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POLICY PAPER

Therapeutic Products Programme and the Food Directorate from the Health Protection Branch

NUTRACEUTICALS/FUNCTIONAL FOODS AND HEALTH CLAIMS ON FOODS

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1. PURPOSE

The purposes of this project were to:

- ▶ analyse the Canadian situation with respect to nutraceuticals/functional foods and health claims for food products
- ▶ review a range of policy alternatives to address issues raised by stakeholders
- ▶ recommend a conceptual framework for regulating health claims on nutraceuticals/functional foods.

2. BACKGROUND

Researchers generally agree that a growing body of evidence from epidemiology, clinical trials and modern nutritional biochemistry underlines the connection between diet and health. This impact is not only in the short term, but also in the development and management of chronic diseases.

Health Canada recognizes that diet may modify the risk of developing or exacerbating certain chronic diseases. Individual components of foods -- both nutrients and non-nutrients -- can affect certain risk factors for disease.

This observation is not new: Humans for centuries have attributed to diet and foods a functional role in health. What is new is the scientific evidence as well as the terminology.

2.1 Growing Interest

Our understanding of the relationships between food, physiological function and disease have progressed in recent years, particularly over the past decade. The National Academy of Sciences report, *Diet and Health*¹, Health Canada's *Nutrition Recommendations*² and, more recently, two reports on dietary reference intakes for nutrients^{3,4} have led the way in making chronic disease prevention a key objective of nutrition recommendations.

At the same time, Canadians have been taking greater control over their health, exploring alternative or traditional medicines, complementary therapies and natural health products. There has been a growing interest in the role that nutrition plays in our state of well being.

As public knowledge of this field has evolved, manufacturers have sought to fulfil a consumer appetite for products derived from foods that could be used to promote good health. The result has been the development and marketing of a growing spectrum of products called "nutraceuticals" and "functional foods."

2.2 Definitions

Although the terms "nutraceutical" and "functional food" are used commonly around the world, there is no consensus on their meaning. Consequently, the Bureau of Nutritional Sciences, of the

¹ National Research Council (USA), 1989. Committee on Diet and Health. *Diet and Health: implications for reducing chronic disease risk*. Washington. National Academy Press.

² Health Canada, 1990, *Nutrition Recommendations: the Report of the Scientific Review Committee*, Ottawa: Supply and Services Canada.

³ Institute of Medicine, 1997. Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride, Standing Committee on the Scientific Evaluation of Dietary reference intakes, Food and Nutrition Board, Washington, D.C., National Academy Press. (prepublication report)

⁴ Institute of Medicine, 1998. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B₆, Folate, Vitamin B₁₂, Pantothenic Acid, Biotin, and Choline, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Washington, DC, National Academy Press. (prepublication report)

Food Directorate of Health Canada, has proposed the following definitions:

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

A *functional food* is similar in appearance to, or may be, a conventional food, 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.

2.3 Regulatory Challenges

As commercial interest in the marketing of these foods and components grows, regulatory agencies face new challenges. Our current understanding of the benefits and risks⁵ related to health claims on such products is more qualitative than quantitative. Therefore, regulators are cautiously exploring the issue from a variety of perspectives. For example:

- ▶ How should nutraceuticals/functional foods be defined with precision for regulatory purposes?
- ▶ Should such products remain as either foods or drugs under the *Food and Drugs Act*?
- ▶ What kinds of health claims, if any, should be allowed on food labels?
- ▶ What standards of evidence would be necessary and sufficient to prove a health benefit?
- ▶ How can nutraceuticals/functional foods be regulated without unduly compromising the right of Canadians to take greater responsibility for their own health?

2.4 Policy Development

To fully examine questions of this nature, a joint project involving the Therapeutic Products Programme and the Food Directorate was initiated in the fall of 1996. The goal was to develop a policy framework to address regulatory issues related to health claims on nutraceuticals/functional foods and related products.

An internal working group from both directorates was appointed, including also representatives from the Health Promotion and Programs Branch, Justice Canada and the Canadian Food Inspection Agency. The group was assisted by an External Advisory Panel with members representing the food and drug industries, consumer groups, academia, and practising health professionals.

⁵ Risk is defined as a measure of both the hazard to health from exposure to a substance and the probability of its occurrence.

Between April 30 and May 2, 1997, the Working Group and the External Advisory Panel met with stakeholders at a workshop to review current policies related to health claims. While many interests and perspectives emerged, there was general support for change.

Initial deliberations concluded that policy development should be guided by the following principles:

- ▶ *Products with proven physiological benefits should be available to Canadians.*
- ▶ *The regulatory environment should fairly and responsibly permit the promotion to consumers of food and drug products that have been shown by valid scientific evidence to improve health.*
- ▶ *To benefit consumers, health claims should be supported by information that is clearly stated, substantiated, truthful, not misleading and not likely to lead to harm.*

The working group incorporated discussions from the stakeholder workshop and other written comments into a draft Policy Options Analysis paper. This draft set out a conceptual framework for regulating health claims on nutraceuticals/functional foods. Within that context, the group reviewed a variety of possible models based on claims rather than form or definition. These models ranged from an unregulated environment to strict government control of health claims on food and food products. At the same time, the working group also established criteria that could be used to evaluate the options.

In light of the criteria, the group suggested a preferred option, which was highlighted in the draft Policy Options Analysis paper. The working group's suggestion was supported by the External Advisory Panel. The draft paper was circulated for public comment in the fall of 1997. The preferred policy option received broad support among interested parties.

This document is the final Policy Paper.

