Health Claims on Foods in Canada: Toward Successful Implementation

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A growing body of scientific evidence supports the role of diet in maintaining health and preventing certain risk-modifiable chronic diseases. For example, it is well accepted that dietary fat type modulates blood cholesterol levels and thus risk of cardiovascular disease.¹ Similarly, the carotenoid lycopene present in tomatoes appears to lower the risk of prostate cancer,² while excess dietary sodium exacerbates hypertension in sensitive individuals³ and antioxidant compounds found in diverse fruits and vegetables may reduce the risk of certain cancers.⁴ Foodstuffs containing such nutrients/bioactive substances in optimal amounts are called “functional foods”, since their consumption may lead to health benefits over and above simple provision of nutrients. Health Canada currently proposes to define a functional food as “similar in appearance to, or may be, a conventional food, consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions”.⁵

The main objective in establishing health claims is to communicate to consumers the role of functional foods to improve health and to reduce disease risk. Assuming that behavioural change can be achieved by health claim implementation, substantial benefits are believed to potentially accrue in terms of reduced morbidity, mortality and health care expenses. A cost-benefit study,⁶ conducted by the Food and Drug Administration in the U.S. on the potential impacts of changing food labeling following the establishment of the Nutrition Labeling and Education Act (NLEA), concluded that 12,600 lives and US\$21 billion could be saved over a 20-year period if consumers were to change their eating behaviour. A more recent estimation⁷ by Agriculture and Agri-Food Canada and Health Canada suggested that CAN\$5 billion could be saved over the next 20 years in reduction of direct and indirect costs resulting from cancer, diabetes, and coronary heart disease and stroke if Canadians were able to alter eating habits. This estimation reflects potential health benefits that could be achieved from recent Health Canada initiatives to improve nutrition information, following the revision of nutrition labeling and nutrient content claims, as well as the establishment of health claims.

Given the evidence for disease risk reduction following consumption of functional foods, Health Canada has initiated the development of a policy to allow the use of health claims on foods. The objectives of this paper are to outline Health Canada’s “*Standards of evidence for evaluating foods with health claims: a proposed framework*”⁸ (June 2000), and to assess three aspects of health claim policy implementation, namely (i) consumer confidence in health claims, (ii) sustainable development of the functional food industry, and (iii) effective strategies for communication of health messages to consumers.

Health claim regulation in Canada

In order to respond to the growing interest in functional foods of consumers and food industries, a policy regarding health claims for foods was initiated in 1996,⁹ and after

extensive consultations and discussions, the Food Directorate and the Therapeutic Products Programme of Health Canada published a policy decision in November 1998.⁵ The policy recommends that structure/function and risk reduction claims, being generic or product-specific, be permitted and implemented under the current Food and Drug Act. Examples of risk reduction generic claims are provided in Table I. The first step in Health Canada’s policy implementation was the development of regulatory amendments to permit diet-related generic health claims, and the publication of a proposed regulatory framework for product-specific authorization of health claims for foods.¹¹

Standards of evidence for evaluating foods with health claims

The proposed framework published in June 2000⁸ describes requirements in product safety, claim validity and quality assurance that would be used to evaluate foods with health claims, as represented in Figure 1. Information required to evaluate these three aspects of health claims is summarized in Table II.

Product Safety

Health Canada considers that high standards of evidence are required for evaluating the safety of foods bearing health claims. Adverse health events must be minimized since food products are destined for unrestricted consumption by the general population, including children. As part of the proposed claim evaluation framework, a basic evaluation of nutritional and toxicological impacts would be conducted for all products bearing health claims, in the context of intended form and intended use. Anticipated exposure to a food, as well as to a bioactive substance, from all sources would then be evaluated.

