A Comparative Analysis of the Regulatory Framework Affecting Functional Food and Functional Food Ingredient Development and Commercialization in Canada, the United States (US), the European Union (EU), Japan and Australia/New Zealand.

August, 2004

This summary report is based on initial work prepared by Sean A. MacDonald on behalf of Agriculture and Agri-Food Canada (AAFC). It combines information from both secondary sources (articles and websites by other organizations) and personal interviews. AAFC would like to acknowledge Kelly Fitzpatrick and Rebecca Sadler for their contributions to the summary report.

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EXECUTIVE SUMMARY

This project was mandated by Agriculture and Agri-Food Canada to provide an update on the current regulatory environment for functional foods in Canada and compare it to that in the United States (US), the European Union (EU), Japan and Australia/New Zealand. Specifically, the purpose was to gain insight on the impact of the regulatory environment on the development and commercialisation of functional foods and functional food ingredients in these jurisdictions. An analysis of the Canadian context was required to determine how Canada’s regulatory system compares in terms of supporting the development of a viable commercial functional foods industry in Canada.

There is widespread recognition that diet plays a role in the development of chronic disease. Estimates in the United States suggest that diet plays a role in 5 of 10 of the leading causes of death. Many people intend to eat a healthy diet but fail to do so because they associate healthy food with poor taste and extensive preparation time. This has created a market demand for foods that do not sacrifice taste and convenience in order to be healthy.

The ability to link a food or food component to health is based on sound scientific evidence, with the desired standard being replicated, randomized, placebo-controlled, intervention trials in human subjects. Once a sound scientific basis has been established for a food or food component, the process for obtaining a health claim for the product can be initiated.

There are three basic types of health claims: structure/function (e.g. calcium helps to build strong bones), risk reduction (e.g. calcium helps reduce the risk and progression of osteoporosis), and therapeutic (e.g. product X is indicated for the treatment of osteoporosis).

Currently the ability to utilize health claims to promote the nutritional value-added attributes associated with functional foods varies internationally. This is further complicated by the fact that only Japan has a legal definition for functional foods; other jurisdictions have focused on the application of health claims rather than establishing a definition that may have difficulty encompassing a range of innovative food products.

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The lack of a formal definition for functional foods makes it difficult to estimate the size of the market. Global sales for functional foods have ranged from a high of $47.6 billion US in 2001\(^4\), to a low of $10 billion US\(^5\). It is estimated that between $300 million and $1 billion CAD of farm production value goes to supplying ingredients for functional foods in Canada\(^6\).

The main issue impacting both regulatory and market perception of functional foods is their hybrid nature – acting like both a food and a drug. In the mind of regulators and consumers, highly technical scientific claims are associated with pharmaceuticals not foods\(^7\). As such, generalized risk reduction health claims about food/food ingredients are more readily accepted as they are only one step further than the structure/function related nutrient claims. These generic risk reduction claims have evolved faster than product-specific disease-based health claims since the regulatory framework more readily accommodates them and they appear to be more easily interpreted and accepted by the consumer.

In 1996, Canada was among the least favourable regulatory environments for allowing health claims. Since that time, progress has been made with respect to the definition of health claims and with the availability of five generic claims. However, Canada still lacks a comprehensive regulatory framework documenting the approval process for functional foods with health attributes. The recent introduction of the Natural Health Product (NHP) regulations are a good first step, however the distinction between a natural health product and a functional food remains unclear. As a result, food manufacturers continue to struggle with product classification and identifying the appropriate regulatory process for products seeking a health claim.

It appears that the key success factor for manufacturers of functional foods is to remember that first and foremost, they are promoting a food. As such, health claims should be seen as a competitive addition to healthy foods, but should not become a replacement for the standard features of a food – namely taste, ease of preparation, and quality. Foods are related to health and drugs to illness; this distinction will be important in the future for any company that wishes to penetrate this market.

INTRODUCTION

The project was initiated by Agriculture and Agri-Food Canada (AAFC) as a way to update information on the current regulatory environment for functional foods in Canada and compare it to that in the United States (US), the European Union (EU), Japan and Australia/New Zealand. The purpose was to facilitate a common understanding of the regulatory environment and its impact on the development and commercialisation of functional foods and functional food ingredients in these jurisdictions. Moreover, an analysis of the Canadian regulatory environment was required in order to gain an appreciation for its impact on the development of a viable commercial functional foods industry in Canada.

The project was initiated in November of 2003. Research and analysis of secondary sources was conducted (with confirmation with primary sources where available), and a draft report was delivered in March of 2004. The contents of the report were used to prepare a condensed summary document.

The regulatory environment pertaining to food is changing in Canada and around the world. This is necessary due to an evolving food science knowledge base, leading to new ideas about how food impacts health. The link between diet and chronic disease development is now widely recognized and has been demonstrated through solid scientific evidence. Human, replicated randomized, placebo-controlled intervention trials have proven to be the most desirable standard of evidence.

