Archived Content

Report of Regional Workshops on Modernizing Canada's Framework for Health Claims on Food

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

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PART 1: SETTING THE CONTEXT

A. Introduction

Six regional workshops were held across Canada in January and February 2008 as part of the Consultation on a Modernized Framework for Managing Health Claims for Foods in Canada. The sessions were held in Toronto, St. Hyacinthe, Halifax, Winnipeg, Edmonton and Vancouver.

The participants at the sessions represented a broad range of stakeholders, including consumers, health professionals, health/disease organizations, academia, industry, and government. Overall, 286 stakeholders participated in the workshops. Participant organizations are listed in Appendix 1. A summary of the Voluntary Statements of Information is provided in Appendix 2.

This report is intended as a snapshot of the input received at each of the six workshops. A final report, incorporating all regional and written input, will provide an analytical overview of all input received during the consultation.

B. Background

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 meaning and integrity of the growing array of health-related messages on foods.

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. The intent is to build on the current strong foundations of the 1998 Policy Paper on Nutraceuticals/Functional Foods and Health Claims on Foods 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 review is an outcome of the *Blueprint for Renewal*, a major Health Canada initiative aimed at modernizing the oversight for health products and food. More information on this overarching initiative can be found on the Health Canada website: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/index_e.html.

C. Consultation Process and Objectives

A discussion document (*Managing Health Claims for Foods in Canada: Towards a Modernized Framework*), including a series of questions, was posted on the Health Canada website in November 2007, with input accepted until the end of March 2008. In addition to accepting written feedback on this discussion document, Health Canada held a series of regional stakeholder consultation workshops during January and February 2008, in:

- Toronto, ON – January 28, 2008
- St. Hyacinthe, QC – January 30, 2008
- Halifax, NS – February 1, 2008
- Winnipeg, MB – February 4, 2008
- Edmonton, AB – February 6, 2008
- Vancouver, BC – February 8, 2008

The objectives of the workshops were to provide a forum for the exchange of ideas, to further develop stakeholder capacity to respond to all of the questions posed on-line and in the discussion document, and to collect feedback related to five key aspects of the discussion document:

1. Substantiation of Claims
2. The Food/Natural Health Products Interface
3. Managing a Broader Range of Function Claims
4. Managing Diverse Front of Package Claims
5. Eligibility Criteria for Foods to Carry Claims

The input and advice received from stakeholders during these workshops and through the on-line consultation process will be used to help develop policies, set the groundwork for proposals for further consultation, and guide priority setting and work plans.

D. Overview of Current Regulatory Context

Health claims are one of several types of information provided on food labels, alongside nutrition labelling (the Nutrition Facts table that appears on food packages) and nutrition content claims, which are strictly regulated in Canada.

For the consultation, "health claims" are defined as: 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 in the context of the total diet.

The *Food and Drugs Act* and its Regulations govern the use of health claims that appear on packaging or in advertising for foods sold in Canada. Health claims vary from general claims, such as "healthy for you" or "healthy choice," to specific disease risk reduction claims, such as "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." Some health claims refer to specific body functions, such as "Vitamin A aids in the maintenance of night vision."

The use of disease risk reduction 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, 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 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 regulations 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."

See Appendix 3 for a table of Regulatory Requirements by Health Claim Type.

Consumers have a growing interest in the health-disease-food connection. Industry is responding with new products and a proliferation of health claims on foods and implied health claims expressed in commercial logos, symbols or slogans. There are concerns with the ability of the existing regulatory system to effectively address the range of health

claims, and with the possible option of having foods with claims about health benefits approved under the *Natural Health Products Regulations*. Stakeholders are looking for more efficient and transparent processes for the approval of health claims.

E. Consultation Discussion Themes

i. Substantiation of Claims

Health Canada's current approach to substantiation of claims is set out in the *Guidance Document for Preparing a Submission for Food Health Claims*. The goal of this approach is to allow credible claims that are truthful, not misleading, and that are not likely to change over time.

All health claims are evaluated using a systematic review process, which includes a structured, comprehensive literature review of all relevant evidence, based on human studies of acceptable quality, that consistently support a causal relationship between the consumption of foods or food constituents and the claimed health benefit. This consistency in results should be observed across studies, including studies of different designs.

When the review is completed, only claims that are supported by convincing evidence are permitted. This means that there is a high level of certainty that a permitted claim is valid and truthful. A high level of certainty is achieved when the body of evidence supporting a claim is of sufficient quality and quantity, such that new studies are not likely to change the conclusion about the claim being made.

The Guidance Document has been updated to provide more detail about how a high level of certainty is determined.

This review process for health claims on food, in particular the amount of scientific substantiation and level of certainty required, has been brought into question because of actual and perceived differences with procedures under the *Natural Health Product Regulations* and those of other jurisdictions. For example, under the NHP Regulations, the nature of the claim and the health risk of the product are considered in determining the level of evidence required. In the U.S., disease risk reduction claims that fail to meet the usual degree of certainty may be made with a qualifying statement set out by the Food and Drug Administration (FDA).

A key issue is whether the standards of evidence to support a health claim on food should always be based on clear, consistent and high standards of evidence (as is the current approach for health claims on foods), or whether standards should not be uniformly rigorous but rather vary according to the level of risk presented by the product and the nature of the claim (as is the approach for health claims on natural health products).

ii. Food/Natural Health Products Interface

The *Natural Health Product Regulations,* created in 2004, do not exclude foods or food constituents. Foods with health claims can be regulated as a food or as a natural health product (NHP). An amendment of the NHP Regulations is being considered to exclude foods.

There are many challenges to managing NHPs in food form. There are a number of differences between foods and NHPs in the pre-market review of claims and in the level of certainty required before a claim is permitted. In addition, there are also differences in how product safety is assessed and how the potential health risk of a product is managed. For example, requirements for pre-market safety assessment of novel foods do not apply to similar foods or similar ingredients added to foods licensed as NHPs.

Of particular concern is how to regulate bioactive ingredients added to food. Some of these added substances are not traditionally associated with food or with the food that contains them. Examples of bioactive ingredients in food are glucosamine (derived from shark cartilage) in beverages; lutein in eggs; and plant sterol added to juice.

There are a number of concerns related to the addition of bioactive ingredients to food:

- some bioactive ingredients raise potential health concerns for some groups, for example children;
- the same bioactive substance could be added to many different foods, making it difficult for consumers to maintain a safe level of intake; and
- the marketing of foods containing bioactive ingredients is expected to expand in the future, posing potential risks for populations for which the product was not intended.

There is a need to consider the types of food to which bioactive substances will be added, the level of the substance to be added to foods, and risk mitigation strategies. Health Canada is considering additional risk management approaches for foods containing bioactive ingredients that pose concerns for some population segments or when used inappropriately. Examples of risk management approaches being considered include:

- Using appropriate claim wording and packaging design to ensure that the product is directed to the appropriate target group.
- Providing directions for use in terms of the amount and frequency of consumption of the product.
- Revising regulations to establish additional controls (e.g., restricting level of addition and types of food vehicles that can be used).
- Establishing labelling requirements similar to those seen on NHPs, such as a statement of contraindications and caution statements or warnings.

iii. Managing a Broader Range of Function Claims

While some function claims have specific regulatory requirements (i.e., biological role claims and claims that would bring a food into the definition of a drug), other function

claims have no regulatory requirements beyond being truthful and not misleading. However, the distinction between the different types of function claims and related requirements is not always obvious.

As industry interest in functional claims increases – along with growing consumer interest in the health benefits of food – the lack of clear regulatory requirements or guidelines for functional claims could lead to inappropriate use of such claims, confusion among consumers, and, ultimately, loss of confidence in the credibility of health claims.

To address these and other concerns, Health Canada is proposing non-regulatory measures to help ensure credibility of a broader range of function claims. Proposed measures include:

- clarifying the nature of acceptable function claims that would not be considered drug claims;
- encouraging voluntary industry consultation with Food Directorate personnel prior to use of a function (type 2) claim; and
- maintaining an up-to-date list of function (type 2) claims that are deemed not misleading.

Type 2 claims are about maintaining or supporting body functions that may be associated with the maintenance of good health or performance. For example: For coarse wheat bran as an ingredient providing 7 g of dietary fibre – "Promotes regularity or laxation."

iv. Managing Diverse Front of Package Claims

In practice, health claims are expressed *explicitly*, in a statement, or implicitly, through slogans, logos or symbols. In Canada and around the world, there has been an increase in the use and variety of implicit "front-of-package" (FOP) claims. Examples of implicit claims include graphics, such as hearts or check marks; logos, such as "Blue Menu"; and slogans, such as "healthy choice" or "good for you." These claims are used alone or in conjunction with more formally accepted claims, such as disease risk reduction claims, biological role claims or nutrient content claims.

Food regulations allow for explicit disease risk reduction claims to be accompanied by implicit claims. However, enforcement is difficult. There are no other specific regulations governing the use of implicit health claims.

Front of package programs have been developed by food manufacturers, retailers, and health/disease organizations, such as the Heart and Stroke Foundation. Criteria vary from one program to another, within programs and from one food category to another.

Studies have shown that foods carrying health-related claims are seen by consumers as healthier choices. Front of package claims may draw attention away from less healthy characteristics of a food, or oversimplify complex nutritional messages. Inconsistency within and among implicit claim programs raises consumer confusion. For these and

other reasons, many jurisdictions are seeking ways to better control and/or prohibit the use of implicit front of package claims. Canada's Standing Committee on Health recommended in March 2007 the implementation of "a mandatory, standardized, simple front of package labelling requirement on pre-packaged foods for easy identification of nutritional value."

Health Canada is proposing several measures to address issues related to front of package claims, including:

- Pursue alternative wording of disease risk reduction claims to provide additional flexibility.
- Consider approaches of other jurisdictions: e.g., prohibition of implied claims without explicit claims.
- Undertake consumer research on the interpretation of symbols or other representations in concert with the Nutrition Facts table.
- Explore applying core eligibility criteria to front of package claims.

v. Eligibility Criteria for Foods to Carry Claims

There are currently no common core criteria in Canada to determine which foods are eligible to carry health claims.

Some jurisdictions (EU, FSANZ, U.S.) have adopted or are planning to adopt core nutritional criteria for foods carrying health claims. The Codex Alimentarius Commission recommends that there be a regulatory framework for qualifying and/or disqualifying conditions for foods to carry health claims.

Establishing common core criteria is challenging, as it is difficult to balance the positive and negative nutritional characteristics of a food, given the wide range of nutritional and health needs of individuals. There is also potential for generally healthy foods to be excluded based on one criterion.

Health Canada proposes to:

- consider the application of minimum standards to foods carrying any type of health claim;
- explore a basic nutritional profile which would apply to all foods with health claims; and
- conduct consumer research to better understand when health claims on foods with negative nutritional attributes are misleading to consumers.

Targeted consultations on more specific options will be held as policy development moves forward.

This approach is consistent with Health Canada's goal to address "food contributors" to chronic disease, as outlined in Health Canada's 2007 *Regulatory Modernization Strategy for Food and Nutrition*.

PART 2: REPORT OF REGIONAL WORKSHOPS

A. Toronto – January 28, 2008

Seventy-five stakeholders attended the workshop on Managing Health Claims for Foods held in Toronto, Ontario, at Crowne Plaza Toronto Don Valley, on January 28, 2008. Participant views on five theme areas are discussed below.

(i) Substantiation of Claims

Should all disease risk reduction and function claims be based on a high level of certainty?

Some participants felt that a high level of certainty is required for all claims regardless of the risk presented by the product and the nature of the claim, as confirming the level of risk is complex and imprecise. For some people, no level of risk is acceptable.

On the other hand, some participants felt that a high level of certainty is only needed for disease risk reduction claims; a lower level of certainty could be permitted for other claims. A matrix approach could be applied, with varying levels of certainty based on claim type, level of risk and the product category. It was noted that health claims on bread, for example, should be subject to the higher level of certainty, as bread may be consumed more frequently than other types of food. It was suggested that the number of levels of certainty be limited to two, to reduce potential for confusion. For example, claims could be associated with either "wellness" or "disease risk reduction."

It was noted that it is very difficult to prove "cause and effect" as it relates to foods and health. Even extensive, well-funded, and reputable research has been unable to conclusively make cause and effect linkages. Alternatives to cause and effect, such as meta-analysis, expert opinions, amount of evidence, should be explored. What is more important (than proof of cause and effect) is that the research and evidence being considered for decisions be of high standard/quality. It was suggested that definitions and guidelines may need to be developed to identify what constitutes "quality" research, such as whether the study is still current, peer review, size, methodology, etc.

Participants noted that the issue of risk associated with health claims on food is more a question of risk associated with consumer interpretation of the claims, rather than risk related to the food. Participants agreed with the Health Canada statement that research has shown that consumers do not differentiate between types of health claims. In addition, participants noted that many consumers do not read qualifying statements; and when statements are read, they are often misinterpreted. It was suggested that additional research on consumer habits, perceptions and understanding of health claims is needed, as is education to help consumers better understand health claims.

Some participants felt that claims about a specific benefit, such as "green tea contains antioxidants" should be able to be used without going through a submission/evidence process. Similarly, it was suggested that health claims about compounds with proven health benefits in one type of food should be permitted in other types of food, provided there is substantiation that the compound is present in an appropriate quantity. (This is the current approach for the regulation of health claims on food.)
It was also suggested that a similar approach for proprietary rights as is used for drugs be applied to health claims research (i.e., if a manufacturer funds research or does a comprehensive literature review – that manufacturer has license/exclusive use for a given number of years, after which others could use it). It was suggested that these measures would help alleviate industry burden and promote product innovation as well as help improve the timeliness of Health Canada reviews.

It was suggested that the submission process for sponsors of new health claims should be clearly articulated, and assistance to sponsors should be provided. Some participants suggested that evidence and decisions from other jurisdictions be accepted by Health Canada.

If Health Canada were to consider allowing claims at different levels of certainty, how should this be communicated to the consumer?

Participants felt that Health Canada has a role to play in preventing misleading claims, and in ensuring health claims are communicated in ways that are clearly understood by consumers.

When a claim is used on food, it should be expressed in language that is understandable to "average" consumers. Standardized wording was suggested as a way to help avoid consumer confusion and misunderstanding. Complex qualifications should not be used, as they will lead to confusion.

It was suggested that the following information be included as part of a claim:
- Directions/suggestions on using the food as part of a healthy diet.
- The level of certainty associated with the claim.
- Claims should be less ambiguous ("will" rather than "may").
- State the effective level and the toxic level.
- Sources of additional information (manufacturer website, Health Canada website).

Some participants suggested that it will be important to address the needs of specific sub-populations (children, pregnant women, elderly, ethnic groups), particularly those that may be more vulnerable to certain additives, substances in different quantities, etc., than other consumers.

It was noted that although many consumers are quite knowledgeable about health and nutrition, particularly in urban areas, there is still a need to provide education about

health claims and to promote awareness of the content and meaning of labels. Some participants felt that consumer education is a shared responsibility of industry and government. In addition, consumers themselves have a responsibility to increase their knowledge and understanding in these areas in order to make informed decisions.