3. REGULATORY CONTEXT

3.1 Canada

There are no regulations dealing specifically with nutraceuticals or functional foods. All foods and drugs fall under the provisions of the *Food and Drugs Act* and *Regulations*.

Under the *Act*, the "food" definition includes:

“any article manufactured, sold or represented for use as food or drink by man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.”

A "drug" includes:

“any substance or mixture of substances manufactured, sold or represented for use in

- ▶ (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
- ▶ (b) restoring, correcting or modifying organic functions in man or animal or,
- ▶ (c) disinfection in premises in which food is manufactured, prepared or kept;”

This latter definition does not specifically exclude foods or make any reference to the form of the product. Many of the claims proposed for functional foods/nutraceuticals are of the type that would normally be considered to bring the product within the definition of a drug. A few products of a form and composition resembling conventional foods have been authorized for sale as drugs, but these were exceptions.

Drug and food products must comply with all the quality and safety requirements of the *Food and Drug Regulations*. In addition to quality and safety requirements, drugs may be approved for sale if they meet the regulatory requirements for efficacy. Products sold which have been authorized for sale carry a Drug Identification Number (DIN) or General Public (GP) number on the label.⁶ Once a drug is on the market, a manufacturer must follow specific guidelines for submitting reports on any adverse reaction to the product.

3.2 International Situation

A description of the regulatory situation of several international jurisdictions is contained in Annex A.

4. ISSUES

4.1 Regulatory

The current regulatory environment is said to discourage innovation and marketing for nutraceuticals/functional foods. Under the *Food and Drugs Act*, only a specified range of claims may be made for foods; otherwise, they are classed as drugs. The food regulations currently permit:

- ▶ positioning the food as part of healthy eating

⁶ This number is located on the label of any drug product that has been approved for sale. It indicates that a product has undergone -- and passed -- a review of its formulation, labelling, and instructions for use.

- ▶ claiming that a nutrient or nutritive substance (as listed in the *Regulations*) is generally recognized as an aid or factor in maintaining the functions of the body, or necessary for the maintenance of good health and normal growth and development⁷ (also known as “biological role claims” and nutrient function claims).

Under the current regulatory framework nutraceuticals/functional foods appear to have an awkward fit. Although some may appear to consumers as ordinary foods, they are known to produce physiological effects. Others appear to be in a “drug-like” form however, some manufacturers are reluctant to consider them as such. There are several reasons why food producers generally want to avoid their products being treated as drugs.

One is the public perception that foods are consumed for “wellness” whereas drugs are necessary to fight “illness”. Moreover, drugs must meet numerous constraints, including stringent regulations governing Good Manufacturing Practices, testing procedures and post-market surveillance. The end result is that few manufacturers have even applied for Drug Identification Number (DIN).

Because of the dichotomy between foods and drugs, manufacturers of nutraceuticals/functional foods are faced with two choices: They can either market their product with no health claims, or they can follow the more stringent regulatory requirements necessary for drugs.

The first option restricts the manufacturer’s freedom to market the goods with health claims, and limits dissemination of information to consumers. The second option can delay a product’s entry onto the market, limit its advertising and potentially add to its cost.

For example, Section 3 of the *Food and Drugs Act* prohibits the sale or advertisement to the general public of any food, drug, cosmetic or device if it is represented as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A. Schedule A includes conditions such as alcoholism, arteriosclerosis, arthritis, asthma, cancer, diabetes, heart disease, hypertension, obesity, thrombotic and embolic disorders.

Subsection 5 (1), makes it an offence to make claims for a food that are false, misleading or deceptive or that may create an erroneous impression regarding the food’s character, value, quantity, composition, merit or safety. Subsection 9(1) creates the same offence for products in the drug category.

The restrictions imposed by Section 3 and the definition of a drug are becoming an issue. Considerable evidence has accumulated from epidemiology, clinical trials and modern nutritional biochemistry supporting the concept that diet does, in fact, affect human health -- not only in the

⁷ *Food and Drug Regulations*, sections B.01.311, D.01.006, D.02.004.

short term, but also in the development and management of chronic disease.

4.2 Definition of Health Claims

The term “health claim” is not defined in Canada. The internal working group, Panel members and stakeholders have decided to use the term in a broad sense. Under the United States *Nutrition Labeling and Education Act 1990* (NLEA), a health claim specifically characterizes the relationship between a nutrient and a disease or medical condition that is related to the diet.

To develop a more focussed definition for this country, the Health Canada internal working group identified the following three categories of “health claims”; therapeutic, risk reduction and structure/function. Definitions for these types of claims are given in Annex B.

Additionally, these claims would be regulated within a risk management framework. Details on the principles of managing risk and other related policy initiatives are presented in Annex C.

5. ANALYSIS OF OPTIONS

5.1 Context

The following are some statements of issues that surround the current discussions of a regulatory framework for nutraceuticals/functional foods:

- The scientific and public understanding of the health benefits that may be derived from foods has expanded in recent years. These benefits are now widely understood to include a reduction in the risk of developing chronic diseases and an improvement in overall health.
- With growing consumer awareness of the potential benefits of nutraceuticals/functional foods, there is a growing need for solid information. Information is required to better inform health professionals and the public about these products to explain what these products can and can not do for them.
- There is no consensus among stakeholders on what claims, if any, should be allowed. Some consumer organizations, for example, are opposed to health claims on products because they believe it may add to cost of the product without overall health benefit to the consumer.
- The terminology and definitions for nutraceuticals/functional foods are not consistent worldwide, and there are no international standards for regulation of nutraceuticals/functional foods to serve as baselines.

