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Product-Specific Authorization of Health Claims for Foods

A PROPOSED REGULATORY FRAMEWORK



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

October 2001

Canada

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Health Canada

Product-Specific Authorization of Health Claims for Foods A Proposed Regulatory Framework

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1. INTRODUCTION

1.1 About this document

This document invites comments and suggestions from Canadians on a proposed approach to regulating product-specific health claims for foods. Comments received in response to this proposed regulatory framework will be considered in drafting proposed regulations to be published in the Canada Gazette Part I.

This document has been posted on the Health Canada Food Program web site (http://www.hc-sc.gc.ca/food-aliment/english/subjects/health_claims/) and distributed to major stakeholder groups who have expressed an interest in the subject through previous contacts with the Food Directorate of the Health Products and Food Branch of Health Canada.

1.2 About this proposed regulatory framework

The approach to regulating health claims for foods proposed in this document may be referred to as “product-specific authorization”. We propose that a food that is manufactured, sold or represented to have a direct, measurable effect on a body function or structure beyond normal growth and development or maintenance of good health (previously termed “structure/function claims”) be required to submit detailed information to support such an effect before being advertised or offered for sale. The conditions which must be met before a food could be authorized to carry a claim or a representation conveying such an effect are outlined in this proposal. An authorized claim would be identified by a Claim Identification Number that would be displayed in product labelling. Authorization would be granted on a product-by-product basis without claim-specific regulatory amendments.

1.3 How this proposal differs from that for diet-related health claims for foods

This proposal differs in several respects from the “generic authorization” regulatory approach proposed for diet-based “risk reduction claims” contained in Schedule No. 1172 and published in Canada Gazette Part I on June 16, 2001. Under generic authorization, an entire food group may be the subject of a claim, for example, “a healthy diet rich in a variety of fruits and vegetables may help reduce the risk of some types of cancer”. A food that has compositional characteristic(s) that contribute to a dietary pattern associated with reducing the risk of a disease or health condition may carry an authorized claim. An authorized claim would be listed in the *Food and Drug Regulations* through a regulatory amendment process. The conditions for carrying a particular authorized claim in food labelling and advertising, including product

composition and labelling, would be specified in the regulations. Once a claim is authorized, any food that meets the specified conditions for composition and labelling may carry the claim without further assessment. The list of authorized claims in the regulations could be amended through submissions.

Annex A compares the two approaches to regulating health claims for foods.

2. IMPLEMENTATION OF POLICY ON HEALTH CLAIMS FOR FOODS

2.1 Progress to date

Health Canada published a policy recommendation on health claims for foods in November 1998 following two years of consultation on the issue (<http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/ffn.html>). The policy recommended that structure/function and risk reduction claims be permitted for foods and the claims may be generic or product-specific. The policy review was initiated in response to representations from interested parties who are concerned that the current *Food and Drugs Act* restricts the nature and extent of health information that may be communicated on the food label and in advertising. The scientific understanding of the relationships between diet and disease has progressed greatly in the past decades. With this growing scientific evidence supporting the important role of diet in modifying the risks of some chronic diseases, there is increasing consumer and marketing interest in nutrition and health.

This policy recommendation is intended to provide more opportunities for communicating information about the role of diet in disease risk reduction and the health benefits of foods to consumers in labelling and advertising. To implement this policy, the Food Directorate of Health Canada has initiated the following steps:

- A consultation document on *Generic Health Claims for Foods* was published in August 2000 (http://www.hc-sc.gc.ca/food-aliment/english/subjects/health_claims/consultation_doc_gen.html) following an initial analysis of the issues and extensive review of the scientific basis of the proposed claims. The document outlines five generic diet-based disease risk reduction claims being considered for adoption in Canada. Proposals for elements and conditions for use of the claims under consideration were presented. Regulatory amendments concerning the five diet-related claims were published in Canada Gazette Part I on June 16, 2001.

- A consultation document on *Standards of Evidence for Evaluating Foods with Health Claims: A Proposed Framework* was published in June 2000 (http://www.hc-sc.gc.ca/food-aliment/english/subjects/health_claims/Consultation_doc_en.pdf). It presents proposals for ensuring that foods with health claims are supported by appropriate evidence with respect to product safety and claim validity, as well as quality assurance of the product and of the procedures and methods for testing the product. A synopsis of the consultation comments received and Health Canada's response and a guidance document will be published on the Food Program web site.

2.2 Legislative framework in Canada governing health claims on foods

All foods and drugs are regulated under the provisions of the *Food and Drugs Act* and its *Regulations* in Canada. The expression "health claim" is not defined, nor is it used in the current legislation. For the purposes of this discussion, "health claim" refers primarily to any claim that relates to paragraph (a) or (b) of the definition of a drug set out in section 2 of the *Food and Drugs Act* (described below), including any claim about reducing the risk of developing a disease or health-related condition.

