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# Canada's Approach to Functional Foods

*by Eileen McMahon and Teresa Reguly*

Today's diet- and health-conscious environment has led to a proliferation of functional food marketing claims that advertise the specific health-enhancing characteristics of a food product. It is not always clear, however, whether a particular health claim will be permissible for a given product. In Canada, can a manufacturer claim on its label, for example, that milk helps to prevent osteoporosis or that orange juice fortified with vitamin D fights cancer cells or that green tea assists with weight loss?

## What Is a Functional Food?

There is currently no statutory or regulatory definition of a functional food claim, although the Bureau of Nutritional Sciences, of the Food Directorate of Health Canada, says: "A functional food is similar in appearance to, or may be, a conventional food, is 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."[1] Generally speaking, a functional food is one that affects a specific function or system in the body. A functional food is associated with a particular physiological benefit in addition to the normal function of food in providing basic nutrition and nourishment. Some examples of functional food components are insoluble fiber found in wheat bran, which is associated with a reduced risk of breast or colon cancer, and long chain omega-3 fatty acids in fish oils, which may reduce the risk of cardiovascular disease.[2]

## Classification of Foods vs. Natural Health Products

Canada lacks a comprehensive statutory framework to deal with functional food claims, and there is currently confusion between the classification of natural health products (NHPs) and functional foods. NHPs and foods are both regulated under the Canadian Food and Drugs Act (Act),[3] in accordance with the applicable provisions of the Food and Drug Regulations[4] or the Natural Health Product Regulations (NHP Regulations).[5] According to section 2 of the Act, a food is broadly characterized as an article manufactured, sold or represented for use as a food or drink for human beings, including chewing gum, and any ingredients that may be mixed with food for any purpose whatever.

An NHP has a much more complex definition as "a substance set out in Schedule 1 of the NHP Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; b) restoring or correcting organic functions in humans; or c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health." Schedule 1 substances include vitamins, minerals, amino acids and essential fatty acids, as well as plant, algal, bacterial, fungal or non-human animal materials and extracts thereof.

A product may be classified as both a food and an NHP, in which case, the product is subject to the NHP Regulations, but is exempt from the provisions of the Act and the Food and Drug Regulations as they specifically relate to food.

**Ms. McMahon** is the co-chair of the IP and Food and Drug Regulatory Practices in the law firm of Torys LLP, Toronto, Canada.

**Ms. Reguly** practices Intellectual Property law in the law firm of Torys LLP, Toronto, Canada.

It is sometimes difficult to determine how a product will be classified for regulatory purposes, as is often the case with energy drinks, protein supplements and nutritional supplements. Similar products, advertised using similar claims, are subject to different premarket review, product safety and risk-management requirements depending on whether they are subject to the Act and the Food and Drug Regulations or to the NHP Regulations.

A guidance document, "Classification of Products at the Food-Natural Health Product Interface"[6] was released in 2009 to assist in determining whether products that share characteristics of both foods and natural health products would be classified as food or NHPs.

The guidance document indicates that classifying a product as a food or an NHP will include assessing the product's risk to public health and safety. Although safety is not the only factor, it is a very important consideration for Health Canada. The following criteria will be considered in classifying a product as either a food or an NHP:

a. *Product composition*. If a product solely provides nutrition or nourishment, it is more likely to be classified as a food. This is often the case even if the product contains an ingredient that falls within a class of substances included in the definition of an NHP. However, a product is more likely to be considered an NHP if it contains an ingredient that is not normally found in foods and especially if that ingredient has a potential therapeutic use.

b. *Product representations*. Products that are represented as having a physiological benefit, either through the claims on the label or in advertisements, are likely to be considered NHPs if the benefit is not based on the use of product as a traditional food.

c. *Product format*. The guidance document defines "in food format" as a form and serving size that is consistent with normal food use, including candy bars or beverages. Classification as a food implies that the product can be consumed without regard to its quantity. On the other hand, NHPs are generally meant for consumption in a measured or controlled amount, and are often sold in dosage forms akin to other drug products (capsules, tablets or single dosage liquid formats).

d. *Public perception and history of use*. If similar products have been traditionally sold as foods rather than as products for therapeutic use, a new product is more likely to be classified as a food as well. Consequently, if the public is unlikely to treat the product as a food, the product is more likely to be an NHP.

These criteria are intended to be a guide only; regulators will make a case-by-case decision for products at the food-NHP boundary.

## Functional Food Claims

As indicated above, food products that are not NHPs must comply with all the quality and safety requirements of the Food and Drug Regulations. Functional food claims can be broadly grouped into three main categories: nutritional claims, general health claims and risk-reduction claims. The labeling restrictions and requirements for functional foods depend primarily on the type of functional claim that is being asserted.

## Risk-Reduction Claims

Risk-reduction claims describe the link between a food or food constituent and the reduction of risk of a particular disease, which includes restoring, correcting or modifying bodily functions. These claims encourage a consumer to infer that the use of a product containing a particular nutrient can reduce certain disease factors. Since 2002, certain risk-reduction claims have been expressly permitted under the Food and Drug Regulations. Claims dealing with the following relationships between a food product and a reduction of a disease state are permissible under the regulations:

- a healthy diet low in sodium and high in potassium *and* reduced risk of high blood pressure;
- a healthy diet with adequate calcium and vitamin D *and* reduced risk of osteoporosis;
- a healthy diet low in saturated and trans fat *and* reduced risk of heart disease;
- a healthy diet rich in vegetables and fruit *and* reduced risk of some types of cancers; and
- non-fermentable carbohydrates in gums and hard candies *and* the non-promotion of dental caries.[7]

Only the exact wording indicated in the regulations is permissible for these risk-reduction claims. No other intervening information or symbol may appear in between the wording of the prescribed claim, and no part of the claim may be written with greater predominance than another.

