Report on Stakeholder Feedback 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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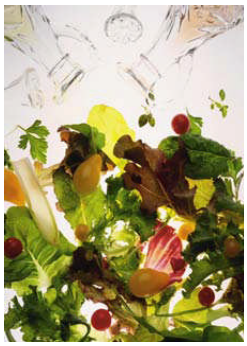


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1. Executive Summary

1.1 Introduction

This Executive Summary provides a brief overview of the consultation regarding health claims on food undertaken by Health Canada between November 2007 and April 2008.

The following pages summarize what Health Canada heard from stakeholders in the course of this consultation. It should be noted that the comments discussed in this report reflect those of stakeholders who provided responses during the consultation and do not necessarily represent the views of all Canadians.

1.2 Context

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.

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. Consumers are 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 to communicate benefits for an expanding number of food products, including innovative products that are not always readily accommodated by the current system.

1.3 Key Themes

To support its review, Health Canada targeted its consultation on the following four themes:

Theme 1 - Efficient and Transparent Processes: Exploring ways to make our processes more efficient and more transparent, so that valid claims can get to the market more quickly, and interested customers and public interest groups can find out more about the underpinnings of health claims.

Theme 2 - Sound Evidence for Consistent, Credible Claims: Looking at the kinds of evidence that industry must presently provide for approval of various sorts of health claims, and considering possible alternatives.

Theme 3 - Clear Policies for Today and Tomorrow: Examining the way the health claims system for food operates in the wider context of the activities of Health Canada, and considering various ways that existing and potential health claims might be managed.

Theme 4 - Supporting Informed Consumer Choice: Assessing the need for improving consumer understanding of health claims, monitoring the impact of health claims on the food supply and consumer choice, and determining associated opportunities and challenges.

1.4 The Consultation Approach

The consultation was initiated with the publication of an extensive Discussion Paper, entitled *Managing Health Claims for Foods in Canada: Towards a Modernized Framework (Nov. 2007).*

The consultation contained two primary components:

1. **Face-to-face meetings with stakeholders in six cities across Canada.** The face-to-face sessions were an opportunity to explain the Food Directorate's current thinking on health claims to stakeholders and to seek their views. Each lasted one day and comprised five discussion areas selected from the questions posed in the Discussion Paper. Overall, 286 stakeholders participated.

2. **The solicitation of written comments in response to the Discussion Paper**, including answers to specific questions posed by Health Canada about this document. Responses were directly solicited from a wide range of stakeholders and comments were accepted from any member of the general public. The closing deadline for comments was mid-April, 2008. In total, 72 submissions were received.

1.5 Summary of Detailed Findings

THEME 1: EFFICIENT AND TRANSPARENT PROCESSES

Business improvements for increased efficiency (Theme 1.1)

- Health Canada offered stakeholders a number of proposed business improvements related to health claims. Asked to rate the effectiveness of Health Canada's plan for improving efficiency, stakeholders award the plan an overall score of 4.7 out of 6 on a scale where 6 means *highly effective* and 1 means *not effective at all* – a positive response overall.
- Many industry stakeholders, however, suggested further business improvements and asked for clear plans and timelines for implementation.
- A number of public health stakeholders questioned Health Canada's overall reliance on an industry-driven system for health claims. A few consumers and disease groups argued that Health Canada should identify a finite number of available health claims and administer them through a single, standardized system of health claims managed by the federal government.

Increased openness and transparency (Theme 1.2)

- All stakeholders support transparency in general. However, industry focuses on the importance of protecting proprietary information while other stakeholders are concerned with public access to information underlying the health claims made on products they may buy.
- Nonetheless, the majority of all stakeholders across all categories agree that both a summary of evidence submitted and a summary of Health Canada's scientific evaluation should be published. All groups strongly support the publication of the proposed health claim.

THEME 2: SOUND EVIDENCE FOR CONSISTENT, CREDIBLE CLAIMS

Scientific substantiation of claims (Theme 2.1)

- Most public health organizations and health professionals want the same standards of evidence applied to general health claims, function claims and disease risk reduction claims. Industry believes different levels of certainty are acceptable.
- The consensus (among those willing to consider a tiered approach) is that disease risk reduction claims require the most evidence, while function claims would require less evidence and general health claims would require the least evidence, if any.
- Among those who believe there should be different levels of evidence allowed, there is disagreement as to whether and how the public should be informed of these different levels of evidence.
- Some respondents – often those who oppose different levels of scientific substantiation in the first place – feel this cannot be done without informing consumers of the level of substantiation. The majority of stakeholders, however, believe that explaining tiers of evidence on product labels will only create confusion and detract from consumers' already limited ability to understand and apply nutrition information.
- There appears to be wide agreement that 'disclaimers' on products with health claims (such as 'qualified health claims' used in the United States) are not a desirable option.

Supporting good quality submissions (Theme 2.2)

- Most stakeholders across all groups approve of Health Canada's proposals to support good quality submissions, and would particularly like to see clearer submission requirements and processes for health claims.
- An underlying view, whether implicit or explicit, is that Health Canada should not expend significant resources in assisting industry with submissions. This is also generally the position of industry itself, although there is concern about the ability of smaller companies to finance the research and submission process.
- Six industry stakeholders also suggest that the proposed pre-market review process should apply to certain claims only, arguing that for more basic claims (function claims that do not bring a food within the definition of drug), the current *Food and Drugs Act* already provides adequate limitations on misleading claims.

- Asked to identify organizations which might provide assistance to industry, stakeholders are most likely to mention private consultants, academia, industry associations and non-governmental organizations.
- Almost all respondents agree that research on the health effects of foods and food components will accelerate in coming years and they typically look to academia for these advances. Some - perhaps a slight majority - feel that such research will advance population health and nutrition. Others feel that such research is unnecessary and unhelpful compared to the more basic task of applying *existing* knowledge to improving the diet of Canadians.

THEME 3: CLEAR POLICIES FOR TODAY AND TOMORROW

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

- Asked to identify upcoming trends in functional food or bioactive ingredients in coming years, stakeholders most often mention prebiotics, probiotics, fatty acids, fiber, antioxidants, as well as a continued development of foods containing vitamins and minerals.
- Many respondents say that there are certain (unnamed) bioactive components which should *not* be allowed to be added to food for general consumption.
- Industry often takes this question as an opportunity to expand on their opinion that varying claims and levels of risk should imply varying standards of evidence. For others – most especially public health organizations and health professionals – this question provides an opportunity to assert that foods with added bioactive substances are of far less public health value than creating better nutritional understanding and habits among consumers.
- Two responses emerge when stakeholders are asked whether manufacturers should be allowed to make a health claim when adding quantities of a bioactive substance to a food below the level needed for a health effect. One group – mainly public health organizations and consumers - sees this addition as confusing and potentially misleading. A second group - led by industry - argues that the addition of a bioactive substance below the level needed for a health effect is a valid and appropriate basis for a health claim because total dietary intake of the substance is what matters and consumers may obtain the substance from a variety of sources.
- There are divergent opinions on the question of allowing the addition of bioactive substances which may pose a *risk* to specific populations. Private companies are in favour of this idea based on the power of risk/benefit analysis. For other stakeholders – primarily health professionals, disease groups and consumers – there can be no question of exposing some consumers to risk in exchange for minor health benefits to the wider population.
- Public health officials and health professionals appear to be most concerned about the possibility that health claims on foods will not help, and may well undermine, efforts to encourage Canadians to choose a healthier diet. In contrast, industry prefers to focus on the potential benefits of various nutritional improvements in the diet Canadians already eat. Industry tends to criticize government for being overly risk-oriented and risk averse while ignoring the potential health benefits of food innovations. Conversely, stakeholders outside industry tend to criticize industry for investing so much energy and emphasis in small, proprietary nutritional improvements instead of the larger dietary issues facing Canadians.
- For those who support the introduction of bioactives despite potential risks to some population segments, the measures used in the labelling of natural health products and drugs are seen

as largely adequate. For those who oppose this step, these measures are often seen as inadequate because they place too much onus on at-risk populations to protect themselves.

Managing a broader range of function claims (Theme 3.2)

- Stakeholders are generally lukewarm to mildly positive when rating the adequacy of Health Canada's proposed non-regulatory measures to manage health claims.
- When asked whether Health Canada should explore a "requirement for the submission of supporting evidence when there are concerns about the credibility of a health claim being used on foods already in the marketplace", stakeholders are generally supportive. Almost all opposition to this idea comes from industry associations. On the other hand, this idea is popular with public health officials, health professionals and disease organizations.
- Asked whether *pre-market* assessments of function claims should be *mandatory*, the vast majority of industry stakeholders oppose this idea, while most public health officials, academics, health professionals and consumer respondents support it.
- Those who support pre-market screening of claims are motivated by concerns about misleading claims (existing and future) and the potential damage to the credibility of health claims in general. Those who oppose pre-market screening are usually of the opinion that it is unnecessary and would place an unsupportable resource and time burden on both industry and Health Canada.

Managing diverse front-of-package claims (Theme 3.3)

- Presented with a list of proposed measures Health Canada might undertake to deal with front-of-package claims, there is strong agreement among private companies and academics that these measures will be *sufficient* to reduce confusion. There is less unanimity among public health officials, industry associations and health organizations that this would adequately reduce confusion however.
- The question of implied health claims appears to divide industry from the public health sector and health professionals. The latter group generally applauds the idea of prohibiting the use of implied health claims without the associated explicit claim, while industry almost unanimously opposes this idea or considers it a very low priority.
- The primary reason advanced for prohibiting the use of implied claims without accompanying explicit claims is that implied claims offer an opportunity to imply a health benefit without having to substantiate it, and can therefore be potentially misleading.

Eligibility criteria for foods to carry claims (Theme 3.4)

- Respondents are evidently confused and divided about the idea of setting core nutritional criteria to determine which foods would be eligible to carry a health claim. There are three basic positions which emerge.
    - One view is that health claims should be denied to products which cannot satisfy core nutritional criteria.
    - A second group – primarily in industry - which opposes core nutritional criteria worry that 'regular' foods might by their nature fail to meet core nutritional criteria.

    - A third group - very much the minority - suggests that it would be beneficial to allow health claims even for foods with very low nutritional value if this encouraged the manufacturers to enhance their products.

- Of the three potential approaches to the application of core nutritional criteria to front-of-package labelling tested with stakeholders, the most positively received is the suggestion that all foods must meet core criteria in order to be eligible to carry a health claim. A voluntary system is rejected as too inconsistent and a mandatory disclaimer system is rejected as confusing. Many in industry entirely reject the idea of using core criteria.

THEME 4: SUPPORTING INFORMED CONSUMER CHOICE

Improving consumer understanding of health claims (Theme 4.1)

- Advice from respondents for communicating information to consumers tends to revolve around three general ideas.
    - First, almost all respondents call for simple, clear language which is easily understood by consumers.
    - Second, all respondents want communication which enhances rather than undermines faith in the Canadian regulatory system.
    - Finally, most see roles for academia, industry and non-government organizations.
- When the written submissions are parsed for suggestions on how to better communicate with consumers about health claims on foods, the following ideas emerge.
    - Simple language
    - New consumer research
    - Consumer education campaigns
    - Advertising

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

- With few exceptions, respondents appear to support the idea of post-market surveillance of the market impact of health claims. In the minds of respondents, industry takes somewhat of a secondary role in post-market monitoring compared to Health Canada, disease groups, health professionals and academics.
- A minority of respondents believe they have a role to play in monitoring the use of health claims in the food supply, albeit an indirect role. Public health and disease organizations often see themselves in a partner role in setting policies and criteria rather than monitoring directly. Industry sees itself primarily as a source of market information for use in monitoring.

1.6 Additional Observations

- The issues are complex and challenging for stakeholders and regulators. Participants often feel overwhelmed by the depth and scope of the issues.
- All respondents want greater predictability in the rules and processes surrounding health claims in Canada.
- Industry is focused on disseminating the benefits of new substances, while non-industry respondents are more interested in preventing misrepresentation and encouraging good basic nutrition.
- Consumer education is universally regarded as good and necessary, but there is uncertainty and ambivalence about the degree of responsibility which should be placed on consumers to make appropriate choices.
- Some respondents wonder if Health Canada will have the resources to properly implement a health claims evaluation program.