Functional foods may become “novel foods” if the full health benefit is achieved through addition of bioactive substances at levels higher than natural sources, or the addition of new bioactive substances not traditionally found in foods. The safety aspects of “novel” foods would have to be assessed before being considered for health claims. In general, safety assessment of foods with health claims would be specific to the novelty and uncertainty regarding the safety of the product, and as such, different levels of scientific evidence and information

La traduction du résumé se trouve à la fin de l'article.

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would be required according to the nature of the food under consideration.⁸

Claim Validity

The proposed framework defines guidelines for evaluating claim validity, including concepts of product efficacy and effectiveness. Efficacy entails the demonstration of a beneficial effect under ideally controlled conditions, such as a clinical trial. Effectiveness (efficacy multiplied by compliance) requires that this effect be observed under average uncontrolled conditions among the population at large. An evidence-based approach, dictated by several principles listed in Table III, would be used to evaluate claim validity in three distinct steps. First, the strength of evidence supporting a causal relationship between a food/bioactive substance and a claimed benefit would be evaluated using a systematic approach, by which the totality of scientific literature is reviewed and conclusions are drawn from the best quality of available evidence. Second, whether the strength of evidence for this causal relationship is sufficient to support the claim, in relation to the nature of the claim, would be determined. Third, whether the total evidence provides sufficient information to characterize the relationship between the claimed benefit and the agent would be established. Such characterization encompasses efficacy and effectiveness, level of intake, target populations, and magnitude and sustainability of effect. These guidelines aim to ensure approval of legitimate and substantiated health claims promoted as part of the total diet.

Quality Assurance

Quality consistency of food products with health claims must be maintained if the alleged benefits are to be realized on a population basis. Excessive levels of a beneficial substance and presence of deleterious ingredients must also be prevented to avoid possible health hazards. The level and quality of bioactive substances must be reliably monitored through thorough testing to ensure efficacy and safety of functional foods. The proposed framework defines guidelines on several aspects of quality assurance. These quality assurance requirements of health claim evaluation aim to protect consumers from fraudulent products with excessive or insufficient levels, or

TABLE I

Generic Health Claims Considered as Part of the Canadian Health Claim Policy Implementation*

Pre-approved Health Claims and Proposed Wording

- A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. This food is a good source of potassium and is sodium-free.[†]
- A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. This food is an excellent source of calcium.[†]
- A healthy diet low in saturated and trans fats may reduce the risk of heart disease. This food is free/low in saturated and trans fats.
- A healthy diet rich in a variety of fruits and vegetables may help reduce the risk of some types of cancer.
- Tooth friendly. Does not promote dental caries.

Health Claims Under Evaluation by Health Canada

- Folate and neural tube defects
- Fibre-containing grain products, fruits and vegetables and cancer
- Fruits, vegetables and grain products that contain fibre, particularly soluble fibre, and risk of coronary heart disease

* Obtained from: Consultation document on generic health claims¹⁰ and Regulations amending the food and drug regulations.⁷

† Different nutrient contents are possible for these health claims.

Figure 1. Aspects of evaluating foods with health claims under the proposed framework of Health Canada*

* Obtained from Standards of evidence for evaluating foods with health claims: A proposed framework.⁸

inactive forms, of bioactive substances, as well as from improper testing and data handling practices. Protection of consumers is essential to the success of this programme.

Evaluation of product-specific health claims

Assessment of product-specific health claims, as outlined in the proposed regulatory framework for product-specific autho-

rization,¹¹ uses the same principles described above for generic claims. However, product-specific claims will be determined on a product-by-product basis and thus require product-specific evidence. It is proposed that these claims be identified with a claim or food identification number,¹² similar to the drug identification number system. It will be the applicant's responsibility to notify regulatory authori-

