

# Canadian Regulation of Functional Foods

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## ■ Take Home Message:

- In the past few years, Canada has put in place regulations which permit greater communication of health benefits of food on product labels.
- Although the number of health claims is currently limited, mechanisms are in place for new claims to be added when sufficient evidence of product quality, safety, and efficacy can be provided.

Foods in Canada are regulated under the Food and Drugs Act and Regulations. Traditionally, Canadian regulations were designed to prevent adulteration of foods. Standards were set to define many food products. For example, jams must have a minimum content of fruit and sugar. Our regulations also provide lists of what quantities of specific ingredients can be added to categories of foods based on their purpose. Companies developing new ingredients must apply to Health Canada to have their ingredient listed in the regulations before it can be used in food products sold in Canada.

In the past two decades consumers have been seeking more information about the nutritional quality of their food. A system of voluntary nutritional labeling was developed which, as of January 2003, has been replaced with a mandatory one. Nutritional labeling allows companies to make nutrient content claims on product labels. The nutrient content claim is based on an established recommended daily value. These values have traditionally been based on deficiency diseases. For example, a minimum amount of vitamin C is required to prevent scurvy. The label may indicate that the food is a “good” or “excellent” source of nutrient “X” which is important for growing or maintaining a healthy body.

The new nutritional labeling regulations allow health claims to be made which link consumption of foods, with certain physiological functions, to reduced risk of chronic diseases. These so-called “functional foods” are not specifically defined in the regulations. The term is generally used in Canada to describe foods which have a physiological function beyond basic nutrition. For example,

calcium is an important nutrient for the development of healthy bones but also has a physiological function in reducing the risk of osteoporosis. Five generic health claims are currently permitted. Applications for additional generic claims are being prepared by companies using the new approved procedure. A procedure for product specific claims has not yet been fully developed in Canada.

In January 2004, Health Canada launched regulations for natural health products. If a physiologically active ingredient is extracted from a plant or animal product and packaged in a pill or powder form then it is a natural health product. All natural health products must have a natural product number (NPN) and carry a health claim to be sold in Canada. An application demonstrating the safety, quality, and efficacy of the product must be approved by Health Canada to get an NPN.

The ability to label products with health claims has increased research into ways to create products which have health benefits. Products are being reformulated by adding specific nutrients (eg. calcium) or reducing/replacing components (eg. saturated and trans-fats) to meet the requirements for health claims. Research is also being conducted into finding ways to grow crops or raise animals to improve the nutritional profile of the basic food or food ingredient. If the process used to create the new crop or animal product has not been previously used and causes a major change in the final product then it may come under the “novel foods” category. A major change may include one which creates a product which is outside the natural variations for composition, structure, nutritional quality, or physiological effects. It also may change the manner in which a food is metabolized.

Novel foods cannot be sold in Canada unless the manufacturer has notified Health Canada of their intention to market the product and received written approval. The novel foods regulations came into effect in 1999 and Health Canada posts a list of all products that have received approval. There is no indication on the packaging to the consumer that the product is a novel food. Examples of novel foods include insect resistant cotton, high DHA milk obtained through a DHA-rich feed additive, and mid-oleic sunflower oil.

When conducting research on nutritionally altered foods, it is important to develop sufficient evidence to show the safety, quality and efficacy of the new product. The novel foods notification process requires research to show that a product can be produced at a consistent quality and that all safety considerations have been reviewed. Once approval to produce the novel food is obtained it then moves over to the nutritional labeling regulations to determine what nutritional content or health claims can go on the label. It is important to demonstrate that the nutrient has a recommended daily value to make “good” or “excellent” source claims. If a link to health is desirable, then scientific papers must be provided to justify the health claim requested.

Neilson's Dairy Oh!<sup>TM</sup>, a high DHA (omega-3) milk, has successfully gone through the novel foods application process and been approved for marketing in Canada. Some of the reasons for its successful application were that DHA is an essential fatty acid, its function in humans is reasonably well understood, it has approved therapeutic uses, it is approved for usage in infant formulas, and there is strong evidence through human clinical trials of its benefits to human health.

In recent years, Health Canada has created new regulations which permit some communication to consumers about the healthy attributes of food products right on the product packaging. The dairy industry has been a leader in taking advantage of nutritional content and health claims regulations by promoting the healthy attributes on product labels and conducting research leading to the approval of new novel foods. The current list of health claims in Canada is much shorter than in the United States. However, Canada has made significant progress to develop the regulations and processes by which linkages to health can be communicated on food products. We can expect to see more health claims in the future as research provides more information on the safety, quality, and efficacy of food products.