- Health claims on products that are truthful and not misleading, combined with effective consumer communication, could be useful in reinforcing healthy eating behaviours. However, the reception of consumers to health claims on foods is undergoing study.
- The different claims will require various levels of evidence. The quality of this evidence must be consistent.
- Health claims on foods and other nutrition education and health promotion tools would require a common scientific basis to provide consistent and credible messages to the public.
- Health claims on products should be established in the context of the total diet and other relevant lifestyle factors, such as physical activity, smoking, obesity and alcohol consumption.
- The addition of high doses of nutrients or other food components to a diet -- either through fortification or non-food sources such as nutrient supplements and over-the-counter pharmaceutical preparations -- may result in adverse health effects.
- Food manufacturers perceive the regulatory requirements for drug approval to be too onerous and inappropriate for most food products. These restrictions have hampered industrial competitiveness. Therefore, few applications have been made to authorize food products to make therapeutic claims.
- Overly stringent regulation of health claims could impair the communication to interested consumers of clear and valid food-health relationships by restricting the scope of acceptable messages.
- Canadian regulations and policies are approximately equivalent to the European Union and the Australia and New Zealand Food Authority, but are more restrictive than in the United States and Japan.
- The impact and cost of enforcement for new regulations is not known.

5.2 Options

There is a spectrum of policy options for the regulation of health claims for foods and food products, ranging from an unregulated environment to strict government controls of claims. The range of options is summarized below. For a detailed analysis of the advantages and disadvantages of each, please refer to Annex D.

i) ALLOW ALL TYPES OF HEALTH CLAIMS ON FOODS WITHOUT ANY REGULATION OF THE EVIDENCE REQUIREMENTS

Under this option, manufacturers and sellers of nutraceuticals/functional foods would not be obliged to provide evidence or health benefits, standardize their consumer messages, or submit products to Health Canada for review.

ii) ALLOW ALL TYPES OF HEALTH CLAIMS ON FOODS BUT WITH REGULATION

Allowing all types of health claims on foods results in food and food products that do not fit comfortably within the current definition of a food or drug under the *Food and Drugs Act*. Thus, under this option, a third category of products would need to be created under the *Food and Drugs Act*. Products in this new category would be allowed to make therapeutic claims, but exist separately from foods or drugs.

iii) PERMIT STRUCTURE/FUNCTION AND RISK REDUCTION CLAIMS FOR FOOD PRODUCTS; CONTINUE TO REGULATE PRODUCTS WITH ALL OTHER HEALTH CLAIMS AS DRUGS

Under this scenario, food products could have claims that affect structures/function, or that reduce the risk of developing an illness or condition, provided they complied with appropriate standards of evidence for composition. Products with therapeutic health claims (said to cure, treat, mitigate or prevent a condition) would continue to be regulated as “drugs” under the current definition in the *Food and Drugs Act*. This model would require the development of a new regulatory framework to permit claims on foods. It would also demand the establishment of appropriate standards of evidence and composition for claims on foods, as well as measures to ensure compliance.

iv) PERMIT STRUCTURE/FUNCTION CLAIMS FOR FOOD PRODUCTS; CONTINUE TO REGULATE PRODUCTS WITH ALL OTHER HEALTH CLAIMS AS DRUGS

This model is similar to option iii, but more restrictive. It would allow only structure/function claims to be made for food and food products. As before, appropriate standards of evidence would apply. A regulatory framework would be required to permit claims for foods and to ensure compliance. Products with all other health claims would continue to be regulated as “drugs” under the existing definition in the *Food and Drugs Act*.

v) PERMIT RISK REDUCTION CLAIMS FOR FOOD PRODUCTS; CONTINUE TO REGULATE REMAINING HEALTH CLAIMS AS DRUGS

This option is a variation on option iv. It would allow foods to bear risk reduction claims with

appropriate standards for composition and evidence. This option too would require the development of a regulatory framework to permit claims for foods and ensure compliance. Products with all other health claims would continue to be regulated as “drugs” under the current definition in the *Food and Drugs Act* except for the current exemptions which exist for structure/function claims.⁸

vi) REGULATE ALL PRODUCTS WITH HEALTH CLAIMS, INCLUDING FOODS, AS DRUGS (*STATUS QUO*)

As in current practice, this option would require all products making health claims to be regulated as drugs. This means all claims must be supported by scientific evidence. Because the current *Food and Drugs Act* and related regulations would not be changed, the existing exemption will continue to apply to established structure/function claims.

vii) REGULATE PRODUCTS ON THE BASIS OF INGREDIENTS OR PHYSIOLOGICALLY ACTIVE COMPONENTS

This model would call for the design of a new regulatory system that would assess products on the basis of their ingredients or physiologically active components rather than by product category. Product evaluations would therefore examine the type of action, the concentration and the toxicity of active components or ingredients, rather than relying on the regulation of the food or drug by definition or form.

viii) PROHIBIT HEALTH CLAIMS ON FOODS

This model, the most restrictive of the options, would prohibit all health claims for foods.

6. FINAL POLICY DECISION

Structure/function and risk reduction claims for foods should be permitted, while all other products claiming to cure, treat, mitigate or prevent illness should continue to be regulated as drugs.

This policy should allow structure/function claims and risk reduction claims for food and food components; appropriate standards for evidence and composition would be required. This model would require the development of a modified regulatory framework to ensure compliance.

Products with claims to cure, treat, mitigate or prevent illnesses would continue to be regulated as

⁸ See Guide to Food Labelling and Advertising, Agriculture and Agri-Food Canada, Page VII - 10.

“drugs”, regardless of their form, under the current definition in the *Food and Drugs Act*.