These risk-reduction claims require no authorization, provided that the claim is within a category specifically permitted by the regulations. Risk-reduction claims must not be confused with therapeutic claims, which are claims about treatment or mitigation of a health-related disease or condition, or about restoring, correcting or modifying body functions. Therapeutic claims have not been approved for any food product in Canada[8] and, as discussed above, the use of therapeutic claims is consistent with classification of a product as an NHP, rather than as a food.

## Nutritional or Functional Claims

Nutritional or functional claims specify the type or quantity of a particular nutrient within the product, and make claims about the nutrient's well-established role in the maintenance or support of specific bodily functions. Functional claims must not state that a product has an effect on a specific disease or its signs and symptoms. These claims may only state the food's effects on the normal functioning of the human body. Claims that a product provides "100 percent of an individual's daily vitamin C intake" and that "Calcium aids in the formation and maintenance of bones and teeth," are examples of acceptable nutritional content claims. This is in contrast to a claim such as "Milk helps build strong bones and teeth," which would not be permissible because the claim is directed to the food product itself, rather than the nutrient within the food.[9]

Nutritional-type claims have fewer requirements than disease-risk-reduction claims. Any food with a nutrient or functional claim must generally contain five percent or more of the recommended daily intake of the nutrient. For foods without recommended daily intakes, claims such as "high in" or "good source of," generally may not be made because the consumer cannot place the statement into a proper context.

## General Health Claims

Functional food claims can also take the form of general health claims, which the Act has no specific rules for. Examples of general health claims would be "healthy" and "include probiotic yogurt in your diet as part of healthy eating." It is also permissible to refer to the provisions of Health Canada's *Eating Well with Canada's Food Guide*,[10] an educational aid directed to consumers that provides recommendations on balanced nutrition. In Canada, no specific criteria have been established for this type of general health claim. The only requirement, as with all functional food claims, is that a statement on a label or in an advertisement cannot make a "false, misleading or deceptive product representation."[11]

According to the Canadian Food Inspection Agency's *Guide to Food Labelling and Advertising*, the following factors will be considered in determining whether a food claim is false, misleading or deceptive:[12]

- Claims must be clear to the consumer; if a claim is too vague, it may be considered misleading if it does not provide meaningful information to the public.
- Health claims must be supported by acceptable scientific evidence.
- A consumer should be able to ingest the food product in an effective amount in order to achieve the health benefit claimed and within the context of a healthy, balanced overall diet.
- For functional claims, a food product making such a claim should include the specified ingredient in an amount that is compatible with established recommended nutrient intakes—that is, the food should be at least a dietary "source" of the nutrient. The serving size and amount of food product necessary to achieve the claimed effect should also be indicated on the label.

General food claims that are directed to achieving or maintaining a healthy body weight must be used with caution. The Act prohibits the advertising of a food (or drug) as a treatment, prevention or cure for certain diseases, including "obesity." The Food and Drug Regulations permit the advertising and labeling of some foods, such as specially formulated meal replacements and foods sold by weight-reduction clinics, to contain indications for use in weight reduction, subject to very specific requirements. Other foods may be represented for use in achieving and maintaining a healthy body weight by indicating that consumption of the food product can "assist in achieving and maintaining a healthy body weight" for a particular reason (e.g., the product is low in fat or portion-controlled).[13] If a food is produced under a brand name that may imply a use for weight reduction, the food label should include a qualification statement such as "for weight maintenance" next to the name to ensure that representations are not misleading.

## Conclusion

Functional food claims is a dynamic and complex area of regulatory law. As health consciousness among consumers continues to rise, manufacturers of food products will seek to competitively represent their products in the marketplace. The key to complying with applicable laws regarding claims for functional food products is to 1) determine the type of claim to be made in association with the product; 2) determine how the product is to be classified (i.e., as a food or as an NHP) on the basis of guidance from Health Canada; 3) determine whether the claim (if for a functional food) is a risk-reduction claim, nutritional claim or functional food claim; and 4) ensure that the claim complies with all applicable laws and regulations relating to the product.

Yolande Dufresne, a summer law student, assisted in preparing this article.

1 Nutraceuticals/Functional Foods and Health Claims On Foods, Health Canada, (1998), *available at*: http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/nutra-funct_foods-nutra-fonct_aliment-eng.php.

2 *What are Functional Foods and Nutraceuticals? Available from Health Canada at* http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1171305207040&lang=eng.
3 R.S.C. 1985, c. F-27.
4 C.R.C., c. 870.
5 SOR, 2003-196.
6 *Available from* Health Canada at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php.
7 Food and Drug Regulations, C.R.C., c. 870 at B.01.600 - B.01.603.
8 *Guide to Food Labelling and Advertising*, chapter 8.1, *available from the Canadian Food Inspection Agency at* http://www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml.
9 *Id.*, chapter 8.6.
10 *Eating Well with Canada's Food Guide*, Health Canada, (2007); *available at* http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/order-commander/index-eng.php.
11 Food and Drugs Act at s. 5(1).
12 *Supra* note 8, chapter 8.2.
13 *Id.*, chapter 8.11.