II identifies and acknowledges the need for consumers' continued access to products.

- **the need for informed choice -- consumers to have a better understanding of product benefits, risks and the purpose of active (medicinal) ingredients**

NHPD deemed it necessary and drafted the NHP Regulations accordingly so as to provide consumers with additional information in product labelling and in product monographs available to health care practitioners and consumers, requiring advisory statements where necessary to manage apparent risk. Compliant health claims (statements of purpose or intended use) are mandatory for NHP labels.

In contrast, nutrition and health claims for foods are highly restricted. The opportunity for communicating with consumers on health benefits of foods through food labelling and advertising is perhaps being foregone.

De-coupling Safety and Efficacy – Potential Graduated Approach to Claims

As noted above, the NHP regulatory framework provides product license applicants and holders with some flexibility in the types of claims for which they may choose to seek NHPD approval. Product license holders may choose to demonstrate safety and opt for a very limited claim in order to have access to market. This provides the opportunity to not only generate sales but to conduct post-market surveillance to assemble additional efficacy data to support a more specific risk reduction, mitigation or therapeutic claim. This is an important consideration for products for which patent protection is not available and for which product formulation is not easily protected by the manufacturer as commercially sensitive information to competitive advantage. Packaged foods have essentially the same characteristics.

Both NHP and food manufacturers seek to gain advantage in the market over their competitors by reformulating and improving products and making packing and labelling changes to render the products more appealing to consumers. While NHP manufacturers (product license holders) are obligated to demonstrate safety and to incorporate a claim statement in the label text, food manufacturers are not, unless they opt to incorporate a health claim in labelling and/or advertising. Provided that they use traditional food ingredients (not novel) and permitted food additives, food manufacturers have a great deal of discretion in product formulation. Such products are assumed to be safe for a lifetime of consumption in an unrestricted consumer choice (ad libitum) environment.

Food manufacturers do have access in Canada to a number of permitted generic nutrient content claims, biological role claims and a limited number (5) of generic health claims. However, as noted in Section 3 of this document, the use of claims other than those already permitted implies a very significant immediate cost (time, financial and human resources) of demonstrating both safety and efficacy (causal relationship between the food and the health benefit). That cost must be incurred as a prerequisite to getting authorization for market access (approval of the food with the proposed claim).

Health Canada's Health Products and Food Branch (HPFB – of which Food Directorate, NHPD, TPD and the Inspectorate are all directorates) has proposed the incorporation of a new approach to the regulation of drugs in the Canadian market as part of regulatory modernization and renewal. That approach is one of graduated or “progressive” product licensing. An excerpt from the HPFB *Blueprint for Renewal II* consultation document that describes graduated product licensing is attached to this report as Appendix 8. Put in simple terms, this concept permits the granting of market authorization with conditions that may be relaxed or augmented over time, depending upon the experience (product license holder and regulators’) gained from product sale and use under the prescribed conditions.

The question for parties holding an interest in health claims for foods and for federal regulators (Health Canada and CFIA) is whether this concept can be successfully applied to foods (food additives, novel foods, foods with health claims, foods fortified with vitamins, minerals and bio-active ingredients).

Comparability of Canadian and U.S. Regulatory Frameworks

Foods and beverages are freely traded in very large quantities between Canada and the United States. There is also a high rate of international travel between Canada and the U.S. and exposure of Canadian and U.S. consumers to media advertising of foods and natural health products (including dietary supplements) emanating from both Canada and the U.S. With this integration of markets, there is often an assumption made on the part of consumers and suppliers that the regulatory requirements of Canada and the United States are similar, if not identical.

In fact there are very few examples where the requirements applying to foods or natural health products are identical. There are also examples where the regulatory requirements are substantially different.

A full comparison of the Canadian and U.S. regulatory systems for foods and health claims is outside the scope of this reference manual.

However, for readers' benefit a brief comparison is presented in the form of a table found in Appendix 8.

V Federal Regulatory Policy and Process as Applied to Foods With Health Claims

As a number of Health Canada's consultation and guidance documents have observed, interest in health claims for foods has intensified in recent years, shared by farmers, the food and beverage processing sector, consumers, health care professionals and public policy-makers. At the time of writing of this reference manual, both Health Canada and CFIA are undertaking regulatory modernization initiatives and activities. Changes in federal regulation and policy governing health claims are already in process. Additional changes are to be anticipated, accompanied by formal public consultation on the part of Health Canada and CFIA.

With this document intended to serve as a reference tool for related discussion, brief examinations of Canada's federal regulatory policy and process are provided below.

Government of Canada Regulatory Policy – Requirement for Cost and Benefit Assessment

Canada has had a federal regulatory policy since 1994. This policy was most recently updated and republished as the *Cabinet Directive on Streamlining Regulation* that came into effect April 1, 2007. This directive applies to the development and amendment of regulations under the authority of all federal departments and agencies and therefore applies to the regulation of foods, foods with health claims, natural health products and drugs.

The following is an excerpt from the directive that sets out the federal government commitment to Canadians.