In section 2 of the *Act*, "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.

Therefore, under the *Act*, a claim for a food that relates to any aspects of the above drug definition will result in the food falling within the meaning of the term "drug". The proposed regulatory framework is designed to exempt foods bearing certain "drug-like health claims" from the provisions of the *Food and Drugs Act* and its *Regulations* relating to drugs and to maintain them under the provisions of the *Act* and *Regulations* relating to foods in order to manage the health risks usually associated with foods.

Section 3 and Schedule A diseases

By virtue of Section 3 of the *Food and Drugs Act*, no person may advertise, sell, or represent by label, any food, drug, cosmetic or medical device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the *Act*. Diseases listed in Schedule A are generally those for which professional medical diagnosis and treatment are recommended.

In the case of the proposed diet-based “risk reduction claims” published in the Canada Gazette Part I on June 16, 2001, Section B.01.600 (proposed) exempts a food bearing a claim set out in that regulation from the provisions of section 3. Claims may thus be proposed for reduction in risk of heart disease, cancer and high blood pressure - all diseases listed in Schedule A. Without this specific exemption, claims for “Schedule A diseases” cannot be made. On the other hand, in the case of product-specific health claims, the authorization of each claim would not entail a claim-specific regulation and claims for “Schedule A diseases” would not be permitted.

2.3 Need for regulatory oversight

Foods with health claims that would fall under this proposed regulatory framework are those that have specific effects on a structure or function of the body, which may be indistinguishable from the effects of some drugs. Therefore, regulations are required to:

- (1) Ensure that foods carrying health claims are subject to food regulations so that health concerns usually associated with foods could be managed using risk management regimes appropriate for foods. Health concerns associated with foods include microbiological and chemical safety, as well as nutritional quality;
- (2) Prevent injury to health and misleading claims by:
 - a) requiring premarket assessment with respect to product safety, claim validity and quality assurance of foods carrying health claims that trigger the drug definition,
 - b) specifying the conditions of approving foods with health claims, including premarket assessment, and requirements respecting labelling, advertising and sale in facilitating the safe use of the product, where warranted.

The proposed regulatory framework responds to the views of consumers and health professionals who commented on the consultation on standards of evidence for evaluating foods with health claims. These stakeholders support the need for premarket review as part of a regulatory system based on strict standards.

3. KEY ELEMENTS OF PROPOSED REGULATORY FRAMEWORK

The proposed regulatory framework is based on the recognition that the regular consumption of a reasonable quantity of a specific food containing a biologically active substance could have a direct, measurable effect on a physiological function or structure of the body.

3.1 Application

- (1) The proposed regulatory framework would apply to all foods and beverages, with or without modification or fortification, that are:
 - a) in a form readily recognizable to consumers as being food products,
 - b) consumed to provide nourishment, nutrition, or hydration, or satisfy hunger or thirst or a desire for taste, texture or flavour under customary conditions of use or according to instructions, and
 - c) manufactured, sold, or represented to have a direct, measurable effect on
 - modifying, restoring, or correcting an organic function or body structure of human beings, beyond normal growth and development or maintenance of good health, or
 - reducing the risk of or facilitating the *dietary* management of diseases or health-related conditions.
- (2) A food or beverage (hereafter referred to as “food”) that meets the criteria described in paragraphs (1)(a), (b) and (c) above would be subject to the proposed regulatory framework, in addition to the current provisions of the *Food and Drugs Act* relating to foods and requirements of Parts A, B and D (Divisions 1, 2 and 3) of the *Food and Drug Regulations*.
- (3) A food meeting the criteria described in paragraphs (1)(a), (b) and (c) above would be required to carry a Claim Identification Number.
- (4) Foods meeting the standards set out in Division 2 (alcoholic beverages), Division 5 (coffee) or Division 20 (tea) of Part B of the *Food and Drug Regulations* for instance would not be subject to the proposed regulatory framework unless they are sold or represented to have effects described in subparagraphs (1)(c)(i) and (ii) above.
- (5) Parts C and D (Divisions 4 and 5) of the *Food and Drug Regulations* and proposed requirements governing natural health products would not apply to a food meeting the criteria set out in paragraphs (1)(a)(b) and (c) above.

3.2 Permitted claims

It is proposed that a claim or representation about an effect described in subparagraphs 3.1(1)(c)(i) and (ii) be permitted for a food that meets and complies with the conditions of authorization listed in sections 3.3 to 3.6 below.

3.3 Proposed conditions of authorization

It is proposed that:

- (1) A manufacturer or importer of a food (“the applicant”) may make a written submission for a Claim Identification Number to the Director. The submission should contain the following types of information:
 - a) applicant’s information, including the applicant’s name, address, telephone number,
 - b) product information, including ingredients, nutrient composition, processing, intended use and target users of the product,
 - c) the proposed claim and information required for assessing product safety, claim validity, and quality assurance.