1.7 Stakeholders assessments of the consultation

- Overall stakeholders who participated were satisfied with the consultation.
- The average satisfaction score for the face-to-face sessions was 4.1 out of 5. This equates roughly to a score of 82 out of 100.
- Generally, stakeholders who responded to the on-line questionnaire expressed satisfaction at the opportunity to provide feedback to Health Canada through the consultation process.
- Many respondents offered comments or suggestions regarding the consultation process.

2. Introduction

This report provides an overview of the consultation regarding health claims on food undertaken by Health Canada between November 2007 and April 2008.

The following pages summarize what Health Canada heard from stakeholders in the course of this consultation. It should be noted that the comments discussed in this report reflect those of stakeholders who provided responses during the consultation and do not necessarily represent the views of all Canadians.

3. The Consultation Approach

The consultation was initiated with the publication of an extensive Discussion Paper, entitled *Managing Health Claims for Foods in Canada: Towards a Modernized Framework* (Nov. 2007).

The consultation contained two primary components:

1. Face-to-face sessions with stakeholders in six cities across Canada.
2. The solicitation of written comments in response to the on-line Discussion Paper, including answers to specific questions posed by Health Canada about this document.

3.1 Face-to-Face Sessions

The face-to-face sessions were an opportunity to explain the Food Directorate's current thinking on health claims to stakeholders and to seek their views. Each lasted one day and comprised 5 discussion areas selected from the questions posed in the Discussion Paper. These were:

1. Scientific substantiation of claims
2. Functional foods and the food/natural health product interface
3. Managing a broader range of function claims
4. Managing diverse front-of-package claims
5. Eligibility criteria for foods to carry claims

For each discussion area, an information session presented by Health Canada officials was followed by small group discussions about specific questions related to the topic. These groups completed workbooks and reported back to the larger group in open plenary. At the close of each day, participants were asked to complete an evaluation sheet which captured their opinion of the process. Due to time constraints, not all issues covered in the on-line consultation (discussed below) could be included in the face-to-face sessions.

A key purpose of the face-to-face sessions was to provide information and background to stakeholders. Thus, these sessions performed a dual role of both communication and consultation. Indeed, of 72 organizations who submitted written comments in response to the Discussion Paper, roughly 32 had previously attended one of the face-to-face consultation sessions.

Invitation lists for the sessions were drawn from existing Health Canada databases of stakeholders in each city, in consultation with Health Canada representatives in each region. In total, 286 individuals attended these sessions. The following table depicts the breakdown of participants by location.

Table 1: Consultation Sessions

Location	Date (2008)	Number of Participants
Toronto, Ontario	Jan. 28	75
Ste-Hyacinthe, Quebec	Jan. 30	30
Halifax, Nova Scotia	Feb. 1	33
Winnipeg, Manitoba	Feb. 4	37
Edmonton, Alberta	Feb. 6	38
Vancouver, British Columbia	Feb. 8	73
Total		**286**

During each session, notes were taken which formed the basis of regional reports. Highlights from those regional results have been incorporated into this report.

3.2 Solicitation of written comments

In November 2007, the Discussion Paper was posted on the Health Canada website, accompanied by a standalone questionnaire addressing each issue area in the Discussion Paper. This questionnaire contained many of the same questions used during the face-to-face sessions. Responses were directly solicited from a wide range of stakeholders and comments were accepted from any member of the general public. The closing deadline for comments was mid-April, 2008. In total, 72 submissions were received. The following table summarizes the responses received from various stakeholder groups

Table 2: Written Submissions Received	
Type of Respondent	**Submissions Received**
Public Health Organization	9
Industry Association	20
Private Company	17
Academic	6
Health /Disease Organization / Health Professional	5
Consumer Group / Private Citizen	6
Consultant / Third Party Organization	9
Total	**72**

Fourteen of the submissions – typically private citizens, academics and health professionals – were submitted as *personal* responses. Fifty-six submissions were explicitly *collective* responses representing organizations. In two cases, this could not be determined.

In one case, two non-governmental organizations submitted a joint response to Health Canada. This has been treated as two individual submissions.

3.3 Analytical Approach

The materials available for this report are of four types:

- Notes taken by Health Canada staff during the face-to-face consultation sessions
- Workbooks completed by break out groups at the face-to-face consultation sessions
- Evaluation forms completed by individuals attending the face-to-face consultation sessions
- Written submissions received in response to the Discussion Paper

The written submissions provide several different types of material. Of the 72 submissions, 57 followed the questionnaire provided by Health Canada. Another 15 did not follow the format of the questionnaire but did address some or all of the general issue areas listed above.

The questionnaires included closed-ended measures for a number of questions which required a Yes/No response or a scale response. This approach is very useful in providing a snapshot of stakeholder thinking. These responses are most meaningful, however, when kept in the context

of the very many assumptions, qualifications and caveats stakeholders mention in their responses, as is done in this report.

To properly analyze the written input, all comments from stakeholders were assembled into a single database. This provided the opportunity to easily calculate overall responses to each closed-ended question (frequencies) as well as the different responses within each stakeholder group. Furthermore it placed all responses to each question together, facilitating comparison and analysis.

For the 15 responses which did not adhere closely to the questionnaire format, the text was parsed and placed into the corresponding categories in the database. Where these stakeholders did not actually answer the closed-ended questions, responses were *not* imputed to them based on their comments except in cases where their response makes their intention absolutely clear. When values were imputed to stakeholders for the purpose of the database, different numerical values were used to ensure that imputed values could never be confused with actual verbatim responses to questions provided by respondents themselves. (For example, where an actual "Yes" or "No" might be coded as "1" or "2" respectively, imputed values would be recorded as "21" or "22'.) While imputing values places a heavy responsibility on the analyst to be accurate, the alternative is to exclude the views of respondents who chose not to offer responses to these questions or, possibly, to abandon the closed-ended question results entirely.

It is important to note that this report does not attempt a narrative retelling of discussion in the consultation, nor does it present the results from the two components of the consultation separately. Face-to-face sessions, along with the written submissions, have been synthesized into a single report intended to provide the reader with an understanding of stakeholder positions on this complex issue.

3.4 Tables in this Report

Throughout this report, written responses to questions posed in the Discussion Paper are presented in tables (with imputed values identified). Two important points should be borne in mind.

First, the tables contain counts, not percentages. Each number reflects a real number of respondents. As not all respondents provided answers to all questions, the total number of responses in each table will vary.

Second, these tables are intended solely to describe the contents of the submissions and cannot claim to represent the wider stakeholder community or all Canadians. Although best efforts are made to include the widest possible range of stakeholders in the consultation – and there is every reason to believe these efforts succeed – there is no reliable scientific basis upon which to generalize these results to the wider population with statistical certainty. That said, it is

very likely that the opinions expressed in consultations reflect the opinions present in the wider stakeholder community. We simply cannot reliably estimate the *proportions* in which each of these views is present. Likewise, when this report refers to stakeholders it is in the same sense as “participants” and ‘contributors’. We are describing the stakeholders involved in this consultation, not all stakeholders in Canada.

A final caveat which must be borne in mind is the fact that this report gives equal numerical weight to each submission. Thus, the submission of an individual or small company has the same numerical weight as that of a large corporation, non-governmental organization or industry association. While this approach poses some difficulties, the alternative approach – weighting the value of submissions based on the size or influence of the stakeholder – is fraught with difficulties. For this reason, the report tables break out results by stakeholder group to allow comparisons and do not provide results for “all stakeholders”.

3.5 Quotations in this Report

This report uses quotations which illustrate a general view or opinion expressed by a significant number of respondents. These quotations – which are all drawn from the *written* submissions – take the following form:

This is a sample quotation (Industry Association)

The respondent group of the submission quoted is always indicated. The specific source of each quotation is not provided, however, partially to preserve confidentiality but primarily because the quotation is intended to illustrate a view held by a number of stakeholders.

3.6 Quantity Qualifiers

The following table describes the meaning of various qualifiers used in this report to describe the written submissions.

Table 3: Definitions: Quantity Qualifiers	
• **In total, 72 submissions were received. The following general definitions are used for qualifiers used in this analysis.**	
Term	**Percentage**
A few participants, a small group, a handful	*Less than 5%*
Some participants, a number of submissions	*Between 5% and 20%*
A minority	*Between 20% and 40%*
One-half	*Between 40% and 55%*
Many participants, a significant number	*Between 30% and 60%*
A majority	*Between 50% and 70%*
Most participants, a solid majority	*Between 60% and 80%*
Almost all, overwhelming majority, near unanimous	*More than 80%*

4. Detailed Results

To support its review, Health Canada targeted its consultation on the following four themes:

Theme 1 - Efficient and Transparent Processes: Exploring ways to make our processes more efficient and more transparent, so that valid claims can get to the market more quickly, and interested customers and public interest groups can find out more about the underpinnings of health claims.

Theme 2 - Sound Evidence for Consistent, Credible Claims: Looking at the kinds of evidence that industry must presently provide for approval of various sorts of health claims, and considering possible alternatives.

Theme 3 - Clear Policies for Today and Tomorrow: Examining the way the health claims system for food operates in the wider context of the activities of Health Canada, and considering various ways that existing and potential health claims might be managed.

Theme 4 - Supporting Informed Consumer Choice: Assessing the need for improving consumer understanding of health claims, monitoring the impact of health claims on the food supply and consumer choice, and determining associated opportunities and challenges.

4.1 THEME 1: EFFICIENT AND TRANSPARENT PROCESSES

4.1.1 Business improvements for increased efficiency (Theme 1.1)[1]

Health Canada offered stakeholders a number of proposed business improvements related to health claims. These were, in brief:

- Dedicating additional resources to the review of health claims for foods.
- Implementing standard operating procedures (SOPs) for the Health Canada (HC) review of submitted claims.
- Developing the parameters for an abbreviated process for claim review where internationally recognized scientific bodies or competent national authorities have recently completed a review.
- Examining ways to improve efficiency administering the current regulation, including dedicating more resources in regulatory drafting and legal services and exploring when it may be possible to expedite the final amendment of the Regulations in *Canada Gazette Part II.*
- Exploring appropriate triggers and processes for deciding when a second review of an approved claim may be needed.

These proposed business improvements are generally met with cautious enthusiasm, especially from industry.

> *It is important to dedicate additional financial and human resources to the review of health claims. (Private Company)*

> *The additional funds, personnel and Standard Operating Procedures will speed the process along and instill more confidence in the overall process. (Academic)*

The provision of additional resources is seen as a positive and necessary step, reflecting a general industry view that approvals have been too slow in the past. There is nonetheless concern that the volume of new health claims for food will prove unmanageable in the years to come.

Standard operating procedures are welcomed because they promise faster approvals and also a more consistent and predictable process. Industry is especially positive about abbreviated processes for internationally accepted claims, which they believe would reduce redundant or unnecessary reviews.

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[1] Questions about this theme were posed only to stakeholders responding to the Discussion Paper, not to participants at the face-to-face sessions.

A list of acceptable claims is also widely approved as a helpful measure, especially for smaller manufacturers.

Industry wants Health Canada to go further, however. In addition to the suggested business improvements, industry often asks for more information about timelines and plans for implementation of these proposals. They stress the need for full transparency about how and when standard operating procedures will be implemented and how this will affect existing claims. Furthermore, they often suggest specific time limits within which Health Canada must respond to a health claim application. In essence, they are looking for greater predictability.

> *Any of the above business improvements could be helpful, but one of the biggest hurdles that we have in industry is understanding timing of milestones. Our business has product development and financial plans on a yearly basis, and it is difficult to advise them of how to factor development of claims for new products that we wanted to launch. (Private Company)*

Respondents outside industry express concern that the focus of the proposed business improvements is to provide *faster* approvals for health claims at the expense, they fear, of rigorous public health oversight.

> *..being aware that the maintenance of safe labelling for the optimal health and well-being of Canadians should be the primary focus. There are limits to how much the process can be speeded up if that focus is maintained. (Academic)*

> *Health Canada has the role and duty to protect public health and allow for complete, independent and rigorous analysis of scientific substantiation related to the approval of various health claims…Claims are not marketing tools and should not be used as such. (Public Health Organization)*

> *Health Canada should not emphasize an application-driven approval system for voluntary company-initiated marketing claims. Such a system will be wasteful of precious government scientific and legal resources, will lead to selective disclosure of information on labels and menus. (Consumer Group)*

Asked to rate the effectiveness of Health Canada's plan for improving efficiency, stakeholders award the plan an overall score of 4.7 out of 6 on a scale where 6 means *highly effective* and 1 means *not effective at all*. The following table shows the scores offered by each stakeholder group.