“The Government of Canada is committed to protecting and advancing the public interest by working with Canadians and other governments to ensure that its regulatory activities result in the *greatest overall benefit to current and future generations of Canadians*.

When regulating, the federal government will:

- **protect and advance the public interest** in health, safety and security, the quality of the environment, and the social and economic well-being of Canadians, as expressed by Parliament in legislation;
- **promote a fair and competitive market economy** that encourages entrepreneurship, investment, and innovation;
- **make decisions based on evidence** and the best available knowledge and science in Canada and worldwide, while recognizing that the application of precaution may be necessary when there is an absence of full scientific certainty and a risk of serious or irreversible harm;
- **create accessible, understandable, and responsive** regulation through inclusiveness, transparency, accountability, and public scrutiny;
- **advance the efficiency and effectiveness** of regulation by ascertaining that the benefits of regulation justify the costs, by focussing human and financial resources

- where they can do the most good, and by demonstrating tangible results for Canadians; and
- **require timeliness, policy coherence, and minimal duplication** throughout the regulatory process by consulting, coordinating, and cooperating across the federal government, with other governments in Canada and abroad, and with businesses and Canadians.”

The directive requires that regulatory departments and agencies assess the costs and benefits of not only regulation but of other interventions that are alternatives to regulations. Such other interventions include Health Canada’s policy regarding pre-market evaluation of foods with health claims. However, no such cost-benefit analysis, including the “quantitative measures” required by the directive, has ever been published. This may be due in part to the fact that neither the generic nor the product-specific has been introduced to the formal “regulatory process” that includes publication of the proposed regulation(s) in Part I of the Canada Gazette. If published, proposed regulations require a RIAS (regulatory impact assessment statement) that as of April 1, 2007 (as a consequence of the new directive) must include findings of a cost-benefit analysis.

Completing a cost-benefit analysis for Health Canada’s policy on pre-market evaluation of foods with health claims will be a difficult task. Because neither generic nor product-specific health claims for foods have been approved in response to a submission filed by a proponent of a claim, the costs of this regulatory framework for foods with health claims have not yet been “experienced” by either the private sector or public sector. There is no “post-market” (real life observations) experience of dietary change and health outcomes associated with product-specific claims. Nor are the authors of this paper aware of any evidence that has been assembled and published regarding changes in dietary behaviour that might be attributed to the 4 currently approved generic health claims.

A further consequence of this lack of experience is that the risk that has been speculated as being presented by additional generic and product-specific health claims has not been demonstrated by Health Canada. As a consequence, a further principle of federal regulatory policy would not appear to have been met. That principle also resides in the directive in Section 4.4 which states that departments and agencies are to, among other things:

“demonstrate that the regulatory response is proportional to the degree and type of risk”

However, the directive also observes that the “application of precaution may be necessary where there is the absence of full scientific certainty and a risk of serious or irreversible harm.”

Federal Regulatory Process

While the Cabinet Directive on Streamlining Regulation (federal regulatory policy) outlines what departments and agencies are obligated to do and observe in the development of regulation and alternatives to regulation their implementation, the “federal regulatory process” refers to the

entire process by which regulations are initially approved and subsequently amended or revoked (cancelled).

There are essentially ten steps in Canada's federal regulatory process. The conception and public consultation on proposed regulatory frameworks and changes is really just the first step. As explained in Section 1 of this document, the first step often takes years to accomplish.

Once the purpose, substance and desired operational characteristics of proposed regulation are determined, the actual process of putting the regulation in place can begin. This assumes that having a legally binding regulation (regulations have the force of law, guidance documents and policies do not) is the preferred outcome to address the identified need. Historically, the process has required between 40 and 50 weeks to complete, representing the cumulative amount of time required for the execution of each step based on policy and procedures. However, more complex regulation(s) often require 18 to 24 months from the beginning of legal drafting to final publication in Part II of the Canada Gazette.

This process is a mix of decision-making at both the political (elected) and non-elected levels of government. Although the majority of work in the regulatory process is undertaken by public servants who are employees of the sponsoring department or agency and other departments involved, all regulatory amendments (new regulations and changes) must be approved by a committee of Cabinet twice – once prior to publication in Canada Gazette Part I and once prior to final publication in Canada Gazette Part II. The practical implication of this process is that it involves interdepartmental scrutiny at various levels and requires the oversight and approval of legal counsel. The significance of this is not to be overlooked, considering that federal regulations are legally binding, not only on the regulated parties and products in the private sector but on the public servants and Ministers responsible for the regulations.

One additional aspect of the federal regulatory process is that it serves to meet the government of Canada's obligations under multilateral trade agreements to publicly consult with trading partners on regulatory matters that have the potential to affect international trade in goods and services. The public comment period that follows Canada Gazette I publication is intended in part to meet this obligation.

In recent years, one additional step has been added, required by the coming into force of a federal law requiring that Canada's Parliament conduct a review of proposed regulation where the costs of administration of the regulation are to be recovered in whole or in part from the users of the regulation (applicants).

