Regulation of Foods with Health Claims: A Proposal

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ABSTRACT

Health claims linking foods and food components to disease are prohibited in Canada because of limitations of the Food and Drugs Act. Changes to the Act to permit such claims would require a Bill to Parliament, a lengthy and impractical solution. In this paper, an alternative approach is proposed, that is, to regulate "Foods with Health Claims" under a subsection of the Drug Regulations. Generic claims would be regulated in a similar manner to Class IV or minimum risk drugs, whereby monographs would be created for constituents for which claims are proposed. Product-specific claims would be individually evaluated. Each food bearing a claim would carry a Food Identification Number (FIN), provided by Health Canada through application. Details of procedures and conditions for the FIN process are suggested. The FIN plan would provide an expedient, balanced and accountable approach to allow health claims on food products in Canada.

Recent surveys conducted by the National Institute of Nutrition^{1,2} have found that most Canadians believe nutrition is important for health and have indicated that it plays a role in their food choices. Food product labels are the most widely identified source of information in Canada.¹ Most Canadians indicate that they would consider more information on labels, and specifically "health claims", useful additions to food packaging.² Health claims are statements that link food, or food constituents, to reduction of risk of chronic diseases or conditions. Health claims are allowed in the United States, but are prohibited in Canada because of restrictions in the Canadian Food and Drugs Act and Regulations (the Act). The purpose of this article is to review steps being taken to move toward health claims in Canada and to propose a mechanism that will permit health claims within the provisions of the Act.

Through its definitions of *food* and *drug*,* the Act restricts health-related claims for foods and food constituents when sold to the public. Any representation to the public of the beneficial physiological effects against diseases like cancer, diabetes, heart disease, hypertension, obesity and arthritis is prohibited. These diseases, listed in Schedule A of the Act, are the most common causes of morbidity and mortality in Canada. Physiological effects which relate to these conditions, for example, lowering of serum cholesterol levels, are included under Schedule A and are precluded from appearing on labels and advertisements. Thus the fundamental impediment to health claims for foods in Canada is the legal definition of food and limitations on what can be said about food under the Act.

Since 1996, Health Canada has been engaged in a consultation process to develop a policy for health claims, and in 1998 produced a final *Policy Paper on Nutraceuticals/Functional Foods and Health*

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

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* A food "includes any article manufactured, sold or represented for use as a food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever". A drug "includes any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms in human beings or animals, (b) restoring, correcting or modifying organic functions in human beings or animals, or (c) disinfection in premises in which food is manufactured, prepared or kept".

*Claims on Foods.*³ This document stated that “structure/function and risk-reduction claims for foods should be permitted while all other products claiming to cure, treat, mitigate or prevent illness should continue to be regulated as drugs”.

The Policy also identified three major components for implementation of health claims:

1. The consideration of adopting generic claims already approved in the US.
2. Development of standards of evidence for evaluating foods with new health claims and a Guidance Document to provide detailed information regarding the preparation of submissions for review.
3. Development of a regulatory framework for foods with new health claims.

Generic claims approved in the US under the Nutrition Labelling and Education Act (NLEA)

Generic claims apply to foods such as fruits and vegetables, as well as food constituents, rather than specific food products. Any food that meets the compositional criteria is eligible to display a particular generic claim. Product-specific claims apply to specific commercial food products only.

At the time of the 1998 paper, 10 generic health claims had been approved in the United States under NLEA. Following extensive evaluation of the scientific evidence, Health Canada has approved 5 of these claims: sodium, potassium and hypertension; calcium, vitamin D and osteoporosis; saturated fat, trans fat and coronary heart disease; fruits and vegetables and cancer; and sugar alcohols and dental caries. Details of the specific wording of these 5 claims, criteria for the nutrient content of the food and standards of scientific evidence to support the claim, have been extensively debated.³⁻⁶

The status of the 5 remaining US claims: dietary fat and cancer; fibre-containing grain products, fruits and vegetables and cancer; fruits, vegetables and grain products and coronary heart disease; folate and neural tube birth defects; and soluble fibre and coronary heart disease, remains undecided.⁷

Development of a regulatory framework for foods with health claims

Although Health Canada has indicated that the scientific evidence supports cer-

Figure 1. Steps in the Canadian approval process for a new regulatory strategy

tain health claims, it remains unclear how these claims will be regulated since the prohibition of statements relating food to Schedule A diseases remains. Opening of the Act to accommodate changes to definitions and policies for foods is an unlikely option because it would require a Bill being presented to Parliament. Once open, the Act would be subject to requests for changes on a number of issues which could take several years to consider. One mechanism would be to exempt specific foods or food constituents from the limitations of Schedule A. However, this route would require each claim to be regulated individually – a lengthy process considering that new regulations within the Canadian Parliamentary system must proceed through the steps outlined in Figure 1. Thus, for each claim, it would take about two years from initial appearance in Canada Gazette Part 1 to final approval and presentation in Gazette Part 2.

In this paper, we propose an alternative approach – one that could be more expedient and yet balanced and accountable. This is to create a subsection of the Drug Regulations called *Foods with Health Claims*. While such foods would be regulated under the Drug Regulations, their claims could be evaluated by standards of evidence appropriate for foods.⁴ They would be called foods in normal

parlance, not drugs. This is analogous to Natural Health Products which are proposed to be regulated under the Drug Regulations but will still be referred to as Natural Health Products.⁸ Regulating *Foods with Health Claims* as a subsection of the Drug Regulations would require only a regulatory amendment through an Order-in-Council and would not require opening of the Act. Furthermore, the timing could be much reduced as the approval of a new claim would be an administrative procedure, not one involving drafting and promulgating of regulations.