A proposed list of information to be included in a submission is provided in Annex B. Further details on the information required will be elaborated in a Guidance Document being developed. Proposed standards by which product safety, claim validity and quality assurance will be assessed were communicated in the consultation document on *Standards of Evidence for Evaluating Foods with Health Claims: A Proposed Framework*, published in June 2000. No major changes to the proposed principles and criteria are expected.

- (2) Where a substance is added to a food to achieve an effect described in subparagraphs 3.1(1)(c)(i) and (ii) and the substance has a limited range of safe intake, a limit may be posed on the use of the substance as an ingredient in foods.
- (3) Where a substance is added to a food or otherwise modified in a food to achieve an effect described in subparagraphs 3.1(1)(c)(i) and (ii), the composition of the food should be such that it does not counteract the beneficial effect of the added or otherwise modified substance.
- (4) The effect described in subparagraphs 3.1 (1)(c)(i) and (ii) should be achieved by physiological process(es) that are generally recognized to be associated with foods.¹
- (5) The applicant would be notified of the status of the submission within 90 days of receiving the submission.
 - a) if the information establishes that the submission complies with all the proposed requirements set out above, the Director would notify the applicant in writing that the information is sufficient and assign a Claim

¹ We propose that the effects be achieved through physiological processes that are generally recognized to be associated with foods, as opposed to pharmacological processes that are generally recognized to be associated with drugs.

Identification Number.

- b) if additional information is necessary in order to assess the safety of the food, the validity of the claim and/or the adequacy of the quality assurance procedures, the Director would request in writing that the applicant submit that information and advise the applicant within 45 days if the additional information is complete.
- c) if the Director believes on reasonable grounds that the product is not a food, does not meet the required criteria, or that the food contravenes the *Food and Drugs Act or the Food and Drug Regulations*, the claim requested would not be authorized and a Claim Identification Number would not be issued and the applicant so notified.

3.4 Compliance with authorization

- (1) It is proposed that a Claim Identification Number (CIN) be issued for a food that meets the required conditions for an authorized claim. In assigning a CIN, the Director would specify the conditions necessary for ensuring the safe use of the product and for ensuring that the claim is truthful and not misleading. The conditions for complying with the authorization would include:
 - a) the required elements of the authorized claim statement,
 - b) the form, compositional and processing specifications of the product relevant to its safety and efficacy,
 - c) conditions for labelling, advertising and sale, such as directions for use, any cautionary statements, the legibility of the required statements, and where warranted, advertising to health professionals only and/or restricted channels of distribution,
 - d) specific data to be collected as part of postmarket surveillance, such as consumption data and adverse reaction reporting.
- (2) It is proposed that the applicant receiving the claim authorization be asked to confirm the information contained in the authorization, the date of product introduction in Canada and to provide samples or facsimiles of all actual labels and promotion materials used before the food is offered or advertised for sale.

3.5 Notification of change

It is proposed that:

- (1) The applicant be required to notify when a change in specified conditions occurred which could reasonably be expected to affect product safety or efficacy or claim validity, such as when:
 - a) new scientific information becomes available,
 - b) the product undergoes a “significant change” in product formulation,

- manufacturing process, facility or equipment, the manufacturing quality control procedures, and/or intended use,
- c) an adverse reaction to the product has occurred in or outside Canada, in which case, all information should be reported within 15 days of receiving the information.
- (2) Notification of change would also be required when other changes render the information previously provided no longer correct. An example of such changes would be a change in product name or manufacturer.
 - (3) The notification of change should be made at least 90 days before sale or advertising for sale and should provide information necessary to reassess the product and the claim.
 - (4) No sale or advertising for sale of a food requiring notification of change should continue until the applicant is informed by the Director in writing that the Claim Identification Number has been retained or re-issued.

3.6 Cancellation or suspension of Claim Identification Number

It is proposed that:

- (1) The assignment of a Claim Identification Number for a food may be cancelled or suspended when:
 - a) new information indicates the need for review of the product and/or the claim authorized,
 - b) conditions of authorizing the claim or applicable provisions of the *Food and Drugs Act* or its *Regulations* are violated, or
 - c) the sale of the product in Canada has been discontinued.
- (2) The suspension of a CIN under paragraph (1)(a) or (b) would be effective when the Director has sent the CIN holder a written notice of the intention that sets out the date of the suspension and the reason for the intended suspension.
- (3) The Director may reinstate a CIN suspended under paragraph (1)(a) or (b), if within 90 days of the effective date of the suspension, the CIN holder has provided the Director with information or documents that demonstrate that the situation giving rise to the suspension did not exist or that it has been corrected.
- (4) The cancellation of a CIN under paragraph (1)(a) or (b) would be effective when
 - a) the CIN holder has not, within 90 days of receiving the notice referred to in paragraph (2), provided the Director with information or documents that demonstrate that the CIN should not be suspended, and

- b) the Director sends the CIN holder a written notice of cancellation that sets out the effective date of the cancellation and the reason for the cancellation.
- (5) The cancellation of a CIN under paragraph 1(c) would be effective when its holder advises that the sale of the product has been discontinued in Canada.
- (6) Where a person has been assigned a CIN for a food and discontinues the sale of the product in Canada, he would, within 30 days of such discontinuation, inform the Director that he is no longer selling the product.