However, the period of time required to complete the regulatory process is often an impediment to regulatory departments keeping pace with change in the private sector, particularly in the food and beverage sector where the pace of product development and modification is rapid. Thousands of new and/or modified food and beverage products come to market in Canada and the United States each year. Canada's food and beverage industries operate in a North American free trade environment provided for under the terms of the North America Free Trade Agreement to which Canada, the U.S. and Mexico are signatories. There are high expectations on the part of

Canada's food and beverage sector, including importers and exporters, that Canada's system of food regulation will keep pace with changes in the market and be aligned to a large extent with that of the U.S.

In light of these expectations, Canada's regulatory framework for foods includes provisions for interim measures that can be applied before the formal regulatory amendment process can be completed. Such provisions (Temporary Marketing Authorization) have existed for many years to permit:

- test marketing of foods in Canada that are not compliant with all of Canada's food packaging and labelling requirements
- temporary marketing authorization to permit foods to be sold under prescribed circumstances when the composition of the product is not compliant with existing regulatory requirements
- ongoing marketing of certain specialty foods that are exempted from some packaging and labelling requirements

More recently, Health Canada sought and received through amendments to the Food and Drugs Act, the power to issue Interim Marketing Authorizations (IMA) permitting the sale of products that will become compliant only after proposed amendments to regulations are completed via the usual regulatory amendment process. This restored a provision that had previously been available by regulation for a period of time. Such authorizations are being used quite frequently to accommodate new food additives and/or new uses and/or specified levels of food additives. To date, no IMA has been issued that applies to a health claim for a food. However, such use of an IMA should be provided for under the authority provided in the Foods and Drugs Act. IMA's may be published in Canada Gazette Part I in a much shorter time period than proposed regulation.

The most recent publicly available document from Health Canada's Food Directorate describing the federal regulatory process as it applies to foods is included in this report as Appendix 4.

Appendices

- 1. Interim Guidance Document- Preparing a Submission for Foods with Health Claims incorporating Standards of Evidence For Evaluating Foods with Health Claims**
- 2. Final Report of the External Working Group – Section 3 & Schedule A of the Food and Drugs Act**
- 3. Proposed Amendments to Schedule A of the Food and Drugs Act**
- 4. Federal Regulatory Process**
- 5. Principal Federal Acts and Regulations Pertaining to Foods and Natural Health Products**
- 6. Division 28 of the Food and Drug Regulations, Novel Foods**
- 7. Progressive Licensing Concept – Excerpt from HPFB Blueprint for Renewal**
- 8. Comparison of Food Legislative & Regulatory Issues/Requirements – Canada vs. U.S.A.**

APPENDIX 1

Interim Guidance Document- Preparing a Submission for Foods with Health Claims incorporating Standards of Evidence For Evaluating Foods with Health Claims

http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/claims-reclam/abstract_guidance-orientation_resume_e.html

APPENDIX 2

Final Report of the External Working Group – Section 3 & Schedule A of the Food and Drugs Act

http://hc-sc.gc.ca/ahc-asc/public-consult/consultations/col/sec_a/sched-ann_a_maj_rep-rap_e.html

APPENDIX 3

Proposed Amendments to Schedule A of the Food and Drugs Act

http://hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/scha_annea_fact-fiche_e.html

APPENDIX 4

The Federal Regulatory Process

Introduction

The Federal Regulatory Process is established by the Privy Council Office and must be followed by all Government Departments/Agencies that intend to have regulations approved by the Governor in Council. Essentially, it is a set of procedural requirements flowing from Government policy, statutes, and Cabinet directives. The Process is closely linked to:

- the Federal Regulatory Policy which has the objective of ensuring that use of the government's regulatory powers results in the greatest net benefit to Canadian society and stresses the importance of consulting with Canadians on regulatory measures; and
- the Federal Regulatory Process Management Standards which set out key elements to be met before proposing regulatory amendments. These elements require that regulatory programs proposing new regulatory requirements or regulatory changes must have evidence that a problem has arisen, that government intervention is required and that new regulatory requirements are necessary. When health, safety and environmental risks are involved, regulatory authorities must consider whether the relative and absolute risks posed are such that intervention is required at this time.

The ten steps of the Federal Regulatory Process, the activities under each step and the potential duration of each step are described below. The indicated duration of each step will vary depending on the complexity of the required regulation; the problem being addressed; the work load and the priority of the problem being addressed.

1. Conception and Development of Regulation (Duration: months to years)

The policy development and consultation process(es) leading to the conclusion that the regulatory option is the best alternative can be lengthy (months to years) depending on the complexity of the problem to be addressed. Once the conclusion has been made to proceed with development of a regulatory amendment, the requirements of the Federal Regulatory Policy and the Federal Regulatory Process Management Standards must be met.

The activities under this step include determining if there is a sound scientific basis for the regulation, the potential scope of the regulatory amendment, how it would interact with other existing regulations, the potential impact on Canadians and industry, whether the regulatory effort is being expended where it will create the most benefit in regard to health, social, economic or environmental risks and how the regulatory amendment would impact on international trade.