In an effort to make the disease-diet link clear to consumers, there has been a global movement by the food industry towards placing health claim statements on food packages. However, the introduction of diet-related health claims has been slow in most countries due to the regulatory constraints. Foods that link diet to a reduced disease risk are functional foods. The main issue impacting both regulatory and market perception of functional foods is their hybrid nature – acting like both a drug and a food. In the mind of regulators and consumers, highly technical scientific claims are associated with pharmaceuticals, not foods. Slowly, regulations world-wide are starting to adapt to include functional foods.

Japan and the United States are at the forefront of the regulatory progression, while Canada, the European Union and Australia/New Zealand are moving more slowly with the concept. This report provides an overview of the changes in the regulatory framework from 1996 – 2004 for these countries. Previously AAFC initiated a benchmarking paper summarizing the regulatory environment leading up to 1996. The original paper, entitled “A Comparative Analysis of the Regulatory Framework Affecting Functional Food Development and Commercialization in Canada, Japan, the European Union and the United States of America” was written by Barry L. Smith, Michelle Marcotte and Gordon Harrison of Inter/Sect Alliance Inc.

There are no regulations dealing specifically with functional foods or nutraceuticals in Canada. The *Food and Drugs Act* (*F&DA*), passed into law in 1953, governs the manufacture, import, advertising and conditions of sale of all food and drug products. The *Act* clearly divides edible items into two separate categories: products that nourish the body are food and products that treat illness or physiological disorders are drugs. Regulations made under the *F&DA* continue to be category-specific meaning that a food is regulated under the food regulations and a drug is regulated under the drug regulations. Foods that offer added health benefits are an awkward fit within this legislative framework. As such, Health Canada applies the food regulatory framework to functional foods and the drug regulatory framework to nutraceuticals.

The *F&DA* stipulates that all products represented for the cure, treatment, mitigation, prevention, risk reduction and correction or modification of body structure and function are regulated as a "drug" regardless of the available scientific evidence. Many of the health claims proposed for functional foods/nutraceuticals are considered to bring the product within the definition of a drug. In November 1998, Health Canada released a policy recommendation to address health claims for foods. The policy paper states 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".

Under current regulations, food package labels may refer to the structure and functions of the human body, such as "Calcium helps build strong bones" or "Canada's Food Guide to Healthy Eating recommends that adults should consume two to four servings of dairy products every day." Section 7.5.2 of the Canadian Food Inspection Agency’s *Guide to Food Labelling and Advertising* provides a table of acceptable biological claims for nutrients (refer to Appendix A).

The prohibition on health claims, and perhaps the most rigid component of the *F&DA* and Regulations is found in Section 3 of the *Act* and includes Schedule A. Together they make it very difficult to use a health claim in the advertising and marketing of food and drug products. Section 3 of the *Act* states that “no person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.” Schedule A lists approximately 40

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medical conditions, including arthritis, cancer, diabetes and heart disease. These restrictions apply even when a health claim is backed by solid scientific evidence. This prohibition on proclaiming the beneficial effects of food products on health has long been regarded by industry as a major obstacle to the growth of the functional food market in Canada.

Despite the barriers surrounding the use of health claims, five generic claims have been authorised for use in Canada. Generic claims apply to a food or a group of foods that have compositional characteristic(s) that contribute to a dietary pattern associated with reducing the risk of a disease or health condition. Once the claim is authorized, any food that meets the specified conditions for composition and labelling may carry the claim without further assessment.

Generic claims were approved through the implementation of a regulatory amendment which provided an exemption to both Section 3 and Schedule A\(^\text{14}\). The allowed statements, labelling and advertising conditions, as well as nutritional content requirements for allowable food were identified in the 2003 amendment to the Regulations\(^\text{15}\).

The five approved generic health claims were chosen following a scientific review by Health Canada. The review, initiated in 1998, looked at the initial ten Nutrition Labeling and Education Act (NLEA) -authorised health claims introduced by the United States. Of the five not included in the 2003 amendments, the claims linking dietary fat and cancer, folate and neural tube defects, fibre and cancer, and soluble fibre and heart disease were deemed to have insufficient scientific backing. Health Canada approved five health claims based on sound scientific support, as well as the ultimate public health benefit associated with a reduction in nutrition-related chronic disease:

1. Sodium/potassium and hypertension
2. Calcium/vitamin D and osteoporosis
3. Saturated/trans fat and coronary heart disease
4. Fruits/vegetables and cancer
5. Sugar alcohols and dental caries.

Each of these health claims required an individual amendment to the F&DA and Regulations. A possible sixth generic health claim, which would link a diet rich in vegetables, fruits, and whole grains with a reduction in the risk of coronary heart disease, is currently being considered by Health Canada, however it has not yet been sent out for public consultation\(^\text{16}\). Health claims based on authoritative statements from organizations (e.g. ‘the Canadian Medical Association recommends…….’) and qualified health claims used in the US were not considered for use in Canada at this time.

To provide industry guidance for the approval of additional claims, Health Canada developed an interim guidance document for preparing health claim submissions. This document, published in


\(^{15}\) Ibid.

\(^{16}\) Personal communication with Margaret Cheney, Health Canada, March 2004.
2000, would apply to both generic and product-specific claims\textsuperscript{17}. Product specific claims have been proposed for specific foods having a direct, measurable metabolic effect beyond normal growth, development or health maintenance, reducing disease risk or aiding in the dietary management of a disease or condition. Of significance, unlike generic health claims, in the case of product-specific health claims, the authorization of each claim would not entail a claim-specific regulation, however claims for “Schedule A diseases” would not be permitted.

