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Managing Health Claims for Foods in Canada: Towards a Modernized Framework

Discussion Paper

November 2007

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EXECUTIVE SUMMARY

Introduction

Rising interest in the health impacts of foods among both industry and consumers has put a spotlight on the management of health claims on foods in Canada. To ensure efficiency and flexibility in the approval of health claims, while retaining high standards needed to maintain the credibility of these claims, Health Canada is reviewing the current framework for the management of health claims on food. As part of this process, Health Canada is seeking input from stakeholders on a number of issues:

1 Efficient and Transparent Processes

- 1.1 Business improvements for increased efficiency
- 1.2 Increased openness and transparency

2 Sound Evidence for Consistent, Credible Claims

- 2.1 Scientific substantiation of claims
- 2.2 Supporting good-quality submissions

3 Clear Policies for Today and Tomorrow

- 3.1 Functional foods and the food/natural health product interface
- 3.2 Managing a broader range of function claims
- 3.3 Managing diverse front-of-package claims
- 3.4 Eligibility criteria for foods to carry claims

4 Supporting Informed Consumer Choice

- 4.1 Improving consumer understanding of health claims
- 4.2 Monitoring the impact of health claims on the food supply and consumer choice

Background

The *Food and Drugs Act* and its Regulations govern the use of the different health claims that appear on packaging or in advertising for foods sold in Canada. Some refer to the reduction of the risk of disease - for example “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis.” Others refer to the maintenance or support of specific body functions, such as “Vitamin A aids in the maintenance of night vision.” More general health claims such as “healthy for you” or a “healthy choice” also appear. While studies show that consumers tend to consider all of these health claims similarly credible, they are in fact subject to quite different regulatory requirements.

The regulation of disease risk reduction claims is the most rigorous. Such claims have only been permitted since 2002, when an amendment to the *Food and Drug Regulations* allowed for five generic disease risk reduction claims. Any foods carrying such claims must satisfy a set of criteria and must use prescribed wording for the claim. To make a new disease risk reduction claim not already included in the list of permitted claims in the Regulations, a regulatory amendment to the list is required, following review of a submission and approval of the claim by Health Canada.

Claims about known nutrients and their well-established roles in the maintenance or support of specific body functions are subject to regulations, but the requirements are less rigorous than for disease risk reduction claims. Generally, a food carrying such claims must generally contain 5 percent or more of the recommended daily intake of the nutrient. For other food substances and for less well-established physiological roles, the rules are less clear.

For general health claims, no specific rules have been established. However, such claims are subject to the *Food and Drugs Act*, in particular its prohibition of “false, misleading or deceptive product representation”.

The structure of the health claims system in Canada has raised concern among both consumer and industry stakeholders, particularly in light of the growing interest in the health benefits of food. The confusion is compounded by a proliferation of implied health claims expressed in commercial logos or slogans, and by the possible option of having foods with claims about health benefits approved under the *Natural Health Products Regulations*. As interest in the health value of foods increases, there is also growing interest among stakeholders for more efficient and transparent processes for the approval of health claims.

Faced with similar pressures, major Canadian trading partners such as the European Union, Australia/New Zealand and the United States are reviewing and updating their regulations in this area. Canada is committed to doing the same through Health Canada's *Regulatory Modernization Strategy for Food and Nutrition* as part of the *Blueprint for Renewal* initiative. Health Canada therefore seeks to engage a wide array of stakeholders, including consumers, health professionals, industry, and organizations concerned with particular illnesses, in a discussion of the policies and processes that govern the use of health claims on food.

Issues

1 Efficient and Transparent Processes

1.1 Business improvements for increased efficiency

Industry has expressed concern that the current pre-market assessment process is

slow, unpredictable, restrictive, cumbersome and inefficient
unclear concerning which types of health claims need to be submitted for
consideration, and the process to be used to evaluate them
not coordinated with other jurisdictions, specifically the US

a disincentive for industry to develop and sell a wider variety of healthy food products

One of industry's key concerns is the time-consuming process to allow a disease risk reduction claim, which requires a regulatory amendment. However, the current regulatory mechanism allows the use of health claims on foods that would otherwise be prohibited. It also ensures consistent enforcement, credibility of the claim, and conformity with international practice. Furthermore, the mechanism was set in place following full consultation. Changing it would be a complex process, and recent reviews of the situation have concluded that the challenges to timely approval are less a function of the regulations than of their administration.

In light of these considerations, Health Canada has decided to give priority to addressing process improvements. In keeping with the Submission Modernization Process in the Regulatory Modernization Strategy for Food and Nutrition, a number of specific actions have been initiated or planned to help address key operational issues (work on the first two initiatives has begun):

- Dedicating additional resources to the review of health claims for foods;
- Implementing standard operating procedures (SOPs) for the Health Canada review of submitted claims. Finalized SOPs will be shared with stakeholders;
- Developing the parameters for an abbreviated process for claim review where internationally recognized scientific bodies or competent national authorities have recently completed a review and deemed the claim as valid. Acceptable ways to deal with different decision outcomes would also need to be considered;
- Examining ways to improve efficiency administering the current regulation, where claim specific regulatory amendments are required. Several options are being considered:
 - dedicating more resources in regulatory drafting and legal services

- exploring when it may be possible to expedite the time taken to proceed to the final amendment of the Regulations in *Canada Gazette Part II*

Exploring appropriate “triggers” and processes for deciding when a second review of an approved claim may be needed. However, this is not considered a priority activity at this time.

Health Canada is seeking feedback at this time on the likely effectiveness of proposed improvements, and any other actions that may improve the efficiency of approvals.

1.2 Increased openness and transparency

Public interest groups, academics, health professionals and consumers would like to have increased access to the decision-making process for health claims, with mechanisms in place for public input. They would like health professionals and the general public to have access to the evidence submitted to support approved claims.

As expressed by HPFB in the *Blueprint for Renewal* and the *Policy on Public Input*, Health Canada is committed to promoting more transparency and openness in decision-making, and wants to explore ways of publishing summarized evidence about health claim decisions in a standardized format. Such publication must provide information on the decision-making process while respecting the proprietary nature of data. A number of different formats that provide information with varying degrees of information are being considered.

Health Canada is seeking input at this time on the depth and breadth of decision documents on health claims to be published.

2 Sound Evidence for Consistent, Credible Claims

2.1 Scientific substantiation of claims

Some stakeholders feel that current standards are too uniformly rigorous, and should vary according to the level of risk represented by the product and the nature of the claim. This view is supported by industry pressure worldwide and, in Canada, by current application of the newly introduced *Natural Health Products Regulations*. According to this view, consumers would benefit from access to safe food products carrying health claims, even when their health benefits cannot be demonstrated with a high level of certainty.

Others believe that application of clear, consistent, high standards of evidence is the cornerstone of a credible health claim system. Their view is supported by international standards, by research that shows that consumers do not differentiate among claim wordings and do not necessarily respond to disclaimers and qualifications, and by concern that less well-substantiated claims may need to be withdrawn at a later date, and which may erode public confidence in the system.

Health Canada is seeking input on the appropriate level of substantiation for claims in light of the obligation not to mislead consumers.

2.2 Supporting good quality submissions

While some stakeholders find the current substantiation requirements to support health claims too costly to fulfill, others are concerned that there should be requirements for more comprehensive studies undertaken by neutral third parties. International firms find the differences between Canadian and U.S. requirements onerous. To help industry

submit the best quality submissions possible, the Food Directorate is considering a number of further activities:

encouraging pre-submission consultations;

updating the 2002 *Interim Guidance Document* to include specific guidance on the preparation of a structured, systematic review with the knowledge gained from the work done by the Program in Food Safety, Nutrition and Regulatory Affairs at the University of Toronto and Health Canada;

supporting in principle the efforts of third parties that can coordinate and assist small-and-medium-sized industry members that are willing to collaborate in making joint submissions on ingredients or food constituents of common interest;

exploring ways to address gaps in the scientific evidence associated with the health-related benefits of food ingredients at a pre-submission stage with interested parties, for example, Agriculture and Agri-Food Canada; and

participating in third party *fora* organized to sustain domestic infrastructure for basic and applied research in food and nutritional science needed to support the development of safe innovative food products with substantiated health benefits.

Health Canada is seeking input on the likely effectiveness of current and proposed actions, on industry responsibility in this regard and on who else can play a role in ensuring good quality submissions.

3 Clear Policies for Today and Tomorrow

Both today's marketplace and anticipated developments in the food industry call for the development of clear, consistent policies to manage a variety of health claims on food.

3.1 Functional foods and the food/natural health product interface

There is some confusion at present because there are differences in standards and processes when food-like products are sold and regulated as Natural Health Products (NHP) rather than as foods. Similar products with similar claims will encounter different pre-market review of claim validity, product safety assessment and risk management approaches under the two regulatory frameworks. Similar products may also be required to be labelled in a different manner.

In the recent NHP Regulatory Review, a proposed priority action was to exclude food-like products from the purview of the NHP regulations. In the interim, the Food Directorate is cooperating with the Natural Health Products Directorate, so that consistent and seamless decisions are made for similar products regardless of the regulatory regime under which the products are managed.

Many products at the NHP/food interface contain added bioactive ingredients. These substances may already be contained in the food but be supplemented to a higher level, or they may not be substances traditionally associated with that food. While some foods containing bioactive ingredients can safely be consumed in any quantity by the general population, others may pose health concerns for certain populations (for example, children). In addition, many foods may contain the same bioactive substance, making it difficult for consumers to maintain safe level of intake.

Since there is a growing interest among both producers and consumers in widening the use of foods containing added bioactive substances, the marketing of such foods is expected to expand in the future, posing potential risks for populations for which the product was not intended.

Health Canada is seeking input on anticipated areas of new development in functional foods, and on the suitability, rationale and risk management strategies for addition of bioactive substances which may present a risk for some segments of the population.

3.2 Managing a broader range of function claims

There is a growing interest on the part of industry to make function claims rather than disease risk reduction claims, in part because there are fewer regulatory requirements for such claims. This perception is only partly true: some function claims, which are considered drug claims under the Food and Drugs Act, have the same regulatory requirements as disease risk reduction claims.

Function claims about known nutrients and their well-established roles in the maintenance or support of specific body functions are also subject to regulations, but there are fewer requirements than for disease risk reduction claims. A food carrying such claims must generally contain 5 percent or more of the recommended daily intake of the nutrient. For other function claims the only requirements they must fulfill are the general ones under the *Food and Drugs Act*, such as the prohibition of “false, misleading or deceptive product representation.” The distinction between the different types of function claims and related requirements is not always obvious and can cause confusion for industry.

Some argue that there need not be as much oversight of these claims because they have a lesser impact than disease risk reduction claims. However, research indicates that consumers do not make clear distinctions between different types of health-related claims and suggests that function claims may be at least as persuasive as disease risk reduction claims on consumer food choices.

The lack of clear regulatory requirements or guidelines for function claims could lead to inappropriate use of such claims, confusion among consumers, and, ultimately, loss of confidence in the credibility of health claims. Those manufacturers who do invest in

appropriate substantiation of their claims may also argue that this lack of regulation and guidance creates an uneven playing field.

The Food Directorate is committed to enabling a broader range of function claims while ensuring their credibility. To this end, the Directorate will provide guidance to clarify which function claims have fewer regulatory requirements and, for these claims, will continue to maintain an up-to-date list of function claims that are deemed “not misleading.” The Directorate will encourage industry to voluntarily submit new claims for review.

However, there are questions about the sustainability and suitability of this approach to manage the innovative types of products and claims foreseen in this area. Feedback is being sought on the level of oversight (regulatory or voluntary) and supportive measures that would help foster credible and responsible use of a broader range of function claims.

3.3 Managing diverse front-of-package claims

In Canada and around the world, there has been a proliferation of health-related “front-of-package” (FOP) claims featuring graphics such as hearts or check marks and slogans such as “healthy choice,” “nutritionist recommended” or “good for you.” These claims are used alone or in combination with more formally accepted claims such as disease risk reduction claims, biological role claims or nutrient content claims.

3.3.1. Implied health claims

Implied claims are claims that suggest a health benefit without explicitly stating it. Implied claims are considered misleading in many jurisdictions, which have considered ways to prohibit them. In Canada, the *Food and Drug Regulations* forbid implied disease risk reduction claims but this is hard to enforce without sufficient consensus among stakeholders.

Improving management of implied health claims will be difficult to achieve without careful consideration of food manufacturers' constraints. Food manufacturers may choose not to use the approved wording on products that meet the conditions for a claim because it is too lengthy (especially in both official languages). Instead, they may turn to FOP labelling with symbols and slogans as a preferred marketing approach. To maintain credibility and clarity of health claims in the marketplace, the Food Directorate is proposing to pursue alternative formats for disease risk reduction claims that provide additional flexibility to food manufacturers.

3.3.2 Simplified nutritional or general health messages

FOP symbols, graphics and slogans may also suggest general nutritional or health values without referring to specific health effects. The overemphasis on certain positive aspects may draw attention away from less healthy characteristics of a food, and may over-simplify complex nutrition messages. Studies have shown that these claims may suggest greater links to health than can be substantiated and reduce the use of the Nutrition Facts table. This may make it more difficult for consumers to make informed choices and fuel scepticism about the validity of health claims.

Different measures have been suggested to reduce consumer confusion. In March 2007, the Standing Committee on Health recognized the potentially influential role that clear, simple, FOP labelling with standardized criteria could have on consumer behaviour and recommended that the federal government take action as soon as possible.

If and how such labelling could be successfully combined with the existing Nutrition Facts table is a question to be resolved in the Canadian context. To cast light on the issue, Health Canada proposes to undertake consumer research on the interpretation of FOP symbols or other representations in concert with the Nutrition Facts table. Health Canada will also be examining the possible forms of nutritional profiling that could underlie standardized nutritional criteria.

Health Canada is seeking input on challenges and opportunities in the management of a variety of health-related FOP claims, and the means to reduce confusion and ensure the credibility of claims.

3.4 Eligibility criteria for foods to carry claims

There are currently no common core criteria to determine which foods are eligible to carry health claims – or, conversely, which foods should not be allowed to carry health claims. As a result, there are some concerns that health claims may lead consumers to ignore other aspects of foods: studies demonstrate that consumers view foods with health claims as healthier overall. This could create conflict with public health messaging around national dietary guidance.

Health Canada proposes to explore the application of minimum standards to foods carrying any type of health claim. This approach is consistent with:

- consumers' expectations of foods carrying health claims, as identified by research;
- a Codex Alimentarius Commission recommendation that there should be a clear regulatory framework for qualifying and disqualifying conditions, including prohibiting claims on foods that contain nutrients or constituents in amounts that increase the risk of disease or adverse health related condition;
- other international approaches taken in the European Union and proposed in Australia/New Zealand;
- the goal to address “food contributors” to chronic disease as outlined in the Health Canada’s 2007 Regulatory Modernization Strategy for Food and Nutrition.

Health Canada is seeking input on the principle of using nutritional criteria to underlie health claims.

4 Informed Consumer Choice

4.1 Improving consumer understanding of health claims

Studies have found that consumers welcome nutrition and health information but are confused and sceptical about the health claims made on food packages. There is evidence that some consumers lack the level of health literacy needed to handle the complexity, sophistication and quantity of information (some of which is contradictory) about diet-health relationships that is available to them to make informed choices. Health Canada proposes to undertake consumer research to determine if and how consumer education could help increase consumer understanding of health claims and nutrition information. There are opportunities for industry and non-governmental organizations to play a role in developing successful public education activities to improve health literacy.

Health Canada is seeking input on means to improve consumer understanding and appraisal of health claims.

4.2 Monitoring impact of health claims on food supply and consumer choice

Some studies find that consumers are using food labels to select “healthier” foods, while others show that actual use of nutrition and health information is much lower. Concerns have been raised about potential unintended effects of health claims: they may draw consumers away from equally healthy products that do not have such claims attached to them and may even make other, sometimes cheaper products less available. To evaluate the effectiveness of its health claims policies, Health Canada plans to monitor the following areas:

- use of health claims on food labels and in advertising
- consumer understanding of health claims
- ability of consumers to use claims in informed purchasing decisions
- long-term impact of health claims on the nature of the food supply in Canada
- effects on dietary patterns

changes in research investment by Canadian companies related to innovations in food ingredients and finished food products with relevance to Health Canada

This is another area where there are significant opportunities for collaboration and partnerships to support the evaluation and monitoring of the policy. A network including partners from government, industry, academia, and non-governmental organizations would be needed to help prioritize the range of indicators and aspects that could be monitored.

Health Canada is seeking to identify organizations that can play a role in the monitoring of health claims.

INTRODUCTION

The regulation of health claims on foods in Canada has been an evolving process. The most recent development is the permission of disease risk reduction claims on foods, which was put in place in December 2002 as one component of nutrition labelling and claims regulations. A number of pressures and influences have recently prompted Health Canada to initiate a review of the current system. A burgeoning market for health-enhancing or functional foods has been fuelled by increased media coverage and consumer awareness of a growing body of scientific evidence linking diet to health and disease. Consumers are also increasingly interested in taking greater personal responsibility and widening their choice of approaches to optimize their health. Responding to this demand, food manufacturers would like to use health claims more and more to communicate benefits for an expanding number of food products, including innovative products that are not always readily accommodated by the current system. At the same time, consumers and public health interest groups have voiced confusion and concern about the growing array of health-related messages on foods and how to know what they should believe.