Table 4: Perceived Effectiveness of Efficiency Improvement Plans		
Stakeholder Group	**Mean score***	**Number of responses**
Public Health Organization	5.0	4
Industry Association	4.6	14
Private Company	4.9	10
Academic	5.3	3
Health /Disease Organization / Health Professional	5.3	3
Consumer Group / Private Citizen	3.5	4
Consultant / Third Party Organization	4.2	7
A scale of 1 to 6, wherein 6 means *highly effective* and 1 means *not effective at all.		

It is notable that the proposed changes at Health Canada score well with most stakeholders, often equivalent to a percentage score of 80% or more. However, the weakest scores come from private citizens and consumers. Consumer dissatisfaction often revolves around a perceived passivity at Health Canada and the perception that Health Canada is not leading on the health claims issue but instead following the lead of industry.

Stakeholders – primarily those from industry - offer a number of *additional* suggestions for changes to Health Canada business practices related to health claims. These are listed below, in order of the frequency with which they are mentioned.

- **International harmonization, cooperation and alignment (9 mentions)**
  Building on the support for an abbreviated system for health claims already approved elsewhere, many call for additional work in this area. Industry suggests that there is no need for significant review of claims already approved and supported by a body of evidence in other countries unless some issue specific to Canada exists. Some non-industry stakeholders are cautious about such harmonization or alignment, feeling that many foreign standards or approaches are not ideal.

- **Automated submission and tracking (7 mentions)**
  Industry especially suggests that the submission system be automated and that sponsors should be able to track the progress of their submissions on-line throughout the process. Some suggest that Health Canada should also automate the tracking of its own performance in meeting efficiency targets, reflecting industry's primary concern about current delays.

- **Submission guides and templates (4 mentions)**
  Some say that industry should be given clear submission guidelines which detail both the criteria used for decisions on health claims and also the exact form of submission which is required. This would be especially useful to small and medium-sized companies.

- **Clarification of the 'food-like NHP' situation (4 mentions)**
  A number of respondents specifically ask for an early end to the apparent overlap between the Natural Health Product (NHP) regulations and food regulations. Most of these (3 of 4) want food-like NHPs excluded from the NHP regulations and brought under food, but one disagrees. Respondents view the NHP regulatory review as an excellent opportunity to begin a clarification process which will simplify changes under consideration for health claims.

- **Opportunities for appeal (3 mentions)**
  A handful of stakeholders say the process should include a simple and transparent avenue for appeal of decisions with which applicants disagree.

- **Separate risk assessment from risk management (2 mentions)**
  Citing international examples (such as the EU) a few stakeholders suggest that Health Canada should place risk assessment of health claims into the hands of an independent third party and confine itself to managing those risks and enforcing the regulations. This stems from a perception that Health Canada cannot keep up with fast-paced evolutions in food science.

4.1.1.(a) The call for standardization of claims

There are differing opinions regarding the overall reliance on an industry-driven system of health claims, and front-of-package claims in particular. A few consumers and disease groups argued a single, standardized system of health claims managed by the federal government. These health claims would be chosen and approved by the federal government and would be the only claims allowed. Companies wishing to use these claims would be required to meet a set of defined criteria set by Health Canada. These stakeholders claim this approach ensures a consistent application of standards across products making health claims and especially prevents the proliferation of multiple, competing front-of-package systems which (they feel) contribute to consumer confusion. This suggestion was specifically raised by participants in the Halifax, Toronto and Winnipeg sessions, when discussing approaches to managing diverse front-of-package claims.

Industry does not want a single standardized federal system of health claims, front-of-package or otherwise. On the contrary, they support an industry driven system. This is for two reasons. First, health claims represent a competitive advantage which companies want to use to

distinguish their product from others. They would prefer, from a marketing perspective, to "own" a specific claim and see it only on their own products. Second, they often think in terms of innovation and new *types* of health claims. Thus, they would not expect a standardized federal system to easily accommodate the sort of new claims which stem from proprietary research and manufacturing methods. Such technical advantages are short-lived and the benefits depend upon bringing them to market quickly. Thus, standardized labelling would discourage research and innovation because it would pose an obstacle to new claims.

As noted later, a number of stakeholders – primarily in industry – suggest that the front-of-package labelling issue is too complex to be included in the current re-evaluation of health claims.

4.1.2 Increased openness and transparency (Theme 1.2)[2]

With regard to the publication of sponsor submissions and Health Canada decisions, four ideas underlie the diverse opinions of respondents.

First, there is a general agreement that transparency is necessary for ensuring accountability of the approvals system. This argument implies that third parties should be able to assess the applications and Health Canada's response to ensure that federal regulations and policies are being applied properly and consistently.

Second, there is a widespread belief that consumers should be able to access criteria and evidence underlying the specific health claims made on products they may buy – both the evidence standards and the evidence itself. This argument tends towards greater availability of submission and decision materials.

In contrast to the first two views, a third view focuses on the importance of protecting proprietary information. Industry is particularly concerned that publication of submission materials will provide competitive intelligence to other companies and nullify the competitive advantages gained from proprietary research and innovation. This view tends toward less availability of information, strictly limited to the Health Canada decision documents (not submissions) and only *after* a decision has been rendered.

A final view is the possibility that in publishing too much information Health Canada will overwhelm the potential users of that information. It is widely accepted that consumers face challenges in understanding and using nutritional information. The technical documents related to approval of health claims may not, by themselves, be especially useful to non-specialists.

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[2] Questions about this theme were posed only to stakeholders responding to the Discussion Paper, not to participants at the face-to-face sessions

Without doubt, concerns about commercial confidentiality are raised almost exclusively by industry. Other stakeholders do not explicitly *oppose* the protection of proprietary information, they simply leave it unmentioned. Evidently, transparency is on balance a higher priority outside industry than is the protection of commercial confidentiality.

However, industry is by no means opposed to transparency overall. They simply place much tighter limits on what should be published and, critically, *when*. For example, they argue that nothing should be published until a decision is rendered by Health Canada and even then only if the application is successful.

Outside industry there is a small cadre of respondents – often health professionals – who argue for maximum disclosure and appear to feel that more transparency is always desirable.

The following table shows the numbers of participants in each category who support the publication of three specific types of information related to a health claim *submission*.

Table 5: The health claim submission documents: Support for publication.

	Public Health	Industry Association	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Total Submissions	*9*	*20*	*17*	*6*	*5*	*6*	*9*
Publish proposed health claim	8	16	12†	4	4	6	8
Publish summary of evidence submitted	7	13	10†	4	4	6	8
Publish full tabulation of evidence submitted	5	6	4†	2	3	2	3

† - ***Includes three positive responses imputed from the submission.***

Overall, the strongest support in all groups is for the publication of the proposed health claim and, to a lesser extent, a summary of evidence submitted. The publication of the full tabulation of evidence submitted is not generally supported.

With regard to Health Canada's decision documents, there is strong support for the publication of the summary of the evaluation and the decision and rationale. There is less support for publishing the detailed evaluation of the submission or the results of consultations, as shown in Table 6.

Table 6: The Health Canada Decision Documents: Support for Publication

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Total Submissions	*9*	*20*	*17*	*6*	*5*	*6*	*9*
Publish summary of HC scientific evaluation of the submission	7	14	15†	4	4	6	7
Publish detailed HC evaluation of the submission	6	3	4†	2	2	2	5
Publish results of consultations, if applicable	5	8	5†	3	4	5	6
Publish decision and rationale	8	16	13††	5	4	6	8

† - Includes three positive responses imputed from the submission.
†† - Includes two positive responses imputed from the submission.

To ensure that there is openness and transparency, it is important that all stakeholders, including health professionals and consumers, have access to this information, possibly on an easily accessed website. (Disease Organization)

Publishing information relating to the submission is not relevant after a decision has been made. However, publishing the assessment including a summary of the scientific evaluation, the decision and rationale would instill public confidence by showcasing the evaluation used to support the claim. (Private Company)

All info should be open and transparent. There should be no reason to limit any of the above listed info. (Public Health Organization)

If private industry is expected to pay for the information which becomes public there will be few private companies willing to undertake the research needed to substantiate claims. (Private Company)

There is little discussion from stakeholders as to whether health claims that are *refused* should be published. A few industry stakeholders specifically oppose this idea (usually for reasons of business confidentiality and preserving market advantage), and they point out that a refused claim may well be reworked and resubmitted by the same sponsor. Most stakeholders are silent on the issue, however.

Stakeholders consider the seven information types listed earlier to be comprehensive insofar as only a few suggest additional items to be published. These other suggestions focus primarily on technical and administrative information:

1. **Technical information (6 mentions)**
    - All technical documents must be available on request
    - Full list of references for evidence raised
    - Any reports from other countries, if available, and particularly if there are any outlier information and risks identified
    - Risk/Benefit profile
    - All science-based and evidence-based data used to make the decision
    - Any gaps in information for a complete or comprehensive assessment to be done
2. **Administrative Information (4 mentions)**
    - Date when Health Canada decision was rendered (and the starting date for when the new health claim can be used, if appropriate)
    - HC adherence to established standard operating procedures
    - List other countries that accept the health claim. Include country where the product is manufactured or will be manufactured
    - Information on how the same claim has been addressed by our trading partners, particularly the USA, EU and Australia/New Zealand, and for that information to be part of the package that is publicly available
3. **Implications of Decision (2 mentions)**
    - Food products that the proposed health claim would possibly cover (e.g. tomatoes, strawberries, watermelon)
    - Description of the benefits to the consumer

Asked to provide a model format for a decision document, few volunteered. Those who offer suggestions sometimes point to FDA or FSANZ formats.

4.2 THEME 2: SOUND EVIDENCE FOR CONSISTENT, CREDIBLE CLAIMS

4.2.1 Scientific substantiation of claims (Theme 2.1)

The question of scientific substantiation is clearly complex and elicits a wide range of complex responses.

It is important to note that semantics plays a clear role in responses to this question. No respondent endorses “low levels” of substantiation or certainty. However, the term “high level” can have different meanings.

For some – typically public health and health professionals – “high level of certainty” means that the same standards of evidence should be applied to general health claims, function claims and disease risk reduction claims. This high standard of certainty – described in the questionnaire – includes evidence published in peer-reviewed journals, human trials and a consistent cause and effect relationship.

In contrast, the majority of industry stakeholders (and a number of others) believe that the evidence standards for function claims may be different than for disease risk reduction claims. They note the difficulty and cost of proving cause and effect relationships related to food components. A few propose specific schemes for evidentiary requirements for different types of health claims, but most simply assert that it is acceptable to set different standards for different claims. A key determinant in the degree of evidence needed, according to these stakeholders, is the degree of risk associated with the food or food constituent in question. In other words, they support a “high level” of certainty *relative to the potential risk*.

As the following table shows, public health organizations and health professionals are inclined to support a “high level” of certainty for health claims, while industry and third parties believe different levels of certainty are acceptable.

Table 7: Should all claims be based on a high level of certainty?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	6	6[†]	1	3	3	3	2
No	2	7	13[†]	2	1	1	6
No Answer / Blank	1	7	3	1	1	2	1
Total	**9**	**20**	**17**	**6**	**5**	**6**	**9**

[†] - ***Includes one response imputed from the submission.***

The idea that evidence standards should vary based on risk assessments is a common perception and includes the important point that when most stakeholders think of varying evidentiary requirements for function claims, they are thinking about standards of *efficacy* not *safety*. Safety is assumed to be known and established in the vast majority of cases. *Risk*, in this case, refers to the consequences to consumers if the substance did not provide the promised benefit.

The assumption that safety must be *proven* before a health claim is even considered points to another important distinction in thinking about evidence in food claims: safety is plainly easier to establish when discussing a component naturally present in foods than for a component which is not present in foods naturally. Proponents of whole and unprocessed foods (inside and outside industry) make this point. Nonetheless, most respondents – including most industry respondents – are thinking of substances added to food when they discuss standards of evidence for health claims.

When asked specifically which types of claims might be subject to lower levels of evidence requirements, the general consensus (among those willing to consider this approach) is that disease risk reduction claims require the most evidence, while function claims would require less evidence and general health claims would require the least evidence. Proposed principles to govern the use of reduced evidence standards are rarely mentioned, but typically relate to the level of risk. Where risk is minimal, lower standards might be allowed.