From a regulatory perspective, generic claims would be permissible through amendments to the list of authorized claims initially published in 2003.\textsuperscript{18,19} No product-specific claims are currently allowed and industry appears reluctant to test the submission process.

The regulatory environment in Canada was also affected by the introduction of the \textit{Natural Health Products (NHP) Regulations}\textsuperscript{20} on January 1, 2004. The new regulations apply to all natural health products, including vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines, probiotics, amino acids, essential fatty acids and other nutraceuticals. Until publication of the \textit{NHP Regulations}, the working definition for a nutraceuticals in Canada has been “a product that has been isolated or purified from foods and generally sold in medicinal forms not usually associated with food. Nutraceuticals have been shown to exhibit a physiological benefit or provide protection against chronic disease”. The product category of nutraceuticals has been encompassed within \textit{NHP Regulations}.

The \textit{NHP Regulations} are built on the philosophy that these products have enjoyed a long history of safe use. They address improved labelling, good manufacturing practices, product and site licensing, and provisions for a full range of health claims supported by evidence. The inclusion of appropriate good manufacturing practices addresses concerns about the quality and safety of these products. Improved labelling will help consumers make informed choices and take more control over their health decisions.

NHP products will be allowed to be manufactured sold or represented for use in: the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans (i.e. claims that are currently allowed in Canada only for drug products); (ii) resorting or correcting organic functions in humans, or (iii) maintaining or promoting health or otherwise modifying organic functions in humans. In order to allow “drug type” claims within the \textit{F&DA and Regulations}, these products will be regulated under a subsection of the Drug Regulations, but will still be referred to as NHPs.


Approval of a NHP would include an issuance of a Natural Product Number (NPN), similar to the Drug Identification Numbers (DIN) used for drug approvals\textsuperscript{21}. The Natural Health Products Directorate (NHPD) has developed the Compendium of Monographs as a tool for the timely and efficient evaluation of both safety and efficacy of many medicinal ingredients\textsuperscript{22}. If an ingredient or product has a monograph, manufacturers can make a health claim without having to generate supporting evidence, and be fast-tracked through the claim approval process.

The introduction of the NHP regulations failed to clarify the distinction between foods, functional foods, and nutraceuticals from a regulatory perspective. Even though the legislation does not include conventional foods and is not intended to capture a product in a food medium, the rule is unclear as to whether foods bearing health claims or structure/function claims relating to a nutrient (e.g., a beverage with the statement "contains calcium to help build strong bones") are outside the scope of the NHP regulations. In not clearly defining the health claim approval process, Canadian regulators risk making future separations of food, functional food and nutraceuticals more complicated\textsuperscript{23}.

One possibility for an enhanced regulatory framework for functional foods and nutraceuticals lies with the ‘legislative renewal’ process initiated by Health Canada. This initiative includes a proposal to replace the \textit{F&DA}, as well as related acts, with a more comprehensive piece of legislation, tentatively referred to as the Canada Health Protection Act\textsuperscript{24}. This new legislation would potentially separate functional foods and nutraceuticals from their current “food” and “drug” definitions.

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\textsuperscript{23} Personal communication with Ted Farnsworth, Agriculture and Agri-Food Canada

Since 1996, the United States has made major advances in their development of regulations for functional foods and nutraceuticals. Although they have no legal definition of a functional food, there are several methods by which the U.S. Food & Drug Administration exercises its oversight in determining whether a health claim may be used on a food label:

1. the 1990 Nutrition Labelling and Education Act (NLEA),
2. the 1997 Food and Drug Administration Modernization Act (FDAMA) and
3. the 2003 FDA Consumer Health Information for Better Nutrition Initiative.

The development of these different pieces of legislation has helped bring the total number of U.S. health claims in use to twenty-one (21).

In 1996, NLEA-approved health claims were just being introduced, with only a few being approved. Currently, 12 NLEA-approved health claims are in place:

1. Calcium and osteoporosis
2. Sodium and hypertension
3. Dietary fat and cancer
4. Dietary saturated fat and cholesterol and risk of coronary heart disease
5. Fibre-containing grain products, fruits, and vegetables and cancer
6. Fruits, vegetables, and grain products that contain fibre, particularly soluble fibre, and risk of coronary heart disease
7. Fruits and vegetables and cancer
8. Folate (0.4mg/day) and neural tube defects
9. Dietary sugar alcohol and dental caries
10. Soluble fibre from certain foods and risk of coronary heart disease
11. Soy protein and risk of coronary heart disease
12. Plant sterol/stanol esters and risk of coronary heart disease

The Food and Drug Administration Modernization Act of 1997 (FDAMA) allows for health claims to be made if such claims are based on current, published, authoritative statements from a recognized scientific body of the U.S. Government, as well as from the National Academy of Sciences. These provisions expedite the process by which the scientific basis for such claims is established. The FDA has prepared a guide explaining how a manufacturer can make use of authoritative statement-based health claims.25

The authoritative statement health claims currently in use are:

1. Whole grain foods and risk of heart disease and certain cancers
2. Potassium and risk of high blood pressure and stroke.

