Agriculture and Agri-Food Canada | Agriculture et Agroalimentaire Canada



March 2010

Function Claims and Probiotic Claims for Food

Questions and Answers

The January 2010 webcast *Health Claims in Canada: An Update on Function Claims and Probiotic Claims for Food*[1] organized by Agriculture and Agri-Food Canada (Food Value Chain Bureau) provided participants with an opportunity to gain a thorough understanding of the new guidance on function claims and probiotic claims for food. Health Canada (Food Directorate) presented the policy background and future directions for managing health claims, as well as details on the requirements for scientific evidence to validate claims. The Canadian Food Inspection Agency (Food Safety and Consumer Protection Directorate) described the enforcement approach related to these claims in the marketplace.

A Question-and-Answer session followed the presentations. The questions included in this report are based on issues raised during the webcast. The answers have been reviewed by Health Canada and the Canadian Food Inspection Agency.

In this report:

[1] See the “Events” section at www.agr.gc.ca/food-regulatory-issues.

Canada

General Questions on Health Claims

- What opportunities for input to the policy development process have stakeholders had?
- How consistent is the overall health claims approach with those of Canada's major trading partners?
- How do the various government departments collaborate in the development and enforcement of health claims policy?
- Are products imported from other countries required to go through the same processes with respect to health claims? If so, how are these products monitored?
- How does the CFIA review products on the market for violations related to health or nutrition claims?
- The criteria for determining whether a health claim is "misleading" appear subjective and open to interpretation. How can industry improve the likelihood of compliance?
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- Why would "helps build antibodies" be acceptable whereas "helps prevent infection" would not?
- Can we expect Canada to take similar action as the United States to curb the use of ambiguous "healthy choices" claims on food products?
- Where can we obtain further information about health claims, especially function claims and probiotic claims?

Q. What opportunities for input to the policy development process have stakeholders had?

A. In early 2008, the Food Directorate of Health Canada undertook consultations to solicit stakeholders' opinions on policy preferences in the area of health claims for food. The process was initiated by online publication in November 2007 of an extensive discussion paper entitled *Managing Health Claims for Foods in Canada: Towards a Modernized Framework*. The consultation process consisted of two primary components:

- Face-to-face sessions were held with 286 stakeholders in six cities across Canada. Invitation lists for the sessions had been drawn from existing Health Canada databases of stakeholders in each city, in consultation with Health Canada representatives in each region. Participants included representatives of the health, consumer, academic and industry sectors to ensure an appropriate mix representing different points of view.
- Written feedback was obtained using an online questionnaire. Responses had been directly solicited from a wide range of stakeholders, and comments were accepted from any member of the public. The breakdown of the 72 responses received is as follows: industry association (20); private company (17); public health organization (9); consultant or third party organization (9); academic (6); consumer group or private citizen (6); health/disease organization or health professional (5).

The *Report on Stakeholder Feedback on Modernizing Canada's Framework for Health Claims on Food* and the *Report of Regional Workshops on Modernizing Canada's Framework for Health Claims on Food* provide a summary and analysis of the stakeholder opinions received by Health Canada through this process.

Q. How consistent is the overall health claims approach with those of Canada's major trading partners?

A. For a comparison of the mechanisms for review and approval of health claims between Canada and other major jurisdictions, as well as the standards of evidence for health claim reviews, please refer to the discussion paper *Managing Health Claims for Foods in Canada: Towards a Modernized Framework*. In general, the different jurisdictions tend to assess the evidence supporting health claims in a similar manner. However, the umbrella legislative and regulatory frameworks in place in different jurisdictions limit in part the extent to which consistency in the health claim approach for foods can be achieved.