4. ISSUES CONSIDERED IN DEVELOPING THE PROPOSED REGULATORY FRAMEWORK

In developing this proposed regulatory framework, we have considered the international situation (Annex C), as well as comments received from previous consultation on standards of evidence for foods with health claims. The following summarizes those comments most relevant to the development of a regulatory framework for product-specific authorization of health claims for foods. Health Canada's complete response to the major comments will be published on the Food Program web site.

4.1 Product-specific authorization

Industry members have expressed the need for a regime that would permit claims based on product-specific evidence without requiring time-consuming claim-specific regulatory amendments. This approach is considered important in facilitating research and development.

In the November 1998 policy, Health Canada recognizes that a claim concerning the effect of a food or its ingredient(s) or component(s) should not be generalized to other similar products unless acceptable supporting evidence was provided. This is the rationale for product-specific authorization outlined in this proposed regulatory framework whereby each product with the intended claim is evaluated on its own merit.

4.2 Product-specific claims

Some health professionals and consumer groups have expressed concerns regarding product-specific claims. They fear that product-specific claims would:

- potentially mislead consumers when a health claim includes the product brand name,
- emphasize specific food(s) rather than the total diet and promote a "magic

- bullet” approach to health,
- favour large companies who could afford to conduct research to support specific products,
- bias the nature of the science supporting product-specific claims as industry-generated science was met with skepticism.

Health Canada recognizes the potential confusion with the term “product-specific claims” used in the November 1998 policy document which could have different meanings for different people. In fact, the principle and intent behind the concept of “product-specific claims” as expressed in this earlier policy paper was that the evidence supporting a claim for a specific product is not necessarily generalizable to other similar products. This recognizes that food matrices and processing conditions could have an effect on the physiological property of foods. Therefore, an application containing product-specific evidence would be required for a similar claim on another product, unless generally accepted or specific nutritional or food science theory or knowledge would indicate otherwise. This is the basis of product-specific authorization set out in this proposed regulatory framework.

A regime that would permit claims based on product-specific evidence, in addition to generic authorization of health claims, has general industry support regardless of company size. This is considered an important step towards encouraging research and development. Industry-generated science also has the potential to facilitate the development of food products that can contribute to health.

Health Canada is aware of the concerns about communicating the role of food products with specific health effects in the context of the total diet. In addition to considering the general principles discussed at Codex (Annex C), we have also noted comments from some stakeholders that a health claim on a food label cannot be expected to convey all desirable information. A variety of off-label communication vehicles could be used in conjunction with health claims to convey the message of healthy eating. **We are particularly interested in receiving comments on the wording of claims approved through the product-specific authorization process.**

4.3 Therapeutic claims

Some industry members believe that therapeutic claims should not be prohibited if they are supported by evidence. Therapeutic claims as described in the November 1998 policy paper refer to “claims that a product can cure/treat/mitigate/prevent a disease or condition.”

The concern has been expressed that foods with therapeutic claims could be misused in place of, or could interfere with, other therapeutic products essential in the management of a disease or condition. However, it is also recognized that some foods can be an important part of the dietary management of

diseases and disease risk factors. To ensure that they are not mistaken to have the same potency or health outcomes as drugs, these foods could be regulated and labelled as “Foods for Special Dietary Use.”² As recognized in the June 2000 proposal on standards of evidence, the different health claims may be considered as part of a health continuum, and in practice it may not be clear where a structure/function, risk reduction or therapeutic claim begins and ends.

To address the above issues, we propose that the use of a food product in the dietary context as part of dietary management of a disease or health condition be permitted in labelling and advertising when accompanied by

- (1) information required to ensure safe product use, and
- (2) a statement to consult health professionals, where appropriate.

Information relevant to the safe use of the product could include directions for use, the population groups for which the product is not appropriate, not intended, or has not been adequately tested.

For example, information on the label of a product demonstrated to lower elevated serum cholesterol levels could include:

- “This product is a food for special dietary use. It contains at least X grams per serving of ingredient Y. When eaten twice a day for a daily total of not less than Z grams of Y, this product has been shown to lower elevated blood cholesterol [in naming the target population where applicable]. Consult your doctor when using this product as part of dietary management of high blood cholesterol.”

We welcome comments on the proposed approach to addressing the issues related to therapeutic claims.