Qualified claims are the third type of health claim available for use in the United States. Initially, qualified health claims were restricted to dietary supplements. Dietary supplements are governed by different regulations than “conventional” food and drug products. In the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplements are defined as

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non-tobacco products intended for diet supplementation. These products are typically in the form of pills, capsules, tablets or liquids consisting of a concentrate, metabolite, constituent, extract of one of or a combination of vitamins, minerals, herbs, other botanicals, amino acids or substances such as enzymes, organ tissues, glandulars and metabolites. Dietary supplements may also be in forms such as bars, as long as they are labeled as dietary supplements and not represented or marketed for consumption as a conventional food or sole item of a meal or diet.

As outlined in DSHEA, dietary supplements are allowed to make a broad range of ‘nutritional support’ statements at the discretion of the manufacturer. The nutritional support statements need not be approved by the FDA, although the agency must be notified no later than 30 days after a product bearing the claim is first marketed\(^{26}\). Initially, the statements were limited to well-recognized ‘structure/function’ claims. Dietary supplements are not allowed, without prior FDA review, to bear statements claiming the prevention, treatment, cure, mitigation or diagnosis of a disease\(^{27}\).

Qualified health claims are used when more evidence is present for than against a nutrient/disease relationship, yet the evidence does not meet the significant scientific agreement validity standard. The claims must include language clearly stating that there is only limited supporting evidence for the claim and must not mislead consumers.

### Standardized Qualifying Language for Qualified Health Claims

<table>
<thead>
<tr>
<th>Scientific Ranking*</th>
<th>FDA Category</th>
<th>Appropriate Qualifying Language**</th>
</tr>
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<tbody>
<tr>
<td>Second Level</td>
<td>B</td>
<td>&quot;although there is scientific evidence supporting the claim, the evidence is not conclusive.&quot;</td>
</tr>
<tr>
<td>Third Level</td>
<td>C</td>
<td>&quot;Some scientific evidence suggests ... however, FDA has determined that this evidence is limited and not conclusive.&quot;</td>
</tr>
<tr>
<td>Fourth Level</td>
<td>D</td>
<td>&quot;Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim.&quot;</td>
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**The language reflects wording used in qualified health claims as to which the agency has previously exercised enforcement discretion for certain dietary supplements. During this interim period, the precise language as to which the agency considers exercising enforcement discretion may vary depending on the specific circumstances of each case.

The development of qualified health claims resulted from a 1999 Court of Appeals Decision. *Pearson v. Shalala*, which concentrated on dietary supplements, successfully challenged the rigid

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\(^{27}\) Ibid.
standards of evidence applied to NLEA health claims\textsuperscript{28}. As a result this court case, the FDA was required to allow qualified dietary supplement claims. The use of qualified health claims was extended to food by the regulatory directive \textit{2003 Consumer Health Information for Better Nutrition Initiative}\textsuperscript{29}.

The new regulation means that substantial agreement among scientists on whether a food or ingredient provides a health benefit will not be required and food manufacturers will be able to petition the FDA to use health claims that already have been approved for dietary supplements. The FDA now will use the standard of the "reasonable consumer" and "weight of evidence" to evaluate claims.

Currently, the FDA has approved qualified health claims for the following nutrient/disease relationships:

1. Selenium and cancer
2. Antioxidant vitamins (E and C) and cancer
3. Nuts and heart disease
   a. Walnuts and heart disease
4. Omega-3 fatty acids and coronary heart disease
5. B vitamins and vascular disease
6. Phosphatidyl serine and cognitive dysfunction and dementia
7. 0.8mg folic acid and neural tube birth defects.

An additional eleven qualified health claims were published for public comment between March 16 and July 13, 2004\textsuperscript{30}:

1. Lutein and eye health
2. Soy protein and cancer
3. Green tea and cancer
4. Calcium and the following:
   - Bone fractures
   - Kidney/urinary stones
   - Menstrual disorders
   - Various cancers
   - Hypertension
5. Lycopene, tomatoes and cancer
6. Eggs with Enhanced Omega-3 Fatty Acid Content and a Balanced 1:1 Ratio of Omega-3/Omega-6 Fatty Acids and Reduced Risk of Heart Disease and Sudden Fatal Heart Attack.

Although the evaluation process for qualified health claims has been well described by FDA, the amount of time required to review a new submission and for public comment is not stated; it appears that the evaluation process will be dealt with on a case-by-case basis.\textsuperscript{31}

Since 1996, the United States has moved to the forefront of the movement on health claims. The large number of health claims allowed makes them an excellent place for manufacturers to market products with health attributes. It also provides the American consumer with a large amount of product choice and information regarding the health effects of the food they are eating. However, the introduction of qualified health claims and the reluctance of Health Canada to accept all of the US-approved health claims may contribute to consumer skepticism over the integrity and amount of the scientific evidence supporting claims.