Q. How do the various government departments collaborate in the development and enforcement of health claims policy?

A. Health Canada, the Canadian Food Inspection Agency and Agriculture and Agri-Food Canada have complementary roles in this area:

- Health Canada's Food Directorate is responsible for the development of policies, regulations and standards that relate to the health and nutritional aspects of foods governed under the *Food and Drugs Act*, including the use of health claims. The Health Canada website is evolving to make the information on the acceptable use of health claims for foods, including guidance documents, more accessible. Health Canada is also responsible for assessing the validity of health claims as specified in its policies.
- The Canadian Food Inspection Agency (CFIA) enforces the policies, regulations and standards established by Health Canada as they relate to food safety and nutritional quality. CFIA maintains the *Guide to Food Labelling and Advertising*, a tool to help industry, consumers and CFIA inspectors interpret food policies and regulations.
- Recently, Agriculture and Agri-Food Canada (AAFC), through the Growing Forward policy framework, has acquired the mandate to provide information and guidance to industry groups, to help them set priorities with respect to health claims and better understand regulatory processes and requirements. The hosting of webcasts related to health claims is an example of AAFC action in this area. More information on other endeavours can be found on the AAFC

website under the Health Claims, Novel Foods, and Ingredients initiative of the Growing Forward Agricultural Regulatory Action Plan.

The three departments communicate regularly to ensure that the policies are developed in a way that stakeholders can better understand and CFIA can enforce.

Q. Are products imported from other countries required to go through the same processes with respect to health claims? If so, how are these products monitored?

A. The *Food and Drugs Act* and its Regulations apply equally to products produced domestically as well as those imported from other countries to be sold in Canada. CFIA's inspection and enforcement approach is also the same for any product for sale in Canada, evaluated case by case and based on risk. Furthermore, any product for sale in Canada, whether imported or domestic, is subject to inspection at any time.

Q. How does the CFIA review products on the market for violations related to health or nutrition claims?

A. The Canadian Food Inspection Agency's enforcement activities are risk based. CFIA's inspectors monitor the marketplace regularly for violations; in addition, sometimes products are brought to CFIA's attention. Risk assessments are conducted case by case based on clear guidelines and questions used by the inspectors (e.g. assessing whether the claim could lead to multiple interpretations, or whether the claim reflects a substantiated health outcome). CFIA works closely with Health Canada to determine whether a health claim in the marketplace is scientifically substantiated. For example, if a function claim has not been approved or posted in the CFIA *Guide to Food Labelling and Advertising*, CFIA inspectors will ask for the evidence and it will be evaluated by Health Canada.

Note that not all health claims require pre-market approval from Health Canada. Anyone having a concern about a potentially misleading health claim on food product labels or in advertising can contact CFIA.

Enforcement measures vary based on potential harm from the violation, the company's compliance history and whether due diligence has been followed. Industry is expected to obtain the scientific data to substantiate the claim **before** using it, and to provide evidence to the inspector upon request that the amount of the substance in the product is sufficient to produce the claimed effect.

In general, when a product is found to be non-compliant with policy or regulations, industry is expected to develop and implement an action plan to correct any non-compliance in a sufficiently short timeframe to avoid harm to consumers. Such a plan should be based on reasonable timeframes consistent with other similar violations. Enforcement measures may include information letters, letters of non-compliance, seizure/detention and prosecution, and may increase in severity with each offense.

Q. The criteria for determining whether a claim is "misleading" appear subjective and open to interpretation. How can industry improve the likelihood of compliance?

A. The following principles will promote the use of health claims that are less likely to be misleading or misunderstood:

- The claim should be meaningful. For example, claims that are too vague in nature may be misleading and may not provide clear and meaningful information to the consumer.
- The health claim should be based on science and supported by adequate scientific evidence.
- It should be feasible to consume the effective amount of the food or the food constituent that is the subject of the claim in the context of a healthy, balanced diet.

- When a claim is made about disease risk reduction, the food carrying the claim should contribute to a dietary pattern associated with the claimed benefit.
- When a function claim is made about the benefit of a nutrient, the food carrying the claim should be at least a dietary "source" of the nutrient.
- Some food constituents do not have established recommended daily intakes (RDIs) and therefore "source" levels of these substances have not been set. Where these are the subject of a health claim, the amount of the food constituent in a serving of stated size of the food should be shown in conjunction with the claim. The amount of the food constituent required to achieve the claimed effect or benefit should also be shown.

Applying these principles and conditions increases the likelihood of developing a claim that is truthful and not misleading under subsection 5(1) of the *Food and Drugs Act*.