4.4 Claims not requiring premarket assessment

As explained in section 2.2 of this document, the current definition of “drug” set out in section 2 of the *Food and Drugs Act* states that a drug includes “any substance or mixture of substances manufactured, sold or represented for use in ...restoring, correcting or modifying organic functions...” By contrast, claims about “maintaining the functions of the body necessary to the maintenance of good health and normal growth and development” are considered as “biological role claims” and foods carrying such claims are not subject to drug regulations. Under sections B.01.311, D.01.006 and D.02.004 of the existing *Food and Drug*

² Foods for Special Dietary Use are regulated under Division 24 of Part B of the *Food and Drug Regulations* and refer to foods that have been specially processed or formulated to meet the particular requirements of a person (a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or (b) in whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods.

Regulations, generally recognized “biological role claims” for **known** nutrients listed in the regulations are already permitted and do not require premarket assessment under the existing regulations or proposed regulatory framework. “Calcium helps build strong bones” is an example of “biological role claim” that does not trigger the drug definition.³ Premarket assessment of this type of claims is not required because the claims concern well-established effects of known nutrients. Foods carrying such claims are required to contain a specified level of the nutrient for which recommended intakes have been established.

Some members of the consumers/public sector have expressed the desire to require premarket approval of all health-related claims, including those currently considered as “biological role claims.” They are concerned that consumers would have considerable difficulty appreciating the nuanced distinctions between the language used in health claims and the language used in biological role claims or other types of health-related claims (e.g. third-party logos/endorsements or claims such as “promotes heart health”). The concerns are particularly valid for those substances that are not known nutrients or are not generally recognized to have a role in normal growth and development and maintenance of good health.

It should be noted that all claims are subject to the general provision of section 5 of the *Food and Drugs Act*. Manufacturers and importers are responsible for ensuring that their products are not labelled or otherwise represented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding a product’s character, value, quantity, composition, merit or safety. A claim would be potentially misleading without stating how the product contributes to the claimed benefit and without acceptable evidence. Further, an important element in addressing the concerns would be to inform the public about how health claims and other health-related claims for foods will be regulated in Canada. We propose that a Claim Identification Number be issued for a food carrying a health claim that meets the required criteria set out in this proposed regulatory framework. We also propose that the Claim Identification Number be displayed on product label to indicate that the product carrying the claim has been reviewed. **We would be interested to know if this method of identifying food products that meet requirements for health claims under this proposed regulatory framework would be useful to the general public, bearing in mind that a drug product is also required to display the Drug Identification Number (DIN) in labelling.** It has also been proposed that natural health products be required to carry product licence numbers on their labels.

³ Examples of acceptable “biological role claims” can be found in the *Guide to Food Labelling and Advertising*, Agriculture and Agri-Food Canada, section 7.5 (<http://www.inspection.gc.ca/english/bureau/labeli/guide/7-0-0e.shtml>).

4.5 Timelines for product review

Industry respondents to the standards of evidence consultation document wanted clear timelines established for the assessment of claims.

Timelines will be identified in the regulatory amendments to be published in Canada Gazette Part I. These timelines refer to the time limit within which an acknowledgement regarding the completeness of submitted or requested information is to be given to the applicant following the receipt of the information. It is not possible to pre-determine or unreasonably limit the length of time available to complete the review of a submission, the complexity of which could vary greatly among submissions.

4.6 Transparency of product review process and access to information

Some respondents across sectors expressed the need for transparency and for having access to all documents pertaining to the evaluation process and information regarding the authorization of a particular claim.

Health Canada is examining various means to increase transparency of the regulatory process while at the same time protecting the proprietary or confidential information presented to Health Canada by petitioners. Re-defining the boundaries of commercial privilege is clearly beyond the scope of this regulatory initiative. Although not part of the proposed regulatory framework, it is the intent of Health Canada to make publicly available on the Food Program web site decision summaries of approved claims (similar to the summaries on novel food decisions). Manufacturers may also consider publishing their research findings advantageous in promoting their products.

5. HOW TO COMMENT

5.1 What I should consider as I prepare my comments

You may find the following suggestions helpful for preparing your comments in a format that would assist us in analysing the different comments received:

1. Explain your views as clearly and as concisely as possible. If your comments exceed ten pages, please provide a summary (1 or 2 pages).
2. Be sure to distinguish between what you support and what you object to in the proposal.
3. Provide the rationale for your views.
4. Offer alternative ways to improve the proposal or what you object to in the proposal.

5. Support your views, particularly your concerns, with facts, data, or specific examples.
6. Describe any assumptions that you used.
7. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
8. Provide copies of any technical information and/or data you used in your comments.
9. Make sure to submit your comments by the deadline (see next section).

