

TORONTO STAFF REPORT

April 28, 2003

To: Board of Health
From: Dr. Sheela V. Basrur, Medical Officer of Health
Subject: Update on Regulatory Changes at Health Canada Related to Food and Nutrition

Purpose:

To inform the Board of Health about recent regulatory changes at Health Canada related to food and nutrition.

Financial Implications and Impact Statement:

There are no financial implications arising from this report.

Recommendations:

It is recommended that:

- (1) the Board of Health communicate its support to the Federal Minister of Health for the new nutrition labelling policy announced by Health Canada in January 2003;
- (2) the Board of Health recommend to Health Canada that they adopt the following recommendations regarding health claims and food fortification:
 - (a) allow sufficient time to monitor the impact of generic health claims on purchasing patterns, dietary practices and population health outcomes before approving product-specific health claim regulations;
 - (b) ensure that fortification is based on sound nutrition rationale and targets nutrients of identified public health significance;
 - (c) demand evidence that the nutritional health of Canadians will be improved with fortification;

- (d) continue to take a leadership role in consumer education and devote resources towards consumer education campaigns relating to fortified foods;
- (3) the Board of Health re-affirm to Health Canada the need for an effective and sustainable national nutrition surveillance system with accurate nutrition methodology; and,
- (4) the appropriate City Officials be authorized and directed to take necessary action to give effect thereto.

Background:

In September 1999 the Board of Health received and approved the report entitled “Response to Health Canada’s Nutrition Labelling Policy Review”, which urged Health Canada to make nutrition labelling mandatory on all foods and to allocate resources to the development of a consumer education campaign to support the new food labelling system. In addition, the Board of Health forwarded the report to other Boards of Health in Ontario, the Ontario Public Health Association and the Canadian Public Health Association, and requested them to join in advocating for mandatory nutrition labelling in Canada.

On January 1, 2003 new regulations published by Health Canada made nutrition labelling mandatory on most food labels; updated requirements for nutrient content claims; and permitted, for the first time in Canada, diet-related health claims for foods. TPH staff provided written comments and feedback to Health Canada throughout this regulatory process, and successfully advocated for inclusion of a question pertaining to mandatory labelling on research conducted into consumer attitudes and behaviours related to nutrition labelling. The findings from this research played an instrumental role in Health Canada’s decision to make nutrition labelling mandatory on all pre-packaged foods.

Since the 1999 Board report, TPH continued to monitor developments, examine the public health implications and provide input to Health Canada on a number of important policy initiatives related to food and nutrition regulations in Canada. Specifically, Health Canada has requested comments and feedback concerning proposed regulatory changes regarding the Standards of Evidence for Evaluation of Safety and Claims of Natural Health Products, and the Standards of Evidence for Evaluating Foods with Health Claims (including the Product-Specific Authorization of Health Claims for Foods). Health Canada has also conducted consultations on the implementation of the Policy on the Addition of Vitamins and Minerals to Foods.

TPH continues to advocate, both directly to the appropriate ministries of the Government of Canada and via formal consultation channels, to indicate their support for evidence-based nutrition policy recommendations and practices in Canada.

Comments:

Health Canada's recent regulatory changes and proposed policy initiatives are intended to provide the consumer with more food choices to help meet nutritional needs, while ensuring that foods can be consumed safely as part of healthy eating patterns. However, strong public health advocacy is needed to help shape food and nutrition-related policies and its implementation.

An overview of TPH's involvement in Health Canada's policy development process related to new standards for nutrition labelling, generic and product-specific health claims, the addition of vitamins and minerals to foods, and natural health products are detailed below.

The New Nutrition Labelling Regulations:

The new regulations coupled with ongoing education are significant supports to improved public health in Canada. Together, improved nutrition labelling on most prepackaged foods, science-based health claims and defined nutrient-content claims are all expected to help consumers make more informed choices about the foods they buy and eat.

Under the new regulations, more information about the nutritional value of most prepackaged food will begin to appear on labels almost immediately. The new regulations require most food labels to carry a mandatory "Nutrition Facts" table listing calories and 13 key nutrients. Producers of prepackaged foods will have from three to five years to declare the number of calories and the amount of fat, saturated and trans fats, cholesterol, sodium, carbohydrate, fibre, sugars, protein, vitamins A and C, calcium and iron in a specified amount of food.

Criteria for nutrient content claims have also been updated to better meet consumer health needs. These criteria apply to all food (both prepackaged and non-prepackaged) regardless of where it is sold; and specify the exact conditions required for a food to qualify for a claim. Only the terms and wording set out in the regulations can be used.

Diet-related health claims about reducing the risk of heart disease, cancer, osteoporosis and high blood pressure will be allowed for the first time in Canada. The permitted claims are restricted to scientifically established relationships between diet and the reduction of risk of chronic disease. The new regulations also provide for a claim with respect to tooth decay for chewing gum, hard candy and breath-freshening products that contain a minimal amount of those carbohydrates that promote tooth decay.