Q. How can people find out about new health claims that have been approved? Is there an email notification service?

A. Once a health claim has been reviewed and approved by Health Canada, the basis of the decision and any conditions for its use will be published on the Health Canada website. The list of approved health claims will be kept up to date regularly in the CFIA *Guide to Food Labelling and Advertising* or through a link to the Health Canada website. In the case of health claims requiring regulatory amendments, the approved claims and their conditions of use will also be published in the table following section B.01.603 of the Food and Drug Regulations.

Both Health Canada and the CFIA have email notification services to which people can subscribe:

- Health Canada's NUTSCI (nutritional sciences) email list
- CFIA's email notification services for food (choose 'Labelling Updates')

Q. Does CFIA's enforcement activity with respect to health claims extend to restaurants (e.g. fast food and beverage outlets) and point-of-purchase displays?

A. The *Food and Drugs Act* and its Regulations apply to all food products and to all food advertising (magazines, websites, advertising flyers, shelf talkers, advertisements and pamphlets displayed in all public spaces, radio and television).

When restaurants make health claims about their foods, they must provide the required accompanying information for comparative claims and a quantitative declaration of the energy or nutrient value that is the subject of the claim. The enforcement approach taken by the CFIA for restaurants and point-of-purchase displays that make a health claim is the same as for a prepackaged food. Further information is available in the *Guide to Food Labelling and Advertising*.

Q. Will Health Canada share the research results on how consumers interpret health claim statements on food?

A. Health Canada recognizes that it is a challenge to accurately translate complex science-based messages into short and appealing claims that are meaningful and easy to understand. To this end, Health Canada undertook consumer research in August 2009 to identify some parameters that could be used to improve the wording of certain claims that must be authorized by regulatory amendment. The results of the consumer research are available in the report *Consumer Understanding of Health Claims — Qualitative Research*.

The goal is to improve consumers' understanding of, and increase their confidence in, these health claims. Based on the findings, the department is developing claim wording that may be used on food labels and in advertising to convey health effects or benefits of food components that are supported by scientific evidence.

Q. What processes are being considered for expediting the approval process for claims that require pre-market authorization?

A. Health Canada is committed to improving the transparency and efficiency of regulatory processes. Process maps of the approval process for health claims will be posted shortly on the Health Canada website.

Before such claims are permitted on foods marketed in Canada, a two-part approval process must be undertaken: review and approval of the scientific basis of the claim by Health Canada followed by publication of the decision on Health Canada's website. In cases where warranted, regulatory amendment will be initiated for publication of final regulations in *Canada Gazette* Part II; the process may also include posting in *Canada Gazette* Part I for a comment period. The Food Directorate is consulting with Legal Services of Health Canada to investigate possibilities for greater regulatory flexibility through delegation of authority to Health Canada for the authorization of claims for foods. Health Canada is also exploring ways to make the regulatory process more efficient through simplification of *Canada Gazette* requirements.

Another option being developed is an abbreviated health claims review process based on authoritative statements.

Q. Is there a grace period for compliance with new guidelines?

A. Manufacturers are expected to comply immediately with new regulations and new guidelines published by Health Canada, unless a transition period has been specified by Health Canada or CFIA. The CFIA *Guide to Food Labelling and Advertising*, which has recently been updated with respect to health claims, is a tool to assist industry with compliance and with the application of guidance documents, and to help inspectors and consumers understand the regulations or guidelines as written by Health Canada.

In the case of probiotics, in recognition of the challenges involved, a specific grace period was allowed. Health Canada released its guidance document on *The Use of Probiotic Microorganisms in Food* in April 2009. CFIA published a Letter to Industry on October 1, 2009, indicating that compliance would be expected within 6 months. Thus, manufacturers using strain-specific probiotic claims are now expected to have data to substantiate such claims.

CFIA enforces new regulations and guidelines in a strong but gradual way. The specific approach taken depends on the potential harm as well as the manufacturer's due diligence and will to comply.

Q. Why would "probiotic that contributes to healthy gut flora" be an acceptable claim whereas "[naming a substance] contributes to healthy cholesterol" is not at present?