2. Departmental Drafting of Regulation, Regulatory Impact Analysis Statement (RIAS) and other documents (Duration: weeks to months)

The wording of the proposed regulation is undertaken in consultation with the Departmental Legal Services Unit, which advises on matters, such as compliance with the supporting Act and consistency with other existing regulations, and is based on the policy development conducted under step number 1 and the work that preceded that step.

The drafting of the RIAS describes the activities undertaken by the regulatory program to comply with the requirements of the Regulatory Policy and the Regulatory Process Management Standards.

3. Examination by Justice and Review by Treasury Board (Duration: weeks to months)

The Department of Justice reviews the proposed regulation to determine whether it is within the authority of the relevant Act, does not pose an unusual use of the authority, and does not raise any constitutional or *Charter of Rights and Freedoms* issues. The Department of Justice would work with the regulatory program to revise the proposed regulation to eliminate or minimize, if possible, any such problems found with the proposed regulations. When the proposed regulations are satisfactory to the Department of Justice, the stamped copies of the proposed regulations are prepared for consideration by Treasury Board and if approved, publication in the *Canada Gazette*, Part 1.

4. Ministerial Approval for Pre-publication in the Canada Gazette, Part I (Duration: weeks)

The drafting of a memorandum to the Minister must be completed and signed off by the various levels in the line of authority up to and including the Minister. Once the Minister has signed the RIAS, the documents are returned to the program and then they are sent to Treasury Board for addition of the file to agenda.

5. Pre-publication Review by Treasury Board (Duration: weeks)

Treasury Board requires that regulatory files be received at least three weeks before the meeting where the regulatory file would be considered. This time period allows the advisor assigned to the file to prepare briefing documents on the regulatory file before it is considered by the Treasury Board members at the next meeting.

6. Prepublication in the *Canada Gazette*, Part I and Comment Period (Duration: Months)

The *Canada Gazette*, Part I is published every Saturday. A comment period of a minimum 75 days is established to provide interested parties (domestic or foreign) to provide comments on the proposed regulation.

The comments received from prepublication of the proposed amendments must be examined to determine if they contain substantive information or reasons to modify the proposed regulation. A response to all comments received must be prepared and sent to the appropriate parties. If a substantive change is made to the proposed regulation, it would have to be republished in the *Canada Gazette*, Part I for further comments.

7. Departmental Preparation of final Proposal for Treasury Board Consideration (Duration: weeks)

See activities under Step 4 above.

8. Final Review by Treasury Board (Duration: weeks)

See activities under Step 5 above.

9. Making, Registering and publishing in the *Canada Gazette*, Part II, Distribution of the Regulations (Duration: weeks)

If the regulatory amendment is approved by the Treasury Board, an Order in Council would be presented to the Governor General for signature. When the Governor General signs the order, the regulation is "made".

Within seven days after a regulation is made, the *Statutory Instruments Act* requires that it be transmitted to the Clerk of the Privy Council to record the title of the regulation, the title of the Regulation-making authority, the date of making and the date of registration. The Clerk assigns it a number preceded by the designation "SOR" (Statutory Orders and Regulations). In general, and unless otherwise specified, a regulation comes into force on the date that it is registered by the Clerk of the Privy Council.

Once registered, the regulation must be published in the *Canada Gazette*, Part II within 23 days.

10. Parliamentary Review by the Standing Joint Committee for the Scrutiny of Regulations (SJCSR) (Duration: variable)

The SJCSR is mandated to monitor the use of regulatory authorities on behalf of Parliament. If a problem with the regulation is found, the Committee will communicate with the Minister of the Department that made the regulation and suggest solutions to the problem.

If the problem is not resolved, the SJCSR can file a disallowance report in the House of Commons and the Senate to have to regulation revoked.

Bureau of Food Regulatory, International and Interagency Affairs Food Directorate
Health Products and Food Branch
January 11, 2007

This document is based on the publication entitled Guide to the Regulatory Process. It can be found on the following URL:

http://www.tbs-sct.gc.ca/ri-qr/ra-ar/default.asp@language=e&page=publications&doc=regguide_2fregguide_e.htm

<http://www.regulation.gc.ca/index-eng.asp>

<http://www.regulation.gc.ca/directive/directive00-eng.asp>

<http://www.regulation.gc.ca/directive/directivetb-eng.asp>

APPENDIX 5

Principal Federal Acts and Regulations Pertaining to Foods and Natural Health Products

NOTE: COMPLETE PRINTABLE TEXTS OF ALL FEDERAL ACTS AND REGULATIONS CAN BE FOUND AT [HTTP://LAWS.JUSTICE.GC.CA](http://laws.justice.gc.ca)