(ii) Food/Natural Health Products Interface

What are the advantages and drawbacks of 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?

It was noted that there should be clear definitions, criteria, parameters, etc., to identify bioactive substances, "food-like" NHPs, and to distinguish "food" from "natural health product." Some participants suggested that the distinction between food and NHP could be related to whether or not there is a health claim associated with the bioactive substance. For example, a food product that contains a bioactive substance but does not carry a claim about that substance, would be considered a food; a food product that contains a bioactive substance but does carry a health claim about that substance, would be considered an NHP. On the other hand, some participants felt that a "food is still a food" regardless of whether it has a bioactive substance added to it.

It was noted that standards for efficacy and quality should be the same regardless of whether the item is considered a food or an NHP. Similarly, the same regulatory requirements (pre-market assessments, etc.) should apply to products promoting the same claim. It was also suggested that bioactive substances should be allowed only if added at a proven functional level (i.e., not for marketing purposes).

The suggestion was made that Health Canada should review the limits and requirements of Codex to determine how they may impact decisions related to food/natural health interface issues.

Advantages associated with adding bioactive substances to food cited by participants included improved consumer choice and convenience. In this connection, it was noted that food products can provide a cost-effective way for consumers to obtain bioactive substances, especially those that they might not otherwise obtain. The addition of bioactive substances to foods will promote the development of new food items, thereby providing benefits to industry as well as increased consumer choice.

Other advantages noted included:

- Food is an "intake limiting substance," thereby reducing risk of overdose.
- International experience with the use of bioactives in foods (in lieu of drugs) has been positive.

A number of key risks associated with foods with bioactive substances were raised by participants. It was noted that consumer perception of what constitutes a "healthy food"

may change with the addition of bioactive substances: a food that was previously considered "unhealthy" may be seen as being "healthy" because of the presence of a bioactive substance, yet it still may be overall "unhealthy." Another key risk is that incremental amounts of a bioactive substance in a number of foods could make it difficult to keep track of total intake, leading to over consumption and potential adverse effects. This risk is heightened when sub-populations, such as children, elderly, etc., are considered.

Another drawback related to the addition of bioactive substances to food is increased risk due to self medication: if a little is good, then a lot must be better. Connected with this is the risk that people will rely on health claims rather than professional medical advice.

Other drawbacks noted included:

- Not much research has been done on the effects of fortified foods.
- Internet sales are a problem – difficult to control access.
- Potential for adverse interactions with pharmaceutical products.

How might the risks associated with these products be managed effectively?

Participants acknowledged that it is very difficult to effectively manage many of the risks associated with the addition of bioactive substances to food. Among the suggestions for addressing risks and drawbacks associated with these products were:

- Clarify and build on existing regulatory regimes – The *Food and Drugs Act* and Regulations and the *Natural Health Products Regulations* should be expanded and standards established to accommodate health claims for food-like NHP products. If a claim falls under the food regulations, then those regulations would apply. If a claim is outside the food regulations, then the NHP Regulations would apply. Some participants felt that the distinction between food and NHP regulations should be clarified to facilitate decisions as to whether the food or NHP regulatory regime and standards would apply. This approach could be facilitated through improved coordination between Health Canada directorates to create a "single window" approach for foods and NHPs. This could avoid creating a third category/additional layer of regulation.

- Ensure clear and complete labelling – Labelling should clearly identify that a product contains a bioactive substance, e.g., by indicating that it is an NHP. It was suggested that food labelling requirements (Nutrition Facts table, ingredients, allergen information) be integrated into labelling requirements for NHPs. In addition, labelling requirements for foods with bioactive ingredients should be expanded to include information on the source of the bioactive ingredient (e.g., fish being the source of Omega-3 that is added to bread). However, there was some concern that labelling requirements may become too complex, leading to increased consumer confusion. The overall goal for labelling should be to provide information to consumers in a clear and understandable manner so that consumers can avoid negative effects.

- Foods must meet nutritional criteria – It was suggested that a product should be required to meet a core/minimum level of nutrition criteria (e.g., fat, salt, sugar content) before it can be enhanced with a bioactive substance. Core levels could vary depending on the product category, target population and use. This would mitigate risks associated with consumer perception that any food with an added bioactive substance should be considered a "healthy" product.

- Establish limits for bioactive substances (quantity and target foods) – Consumption studies should be conducted to address concerns related to over-consumption of foods with bioactive ingredients. The results of the studies would help determine limits and parameters for bioactive ingredients (e.g., restrictions on the level of bioactive substance that may be added or restrictions on the types of food to which the bioactive substance may be added). It was suggested that a bioactive substance be restricted to certain foods, with monitoring of intake, before introducing it to a wider variety of foods (although this raises issues related to restricting innovation and competitiveness).

- Tie bioactive substances to Canada's Food Guide recommendations – It was suggested that Canada's Food Guide include guidelines for consumption of foods with bioactive ingredients, tied to food categories and population groups.

(iii) Managing a Broader Range of Function Claims

Are the measures proposed in the discussion document for Type 2 claims sufficient or should Health Canada consider other regulatory or non-regulatory measures? If so, what are they?

There was a general sense that the proposed measures are a good first step.

There was concern that Type 2 function claims may be too generic to be of any value to the consumer. Many non-nutrients have specific functions or roles which may not be clear in a general statement. There is a need to ensure that claims tell *why* the ingredient/ component is important/useful.

Clarification of Type 2 as well as other claim types is important. Some participants suggested that Type 2 claims should focus on the component/ingredient rather than the product. Another suggestion called for three types or levels of claims: Type 1 – disease risk reduction; Type 2 – function claims that relate to biological markers; and Type 3 – general health claims. Each Type would have a corresponding requirement to meet regarding scientific evidence.

Some participants felt that non-regulatory measures provide a proactive approach and an ability to move forward toward solutions now, without waiting for regulations to be in place. There was also a perspective expressed that Type 2 claims are really marketing

tools, and therefore do not require government regulation. If a non-regulatory approach is taken, products should be required to indicate that the claim is not "approved" by Health Canada (similar to the U.S. system).

Some participants suggested the creation of a non-governmental, self-regulatory body, along the lines of the Advertising Standards Council, which would establish standards, review claims, be accountable for decisions and provide oversight. Such a body would be comprised of representatives of Health Canada as well as industry, health professionals, consumers and others. However, some participants cautioned that this approach has not always been successful (e.g., for organics), and therefore prefer that oversight and accountability remain government responsibilities.

There were also many participants who felt that voluntary and/or non-regulatory measures do not provide the level of rigour needed given the range of potential risks related to health claims on food. Regulatory measures were considered to be the only way to protect safety, minimize risk, ensure a level playing field and ensure government accountability for monitoring and enforcement. A regulatory system that provides transparent, efficient, timely reviews of proposed health claims around clear parameters would be welcomed. Some participants felt that a mandatory notification system is required.

Participants cautioned against trying to make existing regulations work for issues that they were not originally intended to address. However, there was support for a non-regulatory approach as an interim measure while regulations are amended and/or developed.

The proposal to provide opportunity for industry to have a claim reviewed by Health Canada was welcomed. This would need to be done in a timely manner.

The proposal to maintain an up-to-date list of claims that are deemed not misleading was generally supported. A system based on approved product monographs was suggested, that would provide notice to interested parties when items were amended or added to the list. Acceptance onto the list of new "ingredients" would require appropriate scientific evidence.

Many participants felt that Health Canada needs to invest in providing consumer education to increase understanding of health claims on food and nutrition in general. Research may need to be undertaken to determine current level of understanding in various populations.

Other comments included:

- The list of accepted function claims should include knowledge from other jurisdictions as well as traditional Aboriginal knowledge.
- An enforcement plan will need to be in place.

(iv) <u>Managing Diverse Front of Package Claims</u>

Would the measures proposed in the discussion document be sufficient to reduce the confusion arising from the increased use of health-related claims on the front of food packages, or are there other measures that Health Canada should be considering?

Participants expressed a variety of views related to front of package claims. Some participants supported a voluntary approach for front of package health-related claims, while others preferred a mandatory review process for all health claims, whether explicit or implicit. Some participants were in favour of prohibiting implied claims unless accompanied with an explicit claim, which would be expressed in clear, standardized (i.e., regulated) wording, and directions to additional information (e.g., website). Another suggestion was for a system for front of package health claims based on achievement of standards and criteria, which would be tied to Canada's Food Guide and/or the Nutrition Facts table.

Participants cited a number of examples of programs in use in other sectors/jurisdictions which may provide a model for Health Canada. An approach similar to the "organic standard" symbol was suggested, as well as the Hannaford "star" model, which provides information about a food product's "healthiness" on a relative basis (e.g., the more "stars" a product receives, the "healthier" it is). The idea of aligning with a U.S. system was raised, similar to what was done with the Dietary Reference Intakes (DRI) system. This would provide benefit to industry, for example by harmonizing marketing and packaging. Regardless of the model chosen, it was suggested that Health Canada should undertake pilot testing of the effectiveness of a front of package program prior to full implementation.

It was also emphasized by some participants that adoption of an existing model or alignment with the U.S. approach should take place only if there is already a strong back of package program affiliated with the front of package approach, and strong tie-in with the Nutrition Facts table. In this connection, many participants agreed that the Nutrition Facts table is a valuable resource that is having a positive impact, and underscored that there is opportunity to build on its success rather than introduce an entirely new system. It was suggested that consumer education could be focussed on "moving consumers to the back of the package." Linking front of package claims to the Nutrition Facts table could help minimize consumer confusion.

Many participants stressed the need for a simple system to reduce and avoid consumer confusion. However, it was noted that issues related to food and nutrition are complex, and dietary needs vary from person to person, and from sub-population to sub-population. What is a healthy food choice for one person may not be a healthy food choice for someone else. Therefore, some participants felt that no one symbol could be expected to capture all "healthy" foods or to apply to all consumers. A range of symbols, with each one tied to a specific criteria, was suggested.

Discussion on this question again focussed on the importance of raising consumer awareness and understanding of health claims and nutrition, including understanding the Nutrition Facts table. Both qualitative and quantitative research on consumer habits and perceptions is needed, and will help identify areas of confusion and direct education programs.

Other ideas and suggestions included:

- A response to the recommendation of the Standing Committee on Health regarding childhood obesity should be part of the outcome of the consultation.
- Research should also be done to determine if health claims are leading to public health benefits.
- Front of package labelling should not be limited to the positive attributes of the food, as what is *not* in a food is just as important as what is in it.

What measures could Health Canada take to ensure a truthful and non-misleading representation of health benefits?

Participants noted that provisions to protect consumers from misleading representation of health benefits already exist, as companies are required to not make false, misleading or deceptive claims under Section 5.1 of the *Food and Drugs Act*. Participants suggested that improved surveillance and enforcement may be required, rather than additional regulatory measures. It is important that adequate inspection resources are in place to provide effective monitoring of the marketplace, especially for imports, rather than only responding to complaints.

Other suggestions for measures to ensure truthful and non-misleading representation raised during the discussions included:

- Health Canada to certify claims based on criteria linked to Canada's Food Guide and/or the Nutrition Facts table.
- Establish a third-party accreditation system to ensure standards are met.
- Require that claims appear in multiple languages to ensure understanding across consumer groups (multi-ethnic messaging).

Industry participants claimed that they have no motivation or desire to mislead consumers.

(v) Eligibility Criteria for Foods to Carry Claims

Should there be a requirement that a set of core nutritional criteria be met in order to be eligible to make a claim? What are the advantages? What are the drawbacks? How might the drawbacks be overcome?

Many participants felt that a set of core nutritional criteria is needed to ensure overall credibility of health claims and the health claims framework. Terms, such as "healthy," should also be defined. However, there was less agreement around the composition of a set of core nutritional criteria and how it should be applied. Some participants felt a set of core nutritional criteria should be applied to general health claims, while disease reduction claims require a higher level of evidence and a regulated, case-by-case approach. Some participants envisioned a universal set of criteria, while others felt a set would be needed for each food product category.

Participants noted that there is the potential for confusion related to a set of core criteria, in terms of distinguishing "good" versus "bad" nutrients and food categories. Cheese was used as an example to illustrate this point: its high saturated fat content could lead to a negative "rating," even though cheese has positive nutritional benefits for many individuals because it is a good source of calcium. A point rating system, whereby points are given for positive nutrients and points are deducted for negative nutrients, was suggested as a model that would balance a food product's "good" and "bad" attributes.

Participants also noted that a set of core nutritional criteria could limit the introduction of beneficial components to "bad" foods – and many people eat "bad" foods. It could also limit innovation and competition.

It was suggested that "a set of core nutritional criteria" be defined and a sample set provided for more in-depth consideration by stakeholders.

A few participants were definitely opposed to the concept of a core set of nutritional criteria and felt that the Nutrition Facts table should be sufficient basis to inform consumers.

Other comments and suggestions that emerged regarding this question included:

- Nutritional needs are varied and complex. A set of criteria would need to be equally varied.
- Include information in Canada's Food Guide that explains and provides context for health claims.
- Link criteria to Canada's Food Guide to facilitate consistency.
- Ensure Canadian and U.S. criteria are the same to minimize confusion.
- Avoid processes/approaches that lead to increased food prices.

B. St. Hyacinthe – January 30, 2008

Thirty stakeholders attended the workshop on Managing Health Claims for Foods held in St. Hyacinthe, Quebec, at the Club de golf St. Hyacinthe, on January 30, 2008. Participant views on five theme areas are discussed below.

(i) Substantiation of Claims

Should all disease risk reduction and function claims be based on a high level of certainty?

The definition of a "high level of certainty" raised concerns among some participants that the level would be similar to that required for medicines. It was felt that it is very difficult to conduct the type of research studies on food that are done for medicines. These participants felt that a "probable" level of certainty is the best that can be achieved.

Some participants felt that the evidence requirements must be consistent with those for NHPs. If a high level of certainty were required for foods with health claims, manufacturers and suppliers of products that qualify as NHPs would have a distinct advantage over food manufacturers, even though the products could be very similar.

Some participants suggested a tiered system based on three categories for health claims on foods: disease risk reduction, function maintenance, and general health. A level of validation (quality, type and amount of scientific evidence) would be associated with each type of claim. A disease risk reduction claim would require a higher standard of scientific substantiation than general health claims.

It was also suggested that the level of certainty could vary within a claim category, provided the degree was part of the statement of claim. For example, a disease risk reduction claim could be based on high, medium or weak evidence, and thereby be identified by Health Canada as a high, medium or weak claim. It would also be positive for industry, as it would encourage product improvements and research necessary to "move up a category."

Some participants observed that it is important to keep the overall objective in mind, which is to provide information that is clear and credible and, above all, to avoid confusing the consumer. It is the consumer who, at the end of the chain, will have to live with the consequences. At the same time, it is important to not impede industry, but rather to provide it with tools to encourage investment and innovation, and to ensure there is an identifiable value-added benefit. Some participants claimed that if the system is too open (i.e., if any claim can be made), less scrupulous companies may make misleading claims for commercial gain, while those willing to undertake rigorous research to support claims will be unfairly disadvantaged.

Some participants raised the point that consumers have confidence in messages from government; any "endorsement" (or appearance of endorsement) of a claim must be based on sound scientific evidence. It is important to maintain credibility, as consumers may become skeptical about all they hear concerning nutrition.