A. A limited number of non-strain-specific claims about the nature of probiotics (such as "probiotic that contributes to healthy gut flora") have been accepted for use on food. These claims refer to the fact that certain probiotics naturally form part of the gut flora. These claims do **not** refer to health effects or benefits of probiotics. The acceptance of these non-strain-specific claims is useful as a transition to allow products to remain in the marketplace while manufacturers have the opportunity to develop the evidence for strain-specific claims.

In contrast, a claim about a substance that has a health effect or benefit should communicate the health outcome that is substantiated by evidence. If a claim such as "[naming the substance] contributes to healthy cholesterol" is based on studies that show a cholesterol lowering effect in individuals with high blood cholesterol, the claim would be potentially misleading when it is made on a food directed to the general population without being clear about who would benefit from consuming the product.

Q. Why would “helps build antibodies” be acceptable whereas “helps prevent infection” would not?

A. The acceptability of a claim depends on the evidence available. The claim “helps build antibodies” is a permitted nutrient function claim for protein as this function has been clearly established for protein as a normal physiological process essential for the maintenance of good health. Provisions for such nutrient function claims exist in the Food and Drug Regulations. However, requirements for stated or implied claims indicating that protein prevents infection or other specific illness or disease include pre-market assessment of evidence followed by regulatory amendment.

Q. Can we expect Canada to take similar action as the United States to curb the use of ambiguous "healthy choices" claims on food products?

A. Health Canada recognizes the plethora of claims, logos and symbols that depict healthy choices on foods in the marketplace. However, stakeholders’ points of view on common criteria are divergent, and obtaining consensus will be a challenge. To advance the process, Health Canada has undertaken an environmental scan of the use of nutrition criteria in programs and policies such as those governing the use of front-of-package symbols at the national and international level. The scan examines the different types of criteria, challenges encountered in their development and the potential implications for population health. The analysis is nearly complete and a summary will be available on Health Canada’s website. Following this review, Health Canada will define a course of action, which is likely to include a targeted consultation with stakeholders.

Q. Where can we obtain further information about health claims, especially function claims and probiotic claims?

A. Health Canada has recently developed a new health claims web page, which includes convenient links to relevant guidance documents, Q&As, etc. (www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/index-eng.php).

Questions may be directed to:

Nutrition Labelling and Claims Section
Food Directorate, Health Products and Food Branch, Health Canada
251 Sir Frederick Banting Driveway
Postal Locator: 2202E
Ottawa, Ontario K1A 0K9
healthclaims-allegationssante@hc-sc.gc.ca

Questions Specific to Probiotics

- What is the basis for the Canadian definition of probiotics?
- Does the *Guidance Document for Preparing a Submission for Food Health Claims* apply to probiotics?
- Does the statement "with active bacterial cultures" imply a probiotic health claim?
- What is the deadline to comply with the requirements for probiotic health claims?
- Is the strain (American Type Culture Collection - ATCC) number required on the label or is it sufficient to cite the strain name only?
- What quantity of live culture is required in a serving size? How should deterioration over the shelf life of the product be addressed?
- How should a mixed culture of probiotics be declared quantitatively on the label?
- Are products with a long shelf life, such as breakfast cereals, required to have a sustained probiotic content at the end of the 'best before' date?
- What was the basis used for approval of general (non-strain-specific) probiotic claims?
- Does a claim for non-strain-specific probiotics have to use the exact wording as it appears in the guidance?
- Was the wording "gut flora", which appears in the acceptable non-strain-specific probiotic claims, tested in consumer focus groups?
- If a probiotic claim has been rejected previously by the European Food Safety Authority (EFSA), will this have a negative impact on new submissions for strain-specific health claims in Canada?
- What is the expected timeline for development of guidelines for pre<u></u>biotics?

Q. What is the basis for the Canadian definition of probiotics?

A. Health Canada uses an internationally accepted definition of probiotics. In the context of foods, the Expert Consultation (2001) conducted by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) defined probiotics as: "Live microorganisms which when consumed in adequate amounts as part of food confer a health benefit on the host".[2]

Q. Does the *Guidance Document for Preparing a Submission for Food Health Claims* apply to probiotics?

A. The *Guidance Document for Preparing a Submission for Food Health Claims* provides guidance for identifying and evaluating the available evidence and the validity of claims. In the case of probiotics, it should be consulted together with the *Guidance Document – The Use of Probiotic Microorganisms in Food*, which sets out the specific conditions under which health claims about probiotics would be considered acceptable.