	Act (Statute, Law)	Regulations Pursuant to Act	Status and Scope of Regulations
1.	Food and Drugs Act	<ul style="list-style-type: none"> • Food and Drug Regulations 	In force as amended, applicable to all foods, novel foods, non-prescription drugs, prescription drugs and biologic drugs, addressing fundamental processing and packaging requirements and product safety, efficacy and composition.
	Food and Drugs Act	<ul style="list-style-type: none"> • Natural Health Product Regulations 	In force as amended, but under review with pending amendments, applicable to all products meeting the definition of “natural health product” as stated in the NHP Regulations, addressing safety, efficacy, packaging and labelling of NHPs
2.	Consumer Packaging and Labelling Act	<ul style="list-style-type: none"> • Consumer Packaging and Labelling Regulations 	In force, providing for certain packaging and labelling provisions that apply to packaged foods and beverages.
3.	Canada Agricultural Products Act	<ul style="list-style-type: none"> • Dairy Product Regulations • Egg Regulations • Fresh Fruit and Vegetable Regulations • Honey Regulations • Maple Products Regulations • Organic Products Regulations • Processed Egg Regulations • Processed Products Regulations <p>And others dealing with arbitration, etc.</p>	An Act to regulate the marketing of agricultural products in import, export and interprovincial trade and to provide for national standards and grades of agricultural products, for their inspection and grading, for the registration of establishments and for standards governing establishments. Compositional standards for foods are incorporated into some of the regulations pursuant to the act, presenting some limitations to the extent to which standardized foods might be modified to render them “functional” in terms of a causal relationship between the food and an expected health outcome.

4.	Canadian Environmental Protection Act 1999	<ul style="list-style-type: none"> Numerous regulations, including New Substances Notifications Regulations 	Requires the assessment of the environmental impact of all new substances imported into or manufactured within Canada, including bioactive substances and ingredients that may be used in foods, natural health products and drugs.
5.	Canadian Food Inspection Agency Act	<ul style="list-style-type: none"> Regulations enforced by CFIA are pursuant to list of acts noted in italics in table cell to right 	The Agency is responsible for the administration and enforcement of the <i>Agriculture and Agri-Food Administrative Monetary Penalties Act, Canada Agricultural Products Act, Feeds Act, Fertilizers Act, Fish Inspection Act, Health of Animals Act, Meat Inspection Act, Plant Breeders' Rights Act, Plant Protection Act and Seeds Act.</i>
6.	Pest Control Products Act	<ul style="list-style-type: none"> List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern Pest Control Products Incident Reporting Regulations Pest Control Product Regulations Pest Control Product Sales and Information Reporting Regulations 	The stated primary objective of the Act is to prevent unacceptable risks to people and the environment from the use of pest control products. These include pest control products used in production of agricultural products, food manufacturing and storage facilities and in foods. Use of pest control products is a condition of registration, governing specific uses, amounts that may be used and which foods may come into contact with or be treated by the pest control product. Maximum residue limits for pest control products in foods are listed in the Food and Drug Regulations.
7.	Plant Protection Act	<ul style="list-style-type: none"> Plant Protection Regulations <p>And others</p>	The purpose of the Act is to protect plant life and the agricultural and forestry sectors of the Canadian economy by preventing the importation, exportation and spread of pests and by controlling or eradicating pests in Canada.

APPENDIX 6

Division 28 of the Food and Drug Regulations, Novel Foods

http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870/bo-ga:1_C::bo-ga:1_D?page=1

(Scroll down to B.28.001 near the end of Part B)

APPENDIX 7

Progressive Licensing Concept – Excerpt from HPFB Blueprint for Renewal

http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/blueprint-plan_ann1_e.html

APPENDIX 8

Comparison of Food Legislative & Regulatory Issues/Requirements – Canada vs. U.S.A.

This document contains information about the following topics:

1. Basic Legislation and subordinate regulations
2. Food Additives – General Regulatory Requirements
3. Food Colours and Colour Additives –General Regulatory Requirements
4. Artificial Sweetening Agents –Vitamins and Mineral Nutrients
5. Health Claims Dietary Supplements
6. General labelling, Nutrition labelling and Allergen Labelling
7. Novel Foods