Other comments and suggestions included:

- The benefit associated with value-added foods must be considered in the context of the total diet.
- Promoting the benefits of a healthy diet is essential, as people often move into value-added foods without a sound dietary base.
- There is a need for long-term monitoring of consumption and dietary habits to help determine long-term effects. Statistic Canada's Grocery Cart, which collects data about consumer behaviour, is a starting point for this information.

If Health Canada were to consider allowing claims at different levels of certainty, how should this be communicated to the consumer?

Participants noted that many consumers do not understand the rigour behind health claims on food, and how to communicate with them remains problematical.

Participants who supported a tiered approach believed that the level of certainty associated with the claim type should be expressed as part of the claim. Any risk associated with the food (even if there is none) should be stated as well.

Participants who suggested that the level of certainty could vary within a claim category also favoured communication as part of the statement of claim. Participants felt that this approach would be straightforward and easy for consumers to understand.

Participants emphasized the importance of making all information about the level of validation publicly available.

(ii) <u>Food/Natural Health Products Interface</u>

What are the advantages and drawbacks of 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?

Advantages associated with adding bioactive substances to food cited by participants included maintaining health, preventing illness and using bioactives to help people who are either allergic to foods or who will only eat certain foods.

Some participants noted that there are also risks associated with adding bioactive substances to food. Drawbacks noted included neglecting a food that is a natural source of bioactives and creating the perception that an enriched food is more healthy than it is

in reality. For example, a food may be enriched with calcium, but also have a very high sugar content. When a health claim is associated with such a food product, it is easy to forget the product's "less healthy" side.

Some participants questioned overall responsibility for evaluation of risk associated with these products. Who would be responsible for evaluating the risk of over consumption of these products – industry? government? Who would be responsible to identify/assign maximum consumption levels? Participants noted that these problems already exist for NHPs sold in food form.

Some participants observed that a concern about all functional foods is that they may make traditional foods obsolete as they lose credibility as "healthy" foods. It was suggested that basic foods be allowed to carry statements such as "contains Y and therefore this product is as good as X".

How might the risks associated with these products be managed effectively?
Participants observed that it is very difficult to determine how to manage these risks. It was suggested that particular attention should be paid to dosage and recommended amounts. Some participants suggested the use of warnings to alert consumers to potential risks related to consumption by non-target populations, such as children and the elderly. The question was raised as to whether people should be told that they could check with a pharmacist, and whether they in fact would do so.

Other participants noted that warnings may not be effective as there is a risk that consumers will not read them (or understand them). Moreover, industry is clearly not in favour of warnings.

Some participants advised Health Canada to look at how bioactive substances are being addressed in other countries. For example, in the United States a warning appears on the product, with a goal of educating the consumer about the bioactive substance. Some participants cautioned that this could lead to a "plethora of labels." Moreover, some felt that the consumer should be responsible to educate him or herself. On the other hand, it was also suggested that Health Canada does have a role to play in educating the public, and should post information on bioactive substances on its website for easy public access.

Some participants suggested that Health Canada provide a list of high-risk bioactive substances, and that these ingredients be regulated. Other participants felt that management of bioactive substances should be the responsibility of industry, although identification of bioactive elements in ingredients could be required by government.

Other suggestions included:

- Consider regulations covering point-of-sale to ensure consumers are able to clearly understand and see the difference between basic foods and the enriched variety. For example, provide a specific location in a grocery or food store for functional foods enriched with bioactive substances. Access to this part of the store might be limited.

- Limit the foods to which these substances may be added.
- Include a suggested use on the product label.
- Undertake a review of policy covering NHPs to ensure the playing field is even.

(iii) <u>Managing a Broader Range of Function Claims</u>

Are the measures proposed in the discussion document for Type 2 claims sufficient or should Health Canada consider other regulatory or non-regulatory measures? If so, what are they?

Participants discussed the types of function claims and the level of rigour required by their corresponding administrative frameworks. Type 1 and 2 function claims were considered "medium level claims" and as such should require research and scientific proof. The risk of disappointment is high for people who consume foods based on these claims, as false expectations are easily created.

Type 3 claims were considered to warrant a high level of regulatory control, as they were seen to be very similar to disease risk reduction claims. Even though a specific disease is not mentioned in a Type 3 claim, a specific disease could easily be inferred by consumers. For example, a Type 3 claim that references cholesterol would have a high probability of being interpreted by consumers as having a connection with reducing the risk of cardiac disease. Some participants emphasized that this is approaching a disease risk reduction claim, and therefore requires the same administrative framework.

Participants noted that claim statements must be scrutinized for appropriate wording. For example, the term "restore" has specific therapeutic meaning and should be used only in higher level claims that have higher level proof. Care must be taken to avoid having consumers perceive a product as a complete solution to their health problem.

Many participants called for improvements to the current approval system. Suggested improvements included:

- Better timeliness of the review process.
- Acceptance by Health Canada of product reviews/monographs that have been accepted by other jurisdictions.
- Establish a list of active ingredients for which claims are already approved.
- The process should be made fairer: all parts of industry and all companies should have to go through the same process.

There was some support for maintenance of an up-to-date list of claims deemed not misleading. In addition to a listing of claims that are deemed not misleading, there should also be a list of "bad" claims.

Some participants suggested the creation of a database at Health Canada to assist companies in identifying the claim type based on the components of the proposed product (vitamins, minerals, saturated fats, etc.). This service will be in high demand as more and

more companies look to market new products with health claims. It was suggested that once a claim is accepted, it would be available for use by other companies.

Participants recognized the complexity of the issues and that "some ingenuity is needed in the approach to health claims for food." Other measures that were suggested included:

- Consumer education (use television spots, pamphlets, promotion by health professionals, etc.) to promote overall good dietary habits and understanding about nutrition and food/health linkages. Companies using health claims on food could pay into a social marketing fund to promote a sound understanding of the claim.
- Develop a means for ensuring health claims on food include a reminder to consumers about the importance of a healthy diet.
- Review wording of claims to ensure they are easy to understand by consumers.
- Develop tax incentives (similar to those for research and development) for companies that develop healthy food products.
- Create a system similar to the carbon impact index, which measures the carbon emitted, for example, in transporting tomatoes to market, and a portion of the product's price is used to plant trees. For food, manufacturers of "unhealthy" food products could contribute to a fund to support the development of healthy foods.

(iv) Managing Diverse Front of Package Claims

Would the measures proposed in the discussion document be sufficient to reduce the confusion arising from the increased use of health-related claims on the front of food packages, or are there other measures that Health Canada should be considering?

The proposed measures are a good start, but further investigation and development of the ideas are needed. There needs to be more consultation and research to identify consumer habits and understanding.

Some participants felt that there should be a stronger regulatory or administrative framework for front of package claims. Logos and symbols should only be used for "healthy" foods, not for chips, or foods high in fat, salt or other such ingredients. All foods should be required to meet certain standards before being able to carry a logo indicating it is a "good" food. The criteria for use of logos should have a maximum and minimum levels for the different elements involved.

Some participants noted that directives to industry must be clear. There needs to be consultation and an open dialogue to ensure logos are satisfactory before they are used. This is a shared Health Canada-industry responsibility. Moreover, all companies – large and small – should have access to the Health Canada approval process.

The proposal to raise consumer awareness will be very beneficial. Participants emphasized the need to ensure less confusion for consumers around nutrition information and both explicit and implicit claims. There are currently too many symbols – and the increasing proliferation of information on labels will only make it more difficult for

consumers. There is a risk that consumers might perceive a product with a logo as preferable or better than a similar product without one.

The harmonization of existing programs and logos could lead to reduced confusion, although this approach may not be realistic on a voluntary basis. However, participants noted that the Nutrition Facts table was initially implemented on a voluntary basis. Some participants noted that the table's success is in part due to its consistency: consumers are used to how the information is presented. A similar approach for providing information on health claims to consumers could greatly raise the level of understanding.

On the other hand, some participants felt that a reason for the proliferation of logos on packaging is that consumers still do not understand the Nutrition Facts table. An approach to raising understanding would be to use colour on the table to identify whether a nutrient content is above or below established thresholds. For example, a fat content above the threshold would appear in red (thereby indicating a "bad" amount); if the content is below the threshold, it would appear in green (indicating a "good" amount). This would help consumers make more informed choices and, over time, the various logos that help to interpret the nutritional panel would disappear.

Other suggestions for ways to reduce confusion while ensuring consumer confidence in the legitimacy of claims and a level playing field for industry included:

- Develop a third-party system to evaluate a manufacturer or a retailer's program and provide a "seal of approval."
- Develop a Health Canada logo that would indicate that the product logo has been verified against criteria. This would bring more credibility to accepted logos and allow for the almost automatic cleaning up of the current number of logos.
- Develop a list of pre-qualified logos, based on set criteria.

(v) <u>Eligibility Criteria for Foods to Carry Claims</u>

Should there be a requirement that a set of core nutritional criteria be met in order to be eligible to make a claim? What are the advantages? What are the drawbacks? How might the drawbacks be overcome?

Most participants agreed that there should be a set of core nutritional criteria. However, there was recognition that there are many variables that must be considered in designing and applying it.

Some participants felt that there is a need to look at the balance of benefits and risks associated with every food before making recommendations. Many foods have both positive and negative nutritional attributes. Cheese, for example, contains a high level of saturated fat, but cheese products also offer nutritional benefits.

Some participants noted that it is important that linkages be made with the Nutrition Facts table and Canada's Food Guide. This would provide a way to establish the nutritional quality of foods before addition of any active ingredient. The Food Guide and Nutrition Facts table could then be promoted along with the claim.

Participants noted that consideration needs to be given to the food category of the product when criteria are applied. Different foods bring different nutrients to people's diets, some products are consumed in greater quantity than others, and there is great variety in the dietary needs of individuals. It is complex and much work needs to be done here. Similarly, it would be important to tie the set of criteria to portion size.

It was suggested that the level or amount of the active substance required to obtain the desired effectiveness in relation to the claim should be determined for each intended target group. The contribution of the product to the recognized daily intake should be part of the package label. This would be similar to the percentage of the daily values that have been established for vitamins and minerals and which appear as part of the Nutrition Facts table.

Interest was expressed around the concept of nutritional density, which could provide a unifying methodology for development of a set of core criteria. A nutritional density criteria system would establish a scale or scales to measure a food's relative nutritional quality. Points would be given or deducted according to nutritional value, and only foods receiving a certain number of points would be eligible to carry a health claim. Because negative nutrients (salt, sugar, saturated fats, etc.) are included in the calculation, this approach could disqualify some "bad" foods from carrying claims.

However, there was concern raised that a nutritional density approach could limit or impede innovation, particularly for foods that are not at present considered "healthy" foods, but which could eventually be improved.

Some participants felt strongly that potato chips and similar products with high fat and salt content should not be permitted to carry any health claims. On the other hand, some participants suggested that any food should be able to carry a health claim, with two restrictions. First, the food must meet a specified minimum amount of the substance that is the subject of the claim. Second, foods not currently considered as contributing to a healthy diet must carry a warning related to the content of nutrients of public health concern. For example, potato chips have high amounts of fat and salt; a manufacturer could add a positive or fortifying ingredient and then affix a health claim along with a warning that consumers should not exceed a given amount of salt and fat. This approach would encourage innovation.

Participants also noted that people, especially young people, will continue to eat chips regardless of their image as a "bad" food. If industry cannot respect the restrictions relative to nutrients of public health concern while adding a benefit to the product, then at least there is a balance between risk and benefit.

C. Halifax – February 1, 2008

Thirty-two stakeholders attended the workshop on Managing Health Claims for Foods held in Halifax, Nova Scotia, at the Maritime Centre, on February 1, 2008. Participant views on five theme areas are discussed below.

(i) Substantiation of Claims

Should all disease risk reduction and function claims be based on a high level of certainty?

There was a mix of opinions in response to this question. Participants acknowledged that it is not easy to balance access to new products, consumer protection, and industry's competitiveness and ability to innovate.

Some participants felt that a high level of certainty (based on sound science) is required for all disease risk reduction and function claims. This would provide consumers with confidence and trust in the claims being made. Different levels of certainty for different claim types could lead to consumer confusion and add time and uncertainty to the review process for product developers.

Some participants felt that disease risk reduction claims should require a high level of certainty, but the level of certainty could be lower for other types of health claims. However, health claims that are targeted to specific populations, such as pregnant women, children, elderly, etc., should require a high level of certainty. Participants noted that a high level of certainty for all claims could prevent products from being developed or marketed, thereby limiting consumer access to innovative products and industry competitiveness. It was also noted that there is a relatively small body of science on these issues, so allowing varying levels of evidence is more realistic.

To help industry and ensure a level playing field, it was suggested that government invest in research related to food and health, and that findings be openly available to industry. On the other hand, companies that invest in research should be able to both protect that investment and reap its benefits.

Another point of view raised was that evidence requirements should be comparable or exceed global standards. Participants noted that Canada has an opportunity to be a leader in this area.

Health Canada will need to ensure it has the capacity in place to respond to an increasing number of submissions for health claims in a timely and transparent manner. Post-market surveillance will also be needed to track more long-term effects. A lengthy submission process places undue burden on industry and delays consumer access to beneficial

products. Consideration should be given to acceptance of reviews and approvals from other jurisdictions, as a means to expedite the submission review process.

Other comments and advice included:
- "High level of certainty" needs to be defined.
- There is a need to distinguish claims based on emerging science from those based on more long-term findings (e.g., Omega 3).
- Have a third party process for review of all claims.
- It would be easier for all parties if all claims were regulated in the same way.

If Health Canada were to consider allowing claims at different levels of certainty, how should this be communicated to the consumer?

Some participants noted that consistent labelling is important, along with consumer education on understanding labels and claims. Health Canada could communicate information to consumers through websites, package labels, point of purchase signage, the media, the school system, and health professionals. It was suggested that point of purchase signage could even be mandated by Health Canada. There may be useful lessons learned from the education and promotion done when the Nutrition Facts table was launched.

Messaging should be simple and easy to understand, and it was suggested that Health Canada could prescribe the wording that must be used for a claim. Literacy issues may need to be considered. The goal is to make it easy for a consumer, based on food package labels, to make a decision. It may be necessary to conduct consumer research to determine current levels of understanding and awareness.

Some participants felt that Health Canada should provide a standard for symbols and labels, rather than having a plethora of label styles from individual companies and/or organizations.

(ii) Food/Natural Health Products Interface

What are the advantages and drawbacks of 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?

Participants noted a number of advantages to the addition of bioactive substances to foods, including:
- They provide a flavourful way for consumers to receive beneficial substances.
- They provide additional choice and convenience for consumers.
- They may provide missing nutrients that are not present in one's "normal" diet or which are not easily obtained.
- They may provide a cost benefit to consumers as the bioactive substances may be less expensive in food form than in drug/tablet form.

- There is less risk of consuming too much (i.e., it is unlikely that people will eat too much food, compared to the risk of overdosing on capsules).
- Information provided regarding added bioactive substances raises consumer awareness of bioactive substances and nutrition. It may also encourage consumers to look for natural sources of bioactive substances, e.g., fish as a source of DHA.