Q. Does the statement "with active bacterial cultures" imply a probiotic health claim?

A. The interpretation would depend on the product and on other information present on the label. For a fermented product in which active microorganisms are usually used, where there is no other indication on the label that the manufacturer is trying to convey a health benefit, this would be an acceptable description of the product and not an implied health claim.

On the other hand, if the statement appears on the label of a product where there is no rationale for microorganisms being present, then a statement about active bacterial cultures would be referring to a benefit of some kind and could imply a health claim.

Q. What is the deadline to comply with the requirements for probiotic health claims?

A. Generally, industry is expected to comply with new policy immediately, unless a transition period has been specified by Health Canada or CFIA. In the case of probiotics, a specific grace period was allowed in recognition of the challenges involved. Health Canada released its guidance document on *The Use of Probiotic Microorganisms in Food* in April 2009. CFIA published a Letter to Industry on October 1, 2009, indicating that compliance would be expected within 6 months. Thus, manufacturers using strain-specific probiotic claims are now expected to have data to substantiate such claims.

Q. Is the strain (American Type Culture Collection – ATCC) number required on the label or is it sufficient to cite the strain name only?

A. To adequately identify the strain, any probiotic claim should be accompanied by the Latin name of the microorganism (i.e. genus and species), along with the identity of the strain of the microorganism, using acceptable nomenclature. For consistency, it is recommended that the strain be identified using the number assigned by an internationally recognized culture repository (e.g. American Type Culture Collection – ATCC). The use of a strain name that is generally scientifically recognized would also be acceptable. However, the use of a Trade Mark would not be acceptable, as it does not adequately identify the strain.

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[2] FAO/WHO (2001). *Health and nutritional properties of probiotics in food including powder milk with live lactic acid bacteria. Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food Including Powder Milk with Live Lactic Acid Bacteria*. Córdoba, Argentina, October 1–4, 2001. (www.who.int/foodsafety/publications/fs_management/probiotics/en/index.html)

Q. What quantity of live culture is required in a serving size? How should deterioration over the shelf life of the product be addressed?

A. The quantity of live culture required depends on the type of claim. For a non-strain-specific claim, the minimum level required is outlined in the CFIA *Guide to Food Labelling and Advertising*. For claims about probiotics outside of the specified accepted non-strain-specific claims, the adequate level would depend on the scientific evidence for the claimed health effect.

Quality and deterioration over the product shelf life is no different from any other quantitative declaration made on the label for a nutrient or other substance in the food. The food should contain, at a minimum, the amount of the probiotic microorganism(s) required to result in the claimed effect or health benefit throughout the shelf life of the product. Stability studies are required to show the rate of deterioration and must be taken into account in the formulation so that at any point during its shelf life the product would contain the declared quantity, taking into consideration analytical variability.

Q. How should a mixed culture of probiotics be declared quantitatively on the label?

A. In terms of quantitative declaration, levels of multiple genera, species or strains in the mixed culture should be declared according to guidance in section 8.7 of the CFIA *Guide to Food Labelling and Advertising*. For a mixed culture where multiple probiotic genera are used, declaration of the quantity of each genus is generally expected. If multiple species or strains of the same genus are added to a food, the need for the separate declaration of individual species would be determined case by case.

If a **non-strain-specific** claim is made on a product containing two or more of the eligible probiotic **species**, the minimum level of 1.0×10^9 colony forming units (cfu) per serving of stated size of the product can apply to the mixed culture.

On the other hand, if a **strain-specific** claim is made on a product containing two or more probiotic **strains** of a species, or two or more species (including those eligible for non-strain-specific claims), the minimum level required per serving of stated size of the product should be based on the effective dose established in the supporting evidence. In determining the quantity of a mixed culture in this case, attention should also be given to the ratio of the microbial strains/species.