TABLE II
Information Required for Health Claim Evaluation*

Safety Evaluation <ul style="list-style-type: none">• Product composition and source, effects of processing, directions for preparation, modification from traditional product• History of safe use/previous human exposure, epidemiological data• Proposed target groups• Dietary significance and physiological role• Identification of susceptible groups• Potential interaction with nutrients/food components• Current exposure and dietary recommendation, upper safety limits, anticipated use, total exposure from different sources• Metabolic fate, metabolic disposition, physiological role• Safety assessment of isolated substance and food matrix	Claim Validity Evaluation <ul style="list-style-type: none">• Experimental and observational studies in humans with acceptable biomarkers supporting the causality of health benefit to food:<ul style="list-style-type: none">– Essential criteria<ul style="list-style-type: none">➤ Consistency of findings➤ Magnitude of effect/strength of association➤ Statistical relationship➤ Temporal relationship➤ Absence of strong opposing evidence– Supporting criteria:<ul style="list-style-type: none">➤ Dose-response relationship➤ Reversal or cessation of effects➤ Biological plausibility➤ Alternative explanations➤ Specificity of effect and of cause➤ Coherence• Product efficacy and effectiveness• Magnitude of beneficial effect or risk reduction• Sustainability of effect• Recommended intake to achieve effect• Target population and impact on population health• Biological mechanism• Time needed to see an effect	Quality Assurance Evaluation <ul style="list-style-type: none">• Critical control points• Specifications and analysis plan• Record retention policy• Recall capability• Evidence of good manufacturing practices• Evidence of good practices in testing procedures• Documentation
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* Adapted from Standards of evidence for evaluating foods with health claims: A proposed framework.⁸

TABLE III
Principles of Health Canada’s Proposed Evidence-based Approach to Evaluating Health Claim Validity*

- Totality of evidence
- Causal relationship
- Study quality
- Relevance and generalizability
- Systematic approach
- Level of certainty

* Obtained from Standards of evidence for evaluating foods with health claims: A proposed framework.⁸

ties of any change relative to available scientific information, occurrence of adverse reactions, product formulation or manufacturing processes.

Consumer confidence in health claims

Consumer confidence must exist in health claims and the regulatory process through which they are generated if effective changes in nutritional behaviour of Canadians are to be maintained. Since behavioural changes are complex and difficult to bring about on a population basis, emphasis should be placed on claims having major health impacts. Claims having little or no effect on health should not be allowed, as they may dilute consumers’ efforts to modify their eating behaviour, and disrupt confidence in the regulatory process and the claims themselves. Unnevehr et al.,¹³ in a review on health claim regulation in the U.S. and its impact on consumer choice and protection, sug-

gest the replacement of the gold standard scientific consensus for evaluating claim validity by a cost-benefit standard of acceptance. A case could be made for permitting a potentially false, but safe, health claim on the grounds that it would not have a negative impact on consumers. Such claims could be based on a lower level of scientific substantiation. However, this position underestimates the negative impact that false claims may have on nutritional balance, behavioural changes towards a healthier diet and health claim credibility. In addition, the consumption of government-authorized health-fraudulent products raises ethical issues and consumer right concerns. It should be considered imperative for consumer confidence in health claims that only credible, legitimate and well-substantiated claims based on established scientific evidence be approved, in order to prevent the misleading or deceiving of consumers.

The framework does not clearly define how the difference in criteria stringency required for evaluation of different health claims will be established. How will evaluators deal with missing evidence for one aspect of the safety evaluation when a claim is likely to provide significant health benefits to a large part of the population? Should publication bias and bias of industry-derived research be taken into consideration when evaluating health claim validity? The absence of widely accepted methodologies for measuring biomarkers in certain fields of nutrition, and the different standards for diagnosis establishment in other countries, may also complicate the accurate assessment of claim validity. Moreover, the concept of effectiveness of a health benefit under the population at large may be incompatible with most existing evidence from experimental or observational studies, which are either overly controlled, or confounded by other dietary and environmental factors. It may be appropriate to omit effectiveness from the claim evaluation process but to include it as a measure of claim impact on dietary patterns and health outcomes.