The need for increased government efficiency and flexibility in the approval of health claims has been identified by some stakeholders as a key component to enable the development of value-added products in a competitive marketplace. At the same time, consumers and public health interest groups expect government to retain the high standards and oversight that have helped ensure the credibility and integrity of the claims along with safety of the products.

Recognizing these challenges, Health Canada is reviewing the current framework for the management of health claims for foods. This review is part of the *Blueprint for Renewal*, a major Health Canada initiative aimed at modernizing the oversight for health products and food. In particular, the health claim framework is a component of the *Regulatory*

Modernization Strategy for Food and Nutrition. (More information on these overarching initiatives can be found on the Health Canada website.¹)

An Inter-departmental Policy Team was established to advise and help guide the development of this discussion document. The intent is to build on the current strong foundations of the health claims policy to develop a modern framework for health claims on foods. The objective is an effective framework that will:

- support informed consumer choice by allowing foods with health benefits to be marketed with substantiated claims;
- continue to protect consumers from misleading and unsubstantiated health claims on foods; and
- support conditions for a fair and competitive market environment that will allow for more consumer choice of food products.

This discussion document has been prepared to provide detailed background information, as well as to raise issues for discussion with stakeholders. Consequently, it has been divided into two parts.

Part A outlines the current regulations, processes and policies pertaining to health claims for foods in Canada (Section A1) and provides an overview of the current international context (Section A2 and Appendices D, E, F and G). A brief discussion is given of the changing context and some drivers for a modernized framework for managing health claims for foods (Section A3).

Part B presents issues and discussions around the current situation, grouped into four main themes:

Theme 1: Efficient and transparent processes (Section B1)

Theme 2: Sound evidence for consistent, credible claims (Section B2)

¹ http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/index_e.html

Theme 3: Clear policies for today and tomorrow (Section B3)

Theme 4: Supporting informed consumer choice (Section B4)

Each of these sections outlines a number of issues relevant to the theme and provides a discussion of related information and some potential actions. While comments are invited on any area of the document, specific questions have been posed at the end of each theme section and three general questions are posed in Section B5.

Information is requested as well on consumer or social research on health claims on foods in the Canadian context. The Food Directorate is interested in how health claims across the spectrum are used and interpreted by consumers in Canada, the nature of the trust and expectations around these claims, and their influence on food purchasing decisions. More detailed discussions of consumer research needs are given in Themes 3 and 4.

Instructions for submitting comments and a Feedback Form are provided in Section B6. The Feedback Form can also be found in Word and WordPerfect format on the following Health Canada website: http://www.hc-sc.gc.ca/fn-an/consultation/init/manager_health_claims-allegations_sante_e.html.

In addition to seeking written feedback on this discussion document, Health Canada plans to hold regional consultation sessions in the winter of 2008 to focus discussions on selected themes.

To explore a system that provides flexibility but maintains credibility, Health Canada would like to encourage discussions with stakeholders regarding the respective roles and responsibilities of government, industry, non-governmental organizations and consumers. All stakeholders will have to play an active role if the framework is to be successful.

The feedback from this paper will be used to help develop policies, set the groundwork for proposals for further consultation, and guide priority setting and work plans.

PART A: BACKGROUND

A1. HEALTH CLAIMS FOR FOODS IN CANADA

1.1 What are health claims for foods?

The term “health claim” is not formally defined in food regulations in Canada. For the purpose of this discussion paper, a health claim for food is considered to be:

any representation in labelling and advertising that states, suggests or implies that a relationship exists between the consumption of foods or food constituents and health.

A health claim for food is generally evaluated for its appropriateness in the context of the total diet.

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

Brief descriptions of the different types of health claims referred to in this discussion paper are given in the following section and further elaborated in Section 2.3. A glossary of the terms related to health claims used in this document is provided in Appendix A.

This paper will distinguish between specific and general health claims.

Specific health claims are claims about the effects of a food, or food constituent, on a specific organ, disease, biomarker or health condition. There are two types of specific health claims:

- disease risk reduction claims; and
- function claims

Disease risk reduction claims are claims that link the consumption of foods or food constituents to a reduced risk of disease in the context of the total diet.

Function claims include:

- a. claims about the maintenance of body functions that are necessary to the maintenance of good health and normal growth and development;
- b. claims about maintaining or supporting body functions associated with the maintenance of good health or performance; and
- c. claims about restoring, correcting or modifying body functions.

The first two categories of function claims are claims related to the physiological effects of foods or food constituents. The distinction between the first two categories of function claim is that the first category applies to a limited number of known nutrients with well-established functions that are essential to health, growth and development, whereas the second category applies to a broader range of substances in foods and to a broader range of physiological functions. The third category of function claims, as well as disease risk reduction claims, would be considered drug claims under the *Canadian Food and Drugs Act (the Act)*.

General health claims, in contrast, do not refer to a specific health effect, disease or health condition. They include broad “healthy for you” or “healthy choice” claims that promote choosing a food for overall health, promote healthy eating, or provide dietary guidance.

Health claims are distinct from nutrient content claims, which are representations, expressed or implied, that characterize the energy value of the food or the amount of a nutrient contained in the food. Provisions for nutrient content claims in Canada were updated as part of the regulations on nutrition labelling and claims introduced in the *Food and Drug Regulations (FDR)* in December 2002 and are outside the scope of this document and initiative.

1.2 History of health claims for foods in Canada

Prior to the promulgation of regulatory amendments in December 2002 to permit disease risk reduction claims for foods, function claims related to the well-established biological roles of known nutrients were the only type of health claims expressly permitted by regulation in Canada. While claims related to healthy eating were made on food labels and in advertising, their use was and is governed by Section 5(1) of the *Food and Drugs Act* (the *Act*), which prohibits false, misleading or deceptive product representations, or those representations that are likely to create an erroneous impression about the character, value, quantity, composition, merit or safety of a product. Guidelines on claims about healthy eating² were published in the 1996 *Guide to Food Labelling and Advertising* (amended in 1997) to guide the use of claims in compliance with the *Act*.

In 1998, recognizing industry's growing interest in a broader range of claims for foods, Health Canada published a policy recommendation that structure/function claims³ (including biological role claims) and disease risk reduction claims should be permitted for

² The *Guide* incorporated *General Principles for Labelling and Advertising Claims that Relate to the Nutrition Recommendations* [Health and Welfare Canada, 1991] and *Guidelines for Health Information Programs Involving the Sale of Foods* [Health Canada, 1995].

³ While the term "structure/function claim" was used in the 1998 policy paper and is adopted in the US to refer to certain claims for dietary supplements and foods, at present in Canada, the term "function claim" is used in line with the terminology adopted in the *Codex Guidelines for Use of Nutrition and Health Claims* [Codex Alimentarius Commission, 2004] that include "nutrient function" claims (corresponding to "biological role" claims in Canada) and "other function" claims that refer to specific beneficial effects of the consumption of foods or their constituents in the context of the total diet on normal function or biological activities of the body.

foods [Health Canada, 1998]. Such claims were considered to be appropriate in describing benefits increasingly recognized as scientifically valid for foods. This policy recommended that products bearing therapeutic claims relating to the cure, treatment, mitigation or prevention of illness should continue to be regulated as drugs.

Since 1998, Health Canada has undertaken a number of initiatives in the health claims area. In 1999, Health Canada committed to consider 10 health claims that were authorized in the United States under the *Nutrition Labeling and Education Act (NLEA)* for use in Canada. Several consultations sought input on generic disease risk reduction claims, standards of evidence required to substantiate claims, and a proposal for product-specific authorization of health claims. Focus group research tested how well consumers and health professionals (including dietitians, nurses and family doctors) understood and responded to a number of proposed formats for health claims and looked at how the rigour of scientific support and specific wording of claim statements may affect consumers' understanding and trust in the claim [Health Canada, 2000, 2001 Jan].

In addition to completing the review of the 10 disease risk reduction claims in the United States, Health Canada also expected that products requiring product-specific authorization would be an area of high industry interest. However, feedback from stakeholders to consultation on *Product-Specific Authorizations of Health Claims for Foods* in 2001 [Health Canada, 2001 Oct] indicated this was of less interest than was expected. The feedback helped to prioritize policy development on the review of disease risk reduction claims.

In December 2002, the food provisions of the *FDR* were amended to permit five generic disease risk reduction claims (table following B.01.603 of the *FDR*) along with claim-specific criteria for foods permitted to make a specific claim. A proposal to permit two additional disease risk reduction claims was published on the Health Canada website in December 2006.⁴

⁴ http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/position_paper-enonce_position_e.html

A chronology of key events related to the development of regulatory provisions for disease risk reduction claims for foods is found in Appendix B.

1.3 Current regulatory framework

It is important to have a clear understanding of the current larger regulatory context since it plays a significant role in shaping the policies and approaches for the management of health claims for foods.

All foods and drugs (including natural health products) sold in Canada are regulated under the provisions of the *Food and Drugs Act*⁵ (the *Act*), the *Food and Drug Regulations*⁶ (*FDR*) and the *Natural Health Products Regulations*⁷ (*NHPR*). With respect to foods, Health Canada is responsible for the development of policies, regulations and standards that relate to health and safety, and the Canadian Food Inspection Agency (CFIA) is responsible for their related compliance and enforcement, as well as the establishment of policies, regulations and standards for non health and safety issues and their subsequent implementation and enforcement.

Food as defined in the *Act* “includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.”

The provisions in the *Act* that are relevant to the discussion of health claims for foods are:

- Section 5(1)⁸ prohibiting false, misleading or deceptive representation or those

⁵ <http://laws.justice.gc.ca/en/f-27/240900.html>

⁶ http://hc-sc.gc.ca/fn-an/legislation/acts-lois/fdr-rad/index_e.html

⁷ http://hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/prodnatur/index_e.html

⁸ Subsection 5(1) of the *Food and Drugs Act* states that “No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.”

- representations that are likely to create an erroneous impression about the character, value, quantity, composition, merit or safety of a product; and
- the definition of “drug.”

According to 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 or abnormal physical state, or its symptoms, in human beings or animals,

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

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

1.3.1 Foods with health claims that require regulatory amendments

The legal status of foods and the way they are regulated may be affected by the use of health claims. Many proposed health claims for foods are of the type that would bring a product within the definition of a drug. In Canada, drugs are defined according to their effect and how they are represented for use. A food product deemed to meet the definition of a drug would be subject to the drug-related sections (Part C) of the *FDR*. Therefore, to permit certain health claims, provisions have been included (Dec 12, 2002) in the *FDR* (B.01.601) to exempt food products with these claims (e.g., disease risk reduction claims) from the regulations governing drugs, as well as Section 3 of the *Act*,⁹ thereby ensuring the continued and consistent application of the food regulations and standards for food products.

⁹ Section 3 of the *Food and Drugs Act* states that “(1) No person shall advertise any food, drug, cosmetic or 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. (2) No person shall sell any food, drug, cosmetic or device a) that is represented by label, or b) that the person advertises 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.”

The conditions of use for each approved disease risk reduction claim are listed in a table following Section B.01.603 of the *FDR*. These include prescribed wording for the claim; nutritional and other criteria that must be met for a food product to be eligible to carry the claim; and conditions for the label or advertisement.

New claims and the conditions for their use can be added to the table through regulatory amendments following a review of the submission and adoption of the amendments by the Government of Canada. Submissions for new claims in this category may be made by any organization including industry, academics, public health organizations or coalitions. Regulatory amendment to permit the use of new health claims of this type is contingent on the submission of acceptable scientific evidence to support the claimed effect in the dietary context. Petitioners interested in making a submission should follow the *Interim Guidance Document on Preparing a Submission for Foods with Health Claims* [Health Canada, 2002].

1.3.2 Foods with health claims that do not require regulatory amendments

Examples of health claims that would not bring a food within the definition of a drug include certain types of function claims and general claims about “healthy choice.”

(i) Function claims expressly permitted by current food regulations

Function claims about the maintenance of body functions that are necessary to the maintenance of good health and normal growth and development are expressly permitted in B.01.311(3), D.01.006 and D.02.004 of the *FDR*. These sections of the regulations provide only for statements or claims “to the effect that the food’s energy value or a nutrient in the food is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.”

Currently, for known nutrients and their well-established functions, examples of acceptable claims are provided in the 2003 *Guide to Food Labelling and Advertising* [CFIA, 2003; reproduced in Appendix C]. These examples provide guidance with respect to the

acceptability of the wording of the claims. These claims are referred to as “biological role” claims in the CFIA guide. For function claims for some key nutrients, the regulations also stipulate that the food must meet specified conditions: for vitamins and minerals, at least 5% of the recommended daily intake in a stated serving (D.01.004 and D.02.002); for protein and amino acids, at least a “source” of protein (B.01.305(1), (2)). No other nutrient criteria must be met to carry such “biological role” or function claims.

The claims that have been accepted to date are based on their “generally recognized” functions. The “generally recognized” standard is not officially defined but is based on a well-established prior history of a high level of scientific evidence and broad scientific agreement that is unlikely to be reversed with new data.

The word “nutrient” is not defined in the *Food and Drugs Act* or *Regulations*. “Nutrient” is generally accepted as defined by Codex Alimentarius as “any substance normally consumed as a constituent of food (a) which provides energy; or (b) which is needed for growth and development and maintenance of healthy life; or (c) a deficit of which will cause characteristic biochemical or physiological changes to occur” [Codex Alimentarius Commission, 1991]. However, the application of relevant sections of the *FDR* to permitting function claim for a nutrient makes use of the availability of reference intake values for that nutrient. For practical reasons, Health Canada and CFIA generally consider a food substance as a nutrient if it is recognized as such by the Institute of Medicine of the National Academies, Washington, D.C., for which dietary reference values have been established [CFIA, 2003].

(ii) Function claims not expressly permitted by current food regulations

Historically, few other function claims for foods or food constituents have been recognized in Canada. In most cases, they are deemed to be drug claims (i.e., falling within the parameters of “modifying, correcting, or restoring organic function”). Nevertheless, occasionally function claims related to foods or food constituents about maintaining or

supporting body functions associated with the maintenance of good health or performance have been reviewed and deemed not misleading. Such claims are not prohibited if they are truthful and not misleading as set out in Section 5(1) of the *Act*. These function claims deal with the effects for which the nature of the effect and the mode of action are consistent with physiological effects of or responses to foods and diets. Two claims in this category are: a claim for a particular sports drink (absorbed up to 30% faster than water) and a claim for coarse wheat bran as an ingredient added to foods providing 7 grams of dietary fibre in a reasonable daily intake (promotes regularity or laxation). Few claims in this category have been proposed by industry and reviewed by Health Canada. Claims that have been reviewed and deemed not objectionable¹⁰ have not been systematically incorporated into a single list in the *CFIA Guide to Food Labelling and Advertising*.

The manufacturer is responsible under the *Act* for ensuring that the claim is truthful and not misleading, and for meeting an acceptable level of substantiation based on scientific evidence. However, there are no guidelines for establishing the validity of this type of claim or for setting out conditions and defining appropriate wording to help ensure they are truthful and not misleading. Manufacturers are encouraged to consult with the Food Directorate.

(iii) General claims about “healthy choice”

There are no specific regulations governing the use of general “healthy choice” claims on foods. However, like all claims, whether there are specific regulations or not, they are subject to Subsection 5(1) of the *Act*: they must not be false, misleading or deceptive. There are no standardized nutritional criteria set for foods to be able to carry these types of claims. However, the CFIA and Health Canada have jointly developed guidelines to support the appropriate use of these claims and limit misleading claims. Guidance is provided for a range of representations: advertising and educational material, third-party

¹⁰ By “not objectionable” it is meant that a claim is considered not to be a drug claim and the claim is considered not misleading based on adequate supporting evidence, but there is currently no requirement for premarket review.

endorsements, logos and seals of approval [CFIA, 2003], and statements related to healthy eating or dietary guidance.¹¹ New guidance has also been published by Health Canada on the principles for using the *Eating Well with Canada's Food Guide* in advertising and labelling.¹²

1.3.3 Natural health products in food form

On January 1, 2004, a new category of products under the *Act*, natural health products (NHPs), was created through the *Natural Health Products Regulations*. These products are a subcategory of drugs but with their own regulations. The definition of NHPs, like the definition of drugs, does not explicitly exclude foods or food constituents. Unlike drugs, the definition expands on the term “modifying organic function” so that it encompasses uses associated with the maintenance and promotion of health that are not generally recognized as a primary purpose of drugs. Many of these NHP claims for use are similar to health claims that could be seen on food labels. Food products that make health claims and that are positioned as NHPs would be required to seek site and product licences. When the health claims made on these products are related to disease risk reduction or are considered drug claims, the regulatory amendment process required of food products would be avoided. Further, food-like products regulated as NHPs are not subject to any of the food-related regulations and standards, including those aimed at protecting health and safety.