Drawbacks suggested by participants included:
- There may be increased perception that food containing bioactive substances is healthy, e.g., Kool Aid with vitamin C.
- Consumers may assume that products with a bioactive substance have the same benefits for everyone.
- There is a potential for over-consumption of a bioactive substance that may be present in a variety of foods.
- There is potential for adverse interactions between different products with different bioactive substances and/or therapeutic products.
- Consumers may overly rely on foods with bioactive substances to provide health benefits and use them in place of a balanced diet, rather than as an enhancement to a balanced diet.

Participants emphasized the importance of eliminating the "loopholes" for foods being considered as NHPs. Participants felt that there are NHPs making claims that have not been proven, and this is harmful for companies trying to make legitimate claims.

Some participants felt that all foods, including those treated as NHPs, should carry the Nutrition Facts table.

How might the risks associated with these products be managed effectively?

Participants felt that foods that have added bioactive substances should be clearly labelled with information for consumers, including the source of the bioactive substance, amount, and dosage or recommended daily consumption limits. Warnings may need to be included to address risks associated with consumption by specific or non-target sub-populations (different ages, physiological groups, health status), as well as cautions regarding known interactions and/or adverse reactions.

It was suggested that a means for collecting information on adverse reactions should be established. In addition, Health Canada should make available a compendium of common bioactive substances in foods with recommended intakes.

Some participants felt that information about bioactive substances should be linked to Canada's Food Guide. It was felt that this would help position consumption of foods with bioactive substances as part of an overall healthy diet.

(iii) Managing a Broader Range of Function Claims

Are the measures proposed in the discussion document for Type 2 claims sufficient or should Health Canada consider other regulatory or non-regulatory measures? If so, what are they?

Some participants questioned Health Canada's ability, from a capacity perspective, to provide industry with voluntary evaluation of claims, noting that this process could take resources away from work on mandatory pre-market submissions. A voluntary process would be welcomed, if service standards are in place and the process is transparent. A voluntary process would lead to a more productive and collaborative system and more proactive relationships (similar to the EU model). Health Canada could also provide a post-review consultation service, to help sponsors understand why a claim is rejected.

It was suggested that an industry-Health Canada advisory group be created to provide a forum for the exchange of information and advice about health claims, for example, acceptable wording (proprietary information would need to be protected). A regular and ongoing discussion forum would provide benefits for both parties and help make the system more efficient, responsive and transparent than a one-on-one voluntary evaluation process.

Participants underscored the importance of transparency throughout the regulatory and voluntary processes, noting that it is not always clear how some claims are deemed acceptable. It is also important that a level playing field be established that enables the participation of both large and small companies.

The proposal for maintaining an up-to-date list of function (type 2) claims that are deemed not misleading was supported. It was considered to provide benefits to all parties – industry, health groups, and consumers. In addition to approved claims, the list should include information about claims that were not approved.

Consideration should be given to both actual benefits that are supported by scientific evidence and perceived benefits, which may have developed over time and have come to be generally accepted, even though there may be a lack of direct evidence. Green tea's reputation for having a calming effect was cited to illustrate this point.

Other comments and suggestions included:

- Regulations should be flexible to respond to emerging science.
- Develop guidelines for interim marketing authorizations; perhaps a similar process could be used for interim claim authorizations. These could expedite decision-making processes.
- Use a committee of scientific experts (from academia) to review abbreviated approvals, assess scientific data, and track international decisions.

(iv) <u>Managing Diverse Front of Package Claims</u>

Would the measures proposed in the discussion document be sufficient to reduce the confusion arising from the increased use of health-related claims on the front of food packages, or are there other measures that Health Canada should be considering?

There was general agreement that the proposals would help reduce confusion arising from front of package claims.

Educating consumers on health claims is challenging when there are different criteria for each front of package symbol or logo. In addition, the overall effectiveness of logos and symbols may be diminished as more enter the marketplace. A standard or policy would help, along with common wording or nomenclature so labels are understood by everyone the same way.

Some participants suggested that a "Health Canada symbol" for front of package be developed, based on Canada's Food Guide recommendations. This would provide confidence for consumers and credibility for the claim. It could also address literacy issues. However, concern was again raised regarding Health Canada's capacity to manage such a program, especially in terms of potential impact on health claim pre-market submission review timelines.

Other participants felt that one front of package symbol could not cover the wide range of dietary and information needs. Different symbols and explanations are needed to reach different target audiences, such as diabetics. It was suggested that one symbol be used to indicate "a healthy choice," and other symbols be used for more specific claims/purposes. All front of package claims should be allowed only on food that meets established criteria. Front of package logos for disease- or targeted claims should be allowed only on foods that qualify for the "healthy choice" logo.

Participants noted the importance of linking the information on the front of the package to the Nutrition Facts table on the back of the package. It was suggested that front of package claims would provide a "pre-screening tool" for consumers, who then would refer to the Nutrition Facts table for additional information on which to base their choice. However, this approach needs to be supported by consumer education on the Nutrition Facts table.

Other issues raised included:

- There are space issues related to the front of packages, yet there is still the need to highlight important information, such as allergens. Point of purchase displays could be used to provide additional information about the claim, and packages should refer to websites or other sources of information.
- Non-packaged foods (e.g., fresh fruits and vegetables, etc.) and foods consumed in restaurants present labelling challenges.
- Standards also need to be developed for expressions such as "all natural," "no preservatives," "contaminant free," etc.

What measures could Health Canada take to ensure a truthful and non-misleading representation of health benefits?

Some participants emphasized the importance of standardized criteria for front of package claims along with consistency in their presentation to consumers. It was suggested that standards should be jointly developed by Health Canada and stakeholders. Manufacturer- and organization-sponsored logos should be required to meet established standards.

It was again suggested by some participants that a Health Canada logo would create a level playing field, raise consumer confidence, and lessen confusion. The logo should be based on Canada's Food Guide and be tied to the Nutrition Facts table. Health Canada would need to promote the logo and increase consumer awareness of claims and nutrition.

Some participants suggested the use of a third party to monitor logos on packages.

(v) <u>Eligibility Criteria for Foods to Carry Claims</u>

Should there be a requirement that a set of core nutritional criteria be met in order to be eligible to make a claim? What are the advantages? What are the drawbacks? How might the drawbacks be overcome?

Some participants supported the concept that a food should meet core nutritional criteria to be eligible for a health claim. It was noted that consumers expect that this is the case. A core set of criteria would involve establishing parameters for nutrients such as fat, sodium, fibre, sugars, carbohydrates, and proteins. Criteria should be related to the Nutrition Facts table, Canada's Food Guide, Daily Recommended Intake, portion size, and other healthy eating concepts. Generally, nutritionally positive foods should be permitted to carry health claims, and nutrient-poor foods should be barred from carrying claims. This approach would provide a strong public health message.

Some participants felt that a single set of criteria would not cover all types of foods and food uses. For example, a core set of criteria could lead to the exclusion of some foods because they are high in one nutrient (cheese for example, would be excluded because of saturated fat). There are also implications related to exclusion of less expensive foods (such as canned vegetables because of sodium content) and product availability issues (e.g., product choices for people living in isolated areas or in the far north). Some foods don't "fit" into any criteria – how would water be treated, for example, as it does not have any nutrients?

Participants emphasized that whatever system is used, it needs to be as simple as possible to avoid consumer confusion. "Common sense" is key.

From an industry perspective, the system should be clear, predictable and consistently applied and enforced to ensure a level playing field.

Advantages of core criteria set(s) noted by participants included:
- Will improve integrity/credibility of front of package program.
- Provides consistency and lessens confusion.
- Could lead to reduced consumption of "bad" nutrients.
- May create an incentive for industry to produce "healthier" foods or to overhaul industry's use of specific ingredients, such as salt.

Disadvantages included:
- Negative perception of "requirement" – any requirement is perceived as a drawback by industry.
- Might stifle industry innovation.

Other comments and suggestions included:
- Health claims in isolation are not good for public health outcomes. An integrated system is needed (front of package, Nutrition Facts table, Canada's Food Guide).
- It is important that the criteria set(s) be flexible to accommodate emerging science and changing market conditions. A regular review process is recommended.
- Provide a tax benefit/incentive for companies that produce foods that meet core criteria.
- Allow a transition period for companies to change labels/packaging should new requirements be introduced.
- Establish a means for companies to appeal a decision (accept exceptions with appropriate rationale).
- Participants noted that it would be helpful to have a sample or a proposed set of criteria for more in-depth and meaningful discussion by stakeholders.

D. Winnipeg – February 4, 2008

Thirty-seven stakeholders attended the workshop on Managing Health Claims for Foods held in Winnipeg, Manitoba, at the Delta Winnipeg, on February 4, 2008. Participant views on five theme areas are discussed below.

(i) Substantiation of Claims

Should all disease risk reduction and function claims be based on a high level of certainty?

Some participants supported the notion that a high level of certainty is needed for all health claims on food. It was noted that there is increasing pressure from industry

regarding new food products and health claims, and therefore it is important to maintain government scrutiny and to require that claims be substantiated by rigorous scientific evidence.

However, many participants felt that just as there are varying levels of claims and risks, there should be varying levels of certainty required. A "one-size-fits-all" approach does not apply. It was suggested that a continuum approach would provide a way to balance risk versus benefit. It could be applied such that disease risk reduction claims would require a high level of certainty, while general health claims would require a lower level of certainty, along with clear connection to Canada's Food Guide. It was pointed out that the application of varying levels of certainty would be challenging given that the distinction among different types of claims is not always obvious.

It was suggested that a continuum or other type of system should be structured to accommodate new evidence and the "evolution of science." A reevaluation of a product should not be seen by consumers as a negative process, but rather as an important part of government oversight and surveillance; this message should be conveyed to consumers.

Some participants questioned whether Health Canada is becoming too "parental," and suggested that an overly restrictive regulatory environment would impede the development of innovative products and restrict consumer access to new products. Again, the need for a balanced approach was underscored. It was also noted that overall potential population health and wellness benefits should be weighed against potential risk. Similarly, potential health care cost savings versus potential cost increases should be part of the considerations when assessing level of risk.

It was noted that some countries (e.g., Japan, China) have a large number of products carrying health claims within a system that has many categories of claims, while other countries (e.g., U.S.) have systems that use claims and extensive warnings and qualifying statements. Health Canada could look to international approaches for best practices and models that may be suited to the Canadian context.

Some participants supported the use of evidence from other jurisdictions to support claims. Some participants supported allowing U.S. claims to be used in Canada. However, claims and evidence would need to be scrutinized to ensure they meet Canada's level of substantiation requirements before being considered for acceptance in Canada.

Participants saw a need to review Canada's requirements against those of other countries, especially the U.S. – how high is Canada's "bar"? Some participants felt that the existing interpretation of "high" appears to be more than in any other jurisdiction. This should be reviewed in terms of what is in the best interest of consumers. Similarly, it would be important to identify what would be the lowest acceptable level of evidence.

It was also noted that continued consumer confidence in the regulatory system and in Canada's food system overall is extremely important. There is a risk that consumer

confidence may be eroded if claims are allowed based on less rigorous evidentiary standards. Requiring a high level of substantiation of a claim would help avoid a need to retract a claim, which could have a negative impact on consumer confidence.

Other comments and suggestions included:

- The issue is complex and requires additional stakeholder consultation and discussion.
- An economic risk/benefit approach should inform the adoption of any substantiation scheme, particularly those related to high level of certainty.
- Definitions related to levels of certainty need to be defined and communicated.
- Provisions are needed to allow participation of all companies (i.e., research grants for smaller manufacturers, assistance with clinical trials).

If Health Canada were to consider allowing claims at different levels of certainty, how should this be communicated to the consumer?

Consumer education was seen by participants as a "must." The overall goal of consumer education should be to provide consumers with the knowledge and understanding needed to support informed decision making.

It is important to recognize that consumers are receiving information from a variety of sources. Some of the information is reliable, some is not reliable, and some information may be contradictory to Health Canada's messages. Government has a role to play in cutting through the clutter of information and misinformation and to be seen as a reliable, credible source of nutritional information. Some participants also emphasized that consumers have personal responsibility to become informed and aware of health claims and nutrition.

Communication and education should be designed to reach the target consumers for the products carrying health claims, as well as at risk populations (e.g., people with allergies, pregnant women).

It may be helpful to have a mechanism for conveying to consumers the level of evidence that has been used to substantiate a health claim on food. Suggested examples included a colour-coded scale, numerical system, warning statements, etc. It was suggested that the Workplace Hazardous Materials Information System (WHMIS) could provide a model, as it uses a label system that is highly recognizable and understandable. Such a system would also support transparency and build overall consumer understanding of health claims.

It was also noted that a high level of substantiation for all claims could help simplify labelling and reduce consumer confusion because there would not be as great a need for complex explanations, caveats and qualifiers.

Other comments and suggestions related to consumer education included:

- Focus on products that are new to the marketplace, not only traditional foods.

- Emphasize the need for proper professional medical advice and care: consumers cannot rely on food products alone to maintain their health and/or prevent illness/disease.
- Emphasize the importance of overall healthy eating.
- Recognize that there may be ethnic, cultural and/or regional differences and perspectives that affect the interpretation of health claims on food.

(ii) <u>Food/Natural Health Products Interface</u>

What are the advantages and drawbacks of 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?

Participants noted that there are many advantages to adding bioactive substances to foods, including increased consumer choice, convenience and lower cost to obtain certain nutrients, as well as the potential to improve overall population health and wellness. As a result of consumer interest in the health-food connection, manufacturers are paying more attention to ingredients and the nutritional composition of their products (e.g., trans fats have now been removed from many products).

Participants noted that there are also risks associated with the addition of bioactive substances to foods. There is a risk of over consumption, particularly when a bioactive substance is added to a staple or common food. Some populations are especially vulnerable, such as the elderly or children.

Questions related to costs associated with the addition of bioactive substances and resulting food claims were raised by participants. Participants noted that there are significant costs associated with research and product development. In addition, there may be different costs associated with different levels of certainty related to claims associated with a bioactive substance. Who should be responsible for additional costs – manufacturers, government, consumers?

Some participants felt that regulations/requirements for safety should not be lessened to allow the addition of bioactive substances to foods: otherwise, there are mixed messages going to consumers. Similarly, health claims related to bioactive substances should be substantiated by the same level of scientific evidence that is required for other health claims. Some participants felt that there could be some flexibility on the level of substantiation for lower risk bioactive substances and/or claims.

How might the risks associated with these products be managed effectively?

Participants suggested a number of ways to effectively manage the risks associated with the addition of bioactive substances to foods. The importance of consumer education and

appropriate labelling that gives consumers the ability to make informed decisions was emphasized.

Some participants supported limiting the addition of bioactive substances to certain foods or food groups, and the establishment of prescribed levels of bioactive substances in relation to specific sub-populations and the specific food or food type (i.e., who is consuming the food and in what quantity). Requirements should be based on credible science, established safe levels and nutritional guidelines (e.g., Canada's Food Guide).

It was suggested that the long-term effects of bioactive substances should be monitored and that a system for reporting adverse reactions should be established.