COMPARISON OF FOOD LEGISLATIVE & REGULATORY ISSUES/REQUIREMENTS
CANADA vs. U.S.A

LEGISLATIVE & REGULATORY ISSUES	CANADA	UNITED STATES	COMMENTS
Basic Legislation and subordinate regulations	<ul style="list-style-type: none"> • Food & Drugs Act & Regulations • Consumer Packaging Act & Regulations • Canada Agricultural Products Act and Regulation 	<ul style="list-style-type: none"> • Food, Drug & Cosmetic Act • Title 21, Code of Federal Regulations • Nutrition Labeling & Education Act (NLEA) • Dietary Supplement Health Education Act (DSHEA) 	<ul style="list-style-type: none"> • In October 2006, Health Canada announced a new initiative entitled “Blueprint for Renewal” which includes a “Regulatory Modernization Strategy for Food and Nutrition” • It is expected that implementation of the concepts outlined in the “Blueprint” will take from 3 to 5 years.
Food Additives – General Regulatory Requirements	<ul style="list-style-type: none"> • Regulated by a “positive listing” technique where the substance must appear on the list or it cannot be used (Part B, Division 16, Food & Drug Regulations). • The regulations are very prescriptive, stating where the additive may be used and the maximum level of use. • More than 250 substances are found in 15 tables which list additives in terms of functional use • The definition of “food additive” includes food colours. • The definition of “food additive” excludes flavours, flavouring agents, agricultural chemicals and “incidental additives” from packaging material and vitamins, mineral 	<ul style="list-style-type: none"> • Regulated in Title 21, CFR by specific regulations rather than tables. These regulations are also quite prescriptive. • The definition includes vitamin and minerals, flavours and incidental additives but excludes food colours. • Many substances have “Generally Recognized as Safe” (GRAS) status and thus are not regulated as food additives • Certain other substances are “prior sanctioned” and are thus not regulated as food additives • New substances that are 	<ul style="list-style-type: none"> • The GRAS and Prior Sanction concepts in the U.S.A. permits much greater flexibility in formulating products as GRAS and Prior Sanction substances are generally not specifically regulated in terms of product use or level of use. This is the major difference between the regulation of food additives in Canada and the U.S.A. • The pre-market safety assessment procedures in Canada and the U.S.A. are largely comparable. • In Canada a “food additive” has only a regulatory definition and

<p>Food Additives –General Regulatory Requirements (continued)</p>	<p>nutrients and amino acids</p> <ul style="list-style-type: none"> • Substances not on the regulatory “positive list” require a pre-market safety assessment and regulatory promulgation as a new entry to the list of food additives • After completion of the safety assessment, making the regulatory amendment to one of the 15 tables of food additive regulations takes between 80 and 120 weeks. • However, the Food Directorate has made increasing use of Interim Marketing Authorizations to permit intended use, pending formal regulatory amendment. 	<p>regulated as food additives require pre-market safety assessment and regulatory promulgation as a new regulation in Title 21, CFR</p>	<p>thus is simply a special type of ingredient that requires pre-market clearance. In the U.S.A. both “food additive” and “color additive” have statutory definitions in the <i>Food, Drug & Cosmetic Act</i>.</p> <ul style="list-style-type: none"> • The “Blueprint” initiative includes a review of the regulatory process for food additives with a view to simplification; e.g. administrative management of food additive tables, streamlining the number of food additive tables, adoption of international (Codex) food additive classification.
<p>Food Colours and Colour Additives –General Regulatory Requirements</p>	<ul style="list-style-type: none"> • Food colours are included in the definition of “food additive”. The term “colour additive” is not applicable in Canada. 	<ul style="list-style-type: none"> • Food Colours are not within the definition of “food additive” and are regulated separately as “colour additives” 	<ul style="list-style-type: none"> • The list of permitted food colours in Canada and the U.S.A. is largely the same, with the exception of F.D. & C Red No. 2 (Amaranth), Citrus Red No. 2 and Ponceau SX which are permitted in Canada but not in the U.S.A. Citrus Red and Ponceau SX are restricted in use to very specific applications.
<p>Artificial Sweetening Agents</p>	<ul style="list-style-type: none"> • Aspartame, Acesulfame K, Sucralose and Neotame permitted in specified food products as regulated food additives • A main panel declaration is required about the presence of Aspartame, Acesulfame K, Sucralose and Neotame in addition to declaring the artificial sweetener in the list of ingredients • Saccharin and cyclamate do not have status as food additives and thus are not permitted in commercially prepared foods. 	<ul style="list-style-type: none"> • Saccharin has had a “tentative status” since 1977 but may be added to foods but must be accompanied by a warning statement. Widely used in fountain sodas and baked goods because of thermal stability. • Cyclamate was banned in 1970 but FDA is considering a petition to re-approve cyclamate • Aspartame, Sucralose and 	<ul style="list-style-type: none"> • Canada is the only jurisdiction that has a regulatory requirement for a PDP declaration of the presence of a high intensity sweetener or a combination of such sweeteners.

	<ul style="list-style-type: none"> • Saccharin when sold in liquid or tablet form must be sold from a pharmacy. • However, as of October, 2007, it is the intent of the Food Directorate to reinstate saccharin as a food additive pursuant to a food additive submission whose evaluation has been completed and for which the intended use has raised no health concerns. • Cyclamate sweeteners when sold as table-top sweeteners must bear warning statements. 	<p>Acesulfame K and Neotame permitted as regulated food additives in the U.S.A.</p>	
<p>Vitamins and Mineral Nutrients</p>	<ul style="list-style-type: none"> • Regulated by a “positive listing” technique similar to the manner in which food additives are regulated. If the food does not appear on the list, then the vitamin or mineral nutrient may not be added. The list is relatively short, containing only some 27 food categories. • Vitamin C may not be added to orange juice, concentrated orange juice, tomato juice or most other juices. • Vitamin C may be added to fruit flavoured drinks when certain specific, rather difficult conditions are met. This requirement is to prevent the addition of Vitamin C to carbonated soft drinks. • Vitamin C may also be added to fruit nectars and vegetable drinks • The exception is apple juice which permits the addition of Vitamin C so that a product typically of Canadian origin could compete nutritionally with orange juice. • Calcium may be added to orange juice only by obtaining a “Temporary Marketing Authorization”. • Health Canada has been in the process of doing a “risk assessment” on the addition of Calcium to food for almost 5 years. As of 	<ul style="list-style-type: none"> • Fortification Policy published in CFR, Title 21, Part 104 – Nutritional Quality Guidelines for Foods. • The guidelines have been interpreted in a manner that permits the addition of vitamins and minerals to many foods including fruit drinks, sports beverages, fruit juices, fruit cocktails, vegetable juices, functional beverages, and many other products. • Calcium is added to hundreds of food products sold in the U.S.A. 	