Health Canada's website contains more highlights of these changes www.hc-sc.gc.ca/hpfb-dgpsa/onpp-bppn/labelling-etiquetage/index_e.html.

TPH's programs that focus on food skills such as Healthiest Babies Possible, the Peer Nutrition and Healthy Lifestyles will continue to provide information, education, consultation, counselling and referral services pertaining to the new nutrition labels for both Public Health staff and the community.

Health Claims:

Changes in regulations on health claims are intended to provide more opportunities for communicating the role of diet and foods in health promotion and disease risk reduction to the general public.

Following two years of consultation on the nature and extent of health information that could be communicated in food labelling and advertising in Canada, Health Canada published a policy recommendation on health claims for foods in November 1998. The policy permitted that; “structure/function and risk reduction claims for foods should be permitted, while continuing to regulate products with therapeutic claims as drugs”. A structure/function health claim describes “the effect of a food or a diet on a structure or physiological function in the human body”. A risk reduction health claim describes “the relationship between the consumption of a food or a diet and the reduction in the risk of developing a chronic disease or abnormal physiological state, by significantly altering a major risk factor or factors recognized to be involved in its development”. Whereas, therapeutic claims are those related to the cure, treatment, mitigation or prevention of diseases or adverse health conditions. A therapeutic claim is not permitted as a structure/function claim for foods. Again, this policy recommendation was intended to provide more opportunities for communicating the role of diet in health and disease risk reduction, thus enhancing informed consumer choice.

In recommending that structure/function and risk reduction claims for food products be permitted, the final policy recognized that these types of claims may be generic (i.e., they can be applied to any food that meets the criteria for the claim) or product-specific (i.e., they cannot be generalized to other similar products unless acceptable supporting evidence is provided). While these two terms (i.e. generic and product-specific) delineate two categories of claims, they in fact portray a broader spectrum of products that form a continuum, increasing in specificity from food groups or dietary patterns, to innovative proprietary products using unique formulation and/or processing. Refer to Appendix 1 for an illustration of the types of claims and types of food products. The policy also recognized the need for appropriate standards of evidence for these claims.

Other Regulations Affecting Food – Still Under Consideration by Health Canada:

(a) Product-Specific Authorization of Health Claims for Foods

Health Canada invited comments and suggestions on the proposed approach to regulating product-specific health claims for foods. The proposed approach is referred to as “product-specific authorization”. This means that authorization would be granted on a product-by-product basis without claim-specific regulatory amendments. Health Canada proposed that a “food which is manufactured, sold or represented to have a direct, measurable effect on a body function or structure beyond normal growth and development or maintenance of good health be required to submit detailed information to support such an effect before being advertised or offered for sale”.

Product-specific claims differ in several aspects from the “generic authorization” regulatory approach outlined above. Under generic authorization, an entire food group may be the subject of a claim; for example, “a healthy diet rich in a variety of fruits and vegetables may help reduce the risk of some types of cancer”. Foods with health claims that would fall under this proposed regulatory framework are those that have specific effects on a structure or function of the body which may be indistinguishable from the effects of some drugs.

TPH forwarded comments to Health Canada on their proposed approach to regulate product-specific health claims to foods. TPH suggested that the proposed generic health claims were sufficient to highlight disease-risk reduction claims. In light of this, TPH encouraged Health Canada to delay the process of approving product-specific health claim regulations, to allow time to monitor the impact of generic health claims on purchasing patterns, dietary practices and population health outcomes. In addition, TPH expressed concerns related to the following:

- (i) The “magic bullet” approach to nutrition. Product-specific health claims on food products may perpetuate the myth that single food items are capable of reducing the risk of diseases. This message undermines other healthy eating initiatives, which focus consumer education on the importance of a “total-diet approach” and consider other aspects of a healthy lifestyle, such as physical activity.
- (ii) Product-specific health claims will increase the complexity of food labelling education for the consumer and for the health professional whose role is to educate the public.

Comments received in response to this proposed regulatory framework are being considered in drafting proposed regulations to be published in the Canada Gazette Part I. To date, there has been no pre-publication notice of these proposed regulatory amendments.

(b) Addition of Vitamins and Minerals to Foods

The term fortification is often used to refer to the addition of nutrients to foods in general. Technically, fortification is the addition of essential nutrients, especially vitamins and minerals, at levels above those normally found in the particular type of food to which they have been added, in order to address a deficiency or inadequate intake of the nutrient in the diet of consumers. Vitamins and minerals may also be added to restore those lost due to processing, to make a substitute food nutritionally equivalent to the food for which it is substituting, or to make a special purpose food, including sole sources of nutrition. These are the rationales for most of the vitamin and mineral additions permitted at present in Canada.

The addition of vitamins and minerals (also known as micronutrients) to foods in Canada is controlled under regulatory provisions first promulgated in 1964. The Food and Drug Regulations specify the foods to which micronutrients may be added, plus the specific micronutrients and levels to which they may be added to these foods. The regulations also state the amount of nutrient that must be present in the food at the time of purchase. The current regulatory controls on the addition of micronutrients to foods, while continuing to support public health objectives, are viewed as overly restrictive by some sectors of the food industry and some consumers.