In 1991, Japan became the first global jurisdiction to implement a regulatory system for functional foods. Under the Japanese system, functional foods are a distinct category within the food supply, Foods for Specific Health Use (FOSHU), with a specific regulatory approval process separate from foods fortified with vitamins and minerals, and dietary supplements not carrying FOSHU claims. FOSHU is one of the five categories covered under “Foods for Special Dietary Uses”. Under FOSHU, foods are defined as “foods in the case of which specified effects contributing to maintain health can be expected based on the available data concerning the relationship between the foods/food’s contents and health, as well as foods with permitted labelling which indicates the consumer can expect certain health effects upon intake of these particular foods”.

Dietary supplements including pills and capsules were included under FOSHU in 2001. Approved FOSHU foods bear a seal of approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) identifying their role in disease prevention and health promotion.

To achieve FOSHU status and an approved health claim, companies submit a scientific dossier to MHLW, which includes scientific documentation demonstrating the medical and nutritional basis for the health claim, including the recommended dose of the functional ingredient. MHLW has established a detailed approval process, which typically takes about one year to complete. Approval is for the food or beverage as it is normally consumed.

The range of functional foods sold in Japan is quite diverse and includes most product categories. Japan has the second largest functional food market behind the U.S. with a value in 2003 of approximately $16.0 billion U.S. The FOSHU market currently accounts for $5.1 billion of the total health food industry in Japan, which is estimated to be worth $12 billion in 2004. As of the end of June 2004, there are 422 permitted and 2 approved FOSHU products (refer to Appendix B). The distinction between "permitted" and "approved" is not well understood. Currently, the “non-health claim” functional food market represents the largest sector of Japan’s food industry at around $8 billion. This is followed by a newer category known as “Foods with Nutrient Function Claims” at an estimated $5 billion and including over 1000 products according to a recent Japan market report.

The FOSHU market is made up of eight specified health use categories, with foods for gastrointestinal health the most popular with 195 approved products and a market share worth $3.2 billion. This product category is followed by foods for cardiovascular health with 59 approved products and a $94 million market share. The remaining categories include foods for

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34 Ibid.
hypertension, diabetes, to help mineral absorption, triglyceride health (foods fortified with fatty acids/plant sterols, for example), bone health and dental health.

The FOSHU system is voluntary, so a product with health benefits does not have to be submitted for FOSHU approval if it refrains from making express disease or health-related claims. Since there has been considerable public education about nutrient deficiencies and the Japanese reportedly have a larger knowledge base about links between diet and disease, non-FOSHU products are able to draw on consumer awareness of the health benefits associated with particular ingredients in products to dominate the marketplace. The competitive marketplace and demand for new products appears to have shifted food manufacturers’ interest away from obtaining government (FOSHU) approval for a health claim, especially with a time and money intensive system.

To increase voluntary participation in the FOSHU system, the government made several significant changes to the regulatory procedure in 1998. The changes included a reduction in the amount of scientific evidence that must be supplied; replacement of the certificate verifying that the submitted scientific documentation had been reviewed by outside experts with a requirement that the studies be published in a scientific journal, including those sponsored by industry; allowing analytical tests to be done in labs other than the National Health and Nutrition Laboratory; and removal of the four year limitation on FOSHU approvals. It is unclear whether these amendments have increased industry participation in the FOSHU approval system.

The Japan Health Food and Nutrition Food Association (JHNFA) set manufacturing standards as well as the criteria for labelling and advertising of health foods. As of July 1997, more than 1,200 brands of food carried the JHNFA seal. Before the 1998 amendments, FOSHU approvals were expedited by a JHNFA approval process. After the 1998 amendments, JHNFA assisted the FOSHU approval process by creating the Journal of Nutritional Food.

For some time there had been pressure on the Japanese government agencies to allow more generic health claims to be made, similar to the structure/function claims allowed for dietary supplements in the U.S. In April 2001, the MHLW decided to recognize this interest by creating a new food category called “Foods with Nutrient Function Claims”, which allows foods (including dietary supplements) and beverages to make specific claims for twelve vitamins and two minerals provided the product meets the minimum and maximum dosage restrictions per serving. The generic claim(s) can be used without a formal approval from MHLW and without

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38 Ibid.
the need for an individual product application. A summary of the Nutrient Function Claims are included in Appendix C.

In 2003, an investigation was initiated to more closely examine the definition and regulation of health foods. This initiative is being undertaken by the Ministry of Health, Labor and Welfare, with the results being available sometime in 2004. The Health Promotion Law was also amended on August 29, 2003 to prohibit food advertising with false or markedly misleading claims.

Despite Japan being the first to regulate and implement programs for functional foods, their system has some characteristics which may be considered weaknesses. Health foods are not allowed to express health claims, although current regulations do not forbid the insinuation of a health link. Some of these health-related links may be misleading. Due to the regulatory framework in Japan, FOSHU approved foods do not have limitations on the levels of so-called “unhealthy” ingredients, such as salt and sugar, allowing health claims on products which have the potential to contribute to conditions such as hypertension and obesity. This potentially misleading situation has been avoided by the regulatory frameworks adopted by Canada, the United States and the European Union.

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40 Ibid.