Other suggestions included:

- Identify the source of any bioactive substance.
- Indicate the addition of a bioactive substance on the Nutrition Facts table (for example, use a different color table for a food with a bioactive substance).
- Use warning statements to provide information about consumption limits and risks associated with consumption by sub-populations.
- Use both the Nutrition Facts table and NHP labelling requirements.
- Set advertising guidelines and/or restrictions.

(iii) Managing a Broader Range of Function Claims

Are the measures proposed in the discussion document for Type 2 claims sufficient or should Health Canada consider other regulatory or non-regulatory measures? If so, what are they?

Generally, participants supported the proposed measures. It was noted that success will depend on the resources devoted by Health Canada to the proposals, including investments to maintain and update the proposed list of approved claims, and to provide marketplace surveillance and enforcement.

The proposal to encourage voluntary industry consultation prior to using a health claim on food was seen as positive and to be beneficial to industry, as it would provide credibility to claims and improved product longevity. Non-regulatory approaches help encourage innovation. It is important, however, that Health Canada be able to address industry requests for information/consultation in a timely manner. In this connection, it was suggested that Health Canada draw on the expertise of others, such as academia, researchers, and the Manitoba Agri-Food Network.

Some participants questioned the need to differentiate claims by type. It was noted that claim types do not have relevance for consumers, who, for example, do not necessarily differentiate between "maintains healthy cholesterol" and "reduces cholesterol." Some participants felt that the need for different claim types is being driven by industry, and emphasized that it is important to focus on the needs of consumers first. A preferred

approach is to ensure that all claims are based on minimum nutritional criteria. If different types of claims are used, they should be clear, understandable and consistent for consumers to help alleviate consumer confusion.

The importance of consumer education was again emphasized. Investment in education about health claims would be worthwhile, as it could lead to overall improvements in wellness and reduced health care costs.

Some participants suggested that Health Canada has an opportunity to address key health issues, such as diabetes, obesity and heart health, by facilitating verifiable claims related to those health areas. It is also important to emphasize healthy food choices overall, rather than reliance on foods with health claims.

Other comments included:

- Permit the use of claims that are already supported by solid research, e.g., plant sterols, fibre, Omega 3.
- Consideration needs to be built in for emerging issues/research gaps/evolving science.
- Labels or point of purchase displays should include ways for consumers to get additional information (website, phone number).

(iv) Managing Diverse Front of Package Claims

Would the measures proposed in the discussion document be sufficient to reduce the confusion arising from the increased use of health-related claims on the front of food packages, or are there other measures that Health Canada should be considering?

A variety of perspectives emerged related to front of package health claims.

It was noted that implicit claims are more applicable to the general health claim category, and could have a more flexible approach. A system that is too rigorous (i.e., that requires an explicit claim) could exclude valid implied claims and impede product innovation, especially for small producers/companies. On the other hand, some participants observed that consumers want a credible system with high standards and low risk, and suggested that evidence-based, minimum standards for front of package claims be required.

Some participants observed that front of package claims have the ability to strongly influence consumers, and noted that they are often primarily a marketing tool. Since they have such an influence on consumers, control and/or regulation are needed, as well as consumer education about front of package claims. Some participants felt that all front of package claims should be eliminated.

Some participants supported a single system for front of package claims, one that would be based on specific criteria and standards. A simple system/symbol could help alleviate consumer confusion and reach low literacy consumers.

It was noted that consumers have developed confidence in the accuracy of the information in the Nutrition Facts table, and suggested that a front of package system/symbol supported by government – "Health Canada approved" – could have similar credibility, as consumers would trust that certain standards had been met. Proponents would want to be associated with such a system/symbol.

Other comments and suggestions included:

- Consumers need to be educated to look at the whole label for complete information, not just the front of the package. This is especially true for people with multiple health problems.
- It is important to standardize wording and the use of terms.
- It needs to be clear to the consumer what the logo means.

What measures could Health Canada take to ensure a truthful and non-misleading representation of health benefits?

It was suggested that a regulatory body be responsible for monitoring the marketplace to ensure health claim symbols are used correctly. It is important that imports be subject to the same standards as domestic products.

Some participants suggested that there be strong linkage between the front of package symbol and the Nutrition Facts table. In that way, for example, a consumer would see a front of package logo and be directed to the Nutrition Facts table, which may indicate a high level of a nutrient that should be limited in the diet, e.g., sodium. The consumer would then be able to make a more informed choice. Some participants suggested that the Nutrition Facts table be expanded to provide information about health claims. On the other hand, some participants recommended avoiding an expanded Nutrition Facts table, as adding more information to the table would further confuse consumers.

It was suggested that point of purchase information should be available to inform and direct consumers to sources of further information and clarification (websites, phone numbers). It was suggested that sources of additional information should be endorsed by Health Canada. Health Canada should promote understanding of food labelling and provide information to consumers on how to report problems.

(v) <u>Eligibility Criteria for Foods to Carry Claims</u>

Should there be a requirement that a set of core nutritional criteria be met in order to be eligible to make a claim? What are the advantages? What are the drawbacks? How might the drawbacks be overcome?

Generally, participants supported the idea of set of core nutritional criteria. However, it would be important to ensure that there is flexibility to allow foods such as cheese, which is considered healthy even though high in saturated fat, to be included. In this connection,

participants suggested that the criteria be consistent with the groupings of food in Canada's Food Guide. This was seen to be a practical and holistic approach that emphasizes the importance of overall healthy eating. It would also enable easy comparisons of the nutritional profiles of similar products. If a core nutritional criteria system is used, it should be re-visited every five years, to recognize new evidence/emerging knowledge.

Some participants suggested that core nutritional criteria be limited to the few key "problem" nutrients, such as sodium, fats, processed sugars, etc., that are linked to major public health issues including diabetes, obesity and heart disease. It was suggested that the core criteria could be linked to the information displayed in the Nutrition Facts table.

Some participants wondered whether Health Canada is the appropriate body for education, regulatory and enforcement roles, noting that there is "a lack of flexibility and continuity within a political organization." The question of whether establishing a core set of criteria represents the best use of resources was also raised. Would it be more beneficial to invest in promoting healthy eating?

Some participants suggested that a third-party monitoring system be created. The third party would audit logos for compliance with minimum standards associated with that logo, and be responsible for enforcement and surveillance. Health Canada would only audit the auditors. Industry would pay a fee to participate, on a sliding scale based on amount of product sold, which would allow smaller companies to participate.

It was suggested that Health Canada investigate the appropriateness of adapting or using existing criteria/standards.

A number of advantages of a set of core nutritional criteria were noted, including:

- Focuses/reinforces consistent messaging about healthy eating.
- Reinforces concept that a product bearing a health claim is a healthy choice.
- Allows industry and government to speak the same language.
- Promotes opportunity for buy-in for various stakeholders and encourages improved understanding of various perspectives (industry, government, etc.).
- Provides consistency.
- Prevents some less nutritious foods from using claims, e.g., potato chips.
- May raise Canada's competitiveness on world markets.
- To meet criteria, a product may need to be reformulated – opportunity for innovation.
- Promotes overall confidence in the food regulatory system.

A number of drawbacks were also noted, including:

- Difficult to define a core set with flexibility given current research on foods.
- May limit industry's ability/desire to develop new products, thereby limiting consumer choices.
- There could be cost implications for consumers (may be costly to formulate new foods against these criteria – costs would be passed on to consumers).

- If there are numerous exemptions (e.g., cheese), there will be increased consumer confusion.
- Reformulating foods to meet criteria can affect the way foods taste.

Participants suggested that these drawbacks could be overcome by consulting with all stakeholders, including industry, researchers, government, and consumers. Other suggestions included:

- Consider harmonization with other jurisdictions.
- Promote healthy eating message: it is the combination of all foods and beverages over the day that is important.
- Recognize that many people do not know how to cook or how to plan meals. Target education approaches to age groups, health professionals, adults, etc.
- Establish regulations to ensure clear labelling.
- Invest in more resources for enforcement and consumers/industry education.
- Provide more support for marginal families (more subsidies to enable healthy choices).
- Use various media to reach target audiences.

E. Edmonton – February 6, 2008

Thirty-eight stakeholders attended the workshop on Managing Health Claims for Foods held in Edmonton, Alberta, at the Edmonton Shaw Conference Centre, on February 6, 2008. Participant views on five theme areas are discussed below.

(i) Substantiation of Claims

Should all disease risk reduction and function claims be based on a high level of certainty?

Some participants felt that a high level of certainty should be applied to all health claims. "If a claim is made it ought to be certain." It was noted that by allowing a claim, Health Canada is in essence giving it a "stamp of approval." Consumers trust that Health Canada is credible, and therefore a high level of certainty should be required for all claims.

However, many participants expressed support for requiring varying levels of certainty depending on the type of claim. In this regard, they supported a high level of certainty for disease reduction health claims, but felt that other health claims could require a lower level of certainty. For example, claims related to cancer would require a high level of certainty, whereas a claim related to the immune system would require a lower level of certainty.

There were differing opinions regarding the criteria for determining the level of certainty required. These opinions included: tie the level of certainty required to the level of risk

associated with the health claim (i.e., the higher the risk, the higher the level of certainty); tie the level of certainty required to the seriousness of the disease/illness referred to in the claim; use a cost-benefit analysis to determine the level of certainty required. It was also suggested that the level of certainty required be tied to the level of certainty expressed by the claim, regardless of the type of health claim. For example, a claim that a food "will" have a stated effect, would need to be supported by a high level of certainty; a claim that a food "may" have a stated effect would require a lower level of certainty. Another suggestion was to allow a lower level of certainty for claims related to disease/illness prevention, while requiring a high level of certainty for claims related to disease/illness treatment.

It was noted that requiring a "gold standard" of certainty could lessen consumer access to beneficial products. There was also concern expressed that requiring a high level of certainty for all claims could be cost prohibitive to many food manufacturers. This could limit innovation and affect competitiveness, particularly for smaller companies.
It was suggested that Health Canada accept decision made by other jurisdictions to help level the playing field and to provide faster submission reviews.

Some participants suggested that Health Canada should give priority to claims that address serious public health issues, such as diabetes, heart health, and obesity.

If Health Canada were to consider allowing claims at different levels of certainty, how should this be communicated to the consumer?

Participants emphasized that consumers would have to be made aware that different standards of evidence have been used for different types of claims. In order to do this, it was suggested that wording needs to be precise and easily understood. It may be necessary to "aggressively" pursue consumer education about health claims. Industry also has a role to play in educating consumers about health claims.

Other comments and suggestions regarding consumer education included:
- Serving size must be communicated.
- Warnings and restrictions must be communicated.
- Distinctive labelling (colour, font) must be used for a health claim.

(ii) <u>Food/Natural Health Products Interface</u>

What are the advantages and drawbacks of 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?

Participants suggested that a key advantage to adding bioactive substances to foods is the potential to provide overall health benefits to the general population through the fortification of common foods such as bread and milk. There is also the potential to reach

particular population segments to target specific health needs. The practice could also increase consumer choice, and possibly provide bioactive substances more cost effectively.

On the other hand, some participants felt that foods should not be fortified with bioactive substances, as the practice is counter to the idea of maintaining health through a balanced diet. There is also a risk that the practice will promote increased consumption of processed foods, rather than whole foods. Concern was also raised about the potential negative impact of adding a bioactive substance to a food product that is normally considered unhealthy. Potato chips, for example, could be perceived as "healthy" with the addition of a bioactive substance, yet still have high amounts of sodium and fat.

Other drawbacks and risks associated with the addition of bioactive substances to foods noted by participants included:

- Potential for over consumption/overdose.
- Potential for consumption by non-target populations.
- Higher prices for products with added ingredients; this may limit access for some people.

How might the risks associated with these products be managed effectively?

It was suggested that consumer education would help mitigate risks associated with the addition of bioactive substances to foods. Although some participants felt that consumers do not read food product labels, others suggested that labels would provide a good way to reach consumers with general information about the bioactive substances as well as warnings, dosage information, and recommended daily consumption limits.

It was also suggested that the addition of bioactive substances be restricted to specific food products. The consumption and effects could be monitored prior to extending the provision to other food products.

Some participants felt that if the bioactive substance has drug effects, the product should have label/information requirements equivalent to those for drugs.

It was also noted that the gap between food regulations and NHP regulations needs to be closed. Some participants felt that all foods should be marketed and regulated as foods, and not as NHPs. Others felt that foods should be allowed to be marketed as NHPs, suggesting that this would help ensure the safety and efficacy of the product.

(iii) <u>Managing a Broader Range of Function Claims</u>

Are the measures proposed in the discussion document for Type 2 claims sufficient or should Health Canada consider other regulatory or non-regulatory measures? If so, what are they?

There was general support for improved clarification of requirements for Type 2 function claims.

There was also general support for a pre-market review process. It would also be beneficial to have a checklist/roadmap for industry, along with examples of acceptable wording. Industry participants expressed the need to protect proprietary information during the pre-market review process. There were concerns, however, with Health Canada's capacity to provide a timely review process.

Some participants felt that the pre-market review process should not be voluntary. They felt industry should be required to submit evidence supporting a claim. Concerns were expressed that, with a voluntary process, claims could be in the marketplace prior to their review.

Some participants felt that there would be great value in applying the same risk management approach as is used for NHPs. It was noted that the NHP framework provides good support material for industry, including, step-by-step guidance regarding the standards and the submission process. However, a pre-market review process is one of the areas that is lacking in the NHP system. Participants emphasized that, for petitioners, transparency, consistency and predictability should be principles of any pre-market review process that is established.

Some participants felt that clarification and support are also needed for Type 1 and Type 3 function claims.

(iv) Managing Diverse Front of Package Claims

Would the measures proposed in the discussion document be sufficient to reduce the confusion arising from the increased use of health-related claims on the front of food packages, or are there other measures that Health Canada should be considering?

Participants agreed that the proliferation of front of package claims is leading to consumer confusion.

A range of views related to front of package claims were expressed:

- A balanced approach is needed that considers public health needs, industry's marketing needs and consumers' needs for clear and reliable information.

- Health Canada should establish a common/standard label format for front of package health claims that would be mandatory for all companies wishing to use front of package claims. The format could dictate requirements such as label placement, size, wording, etc. This was seen as a way to greatly reduce consumer confusion.

- Private/sponsored logos (e.g., Blue Label, Heart Check) should be permitted provided their criteria and use conditions are clearly stated (i.e., whether paid/licensed use, nutrition standards, etc.).

- Private/sponsored logos should be permitted, provided they all meet the same nutritional criteria/standards, which would be established by Health Canada.

- Health Canada should establish a system similar to the ONQI (Overall Nutritional Quality Index) system, which rates foods based on nutrient density. Other systems suggested included rating foods with symbols such as red, orange and green lights; or gold, silver, bronze stars.

- A holistic approach is needed to capture restaurant meals as well as grocery sales.

- Front of package claims should be tied to overall healthy eating recommendations, including choosing whole foods over processed foods.

What measures could Health Canada take to ensure a truthful and non-misleading representation of health benefits?

Many participants suggested that consumer education is important to help reduce confusion over front of package claims as well as to improve overall nutrition awareness and understanding.