Sustainable development of the functional food industry

Since food industries may voluntarily provide functional foods to the Canadian mar-

ket, the success of health claim implementation will be dependent on companies' interests to market new products with authentic functional qualities, and to include health claims on existing and future products. Therefore, regulatory impact on functional food industry sustainability will likely affect the availability of foods with health claims, and thus the possibility for consumers to derive health benefits from them. As such, regulators must ensure that generic and product-specific health claim approval is reasonably straightforward and efficient, in terms of approval time, required documents and criteria stringency, to avoid unnecessary burden to food companies, and to ensure a viable future for health claims and functional foods.

While approval of product-specific claims may require extensive testing and documentation, generic claims may be easily applied to a range of products once safety and validity have been established. Subsequently, only quality assurance assessments of manufacturing and testing practices, and perhaps issues of safety and efficacy in different food matrices, would need to be evaluated for products bearing generic health claims. Conversely, the evaluation of product-specific claims requires extensive documentation and scientific literature to describe the different aspects of safety, validity and quality assurance evaluation, as detailed in Table II. The extent to which food companies would be responsible for this extensive documentation has not been established so far in the proposed framework. Furthermore, many aspects of scientific evidence and safety assessment used for claim approval may not be available due to insufficient human studies. Considering the potential health benefits for the population and the costly nature of properly controlled clinical trials in humans, government sources of funding directed to academia for this express purpose may be necessary to promote quality, unbiased nutrition research.

Regulatory approval for the use of product-specific claims is likely to promote the development of new functional food products and the demonstration of their safe and efficacious nature. Consequently, food industries should be able to derive benefits from their investments in innovative products, and ensure that competitors do not

rapidly saturate the market to compromise their margin of profit. Although health claim evaluation will be carried out using product-specific documentation, it is unclear whether competitors could easily demonstrate that their product is similar in composition and action to an established one bearing a product-specific claim, without undergoing extensive testing in clinical settings. Moreover, if the evidence supporting a product-specific claim is made accessible to the public (as mentioned in the proposed regulatory framework),¹¹ this may undercut profitability by neglecting to protect proprietary information.

It may be profitable for the development of the functional food industry to consider intellectual property assignment as part of health claim regulation. Patent issues could only be applied to product-specific claims. Restricting claim use of a specific product for a certain time period is expected to promote the development of functional foods with added health benefit, but also to increase prices of these foods due to lack of commercial competition, thus making them available only to a sub-section of the population. Determination of a suitable time period to allow patents on functional foods, which logically should be shorter than that permitted on drugs, may help to keep a balance between these two opposing factors and maximize health benefits to consumers.

Development and implementation of health claim regulations can be a lengthy process; however, delaying the introduction of food products bearing health claims on the Canadian market, in an extensive or unreasonable manner, may undermine the commercial and health-benefit success of functional foods. In 1997, the US FDA authorized health claims on the relationship between soluble fiber from whole oats and coronary heart disease, following a petition submitted by General Mills in 1995.¹⁴ While Health Canada's policy regarding health claims was initiated in 1996, it is questionable whether we could expect to see foods with health claims in the local supermarket in the near future. This delay period may promote shifting of interest of consumers or discrediting of functional foods by available but unregulated products, thus preventing the establishment of a flourishing industry and of health benefits to consumers.

The recent controversy over the introduction of phytosterol-enriched margarine BecelTM Pro.activTM, for use in reducing blood cholesterol levels, provides an example of possible hazard to the credibility of functional foods and the need for CFIA enforcement. Following introduction of the phytosterol product on the market without official governmental approval, Health Canada issued an advisory¹⁵ against plant sterol use in pregnant women, children, people predisposed to hemorrhagic strokes and people on cholesterol-lowering medication. In response, the manufacturer, Unilever Canada agreed to include warnings of nutritional inadequacy for those susceptible groups on labels, but continued to stand behind the safety and positive cardiovascular influence of its product.¹⁶ In this case, there is extensive evidence for phytosterols' cholesterol-lowering efficacy,^{17,18} as well as safety.^{17,19,20} Time will tell whether this unapproved introduction of BecelTM Pro.activTM will affect consumers' perception, future use and consequent benefit from use of these phytosterol-enriched products.