41 Ibid.

42 Ibid.

43 Ibid.

44 Ibid.

The European Union (EU) has no legal functional food definition, although it developed a working definition in 1995. Currently, there is no harmonized legislation for health claims but the labelling legislation prohibits attributing preventing, treating, or curing a human disease or referring to such properties to any food product. However, each EU Member State has applied different interpretations of the existing labelling legislation.

Since 1996, action has been taken to establish a coordinated and science-based approach to health claims for foods. The EU established the European Commission Concerted Action on Functional Food Science in Europe (FUFOSE). Coordinated by ILSI Europe, the aim was to establish a science-based approach to identifying and analyzing the evidence required to support the link between food products and their beneficial effects on an identified physiological function; individual state of health and well-being; or disease risk reduction. Their final report positions functional foods in the form of normal foods and demonstrate their health effects in the amounts normally consumed in the diet.

Enhanced function and reduction of disease risk are the two types of health claims supported by FUFOSE. Enhanced function claims refer to specific physiological, psychological functions and biological activities of foods or ingredients which exceed that which is established in normal body functions without referring to diseases or pathological states. Reduction of disease-risk claims link food or food ingredient consumption to the reduced risk of a specific disease or condition.

A second Concerted Action initiative, Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) was initiated to develop an implementation process to support the FUFOSE claim system. The PASSCLAIM project aims to establish common criteria to assess the scientific substantiation of health-claims and provide the framework to assist with the validation, substantiation and communication requirement for approval of and use of the claims.

A proposed regulation on nutrition and health claims made on foods was set to be voted on by the Committee on the Environment, Public Health and Consumer Policy on April 6, 2004. In this proposal, “enhanced function” claims were deleted, leaving only claims relating to reduction of a risk of disease. Both the scientific support for any such claims and their proposed wording would require pre-market approval from the European Food Safety Authority (EFSA) – the EU body that will oversee claim approvals. The labels of products that make such claims must also bear a statement that diseases have multiple risk factors and that “altering of these risk factors may or may not have a beneficial effect”. The new regulations could impact existing self-regulatory systems used in the EU Member States.

Following a vote, the regulations will be read in the European Parliament. However, the vote may have been pushed back by a large number of proposed amendments to the regulation.

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Whether it was voted on is not clear. Industry has reacted strongly to the proposals indicating that the regulations propose the allowance of health claims only under strict conditions. A brief set of guidelines was issued as a press release following media-issued confusion over what the proposed regulations contained. The implementation of these regulations is projected to take three to six years. The approval and implementation of these regulations would bring the EU to a regulatory environment similar to Canada.

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AUSTRALIA AND NEW ZEALAND

At present, Australia and New Zealand do not have a comprehensive regulatory framework for functional foods. In Australia, products which are ingested are regulated as either foods or therapeutic goods (medicines). In New Zealand, three regulatory categories of products exist: foods, medicines and dietary supplements. Within the category of dietary supplements, some are regulated as food-type products and others as medicinals. Australia and New Zealand share common regulations for foods under the Australia New Zealand Food Standards Code. No similar common legislation exists currently for dietary supplements and medicines/therapeutic goods.

Within the Australia New Zealand Food Standards Code, foods are regulated according to their intended uses either as part of the general dietary intake for nutritional purposes (i.e. general purpose foods), or for special nutritional purposes such as meal replacement and infant formulae (i.e. special purpose foods)\(^\text{49}\). Functional foods are not defined in food legislation and do not fall within either of the previously described categories.

Using similar wording to Canada, Food Standards Australia New Zealand (FSANZ) has proposed a definition for functional foods:

*Functional foods are similar in appearance to conventional foods and are intended to be consumed as part of a usual diet, but have been modified to have physiological roles beyond the provision of simple nutrient requirements.*\(^\text{50}\)

For foods that fall within the ‘functional’ category, FSANZ has indicated that such foods should be: 1) presented as foods and available as part of a normal food supply (eg, in grocery stores and speciality shops, such as health food stores); 2) are not foods that are essential for the maintenance of life - there are no sub-groups in the population who require these foods for survival; and 3) should have a physiological function over and above that provided by the nutrients found in the traditional diet. Currently, only one health claim is permitted in Australia that being for the relationship between folate intake and the reduction of the risk of neural tube defects in unborn babies. This claim was permitted in 1998.

In August 2004, FSANZ issued a 297 page consultation document, with the intention of developing health claims standards for Australia by December 2005\(^\text{51}\). FSANZ is calling for public and industry comments on its consultation document; the closure date for comments is October 13\(^\text{th}\) 2004.

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The proposal describes four types of claims. *General level claims* refer to “a claim which does not reference a biomarker or a serious disease condition and [includes] [content] claims, function claims, enhanced function claims and risk reduction claims that reference a non-serious disease or non-serious condition.” According to FSANZ, such claims would not be subject to pre-market approval but the manufacturer would have to have evidence to substantiate the claim and be able to produce this evidence at the request of the regulator.