Some participants noted that information on a website does not constitute "guidance" for industry. Communication channels are needed to facilitate information sharing across stakeholder groups, including provincial and municipal governments, consumers and industry. Guidance needs to be supported with a proactive approach to informing stakeholders, particularly industry, of requirements.

Participants expressed concern that enforcement is highly under-resourced. They suggested that investment is needed to ensure products with misleading claims and/or labelling are removed from the marketplace. Information about products and companies who abuse health claims should be publicized.

(v) <u>Eligibility Criteria for Foods to Carry Claims</u>

Should there be a requirement that a set of core nutritional criteria be met in order to be eligible to make a claim? What are the advantages? What are the drawbacks? How might the drawbacks be overcome?

Many participants supported the establishment of a set of core nutritional criteria that must be met in order for a food product to carry a health claim. Many participants felt that health claims should not be permitted on foods that are "nutritionally questionable."

For example, potato chips should not be permitted to carry a health claim. Health claims should be applicable to the overall product, not just the presence (or lack) of one ingredient. At the same time, there were some participants who felt health claims are subjective and should therefore be allowed on any food product regardless of the nutritional makeup.

Some participants noted that a set of core nutritional criteria would encourage people to eat a more nutritious diet. It was felt that given the proliferation in the marketplace of health claims, a standard would help create a more level playing field for industry. In addition, the need to meet a set of core nutritional criteria in order to use a health claim could move companies to develop new healthy products or modify existing products to be healthier. In this connection, it was noted that Health Canada has an opportunity to show leadership in encouraging and supporting innovation that could lead to overall population health improvement. On the other hand, some participants felt that the need to meet a standard could have detrimental impacts on innovation, competitiveness and trade.

It was noted that a standard would also contribute to reducing consumer confusion about health claims. In this connection, it was suggested that a simple system would be best, one that would provide clear messaging and easy recognition. The use of coloured symbols was provided as an example.

Some participants suggested that the number of criteria should be limited to keep the system simple, for example limited to salt, sugar and fat content. Some participants felt that the criteria should be tied to Canada's Food Guide. However, it was felt that a set of core nutritional criteria would need to provide for some exemptions, for example, to accommodate foods such as cheese, which could potentially "fail" because of its high saturated fat content. Different criteria may be needed for whole foods versus processed foods, and to accommodate the nutritional needs of specific population groups.

Other participants suggested a more comprehensive nutrient profiling system, like the ONQI system.

Opinions diverged regarding the use of these criteria. Some participants felt that the core set of criteria should be a tool only for Health Canada in determining whether a food qualifies to carry a health claim, and not information to be conveyed on product labels or in consumer education materials.

F. Vancouver – February 8, 2008

Seventy-three stakeholders attended the workshop on Managing Health Claims for Foods held in Vancouver, British Columbia, at the Firefighter's Club, Burnaby, on February 8, 2008. Participant views on five theme areas are discussed below.

(i) Substantiation of Claims

Should all disease risk reduction and function claims be based on a high level of certainty?

Some participants felt that a high level of certainty should be required for all health claims. They argued that since many consumers do not read or understand product labels, nor do they differentiate between claim types, they must be able to trust that all products have received the same level of oversight and scrutiny. They also maintained that requiring a high level of certainty would reduce the potential for withdrawal of products/claims as the result of subsequent studies and protect consumers from misleading or false claims, which would have a positive effect on consumer confidence.

On the other hand, some participants felt that only disease risk reduction claims should be subject to a high level of certainty. It was suggested that function claims and general health claims could be subject to a sliding scale, with the level of certainty dependent on the risk associated with the claim. Some participants felt that the level of certainty should be tied to the language of the claim: a claim that a food product "may" have a particular effect/benefit would require a lower level of certainty, while a claim that a food product "will" have a particular effect/benefit would require a high level of certainty.

The point was expressed that by requiring different levels of certainty depending on the type of claim, both large and small companies would be able to use health claims on their food products. Companies wishing to use a disease risk reduction claim would have to invest in research to support that claim; companies wishing to use a function claim would not need as much of a research investment. It was felt that this flexibility would encourage innovation and enable the introduction of beneficial products to the marketplace more easily.

It was suggested that results of animal studies (rather than clinical trials on humans) be considered acceptable evidence for lower-risk claims. It was even suggested that "safe history of use" of an ingredient or product be sufficient to support a health claim.

It was suggested that reviews of other jurisdictions and recognized authorities be acceptable to support a health claim.

If Health Canada were to consider allowing claims at different levels of certainty, how should this be communicated to the consumer?

Participants generally said that consumer education would be important to raise awareness and understanding of the varying levels of certainty of health claims, but that consumers also need to take responsibility for their decisions, and become knowledgeable about health claims and healthy eating.

Some participants suggested that product labelling should be used to explain health claims and the level of certainty used to substantiate a claim. For example, products could carry a statement about the type of scientific evidence that was used (e.g., human clinical trials, animal studies).

Some participants suggested that mandatory wording requirements for disease reduction claims should be maintained, while other health claims could be stated in less prescriptive ways.

(ii) Food/Natural Health Products Interface

What are the advantages and drawbacks of 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?

Participants identified a number of advantages of adding bioactive substances to foods, including:

- Increased consumer choice, both economically and nutritionally.
- Opportunity to improve overall population health.
- Opportunity to reach certain populations with bioactive substances they might otherwise not get.
- Increased profitability for food industry.
- Opportunity to improve the nutritional quality of low nutrient foods.

The potential drawbacks and risks noted included:

- Risk of over-consumption of food products with bioactive substances.
- Risk of consumption of food products with bioactive substances by non-target sub-populations.
- Risk of cumulative effects through consumption of many foods with the same bioactive ingredient.

Some participants felt that the current NHPs standards for bioactive substances in foods are too high; this limits innovation and choices for consumers. Participants voiced that government should continue to encourage innovation by not creating new and/or additional barriers for industry.

Some participants felt that Health Canada should encourage industry and consumer use of bioactive substances that have proven population health benefits. In this connection, it was suggested that food products with recognized beneficial bioactive substances should be included in Canada's Food Guide and promoted as part of a healthy diet.

Some participants said that, because of Canada's proximity to the United States, Canadian consumers receive American marketing information about foods with bioactive substances. It is therefore important to not create an entirely different approach to

bioactive substances, as this would further add to consumer confusion about these products and their related health claims.

How might the risks associated with these products be managed effectively?

Some participants acknowledged the difficulty and complexity associated with addressing the risks related to the addition of bioactives substances to foods. It was suggested that any food containing a bioactive substance with proven negative effects should be treated as a drug; a food with a low-risk bioactive substance should be treated as a food. It is important that there be ongoing monitoring of potential adverse effects related to foods with bioactive substances.

Some participants emphasized that consumers should take a "buyer beware" attitude toward bioactive substances. As such, they should become knowledgeable about these substances in order to make decisions that are right for themselves and their families. In this connection, the importance of consumer education was again highlighted by some participants. Tools should be provided to enable consumers to make informed decisions; suggestions included websites, point of purchase information, and clear labelling. However, some participants cautioned against placing too much reliance on product labelling to "educate" consumers about bioactive substances, as labels may not be read or understood by all consumers.

A number of other risk management strategies were suggested by participants, including:

- Establish upper and lower limits for the addition of bioactive substances to foods. However, it was noted that there is a lack of knowledge for setting consumption limits related to some bioactive substances.
- Limit the addition of bioactive substances to specific foods. For example, do not allow the addition of a bioactive substance that may be harmful to children to a food that is commonly consumed by children (e.g., peanut butter).
- Establish a standardized "warning" on all labels with bioactive substances that includes information about consumption amounts, serving size and who should/should not consume the product.
- Limit marketing and advertising of products with bioactive substances.
- Create a specialty category within Canada's Food Guide for products with bioactive substances.

(iii) <u>Managing a Broader Range of Function Claims</u>

Are the measures proposed in the discussion document for Type 2 claims sufficient or should Health Canada consider other regulatory or non-regulatory measures? If so, what are they?

There was general support for the proposed measures to clarify the nature of acceptable claims and to maintain an up-to-date list of function claims.

There were differing views regarding the proposal to encourage voluntary industry consultation with the Food Directorate prior to use of a function claim.

Some participants supported a voluntary consultation process; however, they expressed concern with Health Canada's capacity to provide this service to industry in a timely and effective manner. They suggested that timelines and service standards should be established to avoid a backlog situation. The process must respect industry confidentiality/intellectual property. It was also noted that the process should include a dispute resolution component, for example an option of an independent scientific review.

Some participants specifically advised that Health Canada should not follow the NHP licensing model, which they perceive to be onerous in terms of standards and not efficient in terms of turnaround.

On the other hand, some participants felt that a mandatory pre-market review system is required. This would ensure all claims are captured and promote an even playing field. In addition, consumers may not have confidence that a voluntary system can deliver an adequate level of oversight. Some participants also felt that enforcement would be very difficult in a voluntary process.

It was suggested that Health Canada develop tools to assist industry in determining the acceptability of health claims. For example, Health Canada could establish an online service for industry to "test" proposed wording for claims. Another suggestion was for the development of guidance documents with examples of acceptable and unacceptable wording, particularly "red flag" terms such as prevent, treat, improve, etc.

Some participants felt that Health Canada could take a more proactive role and develop standardized wording for function health claims. Some participants did not support a prescriptive approach.

It was noted that there is a need for improved communication among industry, Health Canada and the CFIA. In addition, Health Canada and the CFIA should ensure that they have a common approach to health claims issues.

(iv) <u>Managing Diverse Front of Package Claims</u>

Would the measures proposed in the discussion document be sufficient to reduce the confusion arising from the increased use of health-related claims on the front of food packages, or are there other measures that Health Canada should be considering?

Participants agreed that there is an ever-increasing proliferation of front of package logos and symbols that is leading to consumer confusion. A number of views were expressed about how to address front of package health claims issues.

Some participants felt that implicit health claims through front of package logos/symbols should not be permitted unless supported by explicit claims.

Some participants felt that the use of symbols developed by manufacturers, retailers, health organizations, etc., should continue to be permitted. These systems should be supported with consumer education and additional explanatory wording. It was also noted that any fee for use of a logo should be clearly noted.

On the other hand, there was also support expressed for a single, national, standardized front of package system. Some supporters proposed that a single symbol be developed and companies would pay to use the symbol, with the fee prorated to enable all companies to participate. Other supporters suggested that a set of guidelines/criteria be developed for the use of any front of package symbol, with the onus on companies to comply with the established criteria, without pre-market approval. This type of system was considered to be more cost effective; however participants emphasized that it would need to be supported with adequate market surveillance and enforcement.

Some participants suggested that a labelling system similar to what is now being used to identify organic foods would provide an effective way to manage front of package claims. Such a system could be Health Canada led, which would add a significant element of credibility. However, it would be important to limit its use, to ensure there is no "endorsement" of unhealthy food products.

A "made in Canada" system, rather than the adoption of an existing system from the U.S. or the EU, was preferred by some participants. It was suggested that a Canadian system should build on existing components, such as Canada's Food Guide, and incorporate traditional knowledge as well.

Some participants suggested a national rating system of symbols (e.g., stars) that would identify the "healthiness" of all foods, not only foods with health claims. Some participants cautioned against over-reliance on symbols to convey information, as it could have the effect of "excluding" non-packaged and whole foods (e.g., fresh fruits and vegetables, meats, etc.).

There was support for undertaking research to better understand consumer perceptions of front of package logos and symbols.

What measures could Health Canada take to ensure a truthful and non-misleading representation of health benefits?

Some participants felt that Health Canada should advise industry that they should be prepared for challenges to any health claims they are making. Some felt that, Health Canada should take a stronger oversight role to ensure that existing front of package symbols are truthful and based on sound nutritional rationale. It is also important that disclosure be made regarding the basis of a logo's/symbol's use (e.g., licensed use, etc.).

It was noted that adequate resources are needed to ensure marketplace monitoring and enforcement of rules/requirements so that action is taken when misleading claims are reported/discovered.

(v) Eligibility Criteria for Foods to Carry Claims

Should there be a requirement that a set of core nutritional criteria be met in order to be eligible to make a claim? What are the advantages? What are the drawbacks? How might the drawbacks be overcome?

There was general agreement that a set of core nutritional criteria should be designed to prevent "unhealthy" foods from using a health claim. The example used to illustrate this point was potato chips with vitamin C added. Some participants felt that health claims on nutrient-poor products would undermine the credibility of health claims on "healthy" products.

There were, however, some participants who felt that a requirement to meet a core set of nutritional criteria is not needed, and that even low-nutrient foods should be permitted to carry health claims.

Participants felt that a key advantage of a requirement to meet a core set of nutritional criteria is that it would help maintain confidence in the regulatory system for health claims. It would also establish an even playing field for industry, and may provide impetus for companies to reformulate existing products or develop new ones.

Although there was support for a process to require products to meet a set of core nutritional criteria to be eligible to carry a health claim, there were a variety of views expressed around its design and implementation.

Some participants supported a holistic approach that integrates other elements of Health Canada's healthy eating strategy, such as Canada's Food Guide and the Nutrition Facts table. Such a system would use multiple sets of criteria based on food categories, rather than a universal set for all foods. This approach would accommodate ethnic or traditional foods, spices and herbs, water, and other similar items, as well as foods such as cheese. It was suggested that "reasonable and achievable" nutrient levels be used when establishing parameters, so that the system is neither too restrictive nor too open.
Participants felt that a key drawback is the difficulty in creating a system that would meet the diverse nutritional needs of Canadians, especially the needs of sub-populations.

In terms of implementation of a process for meeting a set of core nutritional criteria, it was suggested that the system should be flexible enough to accommodate exceptions, to provide for case-by-case assessments, and to respond to new science. Other suggestions included that the process be based on guidelines rather than regulations; that decisions be science based; and that disputes be reviewed by an independent third party. Some

participants suggested that a fee be charged to companies to offset the costs of implementation; however, it should not be a barrier to participation.

Some participants felt that foods should have to meet minimum standards for many "healthy" nutrients, not only one or two within a set of criteria, to be eligible to make a health claim. An alternative suggestion was to base the set of criteria around thresholds/maximum amounts of "unhealthy" nutrients. So instead of food products having to meet established levels of "good" nutrients, products would be required to not have more than set amounts of identified "bad" nutrients (e.g., sodium, fat, etc.). Another suggestion was for a rating system, in which points would be given for "good" nutrients and deducted for "bad" nutrients.

Some participants felt that a core set of criteria should vary depending on the health claim. For example, a food with a claim related to heart health would have to meet a core set of nutritional criteria with an emphasis on cholesterol lowering, while a different set of core nutritional criteria would apply to claims related to obesity. Similarly, claims that are tied to specific ingredients would be required to meet a minimum amount of that ingredient.

PART 3: NEXT STEPS

Health Canada noted that the issues associated with health claims on food are complex. Participants provided a wide range of perspectives, raised interesting questions, and contributed insightful advice and suggestions.

These consultation workshops are part of Health Canada's initial steps toward developing a modernized framework for the regulation of health claims on food in Canada. They have been designed to raise awareness within the stakeholder community and within Health Canada of the spectrum of challenges and opportunities related to health claims on food. The discussions at these six regional workshops will help inform Health Canada's future direction on the various issues and identify priority areas for focus.