For implementation the model would require an exemption by regulation for products with structure/function and risk reduction claims.

Under this regime, the requirements for supporting evidence and other controls on food products with claims would be likely to vary, depending on the risk-benefit profile of the product submitted for review. This would be consistent with the principles and practices in place and under development for therapeutic products.

An analytical framework for the recommendation is outlined in Annex E.

7. NEXT STEPS

- Communicate this policy to stakeholders and make it available to the House of Commons Standing Committee on Health;
- develop an implementation strategy in conjunction with stakeholders;
- establish working groups to develop standards of evidence , in consultation with stakeholders, for nutraceuticals/functional foods; and,
- initiate regulatory changes in accordance with Treasury Board policy.

ANNEX A. International Situation

United States

In the United States, health claims may be made for foods and dietary supplements in accordance with the 1990 *Nutrition Labelling and Education Act* (NLEA) and the 1994 *Dietary Supplements Health and Education Act* (DSHEA), an amendment to the *Food, Drug and Cosmetic Act*.

The NLEA clarified and strengthened the authority of the Food and Drug Administration (FDA) to require nutrition labelling on foods and to establish the circumstances under which claims may be made about nutrients in foods.

The legislation also provided a process for the orderly regulation of disease claims. The Act states:

"The Secretary shall promulgate regulations authorizing claims [characterizing the relationship of a nutrient to a disease or health-related condition which is diet-related] only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."⁹

The options for establishing a legitimate basis for health claims were expanded in 1997 with the passage of the *Food and Drug Administration Modernization Act*. Health claims may now be approved on the basis of authoritative statements from certain federal agencies in the Department of Health and Human Services and the Department of Agriculture, and from the National Academy of Sciences or any of its subdivisions. Under the new terms, manufacturers must notify the FDA at least 120 days before introducing a food with a label that makes a health claim. If, during this period, the FDA finds the notification incomplete, or issues a ruling denying or modifying the claim, the claim may not be made.

Ten claims have so far been approved under this modernized regime. For example, one authorized claim links a diet containing fruits, vegetables, and grain products containing fibre (particularly soluble fibre) with a reduced risk of coronary heart disease.

In 1994, the *Dietary Supplements Health and Education Act* (DSHEA) allowed for the use of "structure and function" claims, which describe "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans."

⁹ Nutrition Labelling and Education Act of 1990. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (Internet address: <http://vm.cfsan.fda.gov/~lrd/newlabel.html>).

Under this legislation, structure and function claims for dietary supplements require post-market notification, with manufacturers obliged to substantiate their claims. The following disclaimer on the label is also required: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.”

To market a dietary supplement containing an ingredient not sold prior to 1994, a producer must notify the FDA 75 days before putting the product on store shelves. The notification must include information supporting the safety of the ingredient. If the FDA feels a product may be harmful, it bears the onus of proving the danger.

A Presidential Commission on Dietary Supplement Labels was appointed to examine issues related to the labelling of dietary supplements following introduction of the DSHEA legislation. In its report of November 1997, the Commission recommended ways to regulate label claims for dietary supplements, including the use of publications or advertisements in connection with the sale of dietary supplements and procedures to properly evaluate claims. The Commission report emphasized the need for public access to the evidence on which label statements are based so that consumers can make informed decisions about the use of dietary supplements.¹⁰

The FDA has recently published proposed rules flowing from recommendations of the Commission on Dietary Supplement Labels¹¹. These rules would define the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. They also establish criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat or prevent disease.

A fact sheet, issued in April 1998, clarified for manufacturers the types of claims they may use on labels for dietary supplements under the DSHEA.¹² The FDA published a response to the recommendations, agreeing and proposing appropriate initiatives in response to the Fact Sheet dated April 27, 1998.¹³

The legal obligations for dietary supplements do not apply to structure and function claims made for nutrients in conventional foods. Under the DSHEA, such claims may be made for nutrients

¹⁰ Report of the Commission on Dietary Supplement Labels. Commission on Dietary Supplement Labels. November 1997.

¹¹ Food and Drug Administration. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. Proposed Rule. Federal Register 63(82):23624-23632, April 29, 1998.

¹² FDA Fact Sheet: FDA's Dietary Supplement Proposal. U.S. Food and Drug Administration, April 27, 1998 (http://www.fda.gov/bbs/topics/FACTSHEETS/fs_diet1.html).

¹³ Federal Register 63(82):23633-23637, April 29, 1998.

and “dietary ingredients”. For example, a manufacturer may claim that “calcium helps to build strong bones and teeth” without being subjected to the regulatory process.

Japan

Under the Japanese Nutrition Improvement Law, there are five categories of "Foods for Special Dietary Uses," including "Foods for Specified Health Use" or "FOSHU". Certain foods are considered by the Japanese to have beneficial ingredients. For example, dietary fibre, sugar alcohols, oligosaccharides, proteins, polyphenols, lacto- or bifido-bacilli, chitosan and sodium alginate are considered to help maintain good health. The FOSHU law regulates the marketing and labelling of products containing these ingredients.

Unlike American “dietary supplements”, such products must be in a food form that can be integrated into the diet. After regulatory review, these foods carry a label indicating the specified health benefit. For instance, some of these products claim to play a role in dental care, control cholesterol, blood sugar or blood pressure, promote healthy intestines, or promote the absorption of minerals. The approval of the Ministry of Health and Welfare must also be displayed on the label of FOSHU food products.¹⁴

Australia and New Zealand Food Authority (ANZFA)

In Australia and New Zealand health claims for foods are generally prohibited unless specifically prescribed by the *Food Standards Code*. However, the Australia and New Zealand Food Authority (ANZFA) has prepared a discussion paper aimed at promoting public discussion of the issues.