*High level claims* are described as “a claim which references a biomarker or a serious disease or condition and includes biomarker maintenance claims, biomarker enhancement claims and risk reduction claims which reference a serious disease or condition.” Such claims would be subject to pre-market approval. *Therapeutic claims* are “a claim outside the context of the total diet which refers to the prevention, treatment, alleviation or cure of a disease, ailment, defect or injury. An example would be ‘this food is high in iron for the treatment or prevention of anaemia.’ Such claims would only be permitted on products regulated under Australia’s existing *Therapeutic Goods Act*, which regulates Over-The-Counter (OTC) products and dietary supplements.

A *content claim* is “a general level claim which describes or indicates, explicitly or implicitly, the presence or absence of energy or a nutrient or a biologically active substance in a food.” Similar to regulations currently under consideration in Europe, FSANZ proposes that “general well-being claims” would not be permitted in a future regulatory environment.

After the first round of consultation is complete, a second round of consultation on a draft standard is required; it should begin in May 2005. The final standard is expected to be completed by December 2005.
GLOSSARY

**Functional foods** are foods which are similar in appearance to, or may be, a conventional food which is consumed as part of the usual diet and has demonstrated physiological benefits and/or reduces the risk of a chronic disease, beyond what is expected by its basic nutritional functions.

**Health Claims** are statements which link eating patterns to health or illness. The three basic types of health claims are structure/function, risk reduction, and therapeutic. These all may be either generic or product specific.

**Therapeutic** health claims assert the ability to cure/treat/mitigate a disease or condition. These require the most rigorous evidence and are typically regulated as a drug.

**Structure/function** health claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans. These claims may also characterize how the nutrient or dietary ingredient acts to maintain the structure or function.

**Risk reduction** health claims describe how the food or food ingredient significantly alters a major risk factor or factors involved in the development of a chronic disease or abnormal physiological condition.

**Generic** health claims apply to a food or group of foods that have compositional characteristic(s) that contribute to a dietary pattern associated with reducing the risk of a disease or health condition. Once the claim is approved, any food that meets the specified conditions for composition and labelling may carry the claim without further assessment. They can be approved through the implementation of a regulatory amendment to the *Regulations* providing an exception to Section 3 & Schedule A of the *Act*.

**Product specific** health claims are proposed to be used on specific foods having a direct, measurable metabolic effect beyond normal growth, development or health maintenance, reducing disease risk or aiding in the dietary management of a disease or condition. Unlike generic claims, the authorization of each product-specific claim would not entail a claim-specific regulation and claims for Schedule A disease would not be permitted.
## Appendix A:

### Table 1: Acceptable Biological Claims for Nutrients - Canada

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Acceptable Biological Role Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protein</strong></td>
<td>Helps build and repair body tissues</td>
</tr>
<tr>
<td></td>
<td>Helps build antibodies</td>
</tr>
<tr>
<td><strong>Fat</strong></td>
<td>Supplies energy</td>
</tr>
<tr>
<td></td>
<td>Aids in the absorption of fat-soluble vitamins</td>
</tr>
<tr>
<td><strong>Carbohydrate</strong></td>
<td>Supplies energy</td>
</tr>
<tr>
<td></td>
<td>Assists in the utilization of fats</td>
</tr>
<tr>
<td><strong>Vitamin A</strong></td>
<td>Aids in normal bone and tooth development</td>
</tr>
<tr>
<td></td>
<td>Aids in the development and maintenance of night vision</td>
</tr>
<tr>
<td></td>
<td>Aids in maintaining the health of the skin and membranes</td>
</tr>
<tr>
<td><strong>Vitamin D</strong></td>
<td>Factor in the formation and maintenance of bones and teeth</td>
</tr>
<tr>
<td></td>
<td>Enhances calcium and phosphorus absorption and utilization</td>
</tr>
<tr>
<td><strong>Vitamin E</strong></td>
<td>Protects the fat in body tissues</td>
</tr>
<tr>
<td><strong>Vitamin C</strong></td>
<td>Factor in the development and maintenance of bones, cartilage, teeth and gums</td>
</tr>
<tr>
<td><strong>Thiamine</strong></td>
<td>Releases energy from carbohydrate</td>
</tr>
<tr>
<td>(Vitamin B&lt;sub&gt;1&lt;/sub&gt;)</td>
<td>Aids normal growth</td>
</tr>
<tr>
<td><strong>Riboflavin</strong></td>
<td>Factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td>(Vitamin B&lt;sub&gt;2&lt;/sub&gt;)</td>
<td></td>
</tr>
<tr>
<td><strong>Niacin</strong></td>
<td>Aids in normal growth and development</td>
</tr>
<tr>
<td></td>
<td>Factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td><strong>Vitamin B&lt;sub&gt;6&lt;/sub&gt;</strong></td>
<td>Factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td><strong>Folacin</strong></td>
<td>Aids in red blood cell formation</td>
</tr>
<tr>
<td><strong>Vitamin B&lt;sub&gt;12&lt;/sub&gt;</strong></td>
<td>Aids in red blood cell formation</td>
</tr>
<tr>
<td><strong>Pantothenic Acid</strong></td>
<td>Factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td><strong>Calcium</strong></td>
<td>Aids in the formation and maintenance of bones and teeth</td>
</tr>
<tr>
<td><strong>Phosphorus</strong></td>
<td>Factor in formation and maintenance of bones and teeth</td>
</tr>
<tr>
<td><strong>Magnesium</strong></td>
<td>Factor in energy metabolism, tissue formation and bone development</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>Factor in red blood cell formation</td>
</tr>
<tr>
<td><strong>Zinc</strong></td>
<td>Factor in energy metabolism and tissue formation</td>
</tr>
<tr>
<td><strong>Iodine</strong></td>
<td>Factor in the normal function of the thyroid gland</td>
</tr>
</tbody>
</table>