Recognizing the difficulties with food-like products being regulated as NHPs, in the recent NHP Regulatory Review¹³, a proposed priority action was to exclude food-like products from the purview of the NHP regulations to ensure that such products are safe if consumed as foods and their representation is consistent with that for foods. In the interim, the Food Directorate is cooperating with the Natural Health Products

¹¹ <http://www.inspection.gc.ca/english/bureau/labeti/guide/7-0-0e.shtml#7-2>

¹² http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/gen_prin_e.html

¹³ http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/chart-course_tracer-voie_e.html

Directorate, so that consistent and seamless decisions are made for similar products regardless of the regulatory regime under which the products are managed.¹⁴

A2. INTERNATIONAL CONTEXT

2.1 Management of health claims for foods is a focus of much international activity

Like Canada, many countries are developing frameworks or revisiting existing frameworks to manage health-related claims for foods in light of a rapidly evolving understanding of diet-health relationships and advances in food science and technology. As in Canada, scientific considerations and the multiple perspectives of stakeholders are considered in addressing issues of relevance to consumers, industry and public health professionals. Recent decisions and announcements with regard to managing health claims internationally include:

the decision by the European Parliament and the Council of the European Union (Oct 12, 2006) to regulate nutrition and health claims made on foods, including claims related to the generally recognized roles of nutrients and other substances and claims related to disease risk reduction.¹⁵ This decision followed the publication of a proposal in 2003, subsequent consultations, and announcement of a common position in 2005. A list of pre-approved claims that are not related to disease risk reduction or children's development and health is expected in 2010.

final recommendations on new standards for health, nutrition and related claims are expected in Australia and New Zealand, following an initial policy decision in 2003 and subsequent consultations on Proposal P293 published by Food Standards Australia New Zealand (FSANZ) in 2004 and 2005. A third consultation document was published in April 2007, which included their proposed list of "high level"

¹⁴ http://www.hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/food_nhp_aliments_psn-2007_e.html

¹⁵ <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2006-0198+0+DOC+XML+V0//EN>

claims.¹⁶ The final proposed regulations will be considered by the Australia and New Zealand Food Regulation Ministerial Council mid-year in 2008.

the recent announcement by the US Food and Drug Administration (FDA) of a number of initiatives directed towards understanding consumer response to claims, the use of function claims, and an examination of symbols and logos on foods.¹⁷

The United States has the longest experience in managing health claims, since the passage of the *Nutrition Labeling and Education Act* in 1990.

2.2 International comparisons are tempting but challenging

There are a number of factors that should be kept in mind when comparing international approaches.

(i) Definition of “health claim”

There is no uniform usage of the term “health claim” internationally; the scope and categorization of claims that are considered health claims vary among countries and international bodies.

For example, the Codex guidelines for the use of nutrition and health claims recognize three categories of health claims: nutrient function claims, other function claims and reduction of disease risk claims [Codex Alimentarius Commission, 2004]. In the United States, what is considered a “health claim” under the *Nutrition Labeling and Education Act* (1990) is much more limited: it specifically characterizes the relationship between a substance (food or food component) and a disease or health-related condition.

¹⁶

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>

¹⁷ <http://www.cfsan.fda.gov/~dms/lab-hlth.html>. Federal Register (2007). 72(139):39815-39818

(ii) Each legislative context is unique

The health claim frameworks in different countries are situated in different legislative and regulatory environments that are influenced by local political systems and social values. What is permitted in one country may not be readily transferable to another country. Without understanding the local context in which health claims are regulated or managed, caution should be exercised when comparing the number and types of claims allowed by different jurisdictions.

In addition, enforcement is an issue in many countries. The fact that certain claims appear in the marketplace in different countries does not necessarily indicate that these are permitted under the policies and regulations in place.

(iii) Global challenge of managing claims across product categories

No comprehensive model currently exists internationally to address all issues related to the effective management of health claims. While the specific gaps and areas requiring attention may vary among countries, the challenges of managing the interface between foods and dietary supplements, natural health products, or drugs appear to be a prevalent problem for regulatory authorities.

2.3 The Canadian situation from a general global perspective

In light of these considerations and the dynamic nature of the global environment, it is difficult to position the situation in Canada. However, keeping these points in mind, it is useful to focus this comparison on selected jurisdictions (Australia/New Zealand, Japan, the European Union and the United States) that reflect a range of regulatory and cultural environments regarding three key aspects of health claim management:

- mechanisms of approval and oversight;
- standards of evidence; and
- nutritional criteria for foods carrying health claims.

A detailed comparison between Canada and these jurisdictions with respect to these three aspects of health claim management is included in Appendix D. A further detailed comparison between the United States and Canada is also provided in Appendices E and F. A reference list has been prepared for readers interested in other aspects of regulatory provisions for health claims for foods in these selected countries and regions (Appendix G).

2.3.1 Mechanisms of approval and oversight

In general, the approaches used currently in Canada to manage disease risk reduction and certain function claims are comparable to the norms in the jurisdictions compared. For example, like Canada, all of these jurisdictions require regulatory authorization for the use of disease risk reduction claims. However, the regulatory system proposed for Australia/New Zealand is unique in distinguishing between "serious" (as defined in regulations) and non-serious diseases. While pre-approval is required for risk reduction claims for serious diseases, risk reduction claims for non-serious diseases do not require pre-approval. Some jurisdictions also consider or use scientific reviews from authoritative bodies as the basis for some disease risk reduction claims. In the United States, under the provisions of the *Food and Drug Administration Modernization Act* of 1997, disease risk reduction claims supported by authoritative statements that meet specified requirements can be used on products after a defined period if the FDA has taken no action on a notification submitted by a food manufacturer to use such a claim [Rowlands and Hoadley, 2006].

For known nutrients and their well-established functions, adoption of a published list of acceptable claims or positive listing is a common approach, and claim-specific regulatory approval is generally not required. The management of new function claims (i.e., claims other than those for the well-established functions of known nutrients) is the most divergent aspect among the countries and regions compared. Depending on the nature of the claim, the management of these function claims ranges from no explicit regulatory

oversight, to submitting evidence only upon request, to submitting evidence for review for inclusion in a positive list, to submitting evidence for authorization of a claim.

With respect to foods carrying general health claims about “healthy choice”, unlike in Canada where there are no specified nutritional criteria, in other jurisdictions, compositional criteria for specified nutrients are required, or these claims are prohibited unless provided for in regulations.

For implied health claims, other jurisdictions have adopted or proposed specific regulatory approaches, including prohibition, unless the implied claim is accompanied by an approved specific health claim. This contrasts with the approach taken in Canada, where implied claims are not addressed directly in the *FDR*.

2.3.2 Standards of evidence

In all of the compared jurisdictions, substantiation of disease risk reduction claims is based on two key principles. First, a structured, comprehensive literature review of the totality of relevant evidence based on human studies of acceptable quality is required. Second, the strength of evidence must be convincing in that it consistently supports a causal relationship between the consumption of foods or food constituents and the reduction of a disease risk. This level of supporting evidence is considered to meet the requirement of “significant scientific agreement” in the United States and “scientific assessment of the highest possible standard” in the EU. These principles of substantiation are also proposed in Australia/New Zealand (FSANZ) for “high level” health claims related to serious diseases. Under an interim policy in the United States, disease risk reduction claims that fail to meet evidence requirements for significant scientific agreement may be made if they carry qualifying language, set out by the FDA in its letters of enforcement discretion, that reflects the level of scientific evidence for that claim. This type of health claim is termed a “qualified claim” (see Appendix E for more details). However, the United States is alone

among the jurisdictions we compared in taking this approach to managing disease risk reduction claims that fail to meet a standard equivalent to significant scientific agreement.

The principles of substantiation used for disease risk reduction claims are also generally applicable for function claims. However, as noted above, the process of adopting acceptable claims may vary, depending on the nature of the claim and whether the claim has a prior history of generally accepted scientific agreement. For example, for established functions of known nutrients, a range of sources of authoritative information are accepted or proposed by various jurisdictions. For function claims based on newly developed scientific evidence, the process for claim acceptance may vary from no mandatory premarket scrutiny (the current status in Canada and the proposal in Australia/New Zealand) to required premarket review based on generally accepted scientific evidence (adopted in the European Union).

2.3.3 Nutritional criteria for foods carrying health claims

Internationally, nutritional criteria are required for foods carrying certain types of health claims, although different models for applying qualifying and disqualifying criteria exist. For example:

In Canada, criteria for disease risk reduction claims are set on a claim-by-claim basis, while other countries look to a common set of core criteria supplemented with additional claim-specific criteria.

In Canada, biological role claims for vitamins and minerals must meet qualifying criteria only, while in the European Union and Australia and New Zealand, consideration will be given to several criteria in setting requirements for nutrient profiles of foods carrying any type of health claim.

In some jurisdictions that have, or plan to have, requirements for nutrient profiles for foods carrying health claims, mandatory criteria apply equally to all foods, while in other jurisdictions under voluntary schemes, the criteria may differ based on the food category.

A3. A MODERNIZED FRAMEWORK FOR MANAGING HEALTH CLAIMS FOR FOODS: THE CHANGING CONTEXT

The context for the Canadian health claim system has evolved since the publication of the original policy position in 1998 and the amendments to the *Food and Drug Regulations* in December 2002. This an opportune time to review and modernize the current approach because of that evolution and the following considerations:

Government, consumers, industry and other stakeholders have gained experience with the current approach and are able to bring lessons learned to the table about the strengths as well as the opportunities for improvement.

Scientific understanding about the relationships between foods and food constituents and health has increased.

Industry has demonstrated a rapidly growing and diverse interest in developing innovative food products with health benefits.

Consumer awareness is growing about food-health relationships, as is consumer interest in being able to make food choices that, indeed, help to optimize health. There has been significant recent policy development for managing health and related claims for foods by the European Union, Australia/New Zealand, the United States and the United Kingdom.

A new health product category was introduced in Canada in January 2004 with the *Natural Health Products Regulations*.

The Canadian regulatory environment is positioned to support modernization, with the *Cabinet Directive on Streamlining Regulations*,¹⁸ the Health Products and Food Branch's *Blueprint for Renewal: Transforming Our Approach to Regulating Health Products and Foods (Blueprint and Blueprint II)*,¹⁹ and the *Regulatory Modernization Strategy for Nutrition and Food (Food Strategy)*.²⁰

¹⁸ <http://www.regulation.gc.ca/default.asp@language=e&page=thegovernmentdirectiveon.html>

¹⁹ http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/blueprint-plan_II_e.html

²⁰ http://www.hc-sc.gc.ca/fn-an/consultation/blueprint_food-plan_aliments/index_e.html

Both the *Blueprint* and the *Food Strategy* recognize the need for Health Canada to be a modern regulator, responding to innovation and change while continuing to protect the health and safety of consumers.

While there are a number of *Blueprint II* objectives with direct relevance to modernizing the framework for health claims, Objective 4 of *Blueprint II* identifies a particular goal related to the food regulatory system: moving to a modernized regulatory approach for food safety and nutrition. In response, the *Food Strategy* (April 2007) discussion document outlines several goals that focus on process improvement, regulatory responsiveness to innovation, leveraging the regulatory toolkit to address food contributors to chronic disease, and improved responsiveness to acute food safety risks while managing ongoing risks. Modernization of the health claim framework for foods is proposed as an early deliverable addressing responsiveness to innovation (Goal 2).

PART B: ISSUES AND DISCUSSION

B1. DISCUSSION THEME 1: EFFICIENT AND TRANSPARENT PROCESSES

A number of the concerns about the status quo have pointed to issues around how the current policies and regulations are implemented, rather than the policies and regulations themselves. Concerns raised in this area point to the need to both:

- modernize or improve processes used to approve claims (Theme 1.1); and
- develop a more transparent and open approach (Theme 1.2).

This theme links directly with the larger related initiatives such as the *Blueprint for Renewal* and the *Regulatory Modernization Strategy for Food and Nutrition*.

Theme 1.1 Business improvements for increased efficiency

Issues

Industry has voiced concerns that the current premarket assessment process is slow and fraught with delays and uncertainties: industry representatives have emphasized the importance of predictable, efficient processes that are as timely as possible. Examples of specific complaints about the process include not being able to track the progress of the review of a submission and having no mechanism to resolve disagreements over decisions. Industry has also raised concerns about the lack of clarity around the types of health claims that need to be submitted for consideration and the process that would be used to evaluate them. Furthermore, the requirement for case-by-case regulatory amendments to permit disease risk reduction claims is often seen as cumbersome and time consuming.

In addition, the lack of cooperation on claim reviews and of comparable processes between regulatory authorities of trading countries further frustrates industry, prompting comments such as “My claim has been approved in the US [or another jurisdiction]; why can’t I use it in Canada as well?” Even if the same scientific review were accepted in Canada for a disease risk reduction claim, a regulatory amendment would still be needed to permit the use of this type of claim on food.

As a result, industry views the current assessment and regulatory processes as restrictive, cumbersome, and lagging behind the demand for responsiveness in a global market [Inter/Sect Alliance, 2001; Michaelides and Cooper, 2005, Doering, 2006]. It is felt that the current processes hamper bringing innovative products to market and hinder industry from doing business in an organized and effective way domestically, while limiting opportunities to compete internationally [FCPC, 2006].

These issues, combined with the smaller Canadian marketplace, can serve as disincentives for industry to develop and sell “value-added” food products, which in turn limits consumer access to innovative healthy food choices in Canada. Canadian companies say, as well, that they are missing opportunities in some countries where the ability to use a new claim depends on having acquired hard-to-get domestic approval in Canada first. This can unintentionally act as a barrier to export markets.

Concerns have also been raised about the need for processes to maintain the credibility of health claims over the longer term, and the need to keep pace with current science supporting existing claims. Although the best available evidence is used at the time of assessment, the evolving nature of science suggests there may be a need to re-evaluate the evidence base supporting approved claims under certain circumstances [IOM, 2002].

Discussion

While the claim-by-claim regulatory amendment process is often cited as a key impediment to more timely authorization of claims, two points need to be kept in mind. First, the process applies only to products with health claims that need to be exempted from the drug regulations (i.e., disease risk reduction and some function claims that would be considered drug claims), as discussed in Section A1.3. Second, the process represents only one of two steps of the authorization process, the other being the review of the scientific basis supporting a claim.

As well, the case-by-case regulatory amendment approach has a number of strengths:

- It allows the setting of clear conditions of use of the claims for industry and consumers, which supports credibility with consumers and provides a level playing field for industry by allowing consistent enforcement.

- For disease risk reduction claims, a regulatory amendment approach is consistent with the approach used and applied internationally.

In addition, the current mechanism was only recently implemented and this was done after full consultation. There are other considerations to keep in mind:

The development of alternative regulatory or legislative mechanisms would require a complex, lengthy legal process adjusting a number of regulations or opening the *Act*. It would have to be shown that there were compelling flaws that needed to be corrected.

A greater and more immediate impact on reducing timelines could be obtained by implementing process improvements (on the part of Health Canada) and improving the quality of submissions (on the part of petitioners). The time required to review the evidence in a premarket submission within Health Canada is affected by many factors, such as the complexity and novelty of the product; the quantity, quality and completeness of the data submitted; the time taken by petitioners to respond to requests for additional information; and the availability of qualified evaluators. Initial analysis of the critical points along the process, from submission of a claim to completion of the regulatory amendments, reveals that significant and immediate reductions in time delays likely could be made through process and business improvements in the submission and review steps preceding the regulatory amendment stage.

Recent reviews of the situation have similarly concluded that the challenges to timeliness are a function less of the regulations than of their administration [Martin and Steifelmeyer, 2006].

In light of these considerations, Health Canada has decided to give priority to addressing process improvements that are expected to provide the greatest improvement to timeliness of decisions, while retaining a high degree of credibility of the claims.

The *Submission Modernization* project in the *Food Strategy* will provide the framework for many of the process improvements for premarket review, most of which will also be

applicable to health claims submissions, such as development of service standards and performance targets.

While the health claim submission review process will be able to call upon the results of the *Submission Modernization* project in general, a number of specific actions have been initiated or planned to address key operational issues (work on the first two initiatives has begun):

Dedicate additional resources to the review of health claims for foods in the Nutrition Evaluation Division in the Bureau of Nutritional Sciences, Food Directorate, Health Canada.

Implement standard operating procedures (SOPs) for the Health Canada review of submitted claims. Finalized SOPs will be shared with stakeholders.

Develop the parameters for an abbreviated process for claim review where internationally recognized scientific bodies or competent national authorities have recently completed a review and deemed the claim valid. Acceptable ways to deal with different decision outcomes would also need to be considered.

Where claim-specific regulatory amendments are required, examine ways to improve efficiency in administering the current regulation. Several options are being considered, including dedicating more resources to regulatory drafting and legal services and exploring when it might be possible to expedite the time taken to proceed to the final amendment of the *Regulations* in the *Canada Gazette Part II*. Consistent with the Health Canada *Decision Making Framework*²¹ (where ongoing review is recognized as a necessary component of policy and regulatory life cycles), explore appropriate “triggers” and processes for deciding when a second review of an approved claim may be needed. However, this is not considered a priority activity at this time.