Since August 1997, ANZFA has been assessing a proposal to permit certain properly substantiated health claims to be made for qualifying foods.

Meantime, a regulatory initiative is being introduced to permit a pilot health claim on specified foods.¹⁵ The scientifically substantiated claim would link peri-conceptional maternal intakes of the B-group vitamin folate with a reduction in the incidence of neural tube defects (such as spina bifida) in babies.

¹⁴ A Quick Guide to: Food for Specified Health Use. The Japan Health Food and Nutrition Food Association 6th Floor, Food Sanitation Center, 6-1, 2-Chome, Jingumae, Shibuya-Ku, Tokyo 150, Japan.

¹⁵ Statement of Reasons, Proposal P170, For Recommending a variation to Standard A1(19) to enable a Pilot of a Health Claims Management Framework, May 13, 1998.

An evaluation of the impact of this pilot claim would then help ANZFA conclude its deliberations on the broader health claims issue. Final recommendations by ANZFA are expected in 1999.

European Union (EU)

Member states of the European Union are governed by one directive for products with specific therapeutic claims. Products with non-therapeutic claims are regulated independently by member states. Currently each member of the European Union has its own set of legislation and regulations governing what are popularly known as “health foods.” (The term “functional foods” is used mostly by industry.)

In general, however, health claims are not permitted on labels for foods or functional foods, although nutritional claims are permitted if they are indicated through proper labelling. Enforcement, however, tends to vary among member states, leading to uncertainty and risk for manufacturers attempting to sell their products across borders.

In an effort to modernize the rules governing these and related matters, a discussion document entitled “General Principles of Food Law in the European Union” was circulated for review by member states and stakeholders in July 1997.¹⁶ The aim of the paper was to measure the extent to which existing legislation meets the needs and expectations of consumers, producers, manufacturers and traders; to consider measures to reinforce official control and inspection systems governing a safe and wholesome food supply; and to launch a public debate on European Union food legislation.

Most member states favoured harmonization of claims and called on the EU to draft a basic framework directive.¹⁷ An annex to the directive would list claims that are scientifically justified, generally uncontested and necessary for the consumer’s information. The work done by *Codex Alimentarius* [see next section] was proposed as a starting point.

During discussions on the claims issues, stakeholders recommended that authorities should focus their efforts principally on post-market evaluation. However, many consumer organizations argued against specific health claims, on the grounds that there are no good or bad foods.

¹⁶ Excerpt from “Summary of the Comments Received on the Commission Green Paper The General Principles of Food Law in the European Union” (<http://europa.eu.int/en/comm/dgiii/publicat/consumer/foodcom.pdf>)

¹⁷ The difference between an EU “Directive” and a “Regulation” is that a Regulation has the direct force of law in each Member State, whereas a Directive requires each Member State to amend its laws as needed to conform with its terms.

November 2, 1998

Codex Alimentarius

The Codex Alimentarius Commission, the intergovernmental food standards setting organization, of which Canada is one of 162 member countries, has recently reviewed the issues of nutrition and health claims.

Draft Recommendations for the Use of Health Claims were originally combined with *Draft Guidelines for the Use of Nutrition Claims*. The Codex Committee on Food Labelling, the general subject committee dealing with food labelling, could not agree on the health claims portion at the 25th Session, held in May, 1997. The nutrition claims portion was adopted at the 22nd Session of the Codex Alimentarius Commission, held in June, 1997. The health claims portion was referred back to the Codex Committee on Food Labelling for further consideration.

At the most recent session of the Codex Committee on Food Labelling (26th), held in May, 1998, the *Draft Recommendations for the Use of Health Claims* were discussed at the 1st level of the Codex process. The Committee decided to refer the draft guidelines to the Codex Committee on Nutrition and Foods for Special Dietary Uses for review of the scientific basis for health claims. This latter committee will meet again in the fall, 1998.

ANNEX B. Definition of Claims

Therapeutic

Claims that a product can *cure*¹⁸/*treat*¹⁹/*mitigate*²⁰/*prevention*²¹ a disease or condition fall into the "therapeutic"²² claims category.

At present, the words "treat" and "mitigate" are mentioned in the definition of a "drug", as well as Section 3 in the *Food and Drugs Act*, but the terms are not themselves defined. The word "cure" appears only in Section 3 of the Act, in relation to the types of claims that cannot be made when selling or advertising a product to the general public.

The term "prevention" is included in both the drug definition and Section 3 of the *Act*. Such a claim is permitted when evidence shows that a factor or product can provide protection, or act to prevent a disease, for a specific individual, or that it could control the progress of a disease.

Therapeutic claims may be generic or product specific (see definition of Risk Reduction below).

Risk Reduction

Risk reduction could be defined as significantly altering a major risk factor or factors recognized to be involved in the development of a chronic disease or abnormal physiological condition through product use. Risk reduction claims would be product specific or generic:

! PRODUCT SPECIFIC

Product-specific claims are made for a single commercial product. They could not be generalized to other similar products unless acceptable supporting evidence was

¹⁸ Cure meaning "restoration to health". The Concise Oxford Dictionary, Ninth Edition.

¹⁹ Treat means "the application of medical care or attention to a patient". *Ibid.*

²⁰ Mitigate means to "make milder or less intense or severe; moderate." *Ibid.*

²¹ Prevent is defined as "stop from happening or doing something; hinder; make impossible." *Ibid.*

²² Therapeutic meaning "of, for, or contributing to the cure of disease." *Ibid.*

provided.