Q. Are products with a long shelf life, such as breakfast cereals, required to have a sustained probiotic content at the end of the 'best before' date?

A. The CFIA *Guide to Food Labelling and Advertising* provides background information on conditions for probiotic claims, including amount in the product. The food should contain, at a minimum, the amount of the probiotic microorganism(s) required to result in the claimed effect or health benefit throughout the shelf life of the product. This requirement holds even if a product is normally consumed well in advance of the best before date. This is why probiotic claims are generally seen most often for products with a short shelf life.

Q. What was the basis used for approval of general (non-strain-specific) probiotic claims?

A. Probiotic microorganisms generally have been isolated from the gastrointestinal tract of healthy individuals. A limited number of non-strain-specific claims about the nature of probiotics (e.g. that they naturally form part of the gut flora) have been accepted for use on food. These claims refer to the nature of probiotics and **not** to their health effects or benefits.

A **closed** list of non-strain-specific probiotic claims that would be acceptable without the need for the manufacturer to conduct a detailed review of the scientific basis for the claim appears in the CFIA *Guide to Food Labelling and Advertising*. Permitting these basic claims allows products to remain in the marketplace while manufacturers may choose to acquire evidence for strain-specific claims.

Following a transition period, manufacturers using strain-specific probiotic claims are now expected to have data to substantiate such claims.

Q. Does a claim for non-strain-specific probiotics have to use the exact wording as it appears in the guidance?

A. For non-strain-specific claims, the four specified claims as published in the CFIA *Guide to Food Labelling and Advertising* (Chapter 8, Table 8-4) should be used. Claims with slight wording changes will be considered acceptable as long as the meaning is consistent with those published in the CFIA Guide. However, a claim such as “Probiotics benefit the digestive system" would not be considered to have the same meaning as the non-strain-specific claims specified in the CFIA Guide.

Q. Was the wording “gut flora”, which appears in the acceptable non-strain-specific probiotic claims, tested in consumer focus groups?

A. This terminology was not tested in focus groups. At present, a limited number of specific claims related to the nature of probiotics may be used. Claims with slight wording changes will be considered acceptable as long as the meaning is consistent with those published in the CFIA Guide (Chapter 8, Table 8-4).

Q. If a probiotic claim has been rejected previously by the European Food Safety Authority (EFSA), will this have a negative impact on new submissions for strain-specific health claims in Canada?

A. Submissions for approval of new health claims are always evaluated in terms of the data submitted. Science is continually evolving; if updated evidence is available to support a health claim, it will be considered.

Q. What is the expected timeline for development of guidelines for prebiotics?

A. Health Canada is presently working on guidelines to clarify the acceptable use of health claims about foods and food components represented as “prebiotics” on food labels and in advertising. It is anticipated that these guidelines will be released in the 2010–2011 fiscal year.

Questions Specific to Function Claims

- Will all acceptable function claims be posted in the CFIA *Guide to Food Labelling and Advertising*?
- What reference indicates that broad claims are ambiguous and not well understood, and thus potentially misleading?
- How would the evidence for maintaining cholesterol levels differ from evidence for reducing cholesterol levels?
- What are examples of the types of function claims that could be considered acceptable for food if substantiated?
- Are mechanistic endpoints considered biologically relevant?
- What is Health Canada's current approach to antioxidant claims or statements?
- For a product with a health claim, is the label required to state the quantity of the product required to have the beneficial effect?
- The wording of the DHA function claim has changed recently. Must manufacturers who already use this claim change their packaging to the new wording?
- Are sufficient resources available for the timely review of voluntary submissions of function claims?
- What is the difference between the scientific evaluation of a function claim and a disease risk reduction claim?
- Would the scientific opinion of the European Food Safety Authority (EFSA) have bearing on acceptable function claims in Canada?

Q. Will all acceptable function claims be posted in the CFIA *Guide to Food Labelling and Advertising*?

A. Pre-market approval of function claims is not mandatory; however, it is encouraged. When Health Canada conducts a review of a function claim upon request, the substantiated claim is posted in the CFIA *Guide to Food Labelling and Advertising*.