²¹ http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/risk-risques_cp-pc_e.html

Questions

1. Several business improvements are proposed to address key operational issues:
Dedicating additional resources to the review of health claims for foods;
Implementing standard operating procedures (SOPs) for the Health Canada (HC) review of submitted claims. Finalized SOPs will be shared with stakeholders;
Developing the parameters for an abbreviated process for claim review where internationally recognized scientific bodies or competent national authorities have recently completed a review and deemed the claim as valid. Acceptable ways to deal with different decision outcomes would also need to be considered;
Examining ways to improve efficiency administering the current regulation, where claim specific regulatory amendments are required. Several options are being considered:
 - dedicating more resources in regulatory drafting and legal services
 - exploring when it may be possible to expedite the time taken to proceed to the final amendment of the Regulations in *Canada Gazette Part II*Exploring appropriate triggers and processes for deciding when a second review of an approved claim may be needed. However, this is not considered a priority activity at this time.

Overall, how effective do you feel these actions would be, using a 1–6 rating, with 6 being highly effective and 1 being not effective at all.

1 2 3 4 5 6

Please explain your rating:

2. What additional business improvements could you suggest?

Theme 1.2 Increased openness and transparency

Issues

The need for increased openness and transparency has been raised from a number of perspectives. Public interest groups, academics and health professionals would like to have increased access to the decision-making process with a mechanism in place for public input. As well, these stakeholders have suggested that the public should have access to the evidence submitted to support a claim, and health professionals would like to see the data that support claim decisions published in peer-reviewed journals (or on the Health Canada website).

Discussion

There has been a great deal of interest, from many areas of government, in promoting more transparency and openness in decision making. As part of the *Blueprint*, the Health Products and Food Branch recently completed stakeholder consultations to develop a policy on public input into decision making for regulated products. The final policy,²² published in May 2007, sets out the standards to follow regarding when, and how, public input should be considered.

With respect to publishing decisions regarding individual health claims, the Food Directorate is interested in exploring a standardized approach to publishing summarized evidence, as well as its decision on the evidence submitted and the rationale for that decision, while respecting the proprietary nature of data. Examples to consider could range from detailed reviews, such as those published by the Food Directorate²³ and the FDA²⁴ to communicate their health claims decisions on their websites, to abbreviated summaries like those used by the Food Directorate to communicate novel food

²² http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index_e.html

²³ http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/position_paper-enonce_position_e.html

²⁴ <http://www.cfsan.fda.gov/~dms/lab-hlth.html>

decisions.²⁵ Other examples include the monographs²⁶ published by the Natural Health Products Directorate (NHPD) in Health Canada and by the European Scientific Cooperative on Phytotherapy [ESCOP, 2003].

Feedback is sought on the depth and breadth of decision documents to be published by Health Canada.

Questions

1. Health Canada is exploring the possibility of publishing decision documents related to health claim applications. All proprietary information would be excluded. Please tick the box beside the information that you think should be included in published decision documents from

the health claim submission:

- proposed health claim
- summary of evidence submitted
- full tabulation of evidence submitted
- other (please specify)

Health Canada's assessment:

- summary of HC scientific evaluation of the submission
- detailed HC evaluation of the submission
- results of consultations, if applicable
- decision and rationale (including conditions of use for an accepted claim and product)
- other (please specify)

Please explain your selections:

²⁵ http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index_e.html

²⁶ http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_list_e.html

Please provide a copy of what you consider to be an appropriate format for a decision document in the Canadian context.

B2. DISCUSSION THEME 2: SOUND EVIDENCE FOR CONSISTENT, CREDIBLE CLAIMS

Sound research that results in strong evidence is key to the development of truthful and credible health claims. While this principle is generally agreed upon, there are a number of issues related to its application. Specific issues related to the substantiation of claims include:

- the nature of the evidence needed to substantiate a health claim and how to interpret it for decision making (Theme 2.1); and
- the capacity of petitioners to provide the evidence (Theme 2.2).

Theme 2.1 Scientific substantiation of claims

Issues

The scientific substantiation of a health claim has two interrelated components: (1) the substantiation process based on systematic review of the totality of relevant evidence in humans and (2) the strength or level of evidence required.

In Canada, both the substantiation process and the level of evidence that is required for determining the acceptability of health claims on foods may be affected by the review process and the level of evidence for substantiating similar claims for NHPs. At present, there may be the potential for inconsistencies between NHPs and foods in both the required process and level of evidence for reviewing similar claims on similar products. Different guidance documents are applied in evaluating and approving acceptable claims in the two programs. More detailed discussion on the food/NHP interface is found under Theme 3.1.

In addition, some stakeholders have noted that there is no flexibility in meeting the current standards of evidence for foods: the requirement is uniformly stringent regardless of the level of the potential risk involved or the nature of the claim. In contrast, some jurisdictions have explored different approaches to dealing with proposed claims for which the highest standard of evidence has not been reached. For example, in the United States, health claims that have failed to meet the required standards of evidence can appear on food packages provided there is at least some evidence and the wording of the claim discloses the weakness of the evidence.

On the other hand, some stakeholders feel that the cornerstone of credible health claims is the application of clear, high standards of evidence and they want health claim approvals to be restricted to those supported by strong science.

Discussion

Regardless of the degree of regulatory oversight required for claims approval (Theme 3), the following key factors seem to support the principle that all specific health claims should be based on similar substantiation requirements and the level of evidence should be high or convincing so that an accepted claim is unlikely to change with new studies on the subject:

The principles of totality of evidence and the requirement for a high or convincing level of evidence (elaborated in the *Interim Guidance Document* [Health Canada, 2002]) remain consistent with international standards that have been adopted or recently proposed for disease risk reduction claims [FDA, 1999; 2007; Aggett et al., 2005; FSANZ, 2005 Dec; Codex Alimentarius Commission, 2006; EFSA, 2007]. Consumers tend not to differentiate among different types of claims about a given food or diet and disease/health relationship [FSANZ, 2005 Apr]. This suggests that their expectations regarding the credibility and "promise" of the different claims are similar. Therefore, to allow for a different degree of certainty or rigour of evidence may not be supportive of informed use.

Allowing claims based on less than convincing evidence would only increase the likelihood of claims needing to be withdrawn and could further erode public confidence in using health claims and scientific developments, in general, when they make food choices.

Research reported to date is not convincing that qualifying statements or disclaimers can appropriately convey the qualification needed to prevent potentially misleading interpretation [Derby and Levy, 2005; France and Bone, 2005; Hooker and Teratanavat, 2005; Mason et al., 2007].

However, there are other significant pressures that suggest the Food Directorate may need to review how it applies the principles of scientific substantiation of health claims on foods and whether there is a need for convincing evidence for all types of specific health claims. This pressure is not unique to Canada. For example, FSANZ have indicated they are considering accepting evidence that is less than convincing (e.g., “probable”) for their “general level” claims. This approach partly addresses the desire from industry to market food products to those consumers who are ready to buy certain products before the claimed benefits are supported by a high level of evidence.

In the case of function claims, there appears to be a perception that these claims present a lower health risk or are less important to health than disease risk reduction. It has been suggested that, function claims should not require the same level of certainty for substantiation as disease risk reduction claims and emerging evidence may be sufficient to substantiate these claims.

The need for the Food Directorate to review its current approach to the scientific substantiation of health claims is also prompted by the number of food products that are seeking claim approvals through the NHP framework, as discussed in Theme 3.1. Under the NHP framework, the level of evidence required for a health claim is commensurate with the level of risk of the product and its intended use. While NHPs have different

purposes than foods, a risk-based approach may also be considered in evaluating the evidence required in substantiating health claims for foods.

The Food Directorate plans to explore (1) whether certain claims may be accepted based on a lower level of evidence than is currently required for disease risk reduction claims and (2) whether it may be reasonable to implement a system of varying levels of evidence in supporting health claims as long as consumers are not misled. This would require:

establishing a risk categorization system for health claims on foods whereby claims considered “lower risk” may be supported by a lower level of evidence; and
developing ways of conveying to consumers the varying levels of evidence supporting the claims.

Questions

1. A high level of certainty in scientific substantiation of claims is based on the following:

structured, comprehensive literature review of all the relevant evidence,
human studies of acceptable quality, and
consistent cause-and-effect relationship between the consumption of foods or food constituents and the claimed health benefit.

Should all claims be based on a high level of certainty? Please provide the rationale for your response.

- 1a. If there is a role for claims based on a lower level of certainty,
what principles should determine which claims could be based on a lower level of certainty?
should consumers be informed of the level of certainty that supports a claim?
what type of information about the level of certainty should be conveyed?

- 1b. How should this be communicated? Please provide evidence (if available) to show that what you suggest would not be misleading to consumers.

Theme 2.2 Supporting good-quality submissions

Issues

Petitioners have indicated that they need more specific guidance on the data required when making a submission (e.g., the type, number and size of studies required). At the same time, small and medium-sized enterprises view the substantiation requirements to support health claims to be too costly. However, other stakeholders have raised concerns about the potential for decisions being based on a small number of industry-funded, short-term studies.

In addition, the differences between the Canadian and American requirements for completeness of the submission package, formatting of the information, and extent of the work required for submission of evidence to substantiate claims can present difficulties for international firms, who would like to see greater consistency between countries for submission requirements.

Discussion

Sound decisions are based on a properly conducted systematic review of the evidence. It is recognized that developing submissions with appropriate substantiation and evidence can require specialized competencies and can be costly, complex and difficult for some industries to undertake. Though at times challenging to produce, quality submissions are a critical component in improving the efficiency of the premarket review process by addressing the essential questions and minimizing the need to request additional information from petitioners, thus reducing delays.

It is the responsibility of petitioners wishing to use a claim to prepare and submit quality submissions. Health Canada does not have the resources to compile all of the evidence around the vast array of health claims that industry may want in a timely manner, nor would industry requests necessarily be consistent with Health Canada's public health mandate or priorities. As the regulator, Health Canada must retain independence from the development of the submission; however, there is a role that Health Canada can play to facilitate the preparation of quality submissions.

For example, to help support quality submissions, a recent pilot project was run between the Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA) at the University of Toronto and Health Canada to assemble and review the evidence needed to support a health claim for certain soluble fibres. This review and tabulation of the scientific evidence greatly aided in the assessment of the usability and validity of the present guidance for claim submissions.

Further activities aimed at providing clear guidance on required standards of evidence and related requirements for submissions include:

- encouraging pre-submission consultations;
- updating the 2002 *Interim Guidance Document* to include specific guidance on the preparation of a structured, systematic review with the knowledge gained from the work done by the PFSNRA and Health Canada;
- supporting in principle the efforts of third parties to coordinate and assist small and medium-sized industry members that are willing to collaborate in making joint submissions on ingredients or food constituents of common interest;
- exploring ways to address gaps in the scientific evidence associated with the health-related benefits of food ingredients at a pre-submission stage with interested parties (e.g., Agriculture and Agri-Food Canada); and

participating in third-party forums organized to sustain domestic infrastructure for basic and applied research in food and nutritional science needed to support the development of safe, innovative food products with substantiated health benefits.

The first two activities have begun and the rest are being explored.

Questions

1. Health Canada is proposing several ways in which it could support industry in drafting good quality submissions:

encouraging pre-submission consultations;

updating the 2002 *Interim Guidance Document* to include specific guidance on the preparation of a structured, systematic review with the knowledge gained from the work done by the PFSNRA and Health Canada;

supporting in principle the efforts of third parties to coordinate and assist small and medium-sized industry members that are willing to collaborate in making joint submissions on ingredients or food constituents of common interest;

exploring ways to address gaps in the scientific evidence associated with the health-related benefits of food ingredients at a pre-submission stage with interested parties (e.g., Agriculture and Agri-Food Canada); and

participating in third-party forums organized to sustain domestic infrastructure for basic and applied research in food and nutritional science needed to support the development of safe, innovative food products with substantiated health benefits.

Overall, how effective would these proposals be, using a 1–6 rating, with 6 being highly effective and 1 being not effective at all.

1 2 3 4 5 6

Please explain your rating:

2. What should be industry's role in preparing good quality submissions?
 - 2a. Which organizations could support applicants in preparing good quality submissions? How?
3. In managing health claims for foods, there is a need for long-term research to substantiate potential health benefits and to identify health risks. Which organizations can help strengthen or support research in these areas? How?

B3. DISCUSSION THEME 3: CLEAR POLICIES FOR TODAY AND TOMORROW

The activities under this theme build on the 1998 policy related to health claims for foods and focus on clear, consistent policies to manage a variety of health claims on foods. A continued effort to look ahead is critical to help Health Canada direct resources and energies appropriately to anticipate and be able to respond to emerging scientific developments and market innovations.

To allow an increasing variety of health claims on an expanding number of food products will require Health Canada to carefully examine its current policies, interpretations and practices. A number of policy areas require development and clarification, including:

- functional foods and foods at the food/natural health product interface (Theme 3.1);
- managing a broader range of function claims (Theme 3.2);
- managing diverse front-of-package claims (Theme 3.3); and
- eligibility criteria for foods to carry claims (Theme 3.4).

Each of these is discussed more fully below. Although they are discussed separately, it should be kept in mind that they form a web of interrelated issues requiring policies that are aligned among themselves, as well as with broader policies in the Health Products and Food Branch and Health Canada.

Social and consumer research will be critical to support policy development. Examples of particular areas of interest are given below:

What are consumer attitudes and expectations towards the display of health claims and health-related representations on foods (e.g., “healthy” symbols and slogans on the front of packages)?

What are their expectations regarding accountability and substantiation?

How do they use and interpret the different types of health claims on foods?

When are health claims considered “misleading” by consumers?

How do consumers use health claims or other health-related representations, and the Nutrition Facts table together?

How do consumers interpret health claims on foods that also contain “negative” nutritional attributes?

What are consumer attitudes towards products that carry health claims compared to similar products without health claims?

The Food Directorate welcomes relevant data and studies about health claims in the Canadian context that would add to our understanding of these or other relevant issues.

Theme 3.1 Functional foods and the food/natural health product interface

Issues

In Canada, foods carrying health claims may fall under one of two regulatory frameworks and policies, depending on how they are represented: those for natural health products (NHPs) and those for foods. The industry is uncertain about which regulatory framework it should be seeking approvals under, and what the implications are of the decision for new products and claims.

The two product categories have, in general, different intended uses. Depending on which system is chosen by the manufacturer, there are differences in standards and processes

regarding (1) premarket review of claim validity, (2) product safety assessment, and (3) risk management approaches to ensure safe use.

As a result, there is a risk of inconsistent regulatory outcomes for similar products processed through the two different frameworks. Similar products (e.g., fortified juices) may be required to be labelled in a different manner. For example, those regulated as foods require Nutrition Facts table, ingredients and allergen labelling, which is not required for the same products marketed as NHPs, which carry directions for use and caution statements. This difference may trigger confusion among consumers and enforcement agencies.

Further, food products regulated as NHPs are not subject to the food safety requirements (such as standards for low-acid canned food, food additive and contaminant limits) or the novel food requirements for novel processes or ingredients. Many products at the food/NHP interface contain added bioactive substances. Depending on the nature of the bioactive substance and represented use, these products can raise concerns about their safety and their role as foods in the diet. Canadians may have a tendency to consume these NHPs in food form in a similar fashion to foods, without taking into consideration the recommended conditions of use, thus increasing the risk of potential adverse effects.

Products are also subject to enforcement and compliance by different agencies, depending on the regulatory regime. The CFIA has responsibility for ensuring compliance with and enforcement of regulations with respect to food products and relies on triggers such as the Nutrition Facts table to clarify whether a product is a food or an NHP. The Health Products and Food Branch Inspectorate has responsibility for ensuring compliance with and enforcement of NHP regulations. If manufacturers of food-like NHPs voluntarily include elements on their product label normally required for foods, such as a Nutrition Facts table, the Inspectorate does not have the authority for enforcing the food provisions in the *FDR*.

Discussion

Gaps and uncertainties in current policies related to the interface between foods and NHPs have already been recognized as major concerns to be addressed. The Natural Health Products Directorate (NHPD) in Health Canada recently initiated the Natural Health Products Regulatory Review²⁷ to guide the process of refining the regulation of NHPs in Canada. A background document was prepared for Phase I of the consultation, Issue Identification, to guide stakeholder consultation and seek broad-based input on the issues [Health Canada, 2007 Feb (comment period now closed)]. Addressing the food/NHP interface has been identified as a priority activity in the short-term work plan of the Review. One objective of the Review is to amend the *Natural Health Products Regulations* to exclude food-like NHPs from their purview. This regulatory amendment would make it clear that these products would not be regulated as NHPs.

The Food Directorate and NHPD are working collaboratively to ensure a consistent approach to the review of products at the interface, including product claims. For example, the risk assessments that were used to establish the safe addition of vitamins and minerals to foods have been applied to the NHPD assessment of food-like NHPs containing these added substances. In addition, Food Directorate staff will participate as members of the NHPD task force in a pilot project on the development of relevant monographs.