5.2 Submitting comments

Individuals and organizations wishing to comment on this document are asked to respond by February 26, 2002 to:
Project Coordinator - Product-Specific Authorization of Health Claims for Foods
Nutrition Evaluation Division
Health Canada
Banting Research Centre, Ross Avenue, PL 2203A
Ottawa, ON K1A 0L2

Fax: (613) 941-6636
e-mail: standards_evidence@hc-sc.gc.ca

Please include an electronic copy of your response. This will help us collate the comments received. Please also include in your response the following identification information:

Respondent Name:

Organization (where applicable):

Address:

Affiliation: Academia/Education/Research
 Industry/Consulting
 Government
 Non governmental organization
 Consumer
 Health/Disease
 Professional
 Other (please specify)

Indicate if comments represent those of an individual or an association/group

If the comments represent an association/group, describe the process used in developing your response.

Please note that in keeping with our commitments to an open and transparent process, comments made to Health Canada in response to this proposed regulatory framework will not be considered confidential. However, the names of the individuals sending comments who are not representatives of groups/organizations will be protected pursuant to the *Access to Information Act*.

Annex A - Comparing Product-Specific and Generic Authorizations of Health Claims for Foods

	Product-specific Authorization	Generic Authorization
The food carrying the claim	- must demonstrate a direct, measurable effect on a body function or structure beyond normal growth and development or maintenance of good health when consumed in a reasonable quantity as part of a diet	- must have composition that contributes to a dietary pattern associated with the claimed benefit
Types of applicable foods	- the product with the intended claim is assessed on a case-by-case basis	- an entire class of foods (e.g. fruits and vegetables) may be the subject of a claim - also applicable to nutrients or other components in foods
Types of applicable claims	- primarily representations that the regular consumption of a reasonable amount of the food carrying the claim has an effect in modifying, restoring or correcting a body function or structure, beyond normal growth and development or maintenance of good health, or can be used as part of dietary management of diseases or health-related conditions, or has a direct effect in reducing disease risks	- primarily representations of a health benefit in the context of dietary pattern and how the composition of the food carrying the claim contributes to the dietary pattern
Evidence requirements		
Product safety	- basic evaluation is required in all cases to ensure no potential for adverse impact on dietary quality and nutrient balance; for novel or modified foods and foods containing added biologically active substances, additional safety concerns will be addressed	- generally not a concern if the food carrying the claim has not been modified and the amount of food to be consumed falls within generally accepted or recommended dietary patterns
Claim validity	- product-specific evidence is required; human experimental studies are emphasized	- a combination of human data, including systematic reviews and observational studies, would be considered for claims involving food groups or dietary patterns; the evidence may be generalized among similar products and dietary patterns

Product-Specific Authorization of Health Claims for Foods

Annex A - Comparing Product-specific and Generic Authorizations of Health Claims for Foods (cont'd)

	Product-specific Authorization	Generic Authorization
Quality assurance	- important in ensuring consistency in the level of biologically active substances in the food in delivering the claimed benefit without compromising product safety, and conformance with acceptable procedures in all aspects of product testing	- generally no special concerns with the manufacturing of an unmodified food carrying the claim; however, following acceptable procedures in analytical testing of product composition would be important
Conditions of authorization	<ul style="list-style-type: none"> - in addition to nutrition labelling requirements applicable under generic authorization, special conditions for labelling, advertising and sale, and postmarket surveillance may be required - the applicant has the duty to notify when new information makes it necessary to reassess the product and the claim - Claim Identification Number may be cancelled or suspended when conditions of authorizing the claim are violated, when the claim can no longer be supported, or when the sale of the product has been discontinued 	<ul style="list-style-type: none"> - include composition and labelling requirements set out in regulations - review mechanism to be developed to ensure that claims remain current
Method of authorization	- issuance of Claim Identification Number following review of product-specific submission where required criteria have been met	- claim-specific regulatory amendments

Annex B

Proposed List of Information to be Included as Part of Premarket Submission Product-Specific Authorization of Health Claims for Foods

Information on the Applicant

- Name and address of the principal place of business of the manufacturer and of facility where the final product is manufactured
- Where applicable, the name and address of the importer/distributor
- The name, title and contact information of the applicant and the date of submission

Product Information

- The common name under which the food will be sold or advertised for sale and the brand name
- A list of all ingredients (including biologically active substances related to the claim, if known), stated quantitatively
- Product form, as sold and as consumed (e.g. liquid, powder, semi-solid)
- Reference amount, serving of stated size and reasonable daily intake [*as defined under B.01.001*]
- Nutrient composition: per 100g as sold, per serving, prepared according to stated directions, where applicable
- The use(s) for which the product is manufactured, sold, or represented, including route of administration (e.g. by mouth, tube feeding)
- All directions, recommendations, and suggestions for use and directions for its preparation
- Target group(s)
- The health claim that the applicant wishes to make respecting the product
- The text of all labels to be used
- Sample of the product

Comments: above information will help determine if the product submitted should be evaluated as a food as part of preliminary evaluation (screening).