Q. What reference indicates that broad claims are ambiguous and not well understood, and thus potentially misleading?

A. Broad claims such as “support immune health” or “supports a healthy immune system” can have several interpretations (http://cspinet.org/new/pdf/fdacomplaint.pdf). Unless each interpretation is supported by scientific evidence, such claims are potentially misleading.

Q. How would the evidence for maintaining cholesterol levels differ from evidence for reducing cholesterol levels?

A. Claims are considered misleading if the wording does not reflect the substantiated health outcome or does not indicate the target group when the health benefit does not apply to the general population. Studies on the effects on serum cholesterol involving individuals with high blood cholesterol would support the claim “lowers serum cholesterol” in that population. The claim “maintains healthy cholesterol” may be supported in the general population by studies showing that individuals with normal cholesterol levels are able to maintain their levels following a challenge expected to raise their cholesterol levels.

Q. What are examples of the types of function claims that could be considered acceptable for food if substantiated?

A. Acceptable function claims for food are those that describe a normal physiological effect or activity. These types of claims, if substantiated, could be considered acceptable for food without the need for pre-market assessment. Examples include “fluid and electrolyte replacement”, “helps to delay muscle fatigue” and “a factor in normal cognitive function”.

Q. Are mechanistic endpoints considered biologically relevant?

A. In supporting a disease risk reduction claim or a therapeutic claim, a biologically relevant endpoint should be one that measures a quantifiable clinical outcome (e.g. incidence of a disease). Where an alternate marker has been validated following scientifically accepted procedures, such a surrogate marker may replace the clinical outcome.

When the evidence is used to support a function claim, biologically relevant endpoints are those that demonstrate a normal body function or physiological effect that has been directly linked to a health benefit in humans. Endpoints measured in animal or in vitro studies to test the mechanism by which a substance achieves its effect would not be acceptable unless the same effect has also been shown in well-controlled human studies and the effect is generally recognized to be relevant to human health.

Q. What is Health Canada's current approach to antioxidant claims or statements?

A. Health Canada generally considers antioxidant statements to be implied health claims. “Antioxidants” is a term for compounds that counter certain chemical reactions that may be harmful to the body. Although many substances may have antioxidant activity, their role in maintaining health is still the subject of scientific debate. In the labelling and advertising of a food product, when an antioxidant claim is made, the claim should be clear about the substance it refers to and the specific health effect or benefit of that substance.

A limited number of antioxidant claims have been accepted by the Food Directorate of Health Canada. Accepted claims are listed in Chapter 8 (Tables 8-2 and 8-3) of the CFIA *Guide to Food Labelling and Advertising*. Accepted antioxidant claims based on the report published by the

Institute of Medicine[3] include "[naming the nutrient] is a dietary antioxidant", which may be used for foods containing a minimum amount of vitamin C, vitamin E or selenium.

Q. For a product with a health claim, is the label required to state the quantity of the product required to have the beneficial effect?

A. The health claim should be accompanied by a statement indicating the contribution of one serving of the product to the daily amount of the substance that would need to be consumed to have the beneficial effect, unless specified otherwise.

Q. The wording of the DHA function claim has changed recently. Must manufacturers who already use this claim change their packaging to the new wording?

A. Manufacturers are expected to be in compliance with the new guidance. The change was made to reflect the available scientific evidence indicating that most of the development of the brain, eyes, and nerves in the human infant takes place very early starting in late pregnancy and up to 2 years of age. Claims on the market tended to imply that the development occurred at a much later age.

Health Canada will continue to follow the evidence, including an upcoming report by the World Health Organization, and will make adjustments as warranted.

Q. Are sufficient resources available for the timely review of voluntary submissions of function claims?

A. Health Canada recognizes the delays in approval of claims and is committed to improving this process. There has been a commitment under the Growing Forward framework Agricultural Regulatory Action Plan that funding will be dedicated to the review of health claims within Health Canada. The team of evaluators at the Nutrition Evaluation Division of the Food Directorate of Health Canada is being developed and trained. Health Canada is establishing standard operating procedures and monitoring the time taken to process submissions to ensure this consistently improves over time.