Through these actions it is hoped that consistent assessments and risk management decisions will be made by the two directorates so that there will be seamless, consistent decisions for similar products regardless of the regulatory regime under which the products were managed. Such collaboration²⁸ is intended to help minimize any disruption that may occur when the revisions to the *NHP Regulations* to exclude foods are completed.

²⁷

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

²⁸http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/bulletins/food_nhp_aliments_psn-2007_e.html

Some of the products at the food/NHP interface are called “functional foods” (a term without a standard definition, but generally used to refer to foods with specific health-enhancing characteristics). Many of these functional foods and associated health claims pose no different issues related to health and safety than traditional foods, and the current policies and regulations in the food framework are suitable for their management.

However, some of these functional foods contain added bioactives and may raise questions of safety under situations usually encountered with foods – for example, when consumed by the general population, or consumed *ad libitum*, or consumed for extended periods.

Current approaches aimed at ensuring safe *ad libitum* consumption by the general population of foods containing added bioactive substances could deny market access to innovative products. Additional measures may need to be considered for some products developed to meet the special needs of population subgroups, or foods used to deliver bioactive substances at doses high enough to achieve the intended benefit, but too high to be considered safe for *ad libitum* consumption by non-targeted groups. Additional measures may need to be considered, including (1) using claim wording, directions for use and packaging design to ensure that the product is directed to the appropriate target group and indicates the appropriate intake level, (2) revising the regulations to establish additional controls, and (3) exploring similar mechanisms as used by NHPs for identification of active ingredients, directions for use and cautionary statements. The effectiveness of these options on food labels remains to be verified.

Functional foods potentially span a wide range of products and claims. At one end of the range, functional foods represented for the diagnosis, treatment, mitigation, or prevention of diseases, or restoring, correcting, or modifying organic function, functional foods may challenge existing views about the role of foods and pose questions about the acceptable use of food as a vehicle for therapeutic substances. At the other end of the range, there

may be food products being marketed without a health claim but with bioactive substances added at levels that would not provide a meaningful health benefit. While this level of addition may not pose health concerns, the simple declaration of the added bioactive substance in the food, when highlighted and positioned on the front of the package, could be misleading to consumers if it is perceived to provide a health benefit. As a result, there is a need for the Food Directorate to review related policies to guide the integration of these products under a food framework.

The Food Directorate is seeking feedback on the role and management of functional foods with added bioactive substances.

Questions

1. What are the expected areas of development of functional foods or bioactive ingredients in the next 1–3, and 3–10 years? Why?

2. Considering the addition of bioactives to foods in general, are there some types of bioactive substances that should not be added to foods at any level? Please identify and explain.
should the addition of bioactive ingredients be allowed in foods at levels that, while safe, are too low to claim any health benefit? Please explain.

3. Is there a case for adding bioactive substances to foods at levels that would benefit some, but be risky to that same group if improperly consumed, or risky to other segments of the population?
 - 3a. If these types of bioactive substances were to be considered, what type of risk management options would be appropriate
to ensure that the untargeted population is not put at risk, and
to ensure the safe use of the product by the target population.

Examples used for managing this type of risk in Natural Health Products (NHPs) and drugs include the following:

- claim wording
- packaging to target specific user groups
- restricting distribution channels
- directions for use
- cautionary statements
- warnings

3b. If possible, explain how the risk management measures you suggest would be effective when applied to products sold as foods.

Theme 3.2 Managing a broader range of function claims

Issues

Concerns have been raised that Canada allows a narrow range of function claims, and that there is uncertainty and a lack of clarity in the current policies and processes that would enable a broader range of function claims to be made on foods.

There is a growing interest on the part of industry to move toward using function claims. There are a number of reasons for this:

Function claims have fewer regulatory requirements than disease risk reduction claims. Disease risk reduction claims are subject to rigorous premarket review, require a regulatory amendment and have strict requirements for both claim wording and conditions of use.

There appears to be a perception that function claims present a lower health risk or are less important to health than disease risk reduction and should not require the same level of certainty for substantiation as disease risk reduction claims.

Research indicates that consumers do not make clear distinctions between different types of nutrition and health-related claims [Katan, 2004; FSANZ, 2005 Apr; Williams, 2005] and suggests that function claims may be at least as persuasive as disease risk reduction claims on consumer food choice. While all claims have to be truthful, not misleading, and not likely to create erroneous impressions as laid out under the *Act*, there is no regulation that specifies when a claim would be deemed “not misleading”.

This lack of clarity contributes to an environment of uncertainty and may inadvertently foster the inappropriate use of function claims. This can lead to confusion for consumers, erode the overall credibility of health claims, make consistent enforcement and compliance difficult, and create an uneven playing field for responsible manufacturers that do invest in appropriate substantiation of their claims.

Discussion

Availability of a broader range of function claims is consistent with the intent of the 1998 policy document. However, responding with policies and processes to enable a broader range of claims while ensuring their credibility presents a number of challenges:

As noted in theme 2.1, compared to well-established functions of known nutrients, there is generally less evidence to support substantiation of claims regarding recently identified functions of nutrients and other food constituents.

For some function claims, the distinction between maintaining body functions (claims acceptable for foods) and restoring or modifying body functions (considered drug claims) is not always obvious. Some function claims may bring a product within the definition of a drug and thus have the same regulatory requirements as disease risk reduction claims.

A number of related activities have been initiated or planned to address some of the issues, including:

- clarifying the nature of acceptable function claims that would not be considered drug claims,
- encouraging industry to submit, voluntarily, new function claims for review by the Food Directorate, and
- maintaining an up-to-date list of function claims that are deemed “not misleading” in the *CFIA Guide to Food Labelling and Advertising*.

However, there are questions about the sustainability and suitability of this approach to manage the innovative types of products and claims foreseen in this area. There may be other mechanisms (regulatory and voluntary) and tools that should be considered to help ensure substantiation of claims and consistent messaging to consumers. Questions remain around the conditions of use, such as minimum and maximum levels of the substance that is the subject of the claim, when dietary reference intakes for the substance are not available.

Feedback is being sought on the level of oversight and supportive measures that would help foster credible and responsible use of a broader range of function claims.

Questions

1. Some measures are proposed in the document to help ensure credibility of a broader range of function claims:

- clarifying the nature of acceptable function claims that would not be considered drug claims,
- encouraging industry to submit, voluntarily, new function claims for review by the Food Directorate, and
- maintaining an up-to-date list of function claims that are deemed “not misleading” in the *CFIA Guide to Food Labelling and Advertising*.

Overall, do you feel these non-regulatory measures would be sufficient to manage an expanding range of function claims, using a 1–6 rating, with 6 being completely sufficient and 1 being not sufficient at all.

1 2 3 4 5 6

Please explain your rating:

2. What other types of non-regulatory measures would you suggest?
3. Health Canada could also rely on regulatory measures for more rigorous control of claims.

Please indicate whether Health Canada should explore the following measures:

3a. requirement for the submission of supporting evidence when there are concerns about the credibility of a health claim being used on foods already in the marketplace.

Yes No

Please explain:

3b. mandatory pre-market review of function claims

Yes No

Please explain:

4. Are there other regulatory measures that Health Canada should consider? If so, please identify the measure(s) and explain your rationale.

Theme 3.3 Managing diverse front-of-package claims

In Canada, as in other countries, there has been a proliferation of health-related claims on the front or principal display panels of food packages. These front-of-package (FOP) claims promote some facet of the nutritional quality or health value of the food. FOP claims range from simple graphics and icons (e.g., hearts, bones, check marks), to multiple graphics, to symbols suggesting “healthy choice,” to slogans (e.g., “healthy choice,” “nutritionists recommend,” “good for you”).

These claims can be divided into two main groups:

- (1) implied claims used as alternatives to specific disease risk reduction or function claims; and
- (2) claims used to convey simplified nutritional or general health messages.

Questions related to both groups of claims are listed at the end of Theme 3.3.2.

Theme 3.3.1 Implied health claims

Issues

Implied health claims include claims that suggest specific product health benefits through the use of symbols, graphics, or adept use of positive wording and slogans and can be influential on food choice behaviour of consumers [FSANZ, 2005 Apr]. Currently, implied claims are not addressed directly in the *FDR*. Further, it is difficult to demonstrate the intended message of an implied claim. Because an implied claim is open to interpretation by the reader and depends on the context, it is difficult to know what message consumers are taking away, or how consistently the message is being understood. Therefore, in cases where the regulator has concerns, it can be difficult to establish that an implied claim is misleading.

Discussion

Implied health claims are sometimes used to convey specific disease risk reduction claims or function claims but are not considered acceptable in Canada:

- prior to appropriate substantiation; or
- where the product does not meet the eligibility criteria for a specific claim; or
- as a mechanism to circumvent the regulatory amendment process where required.

However, there may be circumstances where a manufacturer may prefer to market a product that meets all the criteria for an approved disease risk reduction claim by using a symbol or a slogan as a more effective way to transmit the message to the consumer than the claim wording specified in regulations. Creative use of FOP symbols or slogans may enhance the brand distinctiveness of the product and help address the space constraints associated with the use of lengthy statements required of disease risk reduction claims. As noted in Section A1.3, currently the wording of disease risk reduction claims is specified in the *FDR* without any provision for alternatives. While this approach has a number of strengths, it also poses challenges for industry, particularly for bilingual labels on small packages. Research also suggests that longer claims may be more difficult for consumers to understand than shorter claims, particularly when consumers are in a hurry [Wansink, 2003; FSANZ, 2005 Apr].

There is a need for measures that would foster the appropriate use of graphics, symbols, or slogans to convey product health benefits in the current unregulated environment. Failure to attain public confidence in voluntary industry practice may result in the need to explore regulatory actions. Approaches taken in other jurisdictions may be considered. For example, in the EU, implied health claims are prohibited unless accompanied by an explicit claim. A similar approach is also being proposed by FSANZ (see Appendix D). At the same time, the Food Directorate recognizes that there is a need to provide additional flexibility in the communication of disease risk reduction claims. Alternative approaches

should maintain credibility and clarity for consumers, as well as clear guidance for compliance and enforcement.

Theme 3.3.2 Simplified nutritional or general health messages

Issues

Symbols or other types of graphics suggesting “healthy choice” are examples of simplified nutritional or general health messages that can be found on the front panel of food product labels. Different FOP symbols or claims are based on different criteria and serve different objectives. With the exception of guidelines surrounding the use of and reference to *Eating Well with Canada’s Food Guide*, which have recently been revised, guidelines on the use of the term “healthy” have not been updated. There are no standardized criteria to ensure consistency among FOP symbols or claims. Some criteria for FOP claims may be based on a single nutrient, others use a group of nutrients (like fat, sugar and sodium) and still others are more complex by taking into consideration dietary guidance. Some criteria have been developed by manufacturers, while others have been developed by third parties. However, consumers cannot readily identify which criteria are used for any particular FOP symbol or claim.

Some of these claims oversimplify complex nutritional messages and can therefore be misleading. Adept wording and images can suggest stronger links to health than can be substantiated [CSPI, 2006; Dietitians of Canada, 2006]. Evidence suggests that FOP claims can reduce the use of detailed back-of-package information such as the Nutrition Facts table, information that might have helped consumers make more-informed choices [Williams, 2005].

As a result, consumers:

- cannot easily compare one product to another based solely on the different symbols because of the varying criteria;

may misinterpret similar FOP claims on products as representing the same product nutrition attributes, when in fact different criteria have been used; and may view these products as “healthier” than those without any type of FOP claims, and may be drawn away from cheaper, equally healthy products not carrying a FOP claim.

Unregulated and unstandardized FOP claims may confuse or mislead consumers, and may fuel mistrust and scepticism about the validity of health claims in general [Health Canada, 2001, 2004; Sullivan, 2003; Marquis et al., 2005; IFIC, 2006]. In spite of this, simplified representations of the nutrient profiles of food products appear to be influential and have appeal for consumers.

Discussion

The recent proliferation in the use of FOP symbols, graphics and slogans to convey simplified nutritional or general “healthy” messages, or a role in the diet in relation to dietary guidance, presents new challenges and opportunities. These marketing trends have prompted different actions in Canada and other jurisdictions. For example, policy initiatives related to the use of symbols or logos have been launched in the UK and by FSANZ in the past year. In the US, a public hearing concerning the use of symbols to communicate nutrition information on food labels was held in September 2007. In its report *Healthy Weights for Healthy Kids*, the Standing Committee on Health (March 2007) recognized the potential influential role that clear, simple FOP labelling with standardized criteria could have on consumer behaviour and recommended that the federal government take action as soon as possible.

In Canada, where mandatory nutrition labelling is already in place and the format of the Nutrition Facts table is standardized, the potential impact and benefit of setting standards for simplified forms of nutrition labelling on the FOP and the type of oversight that would be required warrant careful analysis [Dietitians of Canada, 2006]. Consumer research is

proposed by Health Canada to help improve understanding of how FOP symbols or other representations are interpreted and used by Canadian consumers in concert with the mandatory Nutrition Facts table and, in particular, how FOP symbols or other representations may influence food purchase behaviour. This research would explore, as well, consumer expectations regarding the roles, responsibilities and accountability of government, industry and other stakeholders for the proper management of these types of claims.

The Food Directorate invites input from stakeholders to help scope out the issues, challenges and opportunities posed in the Canadian context by the management of a variety of health-related claims on the front of package. Health Canada would welcome data related to any of the issues raised above. At this time, consultation will focus on exploring core eligibility criteria for foods carrying health claims, as discussed in the following theme.

Questions

1. Several measures are proposed to ease confusion by consumers over the proliferation of health-related claims on the front of food (FOP) packages:
 - educating consumers on the Nutrition Facts table and ingredient listings in conjunction with FOP symbols and claims,
 - providing guidance to industry on conditions and wording that would help ensure that claims are not misleading,
 - improving nutrition labeling regulations as needed, and
 - monitoring the marketplace to ensure that activities related to consumer education, industry guidance, and regulatory changes are evidence-based.

Would these measures be sufficient to reduce the confusion arising from the proliferation of health-related claims on the front of food packages?

Yes No Please explain:

2. Prohibiting implied claims of a health benefit, unless the health effect is clearly stated, could also reduce consumer confusion. How worthwhile would it be to explore this measure, using a 1–6 rating, with 6 being highly worthwhile and 1 being not worthwhile at all.

1 2 3 4 5 6

Please explain your rating:

Theme 3.4 Eligibility criteria for foods to carry claims

Issues

The concept that foods eligible for health claims should meet certain nutritional criteria other than the criterion for the substance that is the subject of the claim is not new in Canada. However, until now, these criteria have been applied on a claim-by-claim basis, and only to disease risk reduction claims. There are currently no common core criteria in Canada to determine which foods are eligible to carry health claims.

As discussed in Theme 3.3.2, the lack of standardized criteria for different simplified nutritional or general health messages or representations on the front of food packages can be confusing for consumers. Similarly, the absence of core eligibility criteria for disease risk reduction and function claims has led to concerns that consumers may be drawn only to the claimed or highlighted product benefit, ignoring other, perhaps less positive aspects. As well, there are suggestions that consumers view food with claims to be healthier overall than foods with no claims (the “halo effect”) [Ford et al., 1996; Murphy et al., 1998; Roe et al., 1999; Health Canada 2004; FSANZ, 2005 Apr]. Further, if foods carrying health claims also have significant negative attributes that are inconsistent with national dietary guidance, conflict with public health messages can arise. On the other hand, it may be difficult to establish core nutritional criteria that would appropriately

balance the positive and negative nutritional characteristics of a food in light of the wide range of nutritional and health needs of the Canadian population.

Discussion

Health Canada proposes to explore whether minimum standards should be applied to foods carrying any type of health claim. This would mean that core eligibility criteria, or a basic “nutritional profile,” would be applied to foods carrying general or implied health claims, as well as to foods carrying function (including biological role) claims.

The objective is not to target “good” or “bad” foods in particular: Health Canada maintains the underlying premise that health is a function of the total diet, and not individual foods. However, health claims can be powerful messages and, as such, the foods they promote can be influential in shaping the overall quality of the diet. Applying nutritional profiles more broadly and more consistently could also encourage industry to review product formulations, and provide more choices that are supportive of healthy eating overall.

This view:

- reflects consumers’ expectations about the healthiness of products carrying health claims [Williams, 2005];

- is consistent with the Codex Alimentarius Commission recommendation (CAC/GL 23, 2004, Section 7.2) that there should be a clear regulatory framework for qualifying and/or disqualifying conditions, including prohibiting claims on foods that contain nutrients or constituents in amounts that increase the risk of disease or adverse health-related condition;

- is consistent with other international approaches taken in the European Union and proposed in Australia/New Zealand (see Appendix D); and

- supports the goal to address “food contributors” to chronic disease as outlined in the Health Canada’s 2007 Regulatory Modernization Strategy for Food and Nutrition.

The development of core nutritional criteria is a complex task. A number of questions need to be considered, including whether to apply a core set of criteria to all or certain types of health claims, what criteria to use in setting the standards, and how the criteria should be applied. Health Canada proposes to conduct consumer research in this area to better understand when health claims on foods with “negative” nutritional attributes are misleading to consumers. Several recent international models can be considered to inform eligibility criteria, such as the work under development in the EU and in Australia/New Zealand.²⁹ While these provide excellent examples, they would require review and assessment in the Canadian context. Additional stakeholder consultations will be needed to get feedback on more specific options as the policy is developed.