> *All claims should have evidence supporting them. Our recommendation would be to implement three tiers of claims. These three tiers include: Nutrition claims (research-based) / Function claims (animal studies) / Disease risk reduction claims (human*

studies). Disease risk reduction claims should be made with the highest level of certainty – they should all be based on evidence based human trials. (Disease Organization)

If all claims are based on a "high level" of certainty, many will never be adopted and serve the purpose of contributing to dietary intake patterns that deliver benefits to consumers. (Industry Association)

All disease risk-reduction and function claims should be supported by a sound and sufficient body of scientific evidence …. However, [we] believe that a high or convincing level of evidence (based on consistent cause-and-effect relationship), as is currently proposed for food, is too rigid for claim approval. A cause-and-effect relationship implies randomized controlled trials which are not possible or ethical to do with many diseases. (Industry Association)

4.2.1.(a) Informing the public

If differing levels of scientific substantiation are to be allowed, stakeholders are divided on whether or not that information should be communicated to the public. They also disagree on *how*.

Some respondents – often those who oppose different levels of scientific substantiation in the first place – feel it will be important to inform consumers of the degree of scientific substantiation of any health claim through labelling. They argue that without this information, consumers will not differentiate between strong claims and weaker claims. This view often stems from a desire to ensure that consumers will be aware of (and possibly discount) claims which have lower substantiation. It also stems from the view, noted elsewhere, that transparency is an inherent Good in matters of health.

The majority of stakeholders, however, believe that explaining tiers of evidence on product labels will only create confusion and detract from consumers' already limited ability to understand and apply nutrition information. They believe that if a claim is considered valid by Health Canada then that is as much information as consumers' need to see on the product label.

There appears to be wide agreement that 'disclaimers' on products with health claims (such as 'qualified health claims' used in the United States) are not a desirable option. These disclaimers are characterized as an attempt to force the consumer to arbitrate a scientific issue which should instead be resolved between manufacturers and the regulator. Health claims with disclaimers are considered to be confusing, unhelpful and potentially misleading.

If basic functional and general claims are approved for a lower level of certainty provided the benefits highly outweigh the risks (e.g. a claim promoting increased fiber consumption) it is not necessary to communicate the level of certainty to consumers and complicate the message. (Industry Association)

Let consumers carry some onus as Government should not be making all decisions for consumers (eg. Anti-oxidants) but letting self education and preference dictate. (Private Company)

We recommend that consumers not be informed of the level of certainty that supports a claim since all health claims will have sufficient scientific support to ensure that the consumer is not being misled. (Disease Association)

A key distinction in the question of informing consumers is where that information resides. While most stakeholders would not endorse placing this information on product labels, almost all suggest that this information should be made available to the public if they are interested. The concern is simply that necessarily brief explanations on labels would create more confusion than understanding among the wider public who do not necessarily want or need this information.

A companion concern raised primarily by industry is the limited space available on labels, especially in the bilingual Canadian marketplace. Label space is at a premium and must perform a number of tasks, so industry is reluctant to devote space to explanations of scientific substantiation which they believe serve no positive purpose.

4.2.2 Supporting good quality submissions (Theme 2.2)[3]

Stakeholders were presented with a list of measures Health Canada might undertake to support good quality health claims submissions. These were, in brief:

- encouraging pre-submission consultations;
- updating the 2002 Interim Guidance Document to include specific guidance on the preparation of a structured, systematic review with the knowledge gained from the work done by the Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA) at the University of Toronto, and Health Canada;
- supporting in principle the efforts of third parties to coordinate joint submissions by small and medium-sized industry members;

[3] Questions about this theme were posed only to stakeholders responding to the Discussion Paper, not to participants at the face-to-face sessions

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

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

There is general support for all of Health Canada's proposals to support good quality submissions for health claims.

Table 8: Perceived effectiveness of proposals to support good quality submissions

Stakeholder Group	Mean score*	Number of responses
Public Health	5.3	4
Industry Association	5.8	15
Private Company	4.3	11
Academic	5.0	4
Health /Disease Organization / Health Professionals	5.5	4
Consumers / Private Citizens	4.5	4
Consultant / Third Party Organizations	4.7	7

A scale of 1 to 6, wherein 6 means *highly effective* and 1 means *not effective at all.

As the foregoing table shows, the proposals receive an average score of between 4.3 and 5.8. Respondents are especially likely to highlight their support for clearer submission requirements and processes, sometimes pointing to existing processes in the Natural Health Products Directorate and the Therapeutic Products Directorate as good models to follow.

Non-industry respondents are quick to point out that quality submissions are an industry responsibility and remark that there are many private consultants and organizations available to assist in this regard. The underlying view, whether implicit or explicit, is that Health Canada should not expend significant resources in assisting industry with what they see as, essentially, a profit-making activity. This is also generally the position of industry itself, although there is concern about the ability of smaller companies to finance the research and submission process.

The idea of collaboration within the industry is sometimes characterized as laudable but unrealistic, given the ultimate goal of market advantage.

Six industry stakeholders also specifically suggest containing the pre-submission process to certain claims only, arguing that for more basic claims (function claims that do not bring a food within the definition of drug), the current *Food and Drugs Act* already provides adequate limitations on misleading claims.

However, there is recognition that there will be a need for information resources and guidance to streamline and improve submission quality, and this responsibility is often placed on the shoulders of existing industry associations and non-governmental organizations, such as the Canadian Council of Food and Nutrition (CCFN) and PFSNRA.

> *These proposals would make the submission process for industry less cumbersome and more cost effective. They would also allow for a more expedient review of the evidence, benefiting all parties involved. (Private Company)*

> *Health Canada's nutrition research agenda should be designed with a view to secure the most significant improvements to public health, not necessarily to assist businesses in advancing their marketing objectives. Using research or administrative resources to create equity between large and small food companies is a use of public resources that probably cannot be justified on public health grounds. (Consumer Group)*

> *[We] would not want to see scarce resources being used to help large food processing companies through the process of making advertising type health claims. However, we do support the concept of systems that enable Canadian small and medium enterprises (SMEs) to compete more effectively in the value added food and agri-food system. (Consumer Group)*

A final point made by a few respondents is that a pre-submission system would require adequate resources across Canada to be useful but that this should *not* divert resources away from evaluation of submissions.

As noted earlier, most respondents believe the primary responsibility for good quality submissions lies with applicants themselves. Asked to identify organizations which might provide assistance to applicants, stakeholders are most likely to mention private consultants, academia, and industry associations, as shown in Table 9.

Table 9: Which organizations could support applicants in preparing good quality submissions?	
Organization	**Number Mentioning**
Private Consultants	12
Academics	7
Industry Associations	7
Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA)	6
Health Canada	3
Agriculture and Agri-Food Canada	3
Provincial Government Departments	3
Disease Groups	2
Advanced Foods & Materials Network (AFMNET)	2
MaRS Landing	2
Nutri-Net	2
Other	7
Total Mentioned	**56**

Almost all respondents agree that research on the health effects of foods and food components will accelerate in coming years, but there is some disagreement about where that research should be done. For some, research should be conducted solely by and at the cost of industry, as the industry stands to benefit financially from health claims. A few see this research as primarily a government responsibility because of potential health benefits in the population and potential bias in industry-generated research. Most, however, believe that credible research should be conducted by third parties.

The disagreement about research sources underlies a key difference in the stakeholder community. Some (primarily in industry) feel that research on the health effects of foods and food components will advance population health and nutrition. Others feel that such research is unnecessary and unhelpful compared to the more basic task of applying *existing* knowledge to improving the diet of Canadians.

As shown in the following table, the most common suggestion is that universities undertake research on health claims, but there is also a role in many minds for government, industry and non-governmental organizations, including the Canadian Institutes of Health Research. (Governments and industry are often seen primarily as funding sources.)

Table 10: In managing health claims for foods, there is a need for long-term research to substantiate potential health benefits and to identify health risks. Which organizations can help strengthen or support research in these areas?

Organization	Number Mentioning
Academics (general)	15
Canadian Institutes of Health Research	7
Industry	6
Private Consultants	4
Health Canada	3
Disease Groups	3
Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA)	2
Agriculture and Agri-Food Canada	2
MaRS Landing	2
Canadian Council of Food and Nutrition (CCFN)	2
Canadian Foundation for Dietetic Research (CFDR)	2
Other	5
Total Mentioned	**53**

The necessary research … can be undertaken by universities and research institutions, and can be encouraged by providing incentives. This will also help to build capacity in the nutrition and health sector. (Industry Association)

A great deal of research is currently underway in these areas, particularly … at the universities of Guelph, Manitoba and Saskatoon. [We] believe that Universities and the private sector are forming partnerships to perform this research and, given the current reduced scientific capacity within Health Canada, these [resources] should be used to oversee and review rather than being engaged in primary research. (Consumer Group)

Industry funding is critically important. Health Canada must be involved in changing the [negative] image of industry-sponsored research, particularly to ensure these evidence-based initiatives succeed. (Industry Association)

4.3 THEME 3: CLEAR POLICIES FOR TODAY AND TOMORROW

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

Asked to identify upcoming trends in functional foods or bioactive ingredients in coming years, stakeholders most often mention prebiotics, probiotics, fatty acids, fiber, and antioxidants, as well as a continued development of foods containing vitamins and minerals.[4]

Table 11: Expected areas of development of functional foods or bioactive ingredients

Expected Development	Number Mentioning
Functional Foods (in general)	12
Prebiotics	7
Probiotics	6
Bioactives (in general)	6
Omega Fatty Acids / EPA / DHA	11
Fiber / Soluble Fiber	6
Vitamins / Minerals / Calcium	5
Antioxidants	5
Bioflavonoids	3
Sterols	3
Lignin	2
Anti-hypertensive peptides	2
Green Tea	1
Total Mentioned	**69**

Many respondents say that there are certain bioactive components which should *not* be allowed to be added to food for general consumption. In no case, however, does a respondent specify a particular bioactive component that should always be excluded.

Industry often takes this question as an opportunity to expand on their opinion that varying claims and levels of risk should imply varying standards of evidence. In other words, they seek

[4] The question actually asked for suggestions for the next 1 to 3 years and 3 to 10 years, but respondents never made this distinction. This question was asked only in the on-line questionnaire, not during the face-to-face sessions.

to clarify and explain the basis upon which the decision to exclude a specific bioactive might be made. For others – most especially public health organizations and health professionals – this question provides an opportunity to champion the value of simple nutrition based on whole foods. They affirm that increased consumption of foods with added so-called healthy substances is of far less value from a public health point of view than creating better nutritional understanding and habits among consumers. They fear that a proliferation of health claims will serve primarily to confuse consumers and further obscure the importance of basic nutrition.

As the following table shows, most stakeholders who answered the question in their written submission agree that some types of bioactives should be excluded from foods. Large numbers chose not to directly answer this question, however, preferring to make the points discussed in the previous two paragraphs.

Table12: Are there some types of bioactive substances that should not be added to foods at any level?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	4	7	4	3	2	4	6
No	1	3	2[†]	0	0	0	0
No Answer	4	10	11	3	3	1	3
Total	9	20	17	6	5	5	9

[†] - ***Includes three positive responses imputed from the submission.***

Two responses emerge when stakeholders are asked whether manufacturers should be allowed to add a bioactive substance to a food at a level that, while safe, is too low to claim any health benefit.

One group – mainly public health and consumers - sees this addition as confusing and potentially misleading. They say that such a health claim would lead many consumers to falsely expect a benefit.

A second group - led by industry - argues that the addition of amounts of a bioactive substance below the level needed for a health effect is a valid and appropriate basis for a health claim because total dietary intake of the substance is what matters and consumers may obtain the substance from a variety of sources. Thus, a food could form one of a consumer's sources for the substance without necessarily delivering a health effect dose by itself. Indeed, they argue

that the chance of over-use of a given bioactive ingredient present in different foods is *lessened* if the amount available in these foods is below the level needed for a health effect.

Some opponents of the idea of adding amounts of bioactives below that needed for a health effect argue that a wide proliferation of this practice would challenge consumers to monitor their intake of the substance, leading to the possibility of overdose. This concern was specifically raised in the Winnipeg and Toronto sessions.

As the following table shows, many public health organizations offering an opinion oppose the idea of adding amounts of bioactives below the level needed for an effect, while the private companies and industry associations that responded tend to support it. Other groups are less cohesive on this issue.