An overall report incorporating feedback from the regional workshops as well as from the written input on the discussion paper has also been prepared. Analysis of feedback will be undertaken by Health Canada for the development of recommendations.

PART 4: APPENDICIES

Appendix 1 – List of Regional Workshop Participants

British Columbia
7 Seas Fish Co.
Agriculture and Agri-Food Canada
Aim Canada
Alberta Barley Commission
Albion Fisheries Ltd.
Alive Magazine
Avalon Dairy Ltd.
B.C. Ministry of Agriculture and Lands
B.C. Ministry of Health
B.C. Dairy Foundation
B.C. Ministry of Environment; Oceans and Marine Fisheries Division
Brand Management Association, Sun Opta Grocery West
Calkins & Burke Ltd.
Can Test Ltd.
Canadian Council on Multicultural Health
Canadian Fishing Company
Canandian Food Inspection Agency
Consumer Interest Alliance Inc.
Danisco Inc.
Dietitians of Canada
Enviro-Health Research Labs Inc.
Faculty of Medicine, Department of Paediatrics, B.C. Children's and Women's Hospital
Flora Manufacturing and Distributing Ltd.
Food Directorate; Health Canada

Fraser Health Authority
GFR Pharma
Hain Celestial Canada
Happy Plant Foods
Hayes & Associates
Health Action Network Society
Health Canada - Health Products and Food Branch
Health Canada - Healthy Environment and Consumer Safety
Health Canada - Western Regional Laboratory
Health Check BC Dining Program of Heart and Stroke Foundation
Honeybee Centre
IRI Separation Technologies Inc.
Leading Brands
Lions Gate Fisheries
M-13 Ventures Ltd.
Natural Factors Nutritional Products Ltd.
Natural Health & Food Product Research Group, Technology Centre, British Columbia Institute of Technology
Natural Health Products Research Group, British Columbia Institute of Technology
Natural Health Products Protection Association
Olympic Dairy Products Inc.
Oppenheimer Group
RLS Consulting Ltd.
Saputo Foods Ltd.
Shafer-Haggart Ltd.
Simon Fraser University
Source Nutraceuticals Inc.
Soyaworld Inc.
Strauss Enterprises Ltd.

Vancouver Chinatown Merchants Association
Vancouver Coastal Health
Viva Pharmaceutical Inc.
Wellgenex Sciences Inc.
Western Canadian Functional Food & Natural Health Product Network (WCFN)
Edmonton, Alberta
Agriculture and Agri-Food Canada - Research Branch - Western Region - Lacombe Research
Agriculture and Agri-Food Council of Alberta
Alberta Advanced Education and Technology - Research Division
Alberta Agriculture and Food - Planning and Competitiveness Sector
Alberta Agriculture and Food - Regulatory Services Division
Alberta Agriculture, Food and Rural Development - Business and Innovation Division
Alberta Agriculture, Food and Rural Development - Food Safety Division
Alberta Agriculture, Food and Rural Development - Leduc Food Processing Centre
Alberta Barley Commission
Alberta Cancer Board
Alberta Canola Producers Commission
Alberta Health and Wellness - Public Health Division - Environment Public Health Program
Alberta Milk
Athabasca University
BIOTECanada
Calgary Health Region
Canada Alberta Partners in Food Safety
Canadian Cancer Society - Alberta/Northwest Territories Division
Canadian Celiac Association - Edmonton Chapter
Canadian Food Inspection Agency - Vice President, Operations - Western Area
Canadian Health Food Association
Canadian Pork Council

CV Technologies Inc.
Lilydale Foods
NHP Consulting Inc.
Ormsbee and Associates
PBR Laboratories Inc.
Unviersity of Alberta - Faculty of Agriculture, Forestry and Home Economics - Department of Agricultural Food and Nutritional Science
Wild Rose Agriculture Producers
Winnipeg, Manitoba
Agriculture and Agri-Food Canada - Cereal Research Centre
Agriculture and Agri-Food Canada - Saskatoon, SK
Ag-West Bio Inc.
Bee Maid Honey Ltd.
Canadian Food Inspection Agency - Dairy Program
Canadian Food Inspection Agency - Regina, SK
Canadian Food Inspection Agency - Regional Food Labelling
Canadian Liver Foundation - Manitoba Chapter
Canola Council of Canada
Consumer Interest Alliance Inc.
CropLife Canada
Dairy Farmers of Manitoba
Doctor/ médecin
Flax Council of Canada
Food Development Centre
Heart and Stroke Foundation of Manitoba
Manitoba Agriculture, Food and Rural Initiatives
Manitoba Agri-Health Research Network
Manitoba Association of Home Economists
Manitoba Health

Manitoba Health and Healthy Living
Minnewashta Valley Organics Canada Ltd.
Nutritech Consulting
Province of Manitoba - Department of Science Technology, Energy and Mines
Pulse Canada
Saskatchewan Flax Development Commission
Source Nutraceutical, Inc.
Student
University of Manitoba - Richardson Centre for Functional Foods and Nutraceuticals
University of Manitoba - Department of Human Nutritional Sciences
Toronto, Ontario
Agriculture and Agri-Food Canada
Advertising Standards Canada
Allergy Asthma Info Association
Alliance Interested Consumers
Alton Mackey and Associates
Associated Brands
BASF
Beef Information Centre
Bereskin & Parr
Board of Directors of Drugless Therapy - Naturopathy
Broadcast Clearance Advisory
Canadian Celiac Association
Canadian Council of Food and Nutrition
Canadian Dental Association
Canadian Diabetes Association
Canadian Health Food Association
Canadian Institute of Food Science & Technology

Canadian Poultry and Egg Processors Council
Canadian Sugar Institute
Cantox Health Sciences International
Centre for Science in the Public Interest
CERES Consulting
Canadian Food Inspection Agency
Coffee Association of Canada
Cognis Canada Corporation
Canadian Produce Marketing Association
Dairy Farmers of Canada
Dairy Processors Association of Canada
Dicentra Inc.
Fleishman-Hillard Canada
Food & Consumer Products of Canada
Gay Lea Foods
General Mills
Globaltox International Consultants Inc.
Guelph Food Technology Centre
Heart and Stroke Foundationr
Kellogg
Kraft Canada Inc.
L/H. Gray & Son
Loblaws
Maple Leaf Foods
Mars
MaRS Landing
McCain
McCarthy Consultant

Mead Johnson Nutritionals
Naturally Nova Scotia Health Products
NDMAC
Nestle
Nutridata Consulting Services
Nutrition Resource Centre
Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA)
Ontario Home Economics Association
Packaging Association of Canada
Peel Region - Chronic Disease and Injury Prevention Division
Peel Region - Health Systems
Pepsi QTG Canada
Produce Smart
Puresource Inc.
Purify Life Health Products
Quadra
Quality Medical Regulations Services
Refreshments Canada
Rivi's Guilt Free Cookie
Sobeys Inc.
Source! Nutrition
Tempo Canada Inc.
Toronto Public Health
Unilever
University of Ottawa
University of Toronto, Department of Nutritional Sciences
University of Toronto, Faculty of Pharmacy
Vegetable Oil Industry of Canada

Weiler Nutrition Communications Inc.
St. Hyacinthe, Quebec
A. Lassonde Inc.
ACTI-MENU
Agence canadienne d'inspection des aliments - Vice-président, opérations - Centre opérationnel du Québec
Agriculture et Agroalimentaire Canada - Direction générale de la recherche - Région de l'Est - Centre de recherches et de développement sur le bovin laitier et le porc
Agropur Canada
Aliments Ultima Inc. (Yoplait)
Alliance pour l'innovation en agroalimentaire
Association pour les ingrédients santé en alimentation
Association québécoise des allergies alimentaires
Bioforce Canada Inc.
Bio-K + International Inc.
Centre québécois de valorisation des biotechnologies
Cintech agroalimentaire (Cintech-aa)
Conseil canadien des aliments et de la nutrition
Conseil de la transformation agroalimentaire et des produits de consommation
Extenso
Les Producteurs laitiers du Canada
Option consommateurs
Ordre professionel des diététistes du Quebec
Santé Naturelle (A.G.) Ltee.
Saputo - Division Boulangerie - Montréal
Saputo - Produits Laitiers - Montréal
Union des consommateurs
Université de Montréal - Faculte de médecine - Département de nutririon
Halifax, Nova Scotia

Agriculture and Agri-Food Canada - Market and Industry Services Branch - Operations - Atlantic Regional Office
Atlantic BioVenture Centre - NSAC
Bristol - Myers Squibb; Mead Johnson Nutritionals
Canadian Council of Grocery Distributors - Atlantic Office
Canadian Egg Marketing Agency
Canadian Food Inspection Agency
Capital Health - Public Health Services
Dairy Farmers of Canada
Food and Consumer Products of Canada
Food Trust of Prince Edward Island
Heart and Stroke Foundation of Nova Scotia
McCain Foods Limited
Memorial University of Newfoundland - Faculty of Science - Department of Biochemistry
National Research Council Canada - Industrial Research Assistance Program - Atlantic-Nunavut Region
National Research Council Canada - Institute for Marine Biosciences – Halifax
Naturally Nova Scotia Health Products Ltd.
Newfoundland and Labrador Women's Institute
Newfoundland Aquaculture Industry Association
Nova Scotia Advisory Commission on AIDS
Nova Scotia Department of Agriculture and Fisheries - Product and Quality Development Services
Nova Scotia Department of Health - Office of Health Promotion - Capital Health
Ocean Nutrition Canada

Note: Additional 8 individuals and 1 organization did not want to be named but attended these consultations

Appendix 2 – Summary of the Voluntary Statements of Information

Public involvement activity: Consultation on Health Claims on Food

Date and location: Regional workshops, January 28 - February 8, 2008

The information in the Voluntary Statement of Information Summary was provided by the participants of this public involvement activity. They completed the Voluntary Statement of Information Form and consented to make the information public. The interests or affiliations reported are limited to those of relevance to the objectives of the public involvement activity.

Out of 286 participants, 26 agreed to complete the form and consented to the inclusion of their information in a published summary.

Terms

Direct financial interests. Current employment, investments in companies, partnerships, equity, royalties, joint ventures, trusts, real property, stocks, shares or bonds, with an organization likely to be affected by the outcome of this public involvement activity.

Indirect financial interests. Any of the following, received in the past year, from an organization or company likely to be affected by the outcome of this public involvement activity other than your present employer: payment for work done or being done; research support; personal education grants; contributions; fellowships; sponsorships or honoraria; and travel, meals or accommodation to attend this public involvement activity.

Intellectual interests. Any of the following: formal advice or opinion to industry, a government organization or a non-government organization on issues of relevance to the topic under consideration, in the past year; public statements on issues of relevance to the topic under consideration; and professional or volunteer affiliations with an organization with an interest in, or likely to be affected by the outcome of this public involvement activity.

Participation in other Health Canada activities. Grants or contributions received by you or your organization from Health Canada, and participation in Health Canada public involvement activities such as workshops, focus groups, roundtables, electronic consultations, public forums, or bilateral meetings.

DMC: Did Not Comment

ALBERTA: Edmonton, February 6, 2008

O'Laney, John
Registered lobbyist: No
Organization name or Individual: Canada Alberta Partners in Food Safety (CAPiFS)
Scope, type or sector: National, Provincial/Territorial, Government
Mandate: The Canada Alberta Partners in Food Safety is a federal/provincial partnership intended to promote a harmonized approach (cooperation, coordination, collaboration) to food safety in Alberta. Partners include Health Canada, the CFIA, Alberta Agriculture and Food, Alberta Health and Wellness and the Regional Health Authorities. A fundamental principle of the partnership is to support a collaborative approach to improve the efficiency and effectiveness of food safety initiatives throughout the food continuum. This organization has been the trigger mechanism for an integrated province wide effort to plan, organize and facilitate the development of an Alberta Food Safety Strategy.
Funding guidelines: No
Direct financial interests: No
Indirect financial interests: Yes – Travel, meals or accommodation to attend this public involvement activity, CAPiFS expenses paid by the CFIA.
Intellectual interests: No
Participation in other HC activities: No

Ormsbee, Susan
Registered lobbyist: No
Organization name or Individual: Individual
Scope, type or sector: Industry
Mandate: N/A
Funding guidelines: N/A
Direct financial interests: No
Indirect financial interests: Yes – Payment for work done or being done, including past employment, contracts and consulting, $25,000 and up.
Intellectual interests: No
Participation in other HC activities: No

BRITISH COLUMBIA: Vancouver, February 8, 2008

Arling, Lynne

Registered lobbyist: No

Organization name or Individual: Consumer Interest Alliance Inc. (CIAI)

Scope, type or sector: National, Academic/research community, Association, Community or consumer, Voluntary

Mandate: CIAI is an incorporated, not-for-profit organization, providing national, grassroots consumer representation and research. Interests include Food and Agriculture, Health and Environmental issues related to Food and Agriculture, National and International Standards, and Financial Services. CIAI has carried out comprehensive research on food issues for Dairy Farmers of Canada on cheese and standards for cheese, as well as that for the Office of Consumer Affairs on the readability of food labels, which are seen as providing basic product information; and a vehicle for food marketing, promotion and advertising.

Funding guidelines: Yes

Direct financial interests: No

Indirect financial interests: Yes – Research support from Office of Consumer Affairs, Industry Canada, received by CIAI, $25,000 and up. Yes – Travel, meals and accommodation to attend this public involvement activity, Health Canada.

Intellectual interests: Yes, March 2007 – Readability of Food Product Labels, Office of Consumer Affairs, Paid.

Participation in other HC activities: No

Corby, Lynda

Registered lobbyist: No

Organization name or Individual: Dietitians of Canada (DC)

Scope, type or sector: National, Association

Mandate: Dietitians of Canada is the national voice for over 5800 dietitians. DC brings the knowledge and skills of its members together to inform decisions that affect food, nutrition and health, with impact at the local, regional/provincial, national and international levels. DC is the national accrediting body for all baccalaureate and practicum training programs that credential dietitians to practice in Canada.

Funding guidelines: Yes

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Yes, October 2007 – Discretionary Fortification of Foods with Vitamins and Minerals, Communication from Dietitians of Canada to the Honorable Tony Clement (Minister of Health). Yes, November 2007 – Childhood Obesity – Brief Presented to the House of Commons Standing Committee on Health. Yes, May 2006 – Response to the Consultation on Canada's Food Guide Revisions.

Participation in other HC activities: Yes, April 2007-March 2008 – Healthy Eating Affiliate for the Canadian Health Network, Public Health Agency of Canada. Yes, January 2008 – Consultation on the launch of the Consumer and Food Safety Action Plan, Health Products and Food Branch. Yes, August 2007 – Consultation on Standards of Identity and Composition of Cheese, Canadian Food Inspection Agency.

Fleming, Colin

Registered lobbyist: No

Organization name or Individual: Organization has no name yet

Scope, type or sector: Industry, International

Mandate: To explore opportunities to market Stevia, and Stevia-related products in Canada.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: No

Joneja, Janice M.