Comments on this concept in principle are requested to help initiate a dialogue.

Questions

1. Health Canada could also create a set of core nutritional criteria that all implied or explicit health claims should meet, and could apply that system through either a voluntary or a mandatory approach. If such measures were pursued, further consultations would be held on the development of the core nutritional criteria.

Please use a 1–6 rating, with 6 indicating that you consider it highly worthwhile to evaluate the following possible measures, and 1 indicating that you do not consider it worthwhile at all:

- 1a. Voluntary: foods carrying a health-related claim would have the option of being evaluated against core nutritional criteria, and if they fulfill those criteria, their packaging would be allowed to carry an agreed upon symbol

1 2 3 4 5 6

Please explain your rating:

²⁹

<http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/nutrientprofilingcal3499.cfm>

To which types of claim should this measure apply?

- All types of claims Disease risk reduction claims Function claims
Other health-related claims or symbols

Please explain your selection:

1b. Mandatory, option 1: foods carrying a health-related claim that do not meet standardized nutritional criteria would be required to highlight or disclose on their packaging where they fail to do so.

- 1 2 3 4 5 6

Please explain your rating:

To which types of claim should this measure apply?

- All types of claims Disease risk reduction claims
Function claims Other health-related claims or symbols

Please explain your selection:

1c. Mandatory, option 2: foods carrying a health-related claim or symbol must meet standardized nutritional criteria.

- 1 2 3 4 5 6

Please explain your rating:

To which types of claim should this measure apply?

- All types of claims Disease risk reduction claims Function claims
Other health-related claims or symbols

Please explain your selection:

2. If any of the approaches identified above was to be pursued, how could it be implemented effectively?

2a. Which organizations could play a role in implementation?

3. Are there other approaches that you would suggest to link core nutritional criteria with health claims?

B4. DISCUSSION THEME 4: SUPPORTING INFORMED CONSUMER CHOICE

As stated in the Introduction, an effective framework to manage health claims on foods supports consumer choice through the use of substantiated claims. It is intended to protect consumers from false and misleading claims while maintaining a fair market environment for industry.

Theme 4 focuses on consumers and their environment, and the critical roles they need to play if the policy objectives are to be met:

improving consumer understanding of health claims (Theme 4.1); and
monitoring the impact of health claims on the food supply and on consumer choice (Theme 4.2)

A number of examples were given in Theme 3 where consumer and social research is needed in the Canadian context to support policy development. Similarly, there are related research needs around educating consumers so that they can understand health claims, be critical and discerning of information they see on packages and in advertising, and be better equipped to make informed choices. Information is welcomed in this area, including:

What are the sources of confusion and scepticism for consumers?

What are the factors that affect the impact of health claims on consumer decision making?

How do different segments of the population understand and use health claims, and what are the differential impacts on purchasing behaviour?

Food Directorate welcomes consumer research on these questions and other relevant issues related to enhancing informed choice.

There are many opportunities for shared leadership and involvement among different organizations to deliver on these activities. However, a proactive role for Health Canada will be critical for the long-term credibility and sustainability of the health claim system.

Theme 4.1 Improving consumer understanding of health claims

Issues

There is evidence that some consumers lack the level of health literacy needed to handle the complexity, sophistication and quantity of information (some of which is contradictory) about diet-health relationships that is available to them to make informed choices. As a result, there are concerns that consumers may not understand health claims sufficiently to be discerning, particularly where claim statements are long and complicated. Consumers report being confused and sceptical of some of the claims that they see, but they still welcome and look for nutrition and health information from various sources, including food labels [Health Canada, 2001 Jan, 2004; Sullivan, 2003; Marquis et al., 2005; CCFN, 2006; IFIC 2006]. As previously noted, some studies show that consumers generally do not distinguish between different types of nutrition and health claims, and are confused about how much benefit to assign to the different promises [Katan, 2004; FSANZ, 2005 Apr; Hooker and Teratanavat, 2005; Williams, 2005]. While health claims are designed to provide information on both the attributes of the food and the link to its health benefit, it has been found that when consumers lack key understanding, they can

be reluctant to believe the connection and act upon the knowledge [Wansink and Cheney, 2005, p. 388].

Discussion

Recognizing that there are many factors that affect consumer understanding of health information, government, industry and non-governmental organizations can play a variety of roles in furthering that understanding. At the same time, there is also a need for consumers to take an active part in gaining the understanding necessary for them to benefit from health claims on foods.

Where the science may still be equivocal, consumer education using a variety of tools (e.g., formally, through information campaigns, through objective information readily available from credible sources on the Internet) will be necessary to help the public to navigate through the vast amount of information available to them through the media and advertising [Williams, 2005]. With greater understanding, consumers may be better able to assess the nature of the claim promise and its relevance to their personal situation, and to incorporate this information into their decision making.

In order to determine how best to inform and educate Canadians about health claims, Health Canada will be conducting consumer research to identify the source of consumer misunderstanding and seek input on the best vehicles for improving consumer understanding of health claims. As we develop communication strategies, we will strive to help consumers be more critical in their assessment of the validity of the claims used in the marketplace. We recognize that there are opportunities for many different stakeholders to play a role in educating the public about health claims, including organizations involved in food production, health promotion and academic research, as well as government and industry.

Questions

1. What could be done to help consumers better understand and appraise health claims?
2. What role could different organizations or networks play in developing partnerships to build health literacy?
3. Do you have any suggestions for how we could ensure that the information we provide to consumers is readily understood?
4. Food Directorate welcomes research on consumer understanding of health claims and the impact of these claims on consumer decision-making. Please let us know if you are aware of any such research, and if possible attach reports.

Theme 4.2 Monitoring the impact of health claims on the food supply and on consumer choice

Issues

Despite a high level of self-reported use of food labels by consumers in selecting “healthier” foods, seen in surveys and focus group research [NIN, 1999, 2002; NIN and CFIC, 2004; CCFN, 2006], other studies show that actual use of nutrition and health information appears to be much lower [Cowburn and Stockley 2005; Williams, 2005]. Some reports indicate that the impact of health claims on purchase decisions about food products is influenced by many factors, such as familiarity with the products, prior awareness of the subject of the claim, and a positive image of the product [Levy et al., 1997; NIN, 1999; Health Canada, 2000, 2001 Jan; FSANZ, 2005 Apr; van Kleef et al., 2005; Wansink et al., 2005].

In monitoring the impact of health claims in the marketplace, several questions arise: are there “healthier” foods on the marketplace, and is their presence sustained? Have consumers integrated these into their diets? Who has, and how?

Concerns have been raised about the potential unintended impacts of the policy. For example, health claims for one product may draw consumers away from equally healthy products that do not have such claims attached to them, products that may sometimes be less expensive. In addition, demand by consumers who can afford the premium-priced products may reduce the availability of quality products that are more affordably priced.

Discussion

A critical component of any new framework will be measuring and reporting on its impacts: to assess and track both those outcomes that are intended by the policy, as well as those that are unintended. Appropriate indicators will need to be developed and critical baseline data collections will need to be put in place. Some areas of active monitoring are expected to include:

- the use of health claims on food labels and in advertising;
- consumer understanding of health claims;
- the ability of consumers to use claims in informed purchasing decisions;
- the long-term impact of health claims on the nature of the food supply in Canada;
- the effects on dietary patterns; and
- changes in research investment by Canadian companies related to innovations in food ingredients and finished food products with relevance to health.

This is another area where there are significant opportunities for collaboration and partnership to support the monitoring and evaluation of the policy. A network that includes partners from government, industry, academia and non-governmental organizations would be needed to help prioritize the range of indicators and aspects that could be monitored.

Questions

1. What organizations and networks could play a supporting role in the monitoring of the impact of health claims on the food supply and consumer choice?
2. Do you see a role for you or your organization?

B5. GENERAL QUESTIONS

Finally, considering the themes discussed in the document,

1. Have these themes adequately captured the critical issues?
2. Are there other themes or issues that should have been included?
3. Any other comments?

B6. INVITING YOUR FEEDBACK

6.1 General instructions

Health Canada would like your feedback on the specific questions and issues discussed in this document. In addition, Health Canada plans to hold regional consultation sessions in the winter of 2008. The department will use this input to help develop short- and long-term plans to work towards modernizing the current framework for managing health claims on foods. A feedback form and complete list of questions raised in each of the themes can be found in section 6.2 and in Word and WordPerfect format on the following Health Canada website:

http://www.hc-sc.gc.ca/fn-an/consultation/init/man-gest_health_claims-allegations_sante_e.html.

The following suggestions are provided to help you prepare your comments in response to specific questions or other issues in ways that will assist us in analyzing them:

1. Please explain your views as clearly and concisely as possible. If your comments exceed 10 pages, please provide a summary (one to two pages).
2. Be sure to distinguish between what you support and what you object to in this document.
3. Provide the rationale for your views, particularly your concerns, with facts, data or specific examples.
4. Describe any assumptions that you used.
5. Please provide copies of any technical information and/or data you used in your comments.
6. Make sure to submit your comments by February 29, 2008.

Please note that in keeping with our commitment to an open and transparent process, **comments made to Health Canada in response to this consultation on Canada's framework for the management of health claims on foods will not be considered confidential.** However, the names of individuals sending comments who are not representatives of groups/organizations will be protected pursuant to the *Access to Information Act* and the *Privacy Act*.

Any information collected during this consultation will only be used for the purpose of input to this consultation. The information collected will be used in conjunction with input obtained from in-person consultations to formulate a summary report that will guide decisions on the development of the framework. This report will be made public once completed. Information protected pursuant to the *Access to Information Act* and the *Privacy Act* collected during this consultation will be stored in a secure location and will not be shared with a third party.

Please send a copy of your completed Word or WordPerfect form by email to:

healthclaims-allegationssante@hc-sc.gc.ca

If you prefer to send your comments by mail, please send them to:

Section Head: Nutrition Labelling and Claims
Nutrition Evaluation Division, Health Canada
Sir Frederick G. Banting Research Centre
251 promenade Sir Frederick Banting Driveway
A.L. 2203E
Ottawa, ON Canada, K1A 0K9

6.2 Feedback form and questions

This can be found in Word and WordPerfect format on the following Health Canada website:

http://www.hc-sc.gc.ca/fn-an/consultation/init/man-gest_health_claims-allegations_sante_e.html.

Please include the following identification information:

Respondent Name:

Organization (where applicable):

Address:

- Affiliation: Academia
 Industry
 Government
 Consumers
 Health/Disease Organization
 Health Professional
 Other (please specify)

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

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

Questions for Consultation

Theme 1.1 Business improvement actions for increased efficiency

1. Several business improvements are proposed to address key operational

issues:

Dedicating additional resources to the review of health claims for foods
Implementing standard operating procedures (SOPs) for the Health Canada (HC) review of submitted claims. Finalized SOPs will be shared with stakeholders.

Developing the parameters for an abbreviated process for claim review where internationally recognized scientific bodies or competent national authorities have recently completed a review and deemed the claim as valid. Acceptable ways to deal with different decision outcomes would also need to be considered

Examining ways to improve efficiency administering the current regulation, where claim specific regulatory amendments are required. Several options are being considered:

- dedicating more resources in regulatory drafting and legal services
- exploring when it may be possible to expedite the time taken to proceed to the final amendment of the Regulations in *Canada Gazette Part II*

Exploring appropriate triggers and processes for deciding when a second review of an approved claim may be needed. However, this is not considered a priority activity at this time.

Overall, how effective do you feel these actions would be, using a 1–6 rating, with 6 being highly effective and 1 being not effective at all.

1 2 3 4 5 6

Please explain your rating:

2. What additional business improvements could you suggest?

Theme 1.2 Increased openness and transparency

1. Health Canada is exploring the possibility of publishing decision documents related to health claim applications. All proprietary information would be excluded. Please tick the box beside the information that you think should be included in published decision documents from

the health claim submission:

- proposed health claim
- summary of evidence submitted
- full tabulation of evidence submitted
- other (please specify)

Health Canada's assessment:

- summary of HC scientific evaluation of the submission
- detailed HC evaluation of the submission
- results of consultations, if applicable
- decision and rationale (including conditions of use for an accepted claim and product)
- other (please specify)

Please explain your selections:

Please provide a copy of what you consider to be an appropriate format for a decision document in the Canadian context.

Theme 2.1 Scientific substantiation of claims

1. A high level of certainty in scientific substantiation of claims is based on the following:

structured, comprehensive literature review of all the relevant evidence,

human studies of acceptable quality, and
consistent cause-and-effect relationship between the consumption of foods or
food constituents and the claimed health benefit.

Should all claims be based on a high level of certainty? Please provide the rationale for your response.

- 1a. If there is a role for claims based on a lower level of certainty, what principles should determine which claims could be based on a lower level of certainty?
should consumers be informed of the level of certainty that supports a claim?
what type of information about the level of certainty should be conveyed?

- 1b. How should this be communicated? Please provide evidence (if available) to show that what you suggest would not be misleading to consumers.

Theme 2.2 Supporting good-quality submissions

1. Health Canada is proposing several ways in which it could support industry in drafting good quality submissions:

encouraging pre-submission consultations;
updating the 2002 *Interim Guidance Document* to include specific guidance on the preparation of a structured, systematic review with the knowledge gained from the work done by the PFSNRA and Health Canada;
supporting in principle the efforts of third parties to coordinate and assist small and medium-sized industry members that are willing to collaborate in making joint submissions on ingredients or food constituents of common interest;
exploring ways to address gaps in the scientific evidence associated with the health-related benefits of food ingredients at a pre-submission stage with interested parties (e.g., Agriculture and Agri-Food Canada); and

participating in third-party forums organized to sustain domestic infrastructure for basic and applied research in food and nutritional science needed to support the development of safe, innovative food products with substantiated health benefits.

Overall, how effective would these proposals be, using a 1–6 rating, with 6 being highly effective and 1 being not effective at all.

1 2 3 4 5 6

Please explain your rating:

2. What should be industry's role in preparing good quality submissions?

2a. Which organizations could support applicants in preparing good quality submissions? How?

3. In managing health claims for foods, there is a need for long-term research to substantiate potential health benefits and to identify health risks. Which organizations can help strengthen or support research in these areas? How?

Theme 3.1 Functional foods and the food/NHP interface

1. What are the expected areas of development of functional foods or bioactive ingredients in the next 1–3, and 3–10 years? Why?

2. Considering the addition of bioactives to foods in general, are there some types of bioactive substances that should not be added to foods at any level? Please identify and explain.

should the addition of bioactive ingredients be allowed in foods at levels that, while safe, are too low to claim any health benefit? Please explain.

3. Is there a case for adding bioactive substances to foods at levels that would benefit some, but be risky to that same group if improperly consumed, or risky to other segments of the population?

3a. If these types of bioactive substances were to be considered, what type of risk management options would be appropriate to ensure that the untargeted population is not put at risk, and to ensure the safe use of the product by the target population.

Examples used for managing this type of risk in Natural Health Products (NHPs) and drugs include the following:

- claim wording
- packaging to target specific user groups
- restricting distribution channels
- directions for use
- cautionary statements
- warnings

3b. If possible, explain how the risk management measures you suggest would be effective when applied to products sold as foods.

Theme 3.2 Managing a broader range of function claims

1. Some measures are proposed in the document to help ensure credibility of a broader range of function claims:

clarifying the nature of acceptable function claims that would not be considered drug claims,
encouraging industry to submit, voluntarily, new function claims for review by the Food Directorate, and
maintaining an up-to-date list of function claims that are deemed “not misleading” in the *CFIA Guide to Food Labelling and Advertising*.

Overall, do you feel these non-regulatory measures would be sufficient to manage an expanding range of function claims, using a 1–6 rating, with 6 being completely sufficient and 1 being not sufficient at all.

1 2 3 4 5 6

Please explain your rating:

2. What other types of non-regulatory measures would you suggest?
3. Health Canada could also rely on regulatory measures for more rigorous control of claims.

Please indicate whether Health Canada should explore the following measures:

3a. requirement for the submission of supporting evidence when there are concerns about the credibility of a health claim being used on foods already in the marketplace.

Yes No Please explain:

3b. mandatory pre-market review of function claims

Yes No Please explain:

4. Are there other regulatory measures that Health Canada should consider? If so, please identify the measure(s) and explain your rationale.

Theme 3.3 Managing diverse front of package claims

1. Several measures are proposed to ease confusion by consumers over the proliferation of health-related claims on the front of food (FOP) packages:

- educating consumers on the Nutrition Facts table and ingredient listings in conjunction with FOP symbols and claims,
- providing guidance to industry on conditions and wording that would help ensure that claims are not misleading,
- improving nutrition labeling regulations as needed, and
- monitoring the marketplace to ensure that activities related to consumer education, industry guidance, and regulatory changes are evidence-based.

Would these measures be sufficient to reduce the confusion arising from the proliferation of health-related claims on the front of food packages?