Table13: Should the addition of bioactive ingredients be allowed in foods at levels that, while safe, are too low to claim any health benefit?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	0	7	9	1	2	1	5
No	4	3	2	2	2	2	4
No Answer	5	10	6	3	1	2	0
Total	**9**	**20**	**17**	**6**	**5**	**6**	**9**

What is the purpose to adding a bioactive ingredient to a food product at a level that is safe but too low for any health benefit? This strongly misleads the public to presume a benefit will be experienced, with an unnecessary cost. (Public Health Organization)

Some industry respondents say that upper thresholds are set on the addition of bioactives because they affect the taste or consistency of foods.

There are divergent opinions on the question of allowing bioactive substances which may pose a *risk* to specific population.

Table 14: Is there a case for adding bioactive substances to foods at levels that would benefit some, but be risky to that same group if improperly consumed, or risky to other segments of the population?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	1	5	11[†]	3	2	1	5
No	6	1	0	1	2	3	2
No Answer	2	14	5	2	1	2	2
Total	**9**	**20**	**17**	**6**	**5**	**6**	**9**

[†] - ***Includes one positive response imputed from the submission.***

Those who responded from private companies and industry associations are in favour of this idea, based on two primary justifications. First, they point to the growing importance and use of risk/benefit assessments in all areas of public health and argue that this model will handle well questions surrounding bioactives that may pose a risk to specific sub-populations. Second, they draw analogies (quite often to food allergies) to support their view that society and consumers are able to manage known risks, provided they are supported by information, labelling etc. They are supported in this view by most academics and third parties.

For other respondents – primarily among health professionals, disease groups and consumers – there can be simply no question of exposing some consumers to risk in exchange for health benefits to the wider population. This is, to some extent, an opinion based on risk/benefit analysis and the perceived health value of bioactives. If these stakeholders expected a new bioactive to prevent most cancers, for example, they would no doubt endorse its use despite some risks. Instead, the lower benefits they anticipate from bioactives (gut health, etc.) do not justify a risk to a minority of the population.

A key aspect of opposition to allowing bioactive substances which might be a risk to a subset of the population is doubt among these stakeholders that labelling could effectively protect that subset of the population from exposure.

Bioactive substances should not be added to foods unless there is sufficient research to show a health benefit without public health risk. (Industry Association)

A risk/ benefit analysis should be used to determine which bioactive substances are appropriate for human intake. The safety of these substances should be based on a number of factors, including dose, percentage of the population at risk, type and

severity of the reaction to consuming these products and history of use (including other jurisdictions). (Private Company)

Current safety assessments for foods and food ingredients (e.g., food additive applications, novel foods) is expected to cover conventional foods, fortified foods, and foods with added bioactives; the safety assessment of foods containing bioactives would not need to be different from existing safety assessments for foods and ingredients. (Academic)

Stakeholders have quite diverse views on the issue of **risk management** in the event that bioactives with potential risks are added to certain foods. Generally, most endorse the examples listed by Health Canada taken from the natural health product and pharmaceutical sectors. These included:

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

For those who support the introduction of bioactives despite potential risks to some population segments, this list is seen as largely adequate. For those who oppose this step, these measures are often seen as inadequate because they place too much onus on at-risk populations to protect themselves.

The only additional risk management approach suggested by stakeholders is to work with health care providers to ensure that they are able to counsel and caution patients appropriately.

We see value in exploring each of the above methods used by the Natural Health Product Directorate to manage risk associated with natural health products and drugs. The management technique chosen should be in line with the results of the risk/ benefit assessment. (Private Company)

Clear language is the preferred mitigation technique in this situation, but it is not a supportable position long-term to deny approval of claims that would benefit a target population because of a desire to mitigate risk to another. (Third Party Organization)

There is concern that warning labels are not adequate on their own as a mechanism for risk management, particularly for a population as diverse as [our city's]. (Public Health Organization)

These diverse quotations tend to confirm the observation, made sometimes by industry, that the public and private sectors have different priorities in the area of health claims. Public health organizations and health professionals appear to be most concerned about the possibility that health claims on foods will not help, and may well undermine, efforts to encourage Canadians to choose a healthier diet. In contrast, industry prefers to focus on the potential benefits of various nutritional improvements in the diet Canadians already eat. Industry tends to criticize government for being overly risk-oriented and risk averse while ignoring the potential health benefits of food innovations. Conversely, stakeholders outside industry tends to criticize industry for investing so much energy and emphasis on small, proprietary nutritional improvements instead of the larger dietary issues facing Canadians. Industry is faulted for being overly focused on competitive advantage and neglecting the importance of a well-informed consumer.

Health Canada should be supporting programs that encourage the intake of whole, unprocessed foods. The health claims program does not do this. (Public Health Organization)

With regard to the food/NHP interface, there is clear preference for clarification of current overlaps or ambiguities. There is no single approach supported by most stakeholders however, as some support excluding foods from the NHP regulations, while others support excluding food-like NHPs from the food regulations.

It may be appropriate to apply provisions of the existing NHP regulations to foods that could otherwise be classified as an NHP. That way, products at the food/NHP interface would all be treated in the same manner. (Private Company)

We support Health Canada's decision to exclude food-like NHPs from availing themselves of the Natural Health Product Directorate's low standards of evidence for assessing the safety and health claims for NHPs. (Consumer Group)

We recommend that food-like products should be excluded from the NHP regulations and instead be regulated as foods and subject to the same risk and safety assessments as foods. (Health Professional)

4.3.2 Managing a broader range of function claims (Theme 3.2)

There is mild support for Health Canada's proposed non-regulatory measures, especially among industry. These are listed below.

1. Clarifying the nature of acceptable function claims that would not be considered drug claims,
2. Encouraging industry to submit, voluntarily, new function claims for review by the Food Directorate, and

3. Maintaining in the *CFIA Guide to Food Labelling and Advertising*.an up-to-date list of function claims that are deemed not misleading.

Of particular value to stakeholders is the proposed list of function claims that are not considered misleading.

However, many outside industry wonder whether *voluntary* pre-market assessments of function claims are adequate or if such assessments should instead be made *mandatory*.

Respondents are generally lukewarm to mildly positive when rating the adequacy of these non-regulatory measures to manage health claims. Using a six-point scale (1 to 6), industry, third parties and health/disease organizations offer scores between 4.2 and 4.5 on average. Academics (3.3), public health organizations (2.2), and consumers (2.2) are markedly less convinced that these measures would be sufficient.

Table 15: Overall, do you feel these non-regulatory measures would be sufficient to manage an expanding range of function claims

Stakeholder Group	Mean score*	Number of responses
Public Health	2.2	5
Industry Association	4.2	13
Private Company	4.4	10
Academic	3.3	4
Health /Disease Organization / Health Professionals	4.5	4
Consumers / Private Citizens	2.2	5
Consultant / Third Party Organizations	4.4	8

A scale of 1 to 6, wherein 6 means *highly effective* and 1 means *not effective at all.

The status quo is simply unacceptable. The explosion of function claims is a direct result of the reduced requirements for their use. This will continue until the appropriate regulatory measures are implemented. The longer we wait, however, the worse the clean up job will be, the more confused and cynical consumers will become and the more damaging the situation will be to the reputation of the Federal Government. (Public Health)

We do not think mandatory pre-market review of function claims is necessary, only voluntary. (Industry Association)

We believe while these are overall great suggestions, function claims should be regulated in order to ensure proper consumer protection. As the research shows in the document, function claims may be at least as persuasive as disease risk reduction claims on consumer food choice. (Industry Association)

When asked whether Health Canada should explore a "requirement for the submission of supporting evidence when there are concerns about the credibility of a health claim being used on foods already in the marketplace", respondents are generally supportive. Most opposition to this idea comes from industry. A minority of private companies did not answer this question precisely because they feel the proposed non-regulatory measures will suffice. As the following table shows, this idea is more popular with public health organizations, academics, and health professionals.

Table 16: Please indicate whether Health Canada should explore ... requirement for the submission of supporting evidence when there are concerns about the credibility of a health claim being used on foods already in the marketplace.

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	4	9	8	5	3	6	7
No	1	6	3[†]	0	0	0	2
No Answer	4	5	6	1	2	0	0
Total	9	20	17	6	5	6	9

[†] - ***Includes one response imputed from the submission.***

Current regulatory measures are already in place to deal with misleading and false advertising (ie. FDA). We do not support new legislation. (Industry Association)

In a context where non-regulatory measures are applied to manage function claims, it will be important for HC to assess potential misleading claims on a case by case basis and ask that industry supplies supporting evidence when there are concerns about the credibility of a function claim being used on foods. (Industry Association)

Cleaning up the misleading and often confusing claims on existing food products would be a benefit. There are confusing and conflicting claims in the marketplace. This could help clarify for consumers what is an acceptable claim. (Private Company)

When asked whether pre-market assessments of function claims should be *mandatory*, the majority of industry stakeholders oppose this idea, while most public health organizations, academics, health professionals and consumers who offered an opinion support it.

Table 17: Should Health Canada require mandatory pre-market reviews of function claims?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	4	3	3	3	3	6	4
No	1	11	8	1	0	0	4
No Answer	4	5	6	1	2	0	0
Total	9	19	18	5	5	6	8

Those who support pre-market screening of claims are concerned about misleading claims (existing and future) and the potential damage to the credibility of health claims. In general, those who oppose pre-market screening are usually of the opinion that it is unnecessary and would place an unsupportable resource and time burden on both industry and Health Canada. There does appear to be common ground insofar as industry is opposed primarily to pre-market screening of simple or straightforward health claims which are already well-established and documented. They are more open to (though by no means enthusiastic about) the idea that complex or novel claims might be assessed in advance.

We believe that it is necessary to require that substantiation be presented to support a decision on the product's impact on public health and on consumers' dietary choices before a food product is put on the market. (Public Health)

This will only result in more delays and is unnecessary for low risk claims. (Private Company)

Having a product reviewed prior to going on the market will ensure consistency of messages for consumers and cut down on confusion. (Private Citizen)

In keeping with their overall position on this issue, industry stakeholders do not generally suggest any additional regulatory measures Health Canada might pursue with regard to function claims. They feel that voluntary measures are appropriate and doubt that Health Canada can provide the resources needed for more interventionist regulatory approach to health claims. Outside industry, despite higher support for mandatory measures there are also few additional suggestions and some doubt about Health Canada's ability to enforce additional regulatory requirements.

Health Canada should be more concerned with those items that are truly health threats, and let consumers make choices for themselves about what they choose to consume. (Private Company)

If Health Canada does choose to pursue regulatory measures for control of function claims, methods through which regulatory measures could be appropriately aligned or harmonized with those in peer jurisdictions should be considered. (Third Party Organization)

Health Canada should try to adopt claims from recognized authorities as soon as those bodies make their recommendations, rather than waiting for an equivalent claim to be received. (Private Company)

4.3.3 Managing diverse front-of-package claims (Theme 3.3)

In the Discussion Paper, Health Canada presented four suggestions for managing front-of-package claims. They were:

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

Presented with the foregoing list of proposed measures, there is strong agreement among private companies and academics that these measures will be *sufficient* to reduce confusion. There is less unanimity among industry associations and health organizations however. What is more, private citizens and public health organizations are largely unconvinced. A number of respondents declined to offer a definitive answer, saying they neither agree nor disagree.

Table 18: Would these measures be sufficient to reduce the confusion arising from proliferation of health-related claims on the front-of-food packages?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	0	7	10	4	2	1	5
No	7	5	0	0	1	5	2
Neither	1	0	1	1	1	0	2
No Answer	1	8	6	1	1	0	0
Total	**9**	**20**	**17**	**6**	**5**	**6**	**9**

As Table 19 shows, the question of *implied* health claims appears to divide industry, third party organizations and academics from public health organizations, health professionals, and consumers. The latter group generally applauds the idea of prohibiting the use of implied health

claims entirely (where they are not associated with an explicit claim), while industry almost unanimously opposes this idea or considers it a very low priority. Academic and third party respondents are largely split on this issue.

The primary reason advanced for banning the use of implied claims without accompanying explicit claims is that implied claims offer an opportunity to imply a health benefit without having to substantiate it, and can therefore be potentially misleading.