Information for the Basic Evaluation of Product Safety

- Details of the method by which the product is manufactured, prepared, preserved, packaged, and stored
- Specifications (chemical, microbiological, physical, purity, contaminants, processing methods) of all ingredients (including components) and packaging materials, and their sources (including names and addresses of manufacturers of all raw materials)
- Information respecting the product's history of safe use as a food, or previous human consumption, including that in a country other than Canada, if applicable
- Identification of susceptible and vulnerable group(s) potentially at risk of adverse effects, including children, pregnant women and the elderly
- Estimated level of consumption by target groups and susceptible/vulnerable groups, including current and expected levels from all anticipated sources, and any potential use of the product as replacement of existing foods
- Relation of current and expected exposures to current dietary recommendations (targets) and safe or tolerable intakes
- Information relied on to establish that the food is safe for consumption, including the physiological role and metabolic fate of any added or modified biologically active substance/microorganism, potential interactions with nutrients, other dietary components, or drugs

Note: If a product is determined to be a novel food, it will be subject to the requirements of Division 28 of Part B of the *Food and Drug Regulations*.

Information for Evaluating Claim Validity and Quality Assurance Capability

- Detailed information and analysis on all studies, and documentation, on which the applicant relies to support the health claim for the food, including copies of published studies
- Details of the method of analysis of the amount of the biologically active ingredient (or an appropriate proxy indicator) present in the finished food. Details should include the use of reference material and how the method is validated
- If a biologically active ingredient is added, its method of fractionation, purification, concentration
- Details of the quality control procedures used throughout the process with respect to raw materials, manufacturing, processing, finished product, packaging and labelling, including documentation of procedures
- Stability data on the final product, including shelf-life and a description of the methods used to obtain the data
- Information to support that all testing and studies on the applicant's product(s) were conducted in accordance with applicable ethical standards and guidelines

Annex C - International Situation

In developing this regulatory proposal, we have reviewed how health claims for foods are regulated or managed in other countries. The type of approaches vary depending on the legislative framework and other factors influencing the acceptance of health claims in each country. The following examples illustrate the range of approaches that are in practice or are being proposed in selected jurisdictions.

1. Codex^{4,5}

Within the Codex Committee on Food Labelling, the issue of health claim has been discussed. “Enhanced function claim” and “reduction of disease claims” are being proposed as part of “health claims”, for which definitions have not been finalized. The conditions under which health claims may be made are also being reviewed, including whether all health claims should be stated within the context of the total diet. Draft scientific criteria for evaluating health claims were published in April 2000 by a working group of the Codex Committee on Nutrition and Foods for Special Dietary Uses. It is expected that the proposed criteria will be discussed in future meetings of the committee. The Canadian proposal on standards of evidence for evaluating foods with health claims is very similar in principles and general criteria to those proposed by Codex.

2. United States (U.S.)^{6,7}

A health claim in the U.S. means any claim made on the label or in labelling of a food, including a dietary supplement, that expressly or by implication, characterizes the relationship of any substance to a disease or health-related condition. The process for approving a health claim is described in the *Code of Federal Regulations*. Once a claim has been finalized by regulation, any food meeting the conditions set out in the regulations can carry the claim without further assessment. “Significant scientific agreement”, elaborated in the *Guidance Document to Industry*, is the standard by which health claims for foods are assessed. The Canadian proposed standards of evidence for evaluating foods with health claims are also very similar in principles and general criteria to those required for approving health claims in the U.S.

The definition of “drug” in the *Federal Food, Drug and Cosmetic Act* in the U.S. excludes food when referring to articles intended to affect the structure or function of the body. This differs from the definition of “drug” in the Canadian *Food and Drugs Act* in that foods and drugs are not

⁴ Proposed draft guidelines for use of nutrition and health claims. ALINORM 01/22A. Report of the 29th session of the Codex Committee on Food Labelling, Ottawa, Canada, 1-4 May, 2001.

⁵ Discussion paper on the scientific criteria for health related claims, prepared for the 22nd session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, Berlin, Germany, 19-23 June, 2000.

⁶ Code of Federal Regulations, Food and Drugs. 21 Parts 100 to 169. Revised as of April 1, 2000, §101.14-101.82.

⁷ Guidance for industry. Significant scientific agreement in the review of health claims for conventional foods and dietary supplements. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Special Nutritionals. Washington, D.C.: U.S. Department of Health and Human Services, December, 1999.

expressly mutually exclusive. Consequently, the approaches to regulating claims about the effect of a food or food component on a body structure or function will be different between Canada and the U.S.