Yes No Please explain:

2. Prohibiting implied claims of a health benefit, unless the health effect is clearly stated, could also reduce consumer confusion. How worthwhile would it be to explore this measure, using a 1–6 rating, with 6 being highly worthwhile and 1 being not worthwhile at all.

1 2 3 4 5 6

Please explain your rating:

Theme 3.4 Eligibility criteria for foods to carry claims

1. Health Canada could also create a set of core nutritional criteria that all implied or explicit health claims should meet, and could apply that system through either a voluntary or a mandatory approach. If such measures were pursued, further consultations would be held on the development of the core nutritional criteria.

Please use a 1–6 rating, with 6 indicating that you consider it highly worthwhile to evaluate the following possible measures, and 1 indicating that you do not consider it worthwhile at all:

1a. Voluntary: foods carrying a health-related claim would have the option of being evaluated against core nutritional criteria, and if they fulfill those criteria, their packaging would be allowed to carry an agreed upon symbol

1 2 3 4 5 6

Please explain your rating:

To which types of claim should this measure apply?

All types of claims Disease risk reduction claims Function claims

Other health-related claims or symbols

Please explain your selection:

1b. Mandatory, option 1: foods carrying a health-related claim that do not meet standardized nutritional criteria would be required to highlight or disclose on their packaging where they fail to do so.

1 2 3 4 5 6

Please explain your rating:

To which types of claim should this measure apply?

All types of claims Disease risk reduction claims Function claims

Other health-related claims or symbols

Please explain your selection:

1c. Mandatory, option 2: foods carrying a health-related claim or symbol must meet standardized nutritional criteria.

1 2 3 4 5 6

Please explain your rating:

To which types of claim should this measure apply?

All types of claims Disease risk reduction claims Function claims

Other health-related claims or symbols

Please explain your selection:

2. If any of the approaches identified above was to be pursued, how could it be implemented effectively?

- 2a. Which organizations could play a role in implementation?
3. Are there other approaches that you would suggest to link core nutritional criteria with health claims?

Theme 4.1 Improving consumer understanding of health claims

1. What could be done to help consumers better understand and appraise health claims?
2. What role could different organizations or networks play in developing partnerships to build health literacy?
3. Do you have any suggestions for how we could ensure that the information we provide to consumers is readily understood?
4. Food Directorate welcomes research on consumer understanding of health claims and the impact of these claims on consumer decision-making. Please let us know if you are aware of any such research, and if possible attach reports.

Theme 4.2 Monitoring impact of health claims on food supply and consumer choice

1. What organizations and networks could play a supporting role in the monitoring of the impact of health claims on the food supply and consumer choice?
2. Do you see a role for you or your organization?

General Questions

Finally, considering the themes discussed in the document,

1. Have these themes adequately captured the critical issues?
2. Are there other themes or issues that should have been included?
3. Any other comments?

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APPENDICES

Appendix A – Glossary

There are no uniform definitions internationally adopted for the terms listed in this glossary. The descriptions of the terms in this glossary are provided to assist readers in understanding their use in the context of this document. Related terms are grouped together.

Examples are provided for illustrative purposes only. The substances and claims used in the examples do *not* necessarily mean that it is acceptable to add them to foods, or that they are acceptable health claims for foods.

Term	General Description and Examples
Bioactive substance	<p>A bioactive substance is a substance that is demonstrated or purported to have a favourable effect on health. Bioactive substances include nutrients or non-nutrients in foods or other substances with medicinal or pharmacological properties from non-food sources.</p> <p><i>Examples:</i> vitamins, minerals, isoflavones from soybeans, probiotic cultures (live microbes), St. John's wort from <i>Hypericum perforatum</i>.</p>
Nutrient	<p>Nutrients are chemical compounds that are generally recognized to provide energy, or to be required for growth and development and maintenance throughout the life cycle. Nutrients are generally regarded as those compounds that are not synthesized in the body at all, or not in sufficient quantities to meet normal requirements, and must be provided by the diet. For the purposes of health claims and nutrition labelling in Canada, known nutrients are those recognized by the Institute of Medicine of the National Academies, Washington, D.C., for which recommended intakes have been established.</p> <p><i>Examples:</i> vitamins, minerals, protein, dietary fibre.</p>
Non-nutrient	<p>In the context of health claims for foods, non-nutrients are constituents of food that are <i>not</i> known nutrients but are demonstrated or purported to have a favourable effect on health.</p> <p><i>Examples:</i> isoflavones from soybeans.</p>
Nutritional criteria	<p>Nutritional criteria are compositional criteria that determine the eligibility of a food to carry health claims. <i>Qualifying</i> nutritional criteria specify the minimum levels of certain nutrients (e.g., some vitamins and mineral nutrients) that should be met for a food to carry health claims. <i>Disqualifying</i> nutritional criteria specify</p>

Term	General Description and Examples
	maximum levels of specified nutrients (e.g., certain nutrients considered to increase the risk of some chronic diseases) that should not be exceeded for a food to carry health claims.
Terms used to describe claims:	
Health claim	A health claim for foods means any representation in food labelling and advertising that states, suggests or implies that a relationship exists between a food category, a food, or a food constituent and health. <i>Examples:</i> disease risk reduction claims, function claims and general health claims about “healthy choice.”
Disease risk reduction claim	Disease risk reduction claims correspond to health claims in the table following B.01.603 in the <i>Canadian Food and Drug Regulations</i> , previously referred to as generic or diet-related health claims. <i>Example:</i> A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer.
Function claim	Function claims include: (1) claims for energy or nutrients about their generally recognized roles as an aid in maintaining the functions of the body that are necessary to the maintenance of good health and normal growth and development, as permitted in B.01.311(3), D.01.006 and D.02.004 of the <i>Food and Drug Regulations</i> (biological role claims); (2) claims about maintaining or supporting body functions associated with the maintenance of good health or performance (other function claims); (3) claims about restoring, correcting or modifying body functions (drug claims). <i>Example of biological role claim:</i> Calcium aids in the formation and maintenance of bones and teeth. <i>Example of other function claim:</i> Beverage X is absorbed up to 30% faster than water. <i>Example of drug claim:</i> Product X lowers elevated blood cholesterol levels.

Term	General Description and Examples
General health claim	<p>General health claims are broad “healthy choice” claims that promote overall health or healthy eating, based on certain nutritional characteristics of the food, without referring to specific health effects, a specific organ, disease, biomarker or health condition.</p> <p><i>Example:</i> Include low-fat product X as part of healthy eating.</p>
Specific health claim	<p>Specific health claims are claims that relate the consumption of a food or food constituent to beneficial effects on a specific organ, disease, biomarker or health condition.</p> <p><i>Examples:</i> function claims and disease risk reduction claims.</p>
Implied health claim	<p>An implied health claim is any representation of a health claim without explicitly stating that a relationship exists between a food category, a food, or a food constituent and health. Examples of such representations include the use of a logo, symbol, name, trade mark, seal of approval, or by association (e.g., hyperlink to a website, or juxtaposition of “educational” material with advertisements for specific products having the characteristics referred to in the former). Such representation may apply to a general health claim or a specific health claim.</p> <p><i>Example:</i> the use of a heart symbol to imply that the food is heart-healthy or that the food may be part of a diet to reduce the risk of heart disease.</p>
Generic health claim	<p>Generic health claims are claims in which a group of foods or a nutrient or other food constituent is the subject of the claim. Such claims can be generalized to similar foods that meet specified nutritional criteria.</p> <p><i>Example:</i> A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer.</p>
Product-specific health claim	<p>Product-specific health claims apply only to food products for which the evidence supporting a claim specific to a particular product is not generalizable to other similar products. This recognizes that food matrices and processing conditions could have an effect on the physiological property of foods.</p> <p><i>Example:</i> no example that can be verified at present (except possibly in the Netherlands).</p>

Appendix B – Chronology of the Development of Policy and Standards for Disease Risk Reduction Claims for Foods in Canada

Year	Description
1996	In the fall of 1996, the Food Directorate and the Therapeutic Products Programme initiated a joint project with the assistance of an expert advisory panel. The goal of the project was to develop a policy framework to address regulatory issues related to health claims on foods and related products.
1997	A consultation workshop with major stakeholders in 1997 resulted in a draft <i>Policy Options Analysis Paper</i> that set out a conceptual framework for regulating health claims, including a preferred option. The draft paper was circulated for comments. The preferred option received broad support from interested parties.
1998	The final <i>Policy Paper on Nutraceuticals/Functional Foods and Health Claims on Foods</i> was published [Health Canada, 1998]. The final policy decision expressed in the 1998 paper was that 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. To implement this policy, two projects were initiated. One project focussed on the development of standards of evidence required to substantiate health claims on foods. The other project focussed on initiating regulatory changes to permit diet-related disease risk reduction claims on foods.
1999	In 1999 Health Canada committed to consider 10 health claims that were authorized in the US under the <i>Nutrition Labeling and Education Act (NLEA)</i> for use in Canada. A meeting with stakeholders was held to review issues related to the appropriateness of applying the general and specific requirements for US health claims to health claims made on foods marketed in Canada. Issues considered included the format and wording of claims on bilingual labels, as well as measures required to ensure the credibility of the health claims system.
2000	In June 2000, Health Canada published a consultation document on <i>Standards of Evidence for Evaluating Foods with Health Claims: A Proposed Framework</i> and organized a consultation meeting on the subject. The document outlined a proposal for ensuring that foods bearing health claims are supported by appropriate evidence with respect to product safety and claim validity, as well as suggesting quality assurance and verification procedures. The standards of evidence requirements were drafted to consider health claims that could receive generic authorization or product-specific authorization. The publication of a consultation document on <i>Generic Health Claims</i>

Year	Description
	<i>for Foods</i> in August 2000 outlined the scientific basis for accepting five generic diet-related disease risk reduction claims authorized in the US under the <i>NLEA</i> , for adoption in Canada.
2001	In October 2001, a document was developed for public consultation on a proposal for <i>Product-Specific Authorization of Health Claims for Foods</i> [Health Canada, 2001]. The authorization was proposed for specific foods having a direct, measurable effect beyond normal growth, development or health maintenance, reducing disease risk, or aiding in the dietary management of a disease or condition. The rationale for product-specific authorization was that food matrix and processing conditions can affect the physical property and health effects of a food product that cannot be generalized to other similar foods.
2002	<p>Based on comments received on the 2000 consultation document on standards of evidence, Health Canada published an <i>Interim Guidance Document</i> [Health Canada, 2002] to facilitate the preparation of submissions for foods with health claims. The guidance document describes the principles underlying the requirements for evidence and a review process that considers the totality of evidence supporting a health claim. In the guidance document, different categories of evidence are recognized and the criteria used in determining acceptable evidence are outlined.</p> <p>To permit the use of disease risk reduction health claims, exemptions from subsections 3(1) and 3(2) of the <i>Food and Drugs Act</i> are required for foods bearing such claims. On December 12, 2002, amendments to the <i>Food and Drug Regulations</i> were promulgated and published in the <i>Canada Gazette Part II</i> (January 1, 2003) to allow for five generic disease risk reduction claims. The guiding principles for allowing any category of health claims are that they must be supported by scientific evidence, be truthful, and not be misleading. Through these regulations, Health Canada established a system that outlined the language, format and compositional criteria for the claims.</p> <p>The claims that were approved are related to:</p> <ul style="list-style-type: none">sodium and potassium and risk of stroke and heart diseasecalcium and vitamin D and strong bones and risk of osteoporosissaturated and trans fats and risk of heart diseasevegetables and fruits and cancer risk reductionfermentable carbohydrates and dental caries

Year	Description
2006	<p>The review and updating of the science on the remaining five disease risk reduction claims continued following the acceptance of the five generic claims in 2003. In December 2006, Health Canada proposed to allow two of the remaining claims, with modifications to the wording of the claims as permitted in the US under the <i>NLEA</i>:</p> <ul style="list-style-type: none">vegetables and fruit and whole grains and risk of heart diseasefolate and risk of neural tube defects <p>A position paper was published that sets out the proposed wording for the two health claims, linking a diet rich in vegetables and fruit and whole grains to a reduced risk of heart disease, and a diet rich in folate, and a folate supplement, to a reduced risk of neural tube defects. The claim related to whole grains will require a definition of “whole grain” and “grain” to be set out in the regulations when the final proposal is implemented. Stakeholders were invited to comment on the position paper, prior to publication of proposed regulatory amendments in the <i>Canada Gazette Part I</i>.</p> <p>Two other claims under review were not supported by the updated science and will not be authorized for use in Canada:</p> <ul style="list-style-type: none">dietary fat and cancerfibre-containing grain products, fruits and vegetables and cancer <p>One other claim will be subject to further consideration through industry submission:</p> <ul style="list-style-type: none">soluble fibre from certain foods (β-glucan/oats, psyllium) and coronary heart disease <p>With these reviews and ongoing submissions, 15 of the 17 US <i>NLEA</i> or <i>FDAMA</i> health claims have been reviewed (see Appendix F for details).</p>

Appendix C – Summary Table of Biological Role Claims for Nutrients

Source: Reproduced from Table 8-2, *2003 Guide to Food Labelling and Advertising* [CFIA, 2003].

The examples of biological role claims listed in the table below have been considered to be acceptable by Health Canada and the CFIA. Other biological role claims for nutrients may also be acceptable and will be evaluated on a case-by-case basis.

Acceptable Biological Role Claims for Nutrients	
PROTEIN	<ul style="list-style-type: none"> helps build and repair body tissues helps build antibodies
FAT	<ul style="list-style-type: none"> supplies energy aids in the absorption of fat-soluble vitamins
DHA	<ul style="list-style-type: none"> DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves
CARBOHYDRATE	<ul style="list-style-type: none"> supplies energy assists in the utilization of fats
VITAMIN A	<ul style="list-style-type: none"> aids normal bone and tooth development aids in the development and maintenance of night vision aids in maintaining the health of the skin and membranes
VITAMIN D	<ul style="list-style-type: none"> factor in the formation and maintenance of bones and teeth enhances calcium and phosphorus absorption and utilization
VITAMIN E	<ul style="list-style-type: none"> protects the fat in body tissues from oxidation
VITAMIN C	<ul style="list-style-type: none"> factor in the development and maintenance of bones, cartilage, teeth and gums
THIAMINE (VITAMIN B ₁)	<ul style="list-style-type: none"> releases energy from carbohydrate aids normal growth
RIBOFLAVIN (VITAMIN B ₂)	<ul style="list-style-type: none"> factor in energy metabolism and tissue formation
NIACIN	<ul style="list-style-type: none"> aids in normal growth and development factor in energy metabolism and tissue formation
VITAMIN B ₆	<ul style="list-style-type: none"> factor in energy metabolism and tissue formation
FOLATE	<ul style="list-style-type: none"> aids in red blood cell formation
VITAMIN B ₁₂	<ul style="list-style-type: none"> aids in red blood cell formation
PANTOTHENIC ACID	<ul style="list-style-type: none"> factor in energy metabolism and tissue formation
CALCIUM	<ul style="list-style-type: none"> aids in the formation and maintenance of bones and teeth

Acceptable Biological Role Claims for Nutrients	
PHOSPHORUS	<ul style="list-style-type: none">• factor in the formation and maintenance of bones and teeth
MAGNESIUM	<ul style="list-style-type: none">• factor in energy metabolism, tissue formation and bone development
IRON	<ul style="list-style-type: none">• factor in red blood cell formation
ZINC	<ul style="list-style-type: none">• factor in energy metabolism and tissue formation
IODINE	<ul style="list-style-type: none">• factor in the normal function of the thyroid gland

Appendix D – International Comparisons

Similarities

Differences

1. Mechanisms of Approval/Oversight

a) Disease risk reduction claims

Canada, Australia/New Zealand (ANZ*), European Union (EU) and United States (US):

- Approved claims for serious diseases require claim-specific authorization or amendments to regulations or standards.
- Food bearing the claim must meet specified requirements.

ANZ: Claims related to risk reduction of non-serious diseases and claims that do not reference a biomarker are considered “general level” claims, for which compliance with criteria for substantiation and conditions for use set out in the Australia New Zealand Food Standards Code would be mandatory. However, pre-approval of general level claims would not be required.

* Proposed -for Australia/New Zealand

b) Claims for established functions of known nutrients

Canada, ANZ, EU:

- Positive or illustrative lists are used without the need for authorization or claim-specific amendments to regulations or standards (except for claims related to children’s development and health in EU).

Differences exist in how positive or illustrative lists are developed and enforced.

Canada: Claims are permitted by general regulatory provisions, and examples of acceptable claims are provided in guidelines.

ANZ: Claims that meet the criteria for general level claims and are not on a list of pre-approved nutrient function statements do not require premarket review, provided supporting data are available upon request.

EU: Claims other than those referring to the reduction of disease risk or to children’s development and health will be included in a Community positive list of permitted health claims following consultation with the European Food Safety Authority. These claims have been approved at the national level in EU member states.

US: There is no specific regulation or other form of positive listing governing the use of function claims for foods¹. However, they must be truthful and not misleading and be derived from the nutritional value of the product under the *Federal Food, Drug and Cosmetic Act*.

Similarities

Differences

c) Other function claims

A range of approaches exist.