Industry does not generally counter this argument but instead notes that any inaccuracies in implied claims are low risk compared to inaccuracies in function and disease risk reduction claims. Industry stakeholders want to preserve the flexibility to market "healthier" products to consumers and do not believe that implied claims pose a risk to Canadians or warrant the resources needed to substantiate. They argue that current legislation already outlaws misleading labelling. They further suggest that Health Canada should focus on regulatory areas where they believe more significant risks and concerns exist.

One challenge noted by industry is the difficulty of identifying when a particular marketing campaign or label constitutes an implied health claim. Bearing a slogan or name which says "Healthy Choice" or "Heart Healthy" is clear enough, but what about a heart logo or a picture of a physician or even a person exercising? These things may be taken as an implied health claim, creating very complex and subjective regulatory situation.

Table 19: Prohibiting implied claims of a health benefit, unless the health effect is clearly stated, could also reduce consumer confusion. How worthwhile would it be to explore this measure, using a 1 to 6 rating, with 6 being highly worthwhile and 1 being not worthwhile at all?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
1 (Not at all)	0	3	6†	0	0	0	0
2	0	2	2†	0	0	0	2
3	0	4	0	2	0	0	2
4	0	0	1	0	0	0	0
5	0	2	2	0	1	0	2
6 (Highly)	4	3†	1	3	4†	6	3
No Answer	4	6	5	1	0	0	0
Average*	6.0	3.3	2.5	4.8	5.8	6.0	4.4
Total	**5**	**14**	**12**	**5**	**5**	**6**	**9**

***A scale of 1 to 6, wherein 6 means highly worthwhile and 1 means not worthwhile at all.**
† Includes one response imputed from survey comments

No symbols or claims should be allowed outside official government regulated factual indicators. (Private Citizen)

The Food and Drugs Act and Regulations already provide the legislative and regulatory authority for compliance monitoring and enforcement intervention. No prohibitions are warranted. (Industry Association)

It would be difficult to draw the line between what is considered an implied health claim and what isn't, especially when it comes to product names and slogans. (Industry Association)

It does not make sense to approve implied health claims if we are concerned about the public's safety and preventing the public from being fooled or gullible. Evidence should always be required to supersede any implied health claims. If evidence does not exist then the implied claim should be prohibited. (Consumer Group)

4.3.4 Eligibility criteria for foods to carry claims (Theme 3.4)

Stakeholders are evidently divided about the idea of setting core nutritional criteria for any food on which a manufacturer wishes to make a health claim. There are three basic positions which emerge.

One view is that health claims should be denied to products which cannot satisfy core nutritional criteria. The motivation for this is primarily the fear that foods with very weak nutritional profiles will be able to adopt the mantle of "healthfulness' through the addition of a single healthy ingredient. The example frequently raised in the face-to-face sessions was that of potato chips or soft drinks which might be augmented with vitamins, minerals or bioactives and marketed as healthy choices. In other words, proponents of core nutritional criteria are typically hoping to use these criteria to foil what they consider to be the misuse of health claims to redeem and market less healthy alternatives.

A second group – primarily in industry - which opposes core nutritional criteria is not usually thinking of health claims being used for low nutrition foods. Instead, they worry that 'regular' foods might fail to meet core nutritional criteria by their nature. Apples, for example, might fail a requirement for protein while cheese might fail based on fat content. These respondents point to the time-tested recommendation for a balanced diet and note that no one food is expected to provide all needed nutrients in a balanced form. They suggest that the core nutritional criteria requirement would directly contradict Canada's Food Guide.

A third group - very much the minority - suggests that it would be beneficial to allow health claims even on very low nutrition foods if this encouraged the manufacturers to enhance their products. The argument they make is that many people consume these products and this is

unlikely to change quickly. Therefore, these products may be good delivery vehicles for nutrients, especially those known to be deficient in a typical Canadian diet.

As noted above, industry is often doubtful of the concepts underlying core nutritional criteria:

> *[We] believe that it may be difficult to establish core nutritional criteria that would be appropriate to all foods as well as health and nutritional needs of all age groups and life-cycles and [we are] worried that certain highly nutrient-dense foods important in the diet of Canadians may be put at a disadvantage. (Industry Association)*

> *Core nutritional criteria are highly challenging to implement and may prevent the delivery of desirable bioactives to consumers through popularly consumed foods. For example, the physico-chemical nature of some valuable bioactives may require lipophilic food matrices to ensure effective delivery. If core nutritional criteria forbid fortification of foods high in fats, this could block availability to the consumer. (Private Company)*

> *All food carrying a health claim or symbol must be required to meet standardized nutrition criteria. It is deceptive and misleading of food companies to place "wellness symbols" on their foods implying healthfulness, when they may have many negative attributes which do not make them a healthy choice. (Public Health Organization)*

4.3.4.(a) Approaches to Core Nutritional Criteria

In the on-line questionnaire, respondents were asked to rate whether three specific approaches to front-of-package health claims are worthwhile, using as scale of 1 (not at all worthwhile) to 6 (highly worthwhile). They were:

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

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

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

The following table provides the responses of each stakeholder group to each of these three ideas.

Table 20: Are Health Canada's proposals for the establishment of core nutritional criteria worthwhile*?

Stakeholder Group		Voluntary		Mandatory 1		Mandatory 2	
	N	Rating	# Responding	Rating	# Responding	Rating	# Responding
Public Health	9	2.9	7	1.1	7	5.4	7
Industry Association**	20	2.8	11	3.4	7	4.6	7
Private Company**	17	1.9	12	1.6	11	1.9	10
Academic	6	2.0	4	5.7	3	6.0	4
Health /Disease Organization / Health Professionals	5	2.8	4	2.8	5	4.8	5
Consumers / Private Citizens	6	1.5	4	2.8	5	4.3	6
Consultants / Third Party Organizations	9	4.0	8	2.5	8	4.4	8

A scale of 1 to 6, wherein 6 means *highly worthwhile* and 1 means *not worthwhile at all.

****Note that large numbers of private companies and industry associations did not explicitly rate these proposals, generally because they oppose the overall idea of core nutritional criteria.**

It is immediately apparent that the second mandatory option – that all foods must meet core criteria in order to be eligible to carry a claim – is the most positively received of the three options tested. However, this is limited to non-industry participants. The industry and industry association results for all options are somewhat misleading, as most elected not to answer the question. This was often because they had already rejected the idea of core nutritional criteria in the previous questions and felt that answering this question would be redundant.

Outside industry, these responses are driven by the belief that a voluntary system would not work and that the Mandatory 1 option would merely lead to excessively complex labels and more consumer confusion.

It should also be noted that a number of stakeholders, who otherwise provided detailed and thorough comments on other questions, declined to respond substantively on the subject of core nutritional criteria as they felt they lacked necessary information. They sometimes suggested that a separate consultation would be required on this issue, supported by a clearer sense of what core nutritional criteria might actually include.

4.3.4.(b) Further detail - Voluntary

A system of voluntary compliance is generally poorly received as noted earlier. While respondents in Toronto and Edmonton were critical of this idea, expecting non-compliance, participants in Winnipeg were more optimistic about its value.

We do not feel this should be voluntary, as the amount of participation may be minimal. (Industry Association)

In general, voluntary systems are not effective and they are confusing for consumers. (Disease Organization)

This does not help us address the challenges we currently face. What happens if a company refuses to compare their product against the set of criteria? (Public Health Organization)

The suggestion that this is voluntary seems awkward. If a set of criteria are required to make a claim, then these should be clear to the manufacturer and they should be required to comply with this. However, if a health claim is supported by evidence and is not misleading, this should be sufficient to make the claim without other nutritional criteria. (Private Company)

4.3.4.(c) Further detail - Mandatory Option 1

The first mandatory concept – that products with claims but not meeting standard nutrition criteria be required to disclose that fact – is widely considered a complex and ineffective solution.

This strategy is not worthwhile. Fruits and vegetables only contain some nutrients that are part of the core nutrients needed, but they are not labeled as failing to meet say for example, the protein requirement. (Private Company)

If a product does not meet standardized nutritional criteria then they should not be permitted to make a health or function claim. (Private Company)

This is redundant information. The nutrition facts table highlights the product's nutritional strengths and weaknesses. (Private Company)

[We do] not recommend the use of a mandatory system (option 1).... Such a system would present consumers with conflicting information that would be difficult to understand. (Disease Organization)

4.3.4.(d) Further detail - Mandatory Option 2

The second mandatory option – that foods carrying a health-related claim or symbol *must* meet standardized nutritional criteria - is favoured overall because it provides greatest clarity to consumers in labelling and provides consistent treatment for all products. That said, industry is still divided on the overall idea of core nutritional criteria.

> *It should be mandatory and enforced that all food companies wishing to carry a claim meet a certain criteria. This would also make it easier to explain and be displayed to consumers and allow for less confusion. (Disease Organization)*

> *We believe this type of system would result in misleading claims. Only permitting claims on foods that meet one set of criteria reinforces the myth that only these foods can be part of a healthy diet regardless of their place within the total diet. (Disease Organization)*

> *A mandatory approach would ensure that products with poor nutritional quality (e.g. high fat, high sodium, low vitamins/minerals/fiber) cannot make health claims. This is reasonable ... (Private Company)*

4.3.4.(e) Application of core nutritional requirements:

The on-line questionnaire asked respondents to specify which types of claims should be subject to each of the three systems discussed earlier. The options for each system were that it should apply to all claims, disease risk reduction claims, function claims, or other health-related claims or symbols.

Response to the three potential systems (Voluntary, Mandatory Option 1 and Mandatory Option 2) was so diverse that the results regarding scope are quite scattered. For example, where stakeholders supported a particular option, they generally wanted it applied to all health claims. Where they did not support an option, they would understandably leave this question blank or specify that it should apply to no types of health claim.

4.3.4.(f) Core nutritional requirements: Implementation

Most stakeholders are not ready to engage on the question of implementing core nutritional requirements. When asked how this might be done effectively, they offer one of three answers. Most offer no suggestions, usually because they have already expressed discomfort with the entire approach. A smaller group emphasizes the importance of beginning consultations with stakeholders about the criteria system and its implementation. A final group – no more than a handful – offer specific suggestions for implementation including streamlined applications and

consumer education. This latter group notwithstanding, it is clear that stakeholders are not yet willing and/or ready to engage on the implementation of core nutritional requirements.

Asked to suggest which organizations could play a role in implementation, few volunteered to comment. Those who do comment stress that implementation is the responsibility of Health Canada and, secondarily, the Canadian Food Inspection Agency.

4.4 THEME 4: SUPPORTING INFORMED CONSUMER CHOICE

4.4.1 Improving consumer understanding of health claims (Theme 4.1)[5]

Advice from stakeholders for communicating information to consumers tends to revolve around two general goals.

First, almost all respondents call for simple, clear language which is easily understood by consumers. Accessibility will require communicating with consumers in their own language and through channels they use.

Second, all respondents want communication which enhances rather than undermines faith in the Canadian regulatory system. This is why they generally reject qualified health claims and disclaimers on labels and further why many oppose multiple tiers of evidence standards in the first place. Stakeholders often explicitly recognize the value and importance of consumer trust in Canadian food standards which has been built over generations.

Finally, most see a role for academia, industry and non-government organizations.

This has always been a challenge given the number of factors to consider; ability to read and comprehend, English as a second language, learning difficulties, handicapped consumers etc. (Private Company)

Having fewer health claims permitted overall would help reduce consumer confusion. As previously discussed, having one simplified standardized format would also reinforce consumer trust. (Public Health Organization)

Simple and consistent messaging and a continued focus on mandatory labelling that has been communicated to consumers consistently over the past few years is essential to consumer understanding. (Industry Association)

[5] Questions about the theme were posed only to stakeholders responding to the Discussion Paper, not to participants at the face-to-face sessions.

When the written submissions are parsed for suggestions on how to better communicate with consumers about health claims on foods, the following ideas emerge.

Table 21: Suggestions for health claim communication with consumers

Suggestion	Number Mentioning
Use very simple language (especially on labels)	14
Conduct consumer research (to determine how info is used)	12
Consumer education campaigns (brochures, signs etc.)	12
Advertising campaigns	11
Standardized (government) system	9
There is a role for industry / retailers	7
Web based information	6
Partnerships with others	4
Focus on students / schools	3
There is a role for Nutrition Facts table / Food Guide	2
No health claims allowed / This idea will not work	2
Consumers should not have to assess/understand claims	2
There is a role for health professionals and health NGOs	1
Total suggestions	**90**

The value of the Nutrition Facts table was raised especially during discussions on front-of-package labelling in Halifax and Winnipeg, and in the written submissions of several large food companies.