Effective communication of health claims

To achieve behavioural changes in the eating habits of Canadians, health claims will need to be clear, understandable, credible and properly directed to the specific target audience. In addition, the length and amount of information contained in health claims, as well as the association of disease/risk relationships with the food, are important characteristics of health claims. In considering these aspects of effective consumer communication, Health Canada has recently conducted a series of focus groups²¹ in various cities across Canada on the wording of claim statements, to see how well consumers understand and relate to claims. Results of this exercise have yielded a number of salient findings regarding consumer perception of claims.

In Canada, it seems there is a general lack of basic nutrition knowledge necessary to understand the meaning of claims. Focus group participants stated the need for information on the appropriate level of a nutrient required to achieve a specific health benefit, based on age, gender, current medical status and family history, as opposed to general information pertaining

to the average Canadian. Overall, nutrition education seems necessary to complement the establishment of health claims.

Participants voiced a strong desire for guarantees. As such, the use of indefinite concepts such as "may" or "might" to describe a health benefit of a food or nutrient was questioned; the government was perceived as insufficiently confident in the anticipated benefit. To address this issue, the everchanging face of science and the multi-factorial nature of disease need to be explained to consumers to justify the necessary use of indefinite terms in health claims. Participants also felt that high standards of evidence should be required to substantiate claims made, and that access to supporting evidence should be made available to the public. The use of the name "Health Canada" on claims was considered to promote credibility. It would also be important to investigate whether including product brand names in product-specific claims would increase credibility of the product or be perceived as a promotional tool by consumers.

The overall objective of health claims to promote a healthier population and reduce strain on the health care system was well understood by participants and was seen as a positive initiative. Testing the specific wording of 4 claims revealed a need for clarification and inclusion of additional information, in order to effectively communicate health messages to consumers. The establishment of a surveillance program that would assess consumer knowledge and attitudes of health claims may be useful to determine whether nutrition messages reach target groups. In addition, the surveillance program would need to monitor changes to food consumption patterns and nutritional status in order to identify problematic health issues.

CONCLUSION

Health Canada's proposed framework for evaluating foods with health claims correctly requires high standards of evidence for assessing safety, validity and quality assurance. Such standards are necessary to

ensure consumer confidence in these claims. The stringency of criteria for evaluating product-specific health claims, the extent to which companies would be required to provide necessary documentation, as well as the possibility for patent assignment under a future regulatory body, exist as central factors influencing the sustainability of the functional food industry. Government initiatives to implement generic health claims will likely promote claim use by food companies through reduction in their administrative burden. Results from focus testing on consumers' perception of health claims reveal that these must be carefully worded, and that consumers must be adequately educated, for health claims to have the anticipated impact on the health of the Canadian population. Health claim regulation should work effectively on these different aspects of claim implementation to ensure that Canadians are provided with a greater variety of safe and efficacious products in the functional food market.