Canada: For a health claim that would bring a food within the definition of a drug, a claim-specific regulatory amendment of the food provisions (Part B) of the *Food and Drug Regulations* is required. For a health claim that would not bring a food within the definition of a drug, a claim-specific regulatory amendment of the *Food and Drug Regulations* is not required.

ANZ: For claims that are considered general level claims (including enhanced function claims that refer to risk reduction of non-serious diseases), an approach similar to that for established function claims for known nutrients has been proposed.

EU: See description for claims for established functions of known nutrients, above. Application for inclusion in the Community list is required when a claim is based on newly developed scientific knowledge and/or when the protection of verifiable proprietary data is requested by an applicant.

Japan: A tiered system of oversight in three subsystems (existing, qualified and standardized) within “Foods for Specified Health Use”² is in place.

US: See description for claims for established function of known nutrients, above.

d) General health claims about “healthy choice”

Differences exist in how to manage a variety of health claims that do not refer to a specific health effect, disease or health condition. This includes claims that promote choosing a food for overall health, that promote healthy eating or that provide dietary guidance.

Canada: Guidelines are provided for the use of claims about “healthy choice” that would not be considered misleading.

ANZ: It is proposed that conditions for claims about dietary information be specified in the *Food Standards Code*.

EU: Reference to general, non-specific benefits may only be made if accompanied by an approved specific health claim.

US: Claims using descriptors such as “healthy” or about a food being useful in maintaining healthy eating

Similarities

Differences

practices are prohibited unless provided for in regulation.

e) Implied health claims

Canada: Implied claims are not addressed directly in the *Food and Drug Regulations*.

ANZ: It is proposed that implied claims be prohibited unless accompanied by a valid claim.

EU: Implied health claims are prohibited unless accompanied by an approved specific health claim.

US: The same regulations apply to health claims made on the label or in labelling of a food, that expressly or by implication characterize the relationship of any substance to a disease or health-related condition (21 CFR § 101.14(a)). Separate regulations govern implied nutrient content claims and related label statements (21 CFR § 101.65(d)).

2. Standards of Evidence

a) Disease risk reduction claims

Canada, ANZ, EU and US:

- Permitted claims are typically based on a structured review of the totality of relevant evidence using a generally accepted scientific process and standards of evidence. In ANZ, this approach applies only to risk reduction claims for serious diseases.

Processes exist to facilitate the assessment of the evidence supporting a claim without lessening the rigour of the assessment.

US: An abbreviated process based on the use of authoritative statements meeting specified criteria to support generic disease risk

ANZ: Different standards of evidence are proposed for risk reduction claims for non-serious compared to serious diseases. Both the process for assessment of substantiation evidence and the level of evidence required for risk reduction claims for non-serious diseases are currently under final consideration.

Japan: A tiered system allows a range of rigour in the scientific basis to support claims, as described in endnote 2.

US: A provision for qualified health claims exists. The Food and Drug Administration may exercise enforcement discretion for a claim that does not meet the standards for “significant scientific agreement” (Section 403(r)(3) of the *Federal Food, Drug and Cosmetic Act* (21 USC § 343(r)(3)) and 21 CFR § 101.14(c)). Under the provision for qualified health claims, a claim is denied if it cannot be made non-misleading with a disclaimer or other qualifying language.

Similarities

Differences

reduction claims has been implemented. Accepted sources of authoritative statements are specified in legislation.

ANZ: A streamlined approach is also proposed for risk reduction claims for serious diseases, under which authoritative reviews from specified sources may form the basis of the structured review of the totality of evidence.

b) Claims for established functions of known nutrients

Canada, ANZ and EU:

- Permitted function claims for known nutrients are typically based on generally accepted scientific knowledge, including authoritative information sources.

c) Other function claims

ANZ and EU:

- For both regions, it is expected/ proposed that function claims would be evaluated based on the totality of evidence or generally accepted scientific knowledge.

US: Function claims for foods are not regulated (see description under Mechanisms of Approval/Oversight), so there are no explicit standards of evidence for making function claims. However, draft guidance for industry is available for substantiating structure/function claims for dietary supplements¹ [<http://www.cfsan.fda.gov/~dms/dsclmgui.html>]. There is also a growing interest in the US in developing a credible system for claims other than those related to disease risk reduction, as seen in the recent FDA hearings (December 5, 2006) on Conventional Foods being marketed as “Functional Foods” [<http://www.cfsan.fda.gov/lrd/fr061025.html>].

d) General health claims about “healthy choice”

Standards of evidence do not apply.

Similarities

Differences

e) Implied health claims

The same standards of evidence generally apply to the respective types of health claims, whether explicit or implied. However, the type of regulatory oversight may differ (see descriptions under Mechanisms of Approval/Oversight).

3. Nutritional Criteria for Foods Carrying Health Claims

a) Disease risk reduction claims

Several countries and regions, including Canada, ANZ, EU and US, adopt a similar principle in applying eligibility criteria for foods carrying disease risk reduction claims, but the specific approaches used to implement this principle vary.

ANZ and EU: A common set of eligibility criteria have been proposed or are required to be applied to disease risk reduction claims and to other types of health claims. In addition, in ANZ, specific composition criteria may also apply to foods carrying risk reduction claims for “serious” diseases.

Specific approaches in applying nutritional criteria to foods carrying disease risk reduction claims vary among jurisdictions.

Canada: Disease risk reduction claims are currently prohibited from foods intended solely for children under two years of age, foods represented for use in a very low energy diet, foods containing more than 0.5% alcohol, and foods that are low in energy. Nutrient or food criteria apply to individual health claims. For example, a food that is not a fat or oil carrying a health claim related to saturated and trans fat and heart disease must meet specified levels for saturated and trans fat, cholesterol and sodium; eligible and ineligible fruits and vegetables are specified for a health claim related to cancer risk and a variety of vegetables and fruit.

ANZ: Proposed approach in Australia/New Zealand also includes limits for certain risk-increasing nutrients and the types of foods that may carry the claims.

EU: The nutrient profiles for foods carrying health claims will be based on the scientific opinion of the European Food Safety Authority following consultations with relevant stakeholders, taking into account: (1) the quantities of certain nutrients and other substances in the food (e.g., fat, sugars), (2) the role and importance of the food or categories of food and their contribution to the diet of the population in general or, as appropriate, of certain risk groups including children, (3) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognized as having an effect on health.

Similarities

Differences

US: Foods carrying any health claims must meet three types of criteria: (1) general nutrient requirements (e.g., for “low saturated fat”), (2) specific requirements for individual claims, and (3) minimum level for one or more of six specified nutrients (e.g., vitamin C).

Japan: Minimum and maximum levels based on recommended dietary allowances for the nutrient that is the subject of the claim are specified for nutrient function claims and disease risk reduction claims that have been approved to date. While no other nutritional criteria are specified, nutrition labelling and a certificate of nutrient analysis are required for food products approved under the existing FOSHU system.

b) Other health claims

Differences exist in the requirements for nutritional criteria for other health claims.

Canada: For nutrient function claims (biological role claims), for some key nutrients (e.g., vitamins, minerals, protein and amino acids), the *Food and Drug Regulations* specify a minimum level of the claimed nutrient; there are no disqualifying criteria. For other function claims or claims about “healthy choice,” no nutritional criteria are specified.

ANZ: It is proposed that foods carrying general level health claims will need to meet the minimum qualifying criteria for corresponding nutrition content claims (either “source” for risk-decreasing nutrients or “low” for risk-increasing nutrients). These foods will also have to meet the common eligibility criteria for all health claims. In addition, it is proposed that conditions for claims about dietary information be specified in the *Food Standards Code*.

EU: Foods bearing nutrition or health claims must meet established nutrient profiles (see description under disease risk reduction claims).

US: Food must meet compositional requirements for specified nutrients when claims are made using descriptors such as “healthy” or about a food being useful in maintaining healthy eating practices.

¹ Structure/function claims for dietary supplements are regulated under the *Dietary Supplement Health and Education Act* in the United States. If a dietary supplement includes such a claim, it must state in a “disclaimer” that the FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure or prevent any disease. However, the FDA does not require conventional food manufacturers to notify the FDA about their structure/function claims, and disclaimers are not required for conventional foods.

² Three subsystems have been developed within the “Foods for Specified Health Use” (FOSHU) system in Japan. The “existing” FOSHU subsystem requires approval of individual food products based on defined criteria for product effectiveness and safety, including the identification of active ingredient and mechanism of action, the conduct of randomized control trial as well as publication in peer-reviewed journals. The “qualified” FOSHU subsystem permits claims based on less stringent requirements with respect to statistical probability and the types of study required. The “standardized” FOSHU subsystem permits foods containing specified ingredients to carry existing health claims without the need for individual approval, if the extent of evidence and experience to support the claims and product safety is considered sufficient because of the extent and duration of use of the active ingredient in foods.

Appendix E – Health-Related Claims in the United States

A brief summary of the US framework for health-related claims is provided below. Detailed information is available at the US Food and Drug Administration (FDA) website [<http://www.cfsan.fda.gov/~dms/lab-hlth.html>]. A comparison of US health claims adopted in Canada follows.

Disease Risk Reduction Claims

As noted in Section A2.2 of this discussion paper, the US defines a “health claim” more narrowly than this paper does. In the US, a health claim is a claim that describes the relationship between a substance (food or food component) and a disease or health-related condition [21CFR 101.14(a)(1)]. This definition matches generally with disease risk reduction claims in Canada. Health claims are used for the labelling of conventional foods and dietary supplements. These types of claims cannot be about the cure, mitigation, treatment or prevention of disease, which are considered drug claims. In the US, the FDA uses three mechanisms to determine which claims may be used.

First, the FDA can issue a regulation authorizing a health claim that it deems meets the significant scientific agreement (SSA) standard under the 1990 *Nutrition Labeling and Education Act (NLEA)*. As of June 1, 2007, there are 12 food/nutrient and disease risk reduction relationships that meet SSA [<http://www.cfsan.fda.gov/~dms/lab-ssa.html>].

Second, if the FDA has no objection within 120 days of receiving a health claim notification, the claim can be permitted under the 1997 *FDA Modernization Act (FDAMA)*. *FDAMA* permits claims based on an authoritative statement from a scientific body of the US government or the National Academies of Science. As of June 1, 2007, there are 5 food/nutrient and disease risk reduction relationships in use with no objections under *FDAMA* [<http://www.cfsan.fda.gov/~dms/labfdama.html>].

Third, the FDA can issue a letter of enforcement discretion for a qualified health claim within 270 days of receipt of a petition, in cases where the strength of evidence falls below the FDA requirements for authorization (i.e., SSA). These health claims must be accompanied by a qualifier set out by the FDA, to ensure accuracy and non-misleading presentation of information to consumers, indicating the nature of the evidence supporting the claim. A qualified health claim and the wording that must be used is illustrated in the following statement for tomatoes and prostate cancer:

“Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.”

As of June 1, 2007, there are 18 letters of enforcement discretion for 25 qualified claims listed on the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) website. Over 75 claims were denied [<http://www.cfsan.fda.gov/~dms/qhc-sum.html>].

All foods carrying disease risk reduction claims in the US must meet a set of core qualifying and disqualifying criteria. Additional criteria are set that are specific to each claim.

Function Claims

In the US, the term “structure/function” claim is derived from the *Dietary Supplement Health and Education Act*. Such claims can also be made on conventional foods under the *Federal Food, Drug and Cosmetic Act*, but are not termed “health claim.” They describe the role of the substances intended to affect the normal structure or function in humans or characterize the means by which the substance acts to maintain the stated structure or function. The claim must derive from the nutritional value¹ of the product.

¹ Nutritive value is defined at 21 CFR 101.14(a)(3) as a value in sustaining human existence by such processes as promoting growth, replacing lost nutrients or providing energy.

These are similar to biological role claims in Canada and, as in Canada, they can be made without receiving FDA review or authorization, but must be truthful and not misleading. Unlike Canada, the US does not provide any form of positive list guiding the range of these claims deemed to be truthful and not misleading.

The FDA held public hearings (Dec 5, 2006) on the regulation of certain conventional foods that companies are marketing as “functional foods.” These include conventional foods that carry structure/function claims [<http://www.cfsan.fda.gov/~lrd/fr061025.html>].

In a subsequent information letter to industry, the FDA reiterated its guidance regarding food labelling, including the use of structure/function claims for conventional foods. These claims must be truthful and not misleading and be derived from the nutritional value¹ of the product, even though they can be made without FDA review or authorization [<http://www.cfsan.fda.gov/~dms/flguid.html>].

General “Healthy” Claims

Foods carrying claims that suggest that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, or that the food is useful in creating a diet that is consistent with dietary recommendations, must meet specified conditions for the levels of fat, saturated fat, cholesterol and sodium, and for certain food categories, other nutrients as well (including vitamin A, vitamin C, calcium, iron, protein and fibre). Details on the specified levels of these nutrients that vary with the food category can be found in 21 CFR § 101.65(d).

Status of US Disease Risk Reduction Claims in Canada

In 1999, Health Canada committed to undertaking a review of the 10 US health claims that met the SSA standards and were authorized under the *NLEA* at that time. A strict comparison of the “number” of claims between the two countries is challenging since some claims in Canada combine or restrict elements of some claims in the US. However, in general in Canada:

5 have been authorized with some modification of wording, through regulatory amendments (2003);

2 have been recommended for approval, with some modification of wording, and have undergone public consultation (Dec 2006);

2 were found not to be supported by updated science and will not be approved in Canada (2003, 2006);

1 is the subject of a current review through an industry submission.

Considering the 6 additional SSA and FDAMA claims used in the US since 1999:

there has been no interest expressed in Canada for one claim (fluoridated water and dental carries);

2 are under review through industry submissions;

3 are incorporated into the claims already approved or proposed in Canada.

A detailed summary of the status of US disease risk reduction claims in Canada is provided in Appendix F.

With regard to qualified claims, Canada does not allow claims that do not meet the standard for substantiation. The US is alone internationally in taking this approach of enforcement discretion. For example, both the recent EU decision (2006) for disease risk reduction claims and proposed Food Standards Australia New Zealand approach (2007)

to managing risk reduction claims for serious diseases require that high standards of evidence be met. Canada's position regarding disease risk reduction claims is consistent with these international norms.

Appendix F – US Disease Risk Reduction Claims* and Their Status in Canada

* Includes health claims based on significant scientific agreement under the *Nutrition Labeling and Education Act (NLEA)* and authoritative statement under the *Food and Drug Administration Modernization Act (FDAMA)*. Qualified health claims are excluded.

US (NLEA & FDAMA) (1)	Status in Canada (2)(4)			
	Accepted	Proposed	Submission Under Review	Rejected
Original 10 Health Claims based on Significant Scientific Agreement (SSA) (Health Canada 1999 commitment)				
1. Calcium & osteoporosis (SSA), proposed inclusion of Vitamin D (Jan 7 2007) (3)	added vitamin D			
2. Sodium & hypertension (SSA)	added potassium			
3. Dietary fat & cancer (SSA)				Rejected
4. Fibre-containing grain products, fruits & vegetables & cancer (SSA)	accepted fruit & vegetable aspect			grains & cancer rejected
5. Fruits, vegetables & cancer (SSA)	accepted			
6. Dietary saturated fat & cholesterol & risk of coronary heart disease (CHD) (SSA)	modified to include trans fat, but not cholesterol			
7. Fruits, vegetables, grain products that contain fibre, particularly soluble fibre, & CHD (SSA)		accept with modification (whole grain); exclude reference to fibre (Dec 2006)		
8. Soluble fibre from certain foods (oats & psyllium, & recently barley) & risk of CHD (SSA)			Yes	
9. Folate & neural tube defect (SSA)		accept (Dec 2006)		
10. Dietary sugar alcohol & dental caries (SSA)	accepted			

US (NLEA & FDAMA) (1)	Status in Canada (2)(4)			
	Accepted	Proposed	Submission Under Review	Rejected
Since 1999 SSA and FDAMA decisions				
11. Potassium & blood pressure & stroke (FDAMA)(2000)	combined with (2)			
12. Whole grain & heart disease , cancer (FDAMA) (2003)		combined with (7) for whole grains & heart disease		grains & cancer rejected in (4) above
13. Soy protein & risk of CHD (SSA) (Oct 1999)			Yes	
14. Plant sterol/stanol esters & risk of CHD (SSA) (2000)			Yes	
15. Fluoridated water & risk of dental carries (FDAMA) (2006)	No interest has been expressed for such a claim in Canada			
16. Saturated fat, cholesterol, trans fat & heart disease (FDAMA)(2006)	see (6) above			
17. Substitution of saturated fat with unsaturated fatty acids & risk of heart disease (FDAMA) (2007)				

- (1) <http://www.cfsan.fda.gov/~dms/flg-6c.html> "Food Labelling Guide Appendix C."
(2) http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/permitted_claims-allegations_autorisees_e.html "Status of Health Claims in Canada – Permitted Health Claims."
(3) <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01543.html>
(4) http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/position_paper-enonce_position_e.html "Position Paper on Five US Health Claims Considered for Use in Canada."

Appendix G – References: Health Claims for Foods in Selected Jurisdictions

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