It is worth noting that many respondents propose consumer research as an important step, suggesting that adequate knowledge does not yet exist upon which to base these decisions.

Many members of the food industry already play an important part in nutrition and health literacy. (Private Company)

Many organizations such as nutritionists, dieticians, consumer groups and "disease" groups could be effectively involved in networks and partnerships on healthy eating literacy. Unfortunately, resources are always a problem within these groups and they would need financial support to participate effectively. (Disease Organization)

Credible third party organizations such as Dietitians of Canada, the Canadian Diabetes Association, the Heart and Stroke Foundation of Canada, the Canadian Cancer Society – all carry a mandate to educate the consumer as such –could form a valuable partnership with Health Canada to develop education tools designed to build health literacy. (Private Company)

When offered the opportunity to share additional research with Health Canada about consumer communications, few volunteered.

4.4.2 Monitoring the impact of health claims on food supply and consumer choice (Theme 4.2)[6]

With few exceptions, stakeholders appear to support the idea of post-market surveillance of the market impact of health claims. They understand this to be a scientific tool for regulators rather than a part of the regulatory process itself. In other words, monitoring might identify issues or opportunities but would not automatically trigger specific requirements or responses within the regulations.

Asked to identify organizations and networks which could play a supporting role in the monitoring of the impact of health claims on the food supply and consumer choice, stakeholders mention many of the potential partners discussed in earlier sections of this report. As the following table shows, industry takes somewhat of a secondary role in post-market monitoring compared to Health Canada, disease groups, health professionals and academics.

[6] Questions about the theme were posed only to stakeholders responding to the Discussion Paper, not to participants at the face-to-face sessions

Table 22: What organizations and networks could play a supporting role in the monitoring of the impact of health claims on the food supply and consumer choice?

Organization	Number Mentioning
Health Canada	9
Disease Groups	8
Health Professionals	7
Academics	6
Private Consultants	6
Industry	5
Agriculture and Agri-Food Canada	3
Industry Associations	3
Food and Consumer Products Canada	3
Canadian Health Food Association	2
Advanced Foods & Materials Network (AFMNET)	2
Nutri-Net	2
Canadian Institutes for Health Research	1
Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA), University of Toronto	1
MaRS Landing	1
Canadian Council of Food and Nutrition (CCFN)	1
Total Mentioned	60

A minority of respondents believe they have a role to play in monitoring the use of health claims in the food supply, albeit an indirect role. Most affirm that this is fundamentally Health Canada's responsibility.

Table 23: Do you see a role for you or your organization in the monitoring of the impact of health claims on the food supply and consumer choice?

	Public Health	Industry Assoc-iation	Private Company	Academic	Health /Disease Org. / Health Professionals	Consumers / Private Citizens	Consultant / Third Party
Yes	2	6	5	2	2	1	4
No	1	6	2	0	0	4	1
No answer	6	8	9	4	3	1	4
Total	**9**	**20**	**17**	**6**	**5**	**6**	**9**

The roles which stakeholders anticipate playing vary widely. Public health groups see

themselves in a partner role in setting policies and criteria rather than active monitoring. Industry sees itself primarily as a source of market information in support of monitoring.

I'm a consumer among consumers. That's the organization you should be putting first. (Private Citizen)

Our organization could be involved in consumer education and monitoring understanding. (Disease Organization)

[Our] industry association should take a leadership role in ensuring companies are made aware of regulations, stipulations, and providing feedback to HC on the effectiveness of its regulations. (Industry Association)

[We] would be interested in entertaining any opportunities to work with HC to support nutrition literacy and empower consumers to make informed food choices. (Private Company)

5. Additional Observations

During the consultation a number of observations emerged which were not specific to any particular question but informed discussion on all the topics presented.

- The question of health claims on food is not an issue about which *most* stakeholders have thought in depth, nor have they reached firm conclusions about the way to proceed. Throughout the discussions it was clear that many were learning aspects of the issue for the first time and just beginning to consider the implications of various approaches. The consensus was that the issue is complex and somewhat daunting. This fact has broad implications for Health Canada as it attempts to develop and refine policies in this area. Stakeholders will require a significant amount of information and explanation to understand the choices Health Canada must eventually make. This lack of certainty among stakeholders identified through the consultation translated into a wide diversity of views and little overall consensus except on very broad questions.

- There is a general desire for standardized, predictable processes and outcomes. This is seen as the only reliable manner to address a policy area where there is much complexity and diversity. However, when it comes to front-of-package labelling, industry would generally prefer to maintain the proprietary labelling systems they have invested in and which they use to differentiate their brands.

- Another observation exposes the differing priorities of industry as compared to other stakeholders. Industry often feels that Health Canada and other public stakeholders are overly focused on the risks associated with health claims and added bioactives at the

expense of seeing the potential benefit. Industry frequently references the potential *benefit* of functional foods. They perceive a desire at Health Canada and elsewhere to limit consumers' access to these foods and, consequently, the benefits they provide.

In contrast, many stakeholders outside of industry take the opposite view. They feel that industry is over-emphasizing special bioactives (such as probiotics) at the expense of promoting a healthy diet comprising primarily simple, unaltered foods. They suggest that the profit motive is driving industry toward developing and promoting proprietary nutritional benefits even though equivalent or better benefits already exist in the public domain.

Industry is more prepared to apply risk-benefit analysis to functional foods than are other stakeholders, who are likely to apply more stringent standards of evidence.

- There is considerable uncertainty and ambivalence with regard to the role that consumers should play in making wise dietary choices. Without question, all stakeholders expect consumers to play *some* role in making healthy choices for themselves and their families, but there is a simultaneous perception that it would be unwise to leave too much discretion in the hands of consumers because they lack the information, training and interest to interpret and apply health claim information. Thus, while all stakeholders support increased consumer education and understanding, there is a doubt that this can ever be adequately achieved.

- A final observation which is often raised both in person and in the written submissions is concern that Health Canada will take on more responsibility (in terms of approvals and pre-market assessments) than it has the resources to support. This is of concern especially to industry stakeholders, who already feel they wait too long to obtain guidance and decisions from Health Canada.

6. Stakeholders' assessments of the consultation

Overall stakeholders were satisfied with the consultation. Due to the different natures of the two components of the consultation, the on-line component and face-to-face sessions are discussed separately.

6.1 Assessment of face-to-face sessions

Stakeholder impressions of the face-to-face sessions were measured formally using an evaluation sheet completed at the close of each session. Of 286 participants, 186 completed evaluations. (This provides an accuracy of approximately ± 4%, 19 times out of 20 when estimating the views of all *participants*.)

In their written comments on the evaluations, participants made a number of things clear:

- The issue of health claims is extremely complicated and somewhat daunting. They acknowledge the challenge facing Health Canada on this issue. Most felt under-informed on the subject.
- They value group discussions and questions in plenary more highly than presentations of information.
- They place high importance on receiving good quality, succinct information in advance which includes clear explanatory examples.
- The table discussions are most useful when they are very focused and well-moderated.

The following table shows the numerical scores drawn from those completed evaluations, using mean scores (arithmetic averages). Each score has a possible range of 1.0 to 5.0 and the mid-point is 3.0. It is immediately apparent that scores are generally positive. Indeed, almost all scores fall between 4.0 and 4.5 indicating solidly (although not overwhelmingly) positive perceptions.

Overall satisfaction with the face-to-face sessions was 4.1 out of 5. This equates roughly to a score of 82 out of 100.

Evidently, participants were least likely to agree that “The information provided was clear and sufficient and allowed me to understand the regulation of health claims for food in Canada.” This echoes earlier suggestions (under Additional Observations) that many participants felt somewhat ill-equipped by the presentations and overwhelmed by the complexity of the subject matter. This view was strongest in Toronto and Vancouver. However, unlike Vancouver, participants in Toronto offered the lower average score of all six locations on *every* measure.

Beyond the lower scores seen in Toronto, small differences of 0.2 to 0.4 in scores between locations and questions are unlikely to indicate meaningful differences. The primary finding of the following table is that the sessions were well received in all locations and along all dimensions evaluated.

Table 24: Responses to evaluation rating scales (1 to 5)							
	Overall	Halifax	St. Hyacinthe	Toronto	Winnipeg	Edmonton	Vancouver
Number of participants	286	33	30	75	37	38	73
Number of evaluations	186	24	23	45	24	20	50
Percentage completing	65%	73%	77%	60%	65%	53%	68%
	***Agree* (5) or *Disagree* (1) with each statement?**						
	Overall	Halifax	St. Hyacinthe	Toronto	Winnipeg	Edmonton	Vancouver
The information provided was clear and sufficient and allowed me to understand the regulation of health claims for food in Canada.	3.7	3.9	4.3	3.4	3.7	3.7	3.5
The facilitation of the session was effective.	4.2	4.5	4.3	4.1	4.1	4.2	4.1
Small group discussions were useful for building awareness/understanding.	4.2	4.5	4.4	4.0	4.2	4.4	4.2
I had the chance to express my views.	4.4	4.3	4.6	4.5	4.4	4.7	4.4
I had sufficient time for discussion and to ask questions	4.4	4.5	4.4	4.1	4.4	4.6	4.4
	***Agree* (5) or *Disagree* (1) that the session achieved each objective?**						
	Overall	Halifax	St. Hyacinthe	Toronto	Winnipeg	Edmonton	Vancouver
To provide a forum for the exchange of ideas related to key aspects of the discussion paper.	4.2	4.3	4.5	4.1	4.1	4.4	4.1
To obtain stakeholder input on these issues.	4.0	4.1	4.3	4.0	3.8	4.2	4.0
To build stakeholder capacity to respond to the on-line questions about the discussion paper.	4.0	4.0	4.3	4.0	3.8	3.8	3.9
	Were the following *poor* (1) or *excellent* (5)?						
	Overall	Halifax	St. Hyacinthe	Toronto	Winnipeg	Edmonton	Vancouver
Facilities and refreshments	4.3	4.4	4.5	4.1	4.4	4.2	4.3
Overall satisfaction with the session	4.1	4.2	4.5	3.9	4.0	4.3	4.0

6.2 Assessment of the On-line Component

The on-line questionnaire did not include a formal evaluation mechanism, but respondents were asked to indicate whether the Discussion Paper and questionnaire had covered all relevant topics appropriately.

Generally, stakeholders who responded to these questions expressed satisfaction at the opportunity to provide feedback to Health Canada through the consultation process. As a general rule, it is difficult to craft a questionnaire which can adequately respond to a wide range of positions without seeming repetitive or redundant to certain points of view. Respondent comments throughout the questionnaire reflect that reality.

A minority raised specific issues, either with the themes addressed in the consultation or with regard to additional issues they believe deserve attention. There were three overall observations:

1. The issues are too complex and require expert knowledge many stakeholders may not possess.

2. Some concepts discussed in the questionnaire (such as core nutritional criteria) are difficult to assess without concrete examples to work from.

3. Two topics – core nutritional criteria and front-of-package labelling – were judged by some to be too complex and new to be included in this round of consultations.

7. Glossary of Terms

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

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

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

criteria	eligibility of a food to carry health claims. *Qualifying* nutritional criteria specify the minimum levels of certain nutrients (e.g., some vitamins and mineral nutrients) that should be met for a food to carry health claims. *Disqualifying* nutritional criteria specify maximum levels of specified nutrients (e.g., certain nutrients considered to increase the risk of some chronic diseases) that should not be exceeded for a food to carry health claims.
Terms used to describe claims:	
Health claim	A health claim for foods means any representation in food labelling and advertising that states, suggests or implies that a relationship exists between a food category, a food, or a food constituent and health. *Examples:* disease risk reduction claims, function claims and general health claims about “healthy choice.”
Disease risk reduction claim	Disease risk reduction claims correspond to health claims in the table following B.01.603 in the Canadian *Food and Drug Regulations*, previously referred to as generic or diet-related health claims. *Example:* A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer.
Function claim	Function claims include: (1) claims for energy or nutrients about their generally recognized roles as an aid in maintaining the functions of the body that are necessary to the maintenance of good health and normal growth and development, as permitted in B.01.311(3), D.01.006 and D.02.004 of the *Food and Drug Regulations* (biological role claims); (2) claims about maintaining or supporting body functions associated with the maintenance of good health or performance (other function claims);

	(3) claims about restoring, correcting or modifying body functions (drug claims). *Example of biological role claim:* Calcium aids in the formation and maintenance of bones and teeth. *Example of other function claim:* Beverage X is absorbed up to 30% faster than water. *Example of drug claim:* Product X lowers elevated blood cholesterol levels.
General health claim	General health claims are broad “healthy choice” claims that promote overall health or healthy eating, based on certain nutritional characteristics of the food, without referring to specific health effects, a specific organ, disease, biomarker or health condition. *Example:* Include low-fat product X as part of healthy eating.
Implied health claim	An implied health claim is any representation of a health claim without explicitly stating that a relationship exists between a food category, a food, or a food constituent and health. Examples of such representations include the use of a logo, symbol, name, trade mark, seal of approval, or by association (e.g., hyperlink to a website, or juxtaposition of “educational” material with advertisements for specific products having the characteristics referred to in the former). Such representation may apply to a general health claim or a specific health claim. *Example:* the use of a heart symbol to imply that the food is heart-healthy or that the food may be part of a diet to reduce the risk of heart disease.