---

### APPENDIX B

**TABLE 2: NUMBER OF APPROVED FOSHU PRODUCTS BY CATEGORY AS OF JUNE 2004**

<table>
<thead>
<tr>
<th>Category</th>
<th>Functional Ingredient</th>
<th>No. of Products Approved</th>
<th>Examples of Products in the Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gut Regulation</td>
<td>Oligosaccharides</td>
<td>195</td>
<td>Soft drink, yogurt, biscuit cookie, table sugar, soyabean curd, vinegar, chocolate, powdered soup, fermented milk, yogurt, miso soup, cereal</td>
</tr>
<tr>
<td></td>
<td>Lactobacillus</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bifidobacterium</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dietary Fibres</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Soya protein</td>
<td>59</td>
<td>Soft drink, meat ball, sausage, soya milk, soup, biscuit, margarine</td>
</tr>
<tr>
<td></td>
<td>Dietary Fibre</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phytosterol esters</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phytostanol esters</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dietary fibres</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Sugar Level</td>
<td>Dietary Fibre</td>
<td>57</td>
<td>Candy, soup, soft drink</td>
</tr>
<tr>
<td></td>
<td>Wheat albumin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>L-arabinose</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Touchi extract</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Polyphenols</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>Peptides</td>
<td>38</td>
<td>Soft drink, soup, lactic acid, bacterium drink, soya bean</td>
</tr>
<tr>
<td></td>
<td>Tochucha saccharide</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Isoleucyl tyrosine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental Care</td>
<td>Sugar alcohols (Manitol, polyphenols, paltinose, xylitol)</td>
<td>29</td>
<td>Soft drink, Chocolate, chewing gum</td>
</tr>
<tr>
<td>Neutral Fats and Body Fat</td>
<td>Diacylglycerol</td>
<td>19</td>
<td>Cooking oil, soft drink</td>
</tr>
<tr>
<td></td>
<td>Sitosterol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium chain fatty acids</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Globin Protein</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrolyzate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Green tea catechins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mineral Absorption</td>
<td>CPP</td>
<td>14</td>
<td>Soft drink, soup, yogurt, milk, cereal, chocolate</td>
</tr>
<tr>
<td></td>
<td>CCM</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poly-gamma-glutamic acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oligosaccharide</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Heme iron</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone Health</td>
<td>Soy Isoflavone</td>
<td>11</td>
<td>Soft drink, fermented soya bean (natto), jelly</td>
</tr>
<tr>
<td></td>
<td>Milk Basic Protein</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vitamin K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Approved</td>
<td></td>
<td><strong>422</strong></td>
<td></td>
</tr>
</tbody>
</table>

---


### APPENDIX C

#### TABLE 3: FOODS WITH NUTRIENT FUNCTION CLAIMS (FNFC) - JAPAN

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Function Claim</th>
<th>Required attention and warning labelling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Helps to maintain vision in the dark. Helps to maintain skin and mucosa healthy.</td>
<td>Women who are pregnant or expecting should be careful of excess intake.</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>Helps to produce energy from carbohydrate and to maintain skin and mucosa healthy.</td>
<td></td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>Helps to maintain skin and mucosa healthy</td>
<td></td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>Helps to produce energy from protein and maintain skin and mucosa healthy</td>
<td></td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>Aids in the red blood cell formation</td>
<td></td>
</tr>
<tr>
<td>Vitamin C</td>
<td>Have an antioxidizing effect. Helps to maintain skin and mucosa healthy</td>
<td>Excess intake of this product neither cures your disease nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>Helps to protect fat in the body from being oxidized and maintain cell healthy.</td>
<td></td>
</tr>
<tr>
<td>Vitamin D</td>
<td>Promotes the absorption of calcium in the gut intestine and aid the development of bones</td>
<td></td>
</tr>
<tr>
<td>Biotin</td>
<td>Helps to maintain skin and mucosa healthy</td>
<td></td>
</tr>
<tr>
<td>Pantothenic Acid</td>
<td>Helps to maintain skin and mucosa healthy</td>
<td></td>
</tr>
<tr>
<td>Folic acid</td>
<td>Aids in the red blood cell formation and which contributes to the normal growth of the foetus</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount. Does not improve the growth of the foetus with excessive intakes.</td>
</tr>
<tr>
<td>Niacin</td>
<td>Helps to maintain skin and mucosa healthy</td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>Is necessary for the development of bone and teeth</td>
<td></td>
</tr>
<tr>
<td>Iron</td>
<td>Is necessary in red blood cell formation.</td>
<td></td>
</tr>
</tbody>
</table>

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REFERENCES


15. Ibid


23. Personal communication with Ted Farnsworth, Agriculture and Agri-Food Canada.


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