The Drug Regulations contain a number of Schedules that stipulate the manner in which classes of drugs are regulated. These vary from stringent regulations for biological products, where conditions of manufacture are tightly controlled, to Class IV drugs, such as medicated shampoos, which are deemed a minimum risk, and subject to minimal scrutiny provided the product conforms to an official monograph.

Since food products generally present minimal risk, provided they are manufactured under sanitary conditions, it would be consistent with the Drug Regulations to develop a special Schedule appropriate for them. A similar process to Class IV drugs could be developed whereby monographs are created for constituents for which claims are proposed.

Figure 2. Proposed procedure for a generic claim once a monograph is in place

Figure 3. Proposed procedure for a product-specific claim

Conditions for Foods with Health Claims

Within the existing Regulations, there are classes of therapeutic products that carry different types of Drug Identification Numbers (DIN). *Foods with Health Claims* could carry distinct identifier numbers – Food Identification Numbers or FINs. Sale of foods with claims would be prohibited without the FIN prominently displayed on the package. The Minister of Health would have the authority to cancel a FIN and order a “stop sale” if the product was no longer safe to consume or if scientific evidence indicated the claim was no longer supported.

Manufacture of foods with health claims would require exemption from drug type Good Manufacturing Practices. Instead, compliance with the provisions of the Food Regulations would apply. The

Minister could exempt these foods from the limitations of Schedule A by utilizing Section 30 (j) of the Act.

Generic claims, such as those already approved in the United States, and new claims of the same type, could have a monograph mechanism similar to that currently used for Class IV drugs. Candidates for development of monographs would be those structure/function or risk-reduction relationships recognized by competent scientific or regulatory authorities and for which the scientific evidence is substantial. All foods containing the ingredient within the ranges stipulated in the monograph, and satisfying all other criteria, could obtain a FIN which would then allow the claim to be displayed.

Product-specific claims would not be covered under the monograph provisions. They would require a full submission with

substantive evidence of the structure/function or risk-reduction relationship. The type of evidence required for a claim could be that indicated in the Food Directorate’s Consultation Document on Standards of Evidence for Evaluating Foods with Health Claims.⁴

Application for a FIN for product-specific claims would be made on an individual basis, in a similar manner as for a DIN. A product-specific FIN would not be available to other manufacturers since the data provided in the submission would be unique to the product. Claim exclusivity would be maintained until sufficient evidence existed to justify development of a monograph.

Evaluation of the scientific data, for either generic or product-specific claims, could be conducted through Third Party Review. Third parties are groups of scientists, distinct from manufacturers or government, with the expertise to evaluate complex scientific evidence. Generally the coordination of Third Party Review is carried out by organizations experienced in scientific review and in convening experts to achieve this. Use of third parties provides an objective and unbiased evaluation in a timely manner.

An Expert Advisory Committee (EAC) comprised of well-established scientists could be appointed to assist Health Canada in reviewing the scientific data for a potential claim and in making recommendations for Third Party Review. Where evidence is supportive of a generic claim, the EAC could recommend the development of an official monograph. For product-specific claims, the EAC could determine whether the Third Party Review recommendation should proceed to a health-related claim.

This approach, to have the monograph option approved, would require many of the steps outlined in Figure 1. However, with the precedent of monographs for Class IV drugs and similar proposed options for Natural Health Products, deliberation by the Justice Department and other branches of government should take less time than for a totally new process.

The application procedure for generic claims using the monograph approach, once the process is in place, is outlined in Figure 2. The timeline for approval could

be of a similar duration as for Class IV drugs or about 30 days.

The procedure for product-specific claims, once the process is in place, is outlined in Figure 3. It is obvious that acquiring scientific evidence to establish a health benefit can take many years. However, once the evidence is in place, it should require only about 6 months for submission, review and approval of the claim.

CONCLUSION

Health Canada has identified the need to provide health-related information to the Canadian population through claims on food packaging. However, the Food and Drugs Act and Regulations prohibits this. The present proposal suggests a mechanism whereby health claims could appear on foods, without opening the Food and Drugs Act.

Not allowing health claims, when the scientific data are substantial and generally accepted, deprives the public of knowledge about relationships between foods and their constituents and disease. Health professionals should encourage Health Canada to develop a process for allowing claims, since food labels are an important source of nutrition information.^{1,7} Once a procedure is in place, the support of dietitians and other health professionals will be crucial in ensuring that health claims are indeed use-

ful in communicating appropriate messages to consumers.

Health Canada has a mandate to ensure and promote the health of the Canadian population. Facilitating health-related claims on packaging is in keeping with this mandate and efforts to enable this to occur should be given serious consideration. We have shown that there is a way if there is a will on the part of those responsible, including the food industry, health professionals and Health Canada.

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RÉSUMÉ

Au Canada, les allégations santé qui font un lien entre des aliments ou composants alimentaires et la prévention de maladies sont interdites aux termes de la Loi sur les aliments et drogues. Pour modifier la loi afin d'autoriser ces allégations, il faudrait déposer un projet de loi au Parlement, une solution peu réaliste en raison du temps considérable que cela prendrait. Nous proposons ici une solution de rechange : réglementer les « aliments visés par des allégations santé » en vertu d'un paragraphe du Règlement sur les drogues. Les allégations générales seraient réglementées un peu comme pour les drogues de catégorie IV (à risque minimum), à savoir qu'il faudrait réaliser des monographies pour les constituants dont on veut vanter les vertus thérapeutiques. Les allégations spécifiques à un produit seraient évaluées individuellement. Chaque aliment visé par une allégation comporterait un numéro d'identification numérique délivré par Santé Canada sur demande. Nous suggérons une procédure et des conditions détaillées pour l'attribution de ces numéros. Une telle solution serait une façon rapide, neutre et responsable d'autoriser au Canada les allégations relatives aux effets de produits alimentaires sur la santé.

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