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

Barry L. Smith
Michelle Marcotte
Gordon Harrison

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Inter/Sect Alliance Inc.
1127, 90 Sparks Street
Ottawa, Ontario
K1P 5B4
Tel: 613-235-5385
Fax: 613-235-5866

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Since it is entirely possible that some of our evaluation of regulations is not in agreement with the views of those who provided us with government information and interpretation, we assure the readers, our evaluations are our own.

***Note**: The authors have gathered the most up to date information and made careful and informed interpretation of complex regulatory situations. Regulations in this subject change frequently; some decisions have not yet been made. We cannot, however, take responsibility for packaging decisions. Manufacturers wishing to make label decisions should first obtain and review the pertinent regulations and, if necessary, obtain approval for claims before labeling their product.*

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Executive Summary

The regulatory framework governing foods generally in Canada, as in other major jurisdictions, is evolving. Food research, product and process innovation and change in consumer behaviour are all outpacing the adaptation of regulation to new market realities. Among these realities is growing consumer awareness of nutrition and interest in health promotion. Increasingly, this awareness is manifested through consumption of particular foods and dietary supplements believed to contribute to good health and in some cases, to hold therapeutic value in the treatment or prevention of specific afflictions or diseases. Many of these food products are becoming commonly known as nutraceuticals or "functional foods".

The regulatory environment governing functional foods is poorly defined throughout the world, with the possible exception of Japan, where an accredited food industry organization, working in close cooperation with government, plays a direct role in the regulation of functional food products. In Canada, the regulatory framework is so restrictive that the development of a functional foods industry or even functional food products in Canada will be severely impaired, if not entirely precluded.

Two earlier studies commissioned by Foreign Affairs and International Trade Canada (FAIT) and Agriculture and Agri-Food Canada (AAFC) identified Canada's regulatory framework as the major impediment to success of Canadian-based functional food manufacturers, both in the domestic and international markets. Both studies pointed to the need for more detailed analysis of Canada's regulatory framework affecting functional foods as compared to those in other jurisdictions that are Canada's leading export markets for food products. Accordingly, this project was defined to yield a comparative analysis of the opportunities and constraints inherent in the existing regulatory frameworks affecting functional foods in Canada, the United States, the EU and Japan.

Our research findings confirm that among the four jurisdictions examined, Canada has the most restrictive regulatory climate for the development and marketing of functional foods, taking into account federal law, regulation, guidelines and evaluation and licensing procedures governing production, manufacture, packaging, labelling and advertising of food products. Health claims associated with food products, even if known to be factual, are prohibited. The current system in Canada effectively offers manufacturers only the option of licensing and sale of functional foods as "drugs", as defined under the *Food and Drugs Act*. We conclude that this option is prohibitively expensive to all but a few Canadian firms. A food product designated as a drug would also face considerable marketing restrictions. As a consequence, consumer access to functional food products in Canada will be unduly restricted, as will investment and competition.

In comparison, the regulatory system in Japan is supportive of the development and marketing of functional foods (Foods for Specified Health Use) and has evolved through close collaboration among industry, government, academia and research organizations. The licensing process is clearly defined, predictable and jointly managed by industry and government. As a

consequence, food manufacturers