REFERENCES

- Hornstra G, Barth CA, Galli C, Mensink RP, Mutanen M, Riemersma RA, et al. Functional food science and the cardiovascular system. *Br J Nutr* 1998;80(1):S113-46.
- Agarwal S, Rao AV. Tomato lycopene and its role in human health and chronic diseases. *CMAJ* 2000;163(6):739-44.
- Weinberger MH. Salt and blood pressure. *Curr Opin Cardiol* 2000;15(4):254-57.
- Craig WJ. Phytochemicals: Guardians of our health. *J Am Diet Assoc* 1997;97(10,2):S199-204.
- Health Canada, Therapeutic Products Programme and the Food Directorate of the Health Protection Branch. Nutraceuticals/functional foods and health claims on foods policy: Policy paper. Ottawa, ON: 1998. Available on-line at: www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/ffn/nutra_pol_e.pdf.
- Food and Drug Administration, US Department of Health and Human Services. Regulatory impact analysis of the final rules to amend the food labeling regulations. *Federal Register* 1993;58:2927-41.
- Public Works and Government Services Canada, Canada Gazette Directorate. Regulations amending the food and drug regulations (nutrition labeling, nutrition claims and health claims). Ottawa (ON): Canada Gazette: Part I, June 16, 2001: 135(24). Available on-line at: www.hc-sc.gc.ca/food-aliment/english/publications/acts_and_regulations/part_1/1172_index.html.
- Health Canada, Bureau of Nutritional Sciences, Food Directorate Branch. Standards of evidence for evaluating foods with health claims: A proposed framework. Ottawa (ON): 2000. Available on-line at: http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/pdf/e_consultation_doc_en.pdf.
- Health Canada, Bureau of Nutritional Sciences, Food Directorate Branch. Chronology of events: Policy development process. Ottawa (ON). Available on-line at: http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_chronology_of_events_.html (updated November 24, 2000).
- Health Canada, Bureau of Nutritional Sciences, Food Directorate Branch. Consultation document on generic health claims. Ottawa, ON: August 2000. Available on-line at: http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_consultation_doc_gen.html.
- Health Canada, Bureau of Nutritional Sciences, Food Directorate, Health Products and Food Branch. Product-specific authorization of health claims for foods: A proposed regulatory framework. Ottawa, ON: October 2001. Available on-line at: http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/pdf/e_finalproposal.pdf.
- Stephen AM, Liston AJ, Anthony SP, Munro IC, Anderson GH. Regulation of foods with health claims: A proposal. *Can J Public Health* 2002;93(5):328-31.
- Unnevehr L, Ward MR, Hasler C. Regulating health claims on food products: The balance between consumer choice and consumer protection. *Choices First Quarter* 1998;26-30.
- Food and Drug Administration, U.S. Department of Health and Human Services. Food Labeling: Health Claims; Soluble fiber from whole oats and risk of coronary heart disease; Final rule. *Federal Register* 1997;62(61).
- Health Canada. Advisory: Health Canada advises that Becel™ Pro-activ™ not approved for sale. Ottawa, ON: October 3, 2001. Available on-line at: http://www.hc-sc.gc.ca/english/protection/warnings/2001/2001_106e.htm.
- Unilever Canada. Unilever Canada Stands Behind Safety of New Becel Pro.activ Margarine. Toronto, ON: October 4, 2001. Available: <http://www.unilever.ca>.
- Miettinen TA, Puska P, Gylling H, Vanhanen H, Vartiainen E. Reduction of serum cholesterol with sitostanol-ester margarine in a mildly hypercholesterolemic population. *N Engl J Med* 1995;333:1308-12.
- Jones PJH, Ntanos FY, Raeini-Sarjaz M, Vanstone CA. Cholesterol-lowering efficacy of a sitostanol-containing phytosterol mixture with a prudent diet in hyperlipidemic men. *Am J Clin Nutr* 1999;69:1144-50.
- Waalkens-Berendsen DH, Wolterbeek APM, Wijnands MVW, Richold M, Hepburn PA. Safety evaluation of phytosterol esters. Part 3. Two-generation reproduction study in rats with phytosterol esters - a novel functional food. *Food Chem Toxicol* 1999;37:683-96.
- Whittaker MH, Frankos VH, Wolterbeek APM, Waalkens-Berendsen DH. Two-generation reproductive toxicity study of plant stanol esters in rats. *Regul Toxicol Pharmacol* 1999;29:196-204.
- Goldfarb: Consultants for Health Canada, Nutrition Evaluation Division Food Directorate. Health Claims Focus Testing: October 2000. Ottawa (ON): October 2000. Available on-line at: http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_hc_focus_testing.html.