! GENERIC CLAIMS

Generic claims may be applied to any food, provided that it meets the criteria for the claim.

Structure/Function

The term “structure/function claim” derives from the U.S. *Food, Drug and Cosmetic Act*. In the Act, drugs are defined as “articles (other than food) intended to affect the structure or any function of the body of man or other animals”. The term is also used in the U.S. *Dietary Supplement Health and Education Act*, which authorizes claims describing “the role of a nutrient or dietary ingredient intended to affect the structure or function in humans.”

Claims about the biological roles of nutrients could be considered as a type of structure/function claim. In Canada, such claims are permitted for generally recognized roles of nutrients in the maintenance of good health and normal growth and development.²³

Structure/function claims may be generic or product specific. (See definition of risk reduction above.)

²³ See Guide to Food Labelling and Advertising, Agriculture and Agri-Food Canada, Page VII - 10.

ANNEX C. Risk Management Framework and Related Policy Initiatives

Risk Management Framework

Health products on the Canadian market are regulated in relation to their benefits and the risks they present. The sponsor evaluates the benefits and risks of their product. It is the role of the regulatory system to validate the sponsor's findings by evaluating the sponsor's submission.

A regulatory structure can have an impact on the accessibility of these products and on the economic well-being of consumers, practitioners and industry.

The conceptual framework underlying the regulatory structure must, first and foremost, ensure the health and safety of Canadians, without presenting an undue barrier to the competitiveness of industry.

When a product is claimed to have an impact on health, two elements of risk are involved. First, the product or its ingredients could have direct adverse effects on the consumer. Second, if the claim is untrue, or improperly described, the consumer may use the product in a way that compromises his or her well-being.

The level of risk posed by products such as nutraceuticals/functional foods varies widely and depends on many factors. These could include the ingredients of the products, and the way they are used by the consumer. It is a fundamental principle that products -- including nutraceuticals and functional foods making health claims -- must be managed and regulated in keeping with the degree of risk they pose.

Models for evaluating food products with health claims are given below. Food products with therapeutic claims will be regulated under the Product Licensing Framework of the Therapeutic Products Programme. The regulation of food products with risk reduction and structure/function claims will be handled by the Food Directorate.

Product Licensing Framework (PLF)

To streamline the review and approval process for therapeutic products (drugs and medical devices) in Canada, the Therapeutic Products Programme of Health Canada has proposed an approach called the Product Licensing Framework.

The PLF has two major components:

- ▶ pre-market categorization, submission requirements, license and reporting requirements
- post-approval surveillance, licence renewal and amendment of reporting requirements.

Under the PLF process, the level of data submission and review for a drug product is directly linked to two factors:

- ▶ the Therapeutic Products Programme's prior knowledge of the safety, quality and efficacy of the product and
- ▶ identified safety, quality or efficacy concerns.

Sponsors of products for which there is extensive prior knowledge, would provide attestation to compliance with a Class Monograph.²⁴

However, drug products with which the Therapeutic Products Programme has little or no prior experience, or products that have identified safety, quality or efficacy issues, will require comprehensive data submission and review. These requirements ensure that the Therapeutic Products Programme is provided with the data necessary to make benefit/risk decisions related to the wide spectrum of products it regulates.

Food Product Evaluation

Food products do not require pre-market evaluation unless they are infant formulas, food additives, irradiated foods or they are considered "novel" (see below). However, manufacturers must abide by the *Food and Drug Regulations* which includes ensuring that their products are safe and are not sold in a misleading or deceptive manner. They may only use ingredients that are permitted by standards, if they exist for that food, and they may only use food additives that are approved and listed in the *Food and Drug Regulations*. They are also restricted with respect to the addition of vitamins, mineral nutrients, and amino acids. Manufacturers must not allow contaminants to exceed maximum limits.

Determining health risks associated with the food supply and developing national strategies to manage them is one of the primary responsibilities of the Health Canada Food Programme. Determining health benefits that may accrue by consuming certain foods and developing strategies to encourage consumers to adopt practices that lead to those benefits is another responsibility. The regulation of claims for risk reduction and for effects on structure or function of the body would come effectively under both those umbrellas. The Food Programme will base all policy development and standard-setting on sound risk/benefit assessment. A standard procedure will be put in place to ensure consistency in conducting risk and benefit assessments both within the Programme and between Food and Therapeutic Products where appropriate.

²⁴ For more details see "Product Licensing Framework III", June 1998. Therapeutic Products Programme, Health Canada (<http://www.hc-sc.gc.ca/hpb-dgps/therapeut/>).

Novel Foods

A proposal published in *Canada Gazette*, Part I, in August 1995 introduced the concept of regulatory requirements for “novel foods”. Although the scope and definition of these foods are currently being established, novel foods are intended to encompass those which have not been previously offered for sale in Canada. These would include foods derived from genetically modified organisms. Nutraceuticals/functional foods may, at times, fit within this definition.

The proposal suggested that novel foods be subject to pre-market notification. This means that manufacturers would need to demonstrate to the satisfaction of Health Canada that the products proposed for sale in Canada meet adequate safety, quality and nutrition standards.

The requirements for pre-market notification are currently outlined in the *Guidelines for the Safety Assessment of Novel Foods*, Vol. I and II²⁵. Although the guidelines are voluntary, the food industry is generally abiding by them. Re-publication in *Canada Gazette* Part I of the proposed amendments mentioned above that would require manufacturers to notify the Branch before marketing a novel food is now expected early this fall.