In 1998, Health Canada initiated a comprehensive policy review on the addition of vitamins and minerals to foods. The purpose of the policy review was to take into account the public health role of nutrient additions to foods, consumer needs and industry concern.

TPH has participated in key consultations on various fortification policies and implementation issues that will help shape the final policy publication in October 2003. TPH believes that the current regulatory controls on the addition of vitamins and minerals to foods support public health objectives and expressed concern to Health Canada around the following points:

- (i) Discretionary fortification of food could potentially undermine the total diet concept by encouraging consumers to rely upon a few, highly fortified foods rather than a well-balanced diet consisting of a variety of foods consumed in moderation.
- (ii) The need for national nutrition surveillance data to substantiate the development of new regulations on the addition of vitamins and minerals to foods for Canada.
- (iii) The inappropriateness of applying U.S. dietary intake data to the Canadian setting due to differences in climate and geography, food supply and general food habits and preferences.
- (iv) Health Canada indicated that no public health benefits have been shown with the discretionary fortification of many nutrients. Hence, the discretionary fortification of many nutrients does not meet the standards set by the Guiding Principles for Policy Review developed by Health Canada's Expert Advisory Panel on the addition of vitamins and minerals to foods. This raises many questions as to why discretionary fortification should be implemented when the evidence to support discretionary fortification of a wider range of foods is not strong, especially in light of the fact that discretionary fortification has no public health benefit for many nutrients.

TPH, in consultation with other public health stakeholders, will continue to monitor this process as developments occur.

(c) Natural Health Products

Current research indicates that over 50% of Canadians use some form of natural health products. In Canada, natural health products, also referred to as complementary medicines or traditional remedies, are subject to the Food and Drugs Act and Regulations.

The regulatory treatment of these products has been an issue for years. They have been inconsistently regulated as food or drugs. As a result, significant confusion exists in the marketplace as consumers are faced with a product labelled as a food (without health claims or full product use information) sitting next to the same substance labelled as a drug (with health claims and adequate directions for use). As a result, consumers have asked for assurances of quality, recognizing that processes are needed to ensure that what is on the label is in the bottle.

In March 2002, TPH provided a response to Health Canada's proposed Regulations for Natural Health Products. The response was generated by a group of TPH staff who interact directly with multi-lingual and ethnically diverse residents of Toronto. Overall, the response applauded the comprehensiveness of the proposed regulatory framework and highlighted the need for a public education campaign using clear language and in a variety of languages. Suggestions that a logo be developed to distinguish products approved by Canadian authorities were included. The response also identified priority target groups for public education and information related to dosage and safety (pregnant women, new mothers and children), and recommended that Health Canada secure adequate funding for monitoring and surveillance (e.g., site inspection, testing, enforcement).

In November 2002, TPH staff participated in one of Health Canada's cross-country information and townhall consultations on the proposed Standards of Evidence for the evaluation of safety and claims of natural health products.

Conclusions:

TPH has been actively involved with food and nutrition related policy initiatives at Health Canada. TPH believes that effective policies and their implementation will provide the consumer with more food choices to help meet nutritional needs while ensuring that foods can be consumed safely as part of healthy eating patterns. TPH will continue to advocate, monitor and examine pertinent food and nutrition issues as they develop.

TPH is pleased with Health Canada's announcement regarding mandatory nutrition labelling. The Board of Health has urged Health Canada to implement and support consumer education related to the nutrition labelling of foods and to set strict standards for preventing the misleading use of health-related marketing claims.

A number of important issues and regulations related to food and nutrition are still available for comment from public health stakeholders. TPH recognizes the need for more public health advocacy on these regulatory changes. The Board of Health can continue to participate in this regulatory process by reiterating their recommendations to Health Canada.

Contact:

Ava Morgan
Public Health Nutritionist
Toronto Public Health
Health Promotion & Healthy Lifestyles
Planning & Policy
Tel: 416-338-8033
Fax: 416-392-0635
Email: amorgan@toronto.ca

Carol Timmings
Regional Director - East Region
Toronto Public Health
Tel: 416-338-7951
Fax: 416-392-0713
Email: ctimming@toronto.ca

Dr. Sheela V. Basrur
Medical Officer of Health

List of Attachments:

Appendix 1: Types of Claims and Types of Food Products

Appendix 1
Types of Claims and Types of Food Products

Types of Claims	Increasing Claim Specificity	Types of Food Products
Product-Specific	High	Innovative food products Processed food with added component (e.g. cereal with added B-glucan) Food enhanced in a certain component (e.g. omega-3 eggs) Food with a nutrient-specific claim (e.g. calcium) Processed food (e.g. oat bran cereal) Basic food (e.g. whole grains, whole wheat)
Generic	Low	Diet (e.g. high in fruits and vegetables)