APPENDIX 1

List of All Participants
7 Seas Fish Co.
A. Lassonde Inc
ACTI-MENU
Advertising Standards Canada
Agriculture and Agri-Food Canada
Agriculture and Agri-Food Canada - Cereal Research Centre
Agriculture and Agri-Food Canada - Market and Industry Services Branch - Operations - Atlantic Regional Office
Agriculture and Agri-Food Canada - Research Branch - Science Bureau
Agriculture and Agri-Food Canada - Research Branch - Western Region - Lacombe Research Centre
Agriculture and Agri-Food Canada - Saskatoon, SK
Agriculture and Agri-Food Council of Alberta
Agriculture and Agri-Food Canada - Research Branch - Eastern Region –Dairy and Swine Research and Development Cenrtre
Ag-West Bio Inc.
Agropur Canada
Aim Canada
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
Albion Fisheries Ltd.
Alliance pour l’innovation en agroalimentaire
Aliments Ultima Inc. (Yoplait)
Alive Magazine
Allergy Asthma Info Association
Alliance Interested Consumers
Arthur's Fresh Company
Associated Brands
Association pour les ingrédients santé en alimentation
Association québécoise des allergies alimentaires
Athabasca University
Atlantic BioVenture Centre - NSAC
Avalon Dairy Ltd.
B.C. Dairy Foundation
B.C. Ministry of Agriculture and Lands
B.C. Ministry of Environment; Oceans and Marine Fisheries Division
B.C. Ministry of Health

Baking Association of Canada
BASF
Bee Maid Honey Ltd.
Beef Information Centre/ Centre d'information sur le Boeuf
Bereskin & Parr
Best Medicines Coalition
Bioforce Canada Inc.
Bio-K + International Inc
BIOTECanada
Board of Directors of Drugless Therapy - Naturopathy
Brand Management Association, Sun Opta Grocery West
Bristol - Myers Squibb; Mead Johnson Nutritionals
Broadcast Clearance Advisory
Calgary Health Region
Calkins & Burke Ltd.
Campell Company of Canada
Can Test Ltd.
Canada Alberta Partners in Food Safety
Canadian Assoication of Naturopathic Doctors
Canadian Cancer Society - Alberta/Northwest Territories Division
Canadian Celiac Association
Canadian Celiac Association - Edmonton Chapter
Canadian Council for Food and Nutrition / PFSNRA
Canadian Council of Grocery Distributors - Atlantic Office

Canadian Council on Multicultural Health
Canadian Dental Association
Canadian Diabetes Association
Canadian Egg Marketing Agency
Canadian Fishing Company
Canadian Food Inspection Agency
Canadian Food Inspection Agency - Dairy Program
Canadian Food Inspection Agency – Regina, SK
Canadian Food Inspection Agency - Regional Food Labelling
Canadian Food Inspection Agency - Vice President, Operations - Western Area
Canadian Food Inspection Agency.V.P. Operations-Quebec Region
Canadian Health Food Association
Canadian Institute of Food Science & Technology & Ontario Home Economics Association
Canadian Liver Foundation - Manitoba Chapter
Canadian Meat Council
Canadian National Millers Association
Canadian Pork Council
Canadian Poultry and Egg Processors Council
Canadian Produce Marketing Association
Canadian Public Health Agency
Canadian Sugar Institute
Canola Council of Canada
Cantox
Capital Health - Public Health Services

Casco
Centre for Science in the Public Interest
Centre québécois d'inspection des aliments et de santé animale, Ministère de l'Agriculture des Pêcheries et de l'Alimentation
Centre québécois de valorisation des biotechnologies
CERES Consulting
Cintech agroalimentaire (Cintech-aa)
Coffee Association of Canada
Cognis Canada Corporation
College of Dietitians of Ontario
Conseil de la transformation agroalimentaire
Consumer Interest Alliance Inc
CropLife Canada
CV Technologies Inc.
Dairy Farmers of Canada
Dairy Farmers of Manitoba
Dairy Processors Association of Canada
Danisco Inc.
Delspastry
Department of Nutritional Sciences, University of Toronto
Dicentra Inc.
Dietitians of Canada
Doctor
Enviro-Health Research Labs Inc.

Extenso
Faculty of Medicine, Department of Paediatrics, B.C. Children’s and Women’s Hospital
Flax Council of Canada
Fleishman-Hillard Canada
Flora Manufacturing and Distributing Ltd.
Food & Consumer Products of Canada
Food Development Centre
Food Trust of Prince Edward Island
Fraser Health Authority
Gary Lea Foods
General Mills
GFR Pharma
Globaltox International Consultants Inc.
Grocery Distributors of Canada
GTC Nutrition
Guelph Food Technology Centre
Hain Celestial Canada
Happy Plant Foods
Hayes & Associates
Health Action Network Society
Health Canada - Health Products and Food
Health Canada - Healthy Environment and Consumer Safety
Health Canada - Western Regional Laboratoryt
Health Check BC Dining Program of Heart and Stroke Foundation

Heart and Stroke Foundation of Canada
Heart and Stroke Foundation of Manitoba
Heart and Stroke Foundation of Nova Scotia
Heart and Stroke Foundation of Ontario
Honeybee Centre
Institut national de santé publique du Québec
International Chewing Gum association
International Food Focus
IRI Seperation Technologies Inc.
Karen Friedman K. Friendman Consulting
Kellogg
Kraft Canada Inc.
L/H. Gray & Son
Leading Brands
Lilydale Foods
Lions Gate Fisheries
Loblaws
M-13 Ventures Ltd.
Manitoba Agriculture, Food and Rural Initiatives
Manitoba Agri-Health Research Network
Manitoba Association of Home Economists
Manitoba Health
Manitoba Health and Healthy Living
Maple Leaf Foods

Mars canada
MARS Landing
McCain Foods Limited
McCarthy Consultant
McNeil Consumer Healthcare
Mead Johnson Nutritionals
Member of public/academia
Memorial University of Newfoundland - Faculty of Science - Department of Biochemistry
Meyers Norris Penny for the Alberta Barley Commission
Minnewashta Valley Organics Canada Ltd.
National Research Council Canada - Industrial Research Assistance Program - Atlantic-Nunavut Region
National Research Council Canada - Institute for Marine Biosciences – Halifax
National Seafood Sector Council
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
Naturally Nova Scotia Health Products Ltd.
NDMAC
Nestle
Nestlé Nutrition Canada and Nestlé Canada Inc.
Newfoundland and Labrador Women's Institute
Newfoundland Aquaculture Industry Association
NHP Consulting Inc.

Natural Health Products Protection Association (NHPPA)
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
Nutridata Consulting Services
Nutritech Consulting
Nutrition Resource Centre
Ocean Nutrition Canada
Office of Nutrition Policy and Promotion
Olympic Dairy Products Inc.
Ontario Ministry of Agriculture, Food & Rural Affairs (OMAFRA)
Ontario Greenhouse Vegetable Growers
Ontario Independent Meat Processors
Oppenheimer Group
Option consommateurs
Ordre professionel des diététistes du Quebec
Ormsbee and Associates
Ottawa Public Health
Packaging Association of Canada
PBR Laboratories Inc.
Peel Region - Chronic Disease and Injury Prevention Division
Peel Region - Health Systems
Pepsi QTG
Produce Smart

Province of Manitoba - Department of Science Technology, Energy and Mines
Pulse Canada
Puresource Inc.
Purify Life Health Products
Quadra
Quadra Chemical
Quality Medical Regulations Services
Refreshments Canada
Regina Qu'Appelle Health Region
Region of Peel - Public Health
Rivi’s Guilt Free Cookie
RLS Consulting Ltd.
Santé Naturelle (A.G.) Ltee.
Saputo Foods Ltd.
Shafer-Haggart Ltd.
Simon Fraser University
Sobeys Inc.
Source Nutraceuticals Inc.
Source! Nutrition
Soyaworld Inc.
Strauss Enterprises Ltd.
Student
Tea Association of Canada
Tempo Canada Inc.

Toronto Public Health
Unilever
Union des consommateurs
University of Alberta - Faculty of Agriculture, Forestry and Home Economics - Department of Agricultural Food and Nutritional Science
University of Guelph
University of Manitoba - Centre for Functional Foods and Nutraceuticals
University of Manitoba - Department of Human Nutritional Sciences
University of Montreal, Faculty of medicine, Dept. of nutrition
University of Ottawa
University of Toronto
University of Western Ontario
Vancouver Chinatown Merchants Association
Vancouver Coastal Health
Vegetable Oil Industry of Canada
Viva Pharmaceutical Inc.
Weiler Nutrition Communications Inc.
Wellgenex Sciences Inc.
Western Canadian Functional Food & Natural Health Product Network (WCFN)
Wild Rose Agriculture Producers

Note: Additional 15 individuals and 1 organization did not want to be named but did participate in these consultations

Appendix 2

Voluntary Statement of Information – Summary

Public involvement activity: Consultation on Health Claims on Food

Date and location: Regional workshops and online input, Nov 2007 to April 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 358 participants, 31 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: No

Organization name or Individual: Nutrition Team , Physical activity and weight problems, 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, Agicultural 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 agrifoods , 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, industriy

Mandate: L'APIA encourages the Quebec Agri-food industry to make optimal use of all its innovative, scientific, technological 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

ONLINE: November 2007 to April 2008

Katharina Kovacs Burns
Registered lobbyist: No
Organization name or Individual: Best Medicines Coalition
Scope, type or sector: National coalition of patient organizations
Mandate: promoting education, care, research and consumer-focused advocacy on issues related to drug review reform, drug acces and health
Funding guidelines: Yes
Direct financial interests: No
Indirect financial interests: Yes – PHAC/HC
Intellectual interests: Yes – Standing Committee on Health and Health Canada
Participation in other HC activities: No grants or contributions this year, but participation in other consultations

Corby, Lynda
Registered lobbyist: No
Organization name or Individual: Dietitians of Canada
Scope, type or sector: National association of health professionals
Mandate: Nation-wide voice of dietitians, advancing health through nutrition
Funding guidelines: Yes
Direct financial interests: No
Indirect financial interests: No
Intellectual interests: Yes – HC/CFIA
Participation in other HC activities: Yes – PHAC grants

Skinner, David
Registered lobbyist: Yes
Organization name or Individual: NDMAC
Scope, type or sector: National association, industry
Mandate: To advance Canadian self-care
Funding guidelines: No
Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Yes – to industry

Participation in other HC activities: No grants – yes participation at HC consultations

Mackey, Mary Alton

Registered lobbyist: No

Organization name or Individual: Individual

Scope, type or sector: Health Professional

Mandate: NA

Funding guidelines: NA

Direct financial interests: No

Indirect financial interests: No

Intellectual interests: Affiliation with Canadian Dietetic Association and Consumer Interest Alliance

Participation in other HC activities: Yes, participated in Bill C-51 consultations with Dieticians of Canada

Brown, Christina

Registered lobbyist: No

Organization name or Individual: Individual

Scope, type or sector: Volunteer

Mandate: NA

Funding guidelines: NA

Direct financial interests: DNC

Indirect financial interests: No

Intellectual interests: Yes, provision of advice (unpaid) to Dieticians of Canada and Beef Information Centre

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 bones and teeth"* may be used for foods providing a	• 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
minimum of 5% of the Recommended Daily Intake of the nutrient per serving of stated size and reference amount of the food.	
General health claims: • 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 required • CFIA 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)