	<p>summer, 2007, the results of this risk assessment are still not available.</p> <ul style="list-style-type: none">• Updating of the Health Canada policy on food fortification has been ongoing since 1998.• In March 2005, the Food Directorate, Health Products and Food Branch (HPFB) released a document outlining a new proposed policy. This policy would create a new provision for food fortification done at the “discretion” of the manufacturer. This “discretion” would be “within defined limits” set by Health Canada.• The proposal calls for the exclusion of standardized foods from discretionary fortification as such products, according to Health Canada, are “staple and pervasive” in the food supply.• An actual regulatory proposal based on the March 2005 consultative document should be published in the <i>Canada Gazette, Part I</i> in late fall 2007.		
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<p>Health Claims</p>	<ul style="list-style-type: none"> • The <i>Food & Drugs Act</i> contains a section (Section 3 & Schedule A) which prohibits claims on the labels or in advertising on foods and drugs sold to the general public which refer to any of the 40 disease conditions listed in Schedule A. The conditions listed include cancer, heart disease, diabetes and 37 other serious disease conditions. • Section 3 and Schedule A is a statutory prohibition that prohibits claims even if the claim could be scientifically validated. This prohibition has been in the statute since 1934. • Based on recommendations from a 1998 Parliamentary Committee, in April 2003, the HPFB established an External Working Group (EWG) to review Section 3 and Schedule A and to make recommendations with respect to short-term and long-term solutions. • The Report of the External Working Group was delivered the Assistant Deputy Minister, Health Products and Food Branch, Health Canada in February 2004. The Natural Health Products Directorate has taken action with draft regulations published in <i>CGI</i> on June 16, 2007 to reduce the effects of Section 3 and Schedule A on labelling and advertising of NHPs. • . As part of new nutrition labelling regulations published in January, 2003, provision was made for four health claims on food labels. The permitted claims pertain to Sodium, Potassium and Hypertension; Calcium, Vitamin D and Osteoporosis; Saturated fat, trans fat, and heart disease; and Vegetables and Fruit and some types of Cancer. 	<ul style="list-style-type: none"> • The 1990 NLEA authorized the FDA to permit health claims on foods that meet certain compositional requirements. Since 1993, 16 claims have been authorized and are now found on a range of foods sold in the U.S.A. • . • Statutory prohibitions analogous to Section 3 and Schedule A do not exist in either U.S. or Mexican food and drug legislations. 	
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	<ul style="list-style-type: none">• Use of an exempting clause in the regulation making power of the Food and Drug Act was invoked to over-ride the prohibition of Section 3 and Schedule A and thus make provision for use of the four generic health claims on food labels providing that the food meets prescribed compositional criteria.		
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<p>Dietary Supplements</p>	<ul style="list-style-type: none"> • The term “dietary supplement” has no status in Canada. Prior to June, 2003, the bulk of the herbal and botanical products in this class were sold as food products by default despite the fact that most are sold in dosage form and resemble drugs. • In June, 2003 Health Canada published final regulations for “Natural Health Products” or NHPs. The new regulations defined NHPs and established a product licensing scheme complete with site licences, good manufacturing practices, clinical trials involving human subjects, and appendices stating what is included as an NHP and what is excluded. • NHPs are not a “stand alone” category but rather are regulated as a sub-category under the general definition of “drug”. • Unlike the U.S. approach to the regulation of dietary supplements, the proposed regulation of NHPs in Canada involves registration, site licensing and related measures. • In order to inform Canadians about research demonstrating the role that certain foods play in reducing the risk of certain diseases, Health Canada announced in the fall of 2005 in the “Smart Regulation Action Plan” that it intends to develop a new regulatory framework for the use of food label and advertising as a means of delivering health information to the public. • The proposed new regulatory framework for foods has been re-branded as “Expanded Health Claims” with stakeholder consultation planned for late 2007. 	<ul style="list-style-type: none"> • Under the DSHEA of 1994, the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe prior to marketing. Generally, manufacturers do not need to register with the FDA or get FDA approval before producing or selling dietary supplements. • Dietary supplements, by virtue of the DSHEA are neither foods nor drugs but rather a new special class of substances. • Health claims on dietary supplements follow the basic rules established under the NLEA. 	<ul style="list-style-type: none"> • Health Canada is initiating a regulatory review to determine the most appropriate way to regulate products marketed at the “NHP/Food Interface”.
<p>General labelling, Nutrition labelling and Allergen Labelling</p>	<ul style="list-style-type: none"> • The “mandatory information” on all consumer products including food must appear in both English and French. This is a “social policy” and is not subject to any sort 	<ul style="list-style-type: none"> • The Nutrition Labelling and Education Act (NLEA) was passed in 1990 which made nutrition labelling mandatory on 	<ul style="list-style-type: none"> • In February 2004, Health Canada proposed regulations to enhance the labelling requirements for specific priority allergens