Registered lobbyist: No

Organization name or Individual: Individual

Scope, type or sector: Academic/researcher, Health professional

Mandate: N/A

Funding guidelines: N/A

Direct financial interests: DNC

Indirect financial interests: DNC

Intellectual interests: DNC

Participation in other HC activities: DNC

Lam, Henry

Registered lobbyist: No

Organization name or Individual: Seven Seas Fish Company Ltd.

Scope, type or sector: International, Industry

Mandate: DNC

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: No

Li, Michael

Registered lobbyist: No

Organization name or Individual: Wellgenex Sciences Inc.

Scope, type or sector: International, Academic/research community, Community or consumer, Industry

Mandate: DNC

Funding guidelines: No

Direct financial interests: Yes, Employment – Wellgenex Sciences Inc., $25,000 and up. Yes, Investments in companies – Wellgenex Sciences Inc., $25,000 and up. Yes, Partnerships – Wellgenex Sciences Inc., $25,000 and up.

Indirect financial interests: No

Intellectual interests: Yes, Membership of professional societies – American Botanical Council. Yes, Membership of trade or industry associations – Western Canadian Functional Food & Natural Health Product Network (WCFN). Yes, Membership of public interest, community or advocacy groups – American Botanical Council, Member.

Participation in other HC activities: Yes

Tabesh, Roya

Registered lobbyist: No

Organization name or Individual: Individual

Scope, type or sector: Other – Student (intern)

Mandate: N/A

Funding guidelines: NA

Direct financial interests: DNC

Indirect financial interests: DNC

Intellectual interests: DNC

Participation in other HC activities: DNC

NOVA SCOTIA: Halifax, February 1, 2008

Baxter, Larry

Registered lobbyist: No

Organization name or Individual: Nova Scotia Advisory Commission on AIDS

Scope, type or sector: Provincial/Territorial, Government, Advisory to Government

Mandate: Provide advice to the Nova Scotia government on issues related to HIV/AIDS; and act as a link between government and the community, as well as coordinator, for the implementation of Nova Scotia's Strategy on HIV/AIDS.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: Yes, January 2008 – Regional consultation on Hepatitis C-Halifax, Public Health Agency of Canada. Yes, Early 2007 – Regional consultation on Canada's Food Guide – Halifax, Health Products and Food Branch. Yes, Early 2007 – National consultation on Knowledge Exchange for HIV/AIDS – Ottawa, Public Health Agency of Canada.

Dwyer, Marg

Registered lobbyist: No

Organization name or Individual: Nova Scotia Advisory Commission on AIDS

Scope, type or sector: Provincial/Territorial, Government, Advisory to Government

Mandate: Provide advice to the Nova Scotia government on issues related to HIV/AIDS; and act as a link between government and the community, as well as coordinator, for the implementation of Nova Scotia's Strategy on HIV/AIDS.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: No

ONTARIO: Toronto, January 28, 2008

DiFrancesco, Loretta
Registered lobbyist: No Organization name or Individual: Individual Scope, type or sector: Health professional, Industry, Other (consultant) Mandate: N/A
Funding guidelines: N/A Direct financial interests: DNC Indirect financial interests: DNC Intellectual interests: DNC
Participation in other HC activities: Yes, September 2007 – DRI Workshop: "Development of ORIs 1994-2004. Lessons Learned and New Challenges" (Health Products and Food Branch).

Lemaire, Ron
Registered lobbyist: Yes Organization name or Individual: Canadian Produce Marketing Association (CPMA) Scope, type or sector: National, Association Mandate: Not-for-profit trade association serving the produce industry since 1925. Vertically integrated representing grower to retailer and food service, with over 675 Canadian and international members.
Funding guidelines: No Direct financial interests: No Indirect financial interests: No Intellectual interests: Yes, September 2007 –- Health Canada. Yes, November 2007 – National Laboratory, Health Canada, Paid.

Participation in other HC activities: Yes, November 2007 – Health Canada/Canadian Food Inspection Agency industry update on Health claims (Health Policy Branch, Health Products and Food Branch, Canadian Food Inspection Agency). Yes, June & August 2007 – Microbiological Safety of Fresh Produce (Health Products and Food Branch).

McCarthy, Jim

Registered lobbyist: No

Organization name or Individual: Canadian Celiac Association (CCA)

Scope, type or sector: National, Academic/Research community, Association, Community or consumer, Voluntary

Mandate: CCA is a national organization dedicated to providing services and support to persons with celiac disease and dermatitis herpetiformis through programs of awareness, advocacy, education and research

Funding guidelines: Yes

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Yes, April & November 2007 – Food Labelling, Health Canada, Volunteer. Yes, May 2007 – Would you like better food labeling? Celiac News (published by CCA).

Participation in other HC activities: No

McCurdy, James

Registered lobbyist: No

Organization name or Individual: Purity Life Health Products

Scope, type or sector: International, Industry

Mandate: Empowering people to create well being in their lives.

Funding guidelines: Yes

Direct financial interests: Yes, Employment – Purity Life and Health Products ($25,000 and up)

Indirect financial interests: No

Intellectual interests: Yes – member of Canadian Health Food Association (CHFA)

Participation in other HC activities: Yes, September 2007 to present– Natural Health Products Directorate Online Electronic Submission Pilot Project, Health Products and Food Branch.

Mokhalalati, Jalal
Registered lobbyist: No Organization name or Individual: Individual Scope, type or sector: Other: consultant to nutraceutical sector, nutritionist, researcher Mandate: NA
Funding guidelines: NA Direct financial interests: No Indirect financial interests: No Intellectual interests: No
Participation in other HC activities: Yes, January 2007 – Industry workshops and information sessions on Product and Site Licensing, Health Products and Food Branch, Health Policy Branch.

Newton, Ian
Registered lobbyist: No Organization name or Individual: Individual Scope, type or sector: Industry Mandate: N/A
Funding guidelines: N/A Direct financial interests: No Indirect financial interests: Yes, Payment for work done or being done, including past employment, contracts and consulting – $0 to $5000. Intellectual interests: Yes, June 2007 – Health claims, Trade, Enterprise, Paid. Member of American Oil Chemists' Society (AOCS), Institute of Food Technologists (IFT), Global Organization for EPA & DHA (GOED).
Participation in other HC activities: No

Noel, Sharon
Registered lobbyist: No Organization name or Individual: Canadian Food Inspection Agency Scope, type or sector: National, Government

Mandate: Protect Canadians from preventable health risks. Protect consumers through a fair and effective food, animal and plant regulatory regime that supports competitive, domestic and international markets. Contribute to security of Canada's food supply and agricultural resource base.

Funding guidelines: Yes

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: No

Scarlett, Rod

Registered lobbyist: No

Organization name or Individual: Wild Rose Agricultural Producers (WRAP)

Scope, type or sector: Provincial/Territorial Industry Association

Mandate: Wild Rose provides an effective voice for Alberta's farmers and develops policies that benefit agriculture. Our organization is comprised of farmers and ranchers who wish to have a voice in shaping the future of their farming operations. As a general farm organization, WRAP is able to look at a broader agricultural picture. Just as your farm is more diverse that the commodities you grow, so to are the issues that affect your farm. WRAP is committed to our goals including, working towards sustainable farm incomes, establishing fair trade practices, improving the rural community and providing producers with accurate information in order to assist them in making informed decisions about their operations.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: No

Skinner, David

Registered lobbyist: Yes

Organization name or Individual: Nonprescription Drug Manufacturers Association of Canada (NDMAC)

Scope, type or sector: National, Association

Mandate: To foster an environment for the growth of evidence-based, cost effective self care health products.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Yes, Every month of every year for the past two years – Science and Regulation of Foods and Drugs. Hundreds of companies, Health Canada and Industry Canada, Volunteer and Paid. Yes, Continuous in 2007 – spoke to media, Good evidence and good science and regulations, daily news, TV, radio, etc. Yes – Membership of trade or industry associations, membership of public interest, community or advocacy groups.

Participation in other HC activities: Yes – Communications, Marketing and Consultations Directorate, Health Policy Branch, Health Products and Food Branch, Healthy Environments and Consumer Safety Branch, and others

Swan, Euan

Registered lobbyist: No

Organization name or Individual: Canadian Dental Association

Scope, type or sector: National, Association

Mandate: The Canadian Dental Association is the national voice of dentistry dedicated to the advancement and leadership of a unified profession and to the promotion of optimal oral health, an essential component of general health.

Funding guidelines: Yes

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: Yes

Swift, Louise

Registered lobbyist: No

Organization name or Individual: Advertising Standards Canada (ASC)

Scope, type or sector: National, Association

Mandate: Advertising Standards Canada (ASC) is the national advertising industry self-regulatory body committed to creating and maintaining community confidence in advertising. ASC administers the Canadian Code of Advertising Standards, the principal instrument of advertising self-regulation in Canada, and a national mechanism for accepting and responding to consumers' complaints about advertising. Complaints are adjudicated by independent volunteer councils, and ASC reports to the community on upheld complaints in its quarterly Ad Complaints report. Through ASC Clearance Services, ASC provides advertising copy review to evaluate compliance in five categories including: food and non-alcoholic beverages broadcast advertising and non-prescription and natural health products broadcast and print advertising.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: No

Participation in other HC activities: No

Wong, Christina

Registered lobbyist: DNC

Organization name or Individual: Program In Food Safety, Nutrition & Regulatory Affairs

Scope, type or sector: National, Academic/Research community, Industry

Mandate: To address the scientific basis of current issues of food and nutrition, health and regulatory activities through collaboration with scientists and health professionals from organizations, to achieve the goal of a healthier Canadian population.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Yes, June 2007 – an evidence-based process for oats and psyllium health claims.

Participation in other HC activities: No

QUEBEC: St-Hyacinthe, January 30, 2008

Boisvert, Paul

Registered lobbyist: No

Organization name or Individual: Canadian Council for Food and Nutrition (CCFN)

Scope, type or sector: National, Academic/research community, Mult-sectoral organization.

Mandate: The CCFN is a multi-sectoral, science based organization on food and nutrition policy and information. The CCFN is a catalyst in advancing nutritional health and well-being of Canadians. Our key priorities and activities serve to influence nutritional health based on solid scientific evidence. CCFN's governance model fosters a multi-sectoral approach to issues while allowing for sound science to be the foundation of our work The Council is comprised of specialists from the public and private sectors.

Funding guidelines: DNC

Direct financial interests: DNC

Indirect financial interests: DNC

Intellectual interests: DNC

Participation in other HC activities: DNC

Gervais, Catherine

Registered lobbyist: Non

Organization name or Individual: Nutriton Team , Physical activity and weight issues, L'Institut national de santé publique du Québec

Scope, type or sector: Provincial/Territorial, government

Mandate: L'Institut national de santé publique du Québec is an expertise and reference public health centre in Quebec. Our mission is to develop knowledge and help monitor the Quebec public's health and well-being and its determinants; evaluate the effects of public health policy on Quebecers; and to promote the transfer and sharing of knowledge and international collaboration in the area of nutrition and weight problems.

Funding guidelines: Yes

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Yes – August, 2007, National consultations on the Agricultural Strategic Framework, Institut national de santé publique du Québec,

Yes– February 2007, Agricultural Strategic Framework, …INSPQ

Yes – September 2007, AAFC : : choosing a future in health Memorandum of the 'Institut national de santé publique du Québec à la Commission on the future of agriculture and agri-foods , public consultations.

Participation in other HC activities: Yes – May 2007, Nutrition File: physical activity and weight problems: Canadian strategy on chronic disease, Canadian Diabetes Strategy, Public Health Agency of Canada.

Leclerc, Josée

Registered lobbyist: No

Organization name or Individual: Alliance pour l'innovation en agroalimentaire (APIA)

Scope, type or sector: Provincial/Territorial, Academic/research community, association, government, industry

Mandate: L'APIA encourages the Quebec Agri-food industry to make optimal use of all its innovative, scientific, technol0gical and research resources in order to improve its competitiveness on the national and international scenes. Its mission is: to be a foundation of Quebec's main innovation and regional economical development strategy; to lead in promoting innovation and awareness of the main stakes in the Agri-food sector; and to be recognized as a reference in innovation support networking, knowledge sharing and expertise born of sector initiatives.

Funding guidelines: No

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Yes – September 2007, Memorandum: l'importance de l'innovation dans l'avenir de l'industrie agroalimentaire au Québec, Commission sur l'avenir de l'agriculture et de l'agroalimentaire québécois (CAAAQ),.

Participation in other HC activities: No

Appendix 3 – Table of Regulatory Requirements by Health Claim Type

Health Claim Type	Regulatory Requirements
Disease risk reduction and therapeutic claims: • These claims are used to describe the link between the characteristics of a diet, a food or food constituent and the risk reduction of a disease or the therapeutic effect of a food or food constituent or diet, (including restoring, correcting, or modifying body functions). • Example: The claim "(naming the diet characteristics, food or food constituent) reduces the risk of heart disease" or "lowers blood cholesterol" can be used when the food carrying the claim meets conditions for use set out in the food regulations.	• These claims would normally make a food subject to the drug-related sections of the *Food and Drugs Regulations*. • A general exemption from the drug regulations has been provided in the food regulations. • A regulatory amendment is required to specify the conditions of sale. • A pre-market assessment of the claim is required. • Prescribed wording. • Conditions for foods carrying the claim • Conditions consistent with relevant dietary guidance (the food can be consumed in reasonable amounts consistent with dietary guidance to obtain the claimed benefit).
Function Claims • These claims are used to describe the specific physiological effects of foods and food constituents associated with health or performance • Example: The claim "(naming the food or food constituent) promotes regularity or laxation" can be used for coarse wheat bran providing a minimum of 7 grams of dietary fibre in a reasonable daily intake of the food. • Nutrient function claims (formerly known as biological role claims or Type I function claim), are a type of function claim that describe the well-established functions of nutrients or energy necessary for the maintenance of good health, normal growth and development • Example: The claim "Calcium aids in the formation and maintenance of	• No specific regulatory requirements • Voluntary pre-market assessment ;no pre-market assessment required • Positive list of acceptable claims could be developed. • Food generally must meet specified conditions: for vitamins and minerals, at least 5% of the RDI/serving; for protein and amino acids, at least a source of protein. • No prescribed wording, but claim must be about the nutrient, not the food; examples of acceptable claims are provided in the CFIA Guide to Food Labelling and Advertising

Health Claim Type	Regulatory Requirements
bones and teeth" may be used for foods providing a minimum of 5% of the Recommended Daily Intake of the nutrient per serving of stated size and reference amount of the food.	
<u>General health claims</u>: • These claims are broad general claims that promote health through healthy eating or that provide dietary guidance. These claims do not refer to a specific or general health effect, disease, or health condition. • Example: The claim "Include low fat product x as part of healthy eating" may be made on a food when the claim is truthful and not misleading (Section 5(1) of the *Food and Drugs Act*).	• No specific regulatory requirements • No pre-market assessment requiredCFIA and Health Canada have jointly developed guidelines to address specific types of general health claims to support their appropriate use and to limit misleading claims • New guidance has been published by Health Canada on the principles for using the Eating Well with Canada's Food Guide in advertising and labelling (Health Canada, 2007)