3. Australia New Zealand Food Authority (ANZFA)^{8,9}

Following a pilot project testing the health claim concerning folic acid and neural tube defect, ANZFA published a *Review of Health and Related Claims Full Assessment Report*, Proposal P153 (August 2000) outlining several proposed options for regulating health claims for foods. Proposed amendments to the *Food Standards Code* were published in the *Inquiry Report* (June 2001). The scope of health claims includes “enhanced function claims” and “reduction of disease risk claims”. “Enhanced function claim” means “a claim about the specific beneficial effects of consuming a food or component in a food in the context of the total diet on the physiological, psychological or biological functions of the body beyond its role in the normal growth, development, maintenance and other like functions of the human body”. The regulatory option adopted is express exemption from the current prohibition by regulatory amendments to allow health claims based on a rigorous process of premarket scientific review by experts. The substantiation framework for health claims was outlined in the *Inquiry Report*. It was suggested that a health claim would unlikely be approved on the basis of less than convincing scientific evidence.

4. European Union (E.U.)¹⁰

There is no uniform approach at the Commission level. The range of support for health claims by regulatory authorities varies with individual countries, with some countries having industry-initiated voluntary codes of practice. A discussion paper published in May 2001 presents the main issues relating to the harmonization of rules on nutrition claims (similar to “nutrient content claims” in Canada) and functional claims (claims relating to beneficial effects of a nutrient on certain normal bodily functions). Health claims as such, including “disease risk reduction claims”, are not dealt with in this paper. The Commission is reviewing this area of legislation with the aim of making proposals later in the year.

⁸ Review of health and related claims. Full assessment report, Proposal P153 and Pilot for management framework for health claims. Draft inquiry report, Proposal P170. Australia New Zealand Food Authority, August, 2000.

⁹ Review of health and related claims. Inquiry report, Proposal P154. Australia New Zealand Food Authority, June, 2001.

¹⁰ Discussion Paper on Nutrition Claims and Functional Claims <http://europa.eu.int/comm/dgs/health_consumer/index_en.htm>

5. Other Countries

(1) Sweden¹¹

In Sweden, an industry self-regulating program specifying the conditions for health claims in the labelling and marketing of food products has been in place since 1990 (revised from 1997). The program allows generic claims in two steps, i.e. providing information about one of eight well-established diet-health relationships, followed by information on the content of the relevant nutrient or dietary fibre in the food carrying the claim. The Swedish Nutrition Foundation has an advisory and coordinating role. A proposal for extending the code on health claims to functional food products was published in June 1998. It was proposed that product-specific claims about the physiological effects of foods be permitted under this scheme when the following conditions are met :

- a) the food carrying the claim must be of such a composition as to positively contribute to a nutritionally adequate diet;
- b) the physiological effect should be documented and reviewed by a panel of qualified experts or published in well-established peer-reviewed international scientific journals;
- c) the physiological effect should arise as a result of a reasonable consumption of the product.

Claims concerning the prevention, detection, palliation or cure of a named disease that can result in the product being classified as a medicinal product would be excluded from the program. It was also proposed that the “The Assessment Board for Diet-Health Information” with postmarket monitoring responsibility with respect to marketing practices be established which would function separately from the scientific review process. The expanded code, expected to become operational in the fall of 2001, would provide an interim standard until EU harmonized legislation is in place.

(2) Japan^{12,13}

A regulated system of claims concerning the specified health use of a food (FOSHU) has been in place in Japan for more than a decade. Under the FOSHU system, a product has to go through an approval process with established criteria to obtain a license. Packaging must carry a statement that the food is FOSHU. The food and food component should not be those used exclusively as medical drugs. The claims allowed are typically related to the structure/function effects of the food or its component(s). Disease claims are not permitted. Regulatory amendments that came into effect in April 2001 classify foods with health claims into two types:

- type 1: types of foods that should be evaluated individually (foods for specified health use)
- type 2: types of foods for which standard regulation is applied (food with nutrient function claims)

Parallel to the regulatory amendments is the development of (1) companion standards for food

¹¹ Proposal for extension of the Swedish code on health claims to functional food products. Swedish Nutrition Foundation (<http://www.snf.ideon.se>). Scandinavian Journal of Nutrition 1998; 3:119.

¹² Foods for Specified Health Use (FOSHU). Ministry of Health and Welfare. Tokyo, Japan, Office of Health Policy on Newly Developed Foods, Environmental Health Bureau.

¹³ Summary of the report of the Joint Committees on the Food Hygiene Investigation Council (provisional translation). Ref: WTO TBT Notif 00.591.

labelling where special attention or warning regarding the safe use of the product is warranted, and (2) guidelines for the application, evaluation and related matters of foods that should be assessed individually (type 1 food). The aim of the standards is to ensure that foods with health claims will be labelled as such to avoid confusion with drugs, and to avoid implying prevention, treatment and diagnosis of human disease. A new guidance “Revision of the criteria regarding the range of drugs” sets out the framework for determining whether a product taken orally by humans can be considered a drug or a food.