Evidence Requirements

If a product is said to have a health benefit, then that claim must be supported by reasonable evidence to demonstrate its efficacy. Under the risk-management framework for product regulation, the standard of evidence must be proportionate to the degree of risk.

For example, a claim that Product X will cure bone cancer (a “therapeutic” claim) would require the highest standards of evidence. However, a claim that Product Y will enhance gastrointestinal function (a “structure/function” claim) could involve a lower standard of evidence.

In these examples, three factors come into play in determining the evidence requirements. They are:

- ▶ the seriousness of the disease (bone cancer versus gastrointestinal function);
- ▶ the strength of the claim (cure versus enhanced function); and
- ▶ the varying chemical complexity among foods and therapeutic products.

Taken together, these factors influence the degree of risk to the consumer. All products must meet requirements for safety and quality. The additional hurdle for products which make claims is

²⁵ Further information can be found at: www.hc-sc.gc.ca/datahpb/datafood/english/.

the requirement to prove efficacy.

Evidence requirements will be addressed in detail in the next phase of the regulatory process.

Other Related Policy Reviews

Several related policy development processes and regulatory initiatives are being conducted by Health Canada. These include

- ▶ review of the regulation of herbal remedies and other natural health products;
- ▶ consideration of regulatory requirements for vitamins and mineral supplements in non-prescription drug products, homeopathic preparations and foods; and,
- ▶ evaluation of nutrient content claims, nutrition labelling, and the implementation of new Dietary Reference Intakes.

Information on these projects is available on the Health Canada web site (www.hc-sc.gc.ca).

ANNEX D. Detailed Analysis of Options

This section summarizes the advantages and disadvantages of each of the eight options listed in section 5.2 above. These issues were taken into account by the internal working group in arriving at its preferred option.

- i) **ALLOW ALL TYPES OF HEALTH CLAIMS ON FOODS WITHOUT ANY REGULATION OF THE EVIDENCE REQUIREMENTS**

This option would permit health claims on foods, without requirements for evidence, standardization of messages, or approval by the federal government. Participation by producers and sellers would be voluntary.

Advantages

- may be a net benefit to the health of Canadians, who are generally becoming more knowledgeable about food and nutrition.
- is consistent with a growing consumer interest in receiving information on such products
- may reduce government liabilities and enforcement costs

Disadvantages

- may be inconsistent with risk management principles
- could represent a departure from the principle of protecting the public from deceptive and misleading claims and products
- has the potential for a measurable, detrimental impact on the health of individuals and possibly the Canadian health care system itself if improperly applied
- because standards and supporting evidence would not be required for claims, product quality and messages may be inconsistent
- potentially unreliable claims could compromise effective measures to promote good health and nutrition
- misleading advertising resulting from unclear policy and standards could compromise the health of Canadians and the credibility of manufacturers and the government.
- liability of manufacturer/seller could increase.
- may have a negative impact on trade if standards of evidence for claims vary among regulatory jurisdictions.
- is inconsistent with existing regulations for therapeutic products, which could complicate therapeutic product enforcement

- ii) **ALLOW ALL TYPES OF HEALTH CLAIMS ON FOODS BUT WITH REGULATION**

Under this model, health claims would be allowed on foods, provided they met regulated standards. A specific regulatory regime would be created for these products, which would be a third category, distinct from foods and drugs. Products in this new category could bear therapeutic claims that adhered to their own class of standards.

Advantages

- addresses the frustration of industry by developing a new category of product that better balances the risks and benefits of health claims for products other than drugs
- may be perceived by stakeholders as a move towards harmonization since the *Dietary Supplements Health Education Act* of the United States establishes a dietary supplement category as a sub-category of foods
- is consistent with current efforts to provide consumers with more information

Disadvantages

- a “third” product category, distinct from foods and drugs, would need to be well defined
- a “third” category may cause consumer confusion.
- health promotion programs and dietary guidance would require modification
- may be viewed by the public as a relaxing of the current regulatory system, compromising credibility of manufacturers and government
- trade issues would have to be taken into account
- dietary supplements in the United States are not permitted to carry claims related to the diagnosis, mitigation, treatment, cure or prevention of disease

iii) PERMIT STRUCTURE/FUNCTION AND RISK REDUCTION CLAIMS FOR FOOD PRODUCTS; CONTINUE TO REGULATE PRODUCTS WITH ALL OTHER HEALTH CLAIMS AS DRUGS

This model would allow structure/function claims and risk reduction claims for food products, provided they were backed with appropriate standards for evidence and composition. Products with all other health claims would continue to be regulated as “drugs” under the current definition in the Food and Drugs Act. This option would require the establishment of appropriate standards of evidence for foods with claims, and the development of a regulatory framework to permit claims and ensure compliance.

Advantages

- valid claims would provide more information to help consumers make nutrition choices
- claims on food products would serve as an excellent educational resource and enable Canadians to improve their diets

- Health Canada would be implementing a key strategy that promotes health and recognizes the importance of diet and lifestyle to health.
- model would offer some protection to consumers by requiring a more rigorous process and supporting evidence for more serious levels of claims
- would provide consistent standards for claims and wording
- could eliminate many of the barriers facing manufacturers who wish to place health claims on food products
- could open doors to trade
- could enhance research and development of beneficial products in Canadian universities, industry and government
- is similar to the direction Japan has taken

Disadvantages

- may require modification to health promotion strategies
- structure/function claims may be unclear to consumers unless there is a meaningful endpoint against which consumers could measure the benefit of the action

iv) PERMIT STRUCTURE/FUNCTION CLAIMS FOR FOOD PRODUCTS; CONTINUE TO REGULATE PRODUCTS WITH ALL OTHER HEALTH CLAIMS AS DRUGS

Allow foods to carry product-specific and generic structure/function claims with appropriate standards. Products with all other health claims would continue to be regulated as “drugs” under the current definition in the Food and Drugs Act. This would require the development of a regulatory framework to permit claims for foods and to ensure compliance.