The evaluation process for the approval of claims is now well structured and the *Guidance Document for Preparing a Submission for Food Health Claims* can be used to assist industry in the preparation of a good quality submission that can be reviewed more quickly. With time, it is anticipated that the implementation of the process will become more efficient as industry becomes more familiar with the requirements for submission and Health Canada gains experience in undertaking more evaluations.

Q. What is the difference between the scientific evaluation of a function claim and a disease risk reduction claim?

A. Pre-market review of stated or implied disease risk reduction claims is necessary before food products carrying such claims are authorized for sale, whereas submission of a function claim is voluntary but encouraged. In both cases, Health Canada would follow the process outlined in the *Guidance Document for Preparing a Submission for Food Health Claims* to evaluate the submission; the principles regarding scientific evaluation are the same. Health Canada will also provide guidance on the most appropriate wording for the claim based on the available scientific evidence.

Q. Would the scientific opinion of the European Food Safety Authority (EFSA) have bearing on acceptable function claims in Canada?

A. An abbreviated health claims review process based on authoritative statements is currently being developed. Based on this process, the scientific opinions or statements of organizations that use

[3] Institute of Medicine (2000). *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium and Carotenoids*. Washington, D.C.: National Academy Press. (www.nap.edu/catalog.php?record_id=9810)

a review process and standards comparable to those described in the *Guidance Document for Preparing a Submission for Food Health Claims* would be considered in the acceptance of health claims for foods in Canada.

In the case of function claims about nutrients with recommended intakes (or Dietary Reference Intakes) and meeting specified criteria, an abbreviated process is already available for documenting supporting evidence. See section 8.6.5 of the CFIA *Guide to Food Labelling and Advertising* for details.

Resources on Health Claims

Health Canada

- Health Claims web page
  www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/index-eng.php
- *Health Canada's Action Plan in Response to Stakeholder Feedback from Consultations on Modernizing Canada's Framework for Health Claims on Food*
  www.hc-sc.gc.ca/fn-an/pubs/label-etiquet/_claims-reclam/2009-plan-action-plan/index-eng.php
- *Guidance Document for Preparing a Submission for Food Health Claims*, 2009
  www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php
- *Questions and Answers on Health Claims*
  www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/qa-qr_claims-allegations-eng.php
- *Probiotic Claims on Food*
  www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/probiotics-probiotiques-eng.php
- *Guidance Document – The Use of Probiotic Microorganisms in Food,* 2009
  www.hc-sc.gc.ca/fn-an/legislation/guide-ld/probiotics_guidance-orientation_probiotiques-eng.php
- *Questions and Answers on Probiotics*
  www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/probiotics_qa-qr_probiotiques-eng.php
- *Classification of Products at the Food–Natural Health Product Interface: Products in Food Format*
  www.hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/food_nhp_aliments_psn-2009-eng.php
- NUTSCI (nutritional sciences) email list
  www.hc-sc.gc.ca/fn-an/res-rech/res-prog/nutri/nustci_mailing_list-liste_correspondant_nutsci-eng.php

Canadian Food Inspection Agency

- *Guide to Food Labelling and Advertising*, Chapter 8 – Health Claims
  www.inspection.gc.ca/english/fssa/labeti/guide/tab8e.shtml
- CFIA's email notification services for food (choose 'Labelling Updates')
  www.inspection.gc.ca/english/util/listserv/listcsube.shtml

Agriculture and Agri-Food Canada

- Growing Forward policy framework, Agricultural Regulatory Action Plan
  www.agr.gc.ca/regulatory-actionplan
  - Health Claims, Novel Foods, and Ingredients initiative – www.agr.gc.ca/health-claims-initiative
  - Food Policy and Regulatory Issues – www.agr.gc.ca/food-regulatory-issues

Contact us to learn more about regulations for health claims, novel foods and ingredients.

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Electronic version available at: www.agr.gc.ca/food-regulatory-issues
(see the Events section and choose the January 2010 webcast on *Health Claims in Canada: An Update on Function Claims and Probiotic Claims for Food*).

Aussi offert en français sous le titre : *Allégations fonctionnelles et allégations relatives aux probiotiques — Questions et réponses*.