<p>General labelling , Nutrition labelling and Allergen Labelling(Continued)</p>	<p>of negotiation. This requirement is part of the Consumer Packaging and Labelling Act that was passed in 1976.</p> <ul style="list-style-type: none"> • Voluntary nutrition labelling was introduced in 1988 following 5 year of extensive consultation. • In October 2000, Health Canada released a proposed new mandatory nutrition labelling scheme which was very similar to the current scheme used in the U.S.A. • .On January 1, 2003, comprehensive mandatory nutrition labelling regulations were published in the Canada Gazette, Part II. • The new regulations and the new “Nutrition Facts” panel became mandatory for most foods on December 12, 2005. Small manufacturers have until December 12, 2007 to comply. • . There are differences between the mandatory Canadian Nutrition Labelling scheme and the U.S. counterpart. In terms of “harmonization” with U.S. nutrition labelling requirements, Health Canada has stated the following: <i>“Increasing the compatibility of these Regulations with those of the U.S. to the greatest extent possible, continues to be a clear objective of Health Canada. However, emerging science, health concerns and differences in diet (e.g. content of trans fat in the Canadian diet) continues to limit the extent of harmonization, as do Canadian bilingual requirements and some differences between units of measurement in both countries.</i> • It is virtually impossible to bring about total “harmonization” and have a label that would be acceptable in both jurisdictions. In Canada, the format of the Nutrition Facts 	<p>virtually all foods sold in the U.S.A.</p> <ul style="list-style-type: none"> • Regulations under the Act became effective in 1994 and almost all foods now bear the standardized “Nutrition Facts” panel. • The NLEA was the enabling statute that permitted health claims on foods. • Effective January 1, 2006, the FDA required food labels to state clearly if a food product contains any ingredients that contain protein derived from the eight major allergenic foods. The list includes protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat or soybeans. 	<p>(peanuts, naming the tree nuts, sesame, milk, eggs, naming the fish, naming the crustaceans, naming the shellfish, soy and wheat, including spelt and kamut or oats, barley rye or triticale or any protein-containing part thereof and hybridized strains of these grains) gluten sources and sulphites in prepackaged foods sold in Canada.</p>
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	<p>panel is subject to regulation. Consequently, it cannot be compromised in any way and must deal only with the official languages of Canada; English and French. Thus, a trilingual panel (English, French and Spanish) would violate the regulations.</p>		
<p>Novel Foods</p>	<ul style="list-style-type: none"> • Regulations respecting Novel Foods became effective on October 27, 1999. • “Novel Foods” are defined as products that have never been used as food, which result from a process that has not been previously used for food; or, foods that have been modified by genetic manipulation. • These regulations thus cover not only genetically modified foods but also other foods that have no history of use in Canada. • The regulations require the company that wishes to sell a food deemed to be a “novel food” to notify Health Canada prior to sale of the food. The notification process permits Health Canada to conduct a pre-market safety assessment. • A listing of “Approved Products” has been posted on the Health Canada website. An example of a non-GMO food listed is “Juices containing Fish Oil”. However, the bulk of the items listed are, in fact, GMO foods. 	<ul style="list-style-type: none"> • In January 2001, the FDA issued a <i>Premarket Notice Concerning Bioengineered Foods</i>. • This proposal would have mandated the submission of data and information regarding plant-derived bio-engineered foods that would be consumed by humans and animals. • It does not seem that these proposed regulations were passed and included in Title 21, CFR. • As an alternative to regulation, it appears that the FDA has instituted a voluntary consultation process whereby the developer can resolve any safety or regulatory issues prior to marketing. Thus, mandatory pre-market approval is not yet required as it is in Canada. 	<ul style="list-style-type: none"> • The Novel Food Regulations in Canada have provided Health Canada with a legal mechanism to require foods that result from a process that incorporates a substance such as Omega-3 Fatty Acids to undergo a pre-market safety assessment. Pork or dairy cattle fed specific feed rations to increase the level of Omega-3 fatty acids would be an example of the use of the novel food regulations as a pre-market assessment mechanism. These assessments are based on individual submissions and do not “carryover” to a similar submission by a competitor. • The notification process is administrative in nature and thus does not require a regulatory amendment.