Advantages

- would have consistent standards for evidence and claim wording
- allowing structure/function claims and related advertising would provide more information to consumers
- some incentives for research and trade could result

Disadvantages

- is overly restrictive
- is inconsistent with risk management principles
- prohibiting risk reduction claims is inconsistent with the direction other regulatory jurisdictions are considering and may hinder harmonization
- nutrition education tools would need to be modified
- raises questions regarding when a structure function claim effect is a food property or a drug property and thus whether the claim could be misconstrued as a therapeutic or

disease risk reduction claim without sufficient support for the conclusion.

v) **PERMIT RISK REDUCTION CLAIMS FOR FOOD PRODUCTS, CONTINUE TO REGULATE REMAINING HEALTH CLAIMS AS DRUGS**

Allow risk reduction claims for foods, provided there are appropriate standards for composition and evidence. Products with all other health claims would continue to be regulated as “drugs” under the current definition in the Food and Drugs Act except the current exemptions for structure function claims.²⁶ This would require the development of a regulatory framework to permit claims for foods and ensure compliance.

Advantages

- allowing risk reduction claims and related advertising would give consumers more information
- some incentives for research and trade could result
- there would be consistent standards for evidence and claim wording, resulting in protection against fraudulent products and claims

²⁶ See Guide to Food Labelling and Advertising, Agriculture and Agri-Food Canada, Page VII - 10.

Disadvantages

- hinders harmonization with trading partners
- is inconsistent with the risk benefit model, in which structure function claims are ordinarily considered to be the lowest risk.
- requires modification of nutrition education tools

vi) REGULATE ALL PRODUCTS WITH HEALTH CLAIMS, INCLUDING FOOD PRODUCTS, AS DRUGS (*STATUS QUO*)

Maintain existing formal practices where all products with data-supported/evidence-based claims (cure, treat, mitigate, prevention, risk reduction and structure function) are regulated as a "drug" under the current definition in the Food and Drugs Act. Maintain current exemptions for established structure function claims.

Advantages

- makes use of well established procedures and standards, defined internationally, to determine safety, efficacy and quality of drugs.

Disadvantages

- may not address the need for information to consumers
- may be incompatible with the emerging goals of the food industry
- is considered inflexible
- may deter market entry of new food products with health claims
- makes demands on product control and other standards that are difficult or impossible for foods to meet
- advertising to the general public is restricted to diseases not listed in Schedule A of the *Act*+
- limits trade since it is inconsistent with the direction other jurisdictions have taken.
- does not create research incentives
- is inconsistent with risk management principles

vii) REGULATE PRODUCTS ON THE BASIS OF INGREDIENTS OR PHYSIOLOGICALLY ACTIVE COMPONENTS

Design a new regulatory system that would regulate products on the basis of ingredients or physiologically active components rather than by product category. The model would examine the type of action, concentration and toxicity of the component or ingredient, rather than relying

on the traditional classification of a food or a drug.

Advantages

- would provide consistent standards for claims because they are based on ingredients/active components rather than product categories
- establishes clear definitions of claims
- could eliminate what is perceived as an inflexible regulatory system.
- eliminates the perception that a regular “food” may not serve a function
- provides consumers with more information

Disadvantages

- creation of a new regulatory system would be a lengthy process.
- model is unlike any other regulatory system and because standards would differ among jurisdictions, trade barriers could result
- unclear distinction between food and drugs may contribute to consumer confusion
- wide availability of ingredients would limit industry interest in investing in health-related research

viii) PROHIBIT HEALTH CLAIMS ON FOODS

Prohibit all health claims for foods.

Advantages

- none identified.

Disadvantages

- would be more restrictive than the *status quo* since it would prohibit advertising of claims that are currently permitted
- foods could not carry claims, even if a DIN is applied for
- is inconsistent with current interest in providing consumers with more information
- conflicts with regulatory models in Japan and the United States, resulting in probable trade restrictions and limits on research

ANNEX E. Analytical Framework

Below is the analytical framework for the recommendation described in Section 6.

Table 1. Analytical Framework for Health Claims for Nutraceuticals/ Functional Foods

	STRUCTURE/ FUNCTION CLAIMS ^a	RISK REDUCTION CLAIMS		THERAPEUTIC CLAIMS ^{a,b}
		PRODUCT SPECIFIC	GENERIC	
DEFINITION	Asserts the role of a nutrient or other dietary component intended to affect a specific structure or physiological function in humans.	Asserts a relationship between a specific food product and a reduced risk of a disease or condition.	Asserts a relationship between a nutrient or other dietary component in a diet, and a reduced risk of a disease or condition.	Asserts a relationship between a nutrient or other dietary component and the cure, treatment, mitigation or prevention of a disease, disorder or abnormal physical state.
TARGET GROUP	General population and sub-groups	General population and sub-groups	General population and sub-groups	Specific individuals with a disease (cure/treat/mitigate) General populations and sub-groups (prevention)
Regulatory Mechanism	Exemption by Regulation for Food	Exemption by Regulation for Food	Exemption by Regulation for Food	<i>Food and Drug Regulations</i> - as at present
Standards of Evidence	To be developed	To be developed	To be developed	As outlined in <i>Food and Drug Regulations</i>

^a Generic and product-specific claims may be applicable here.

^b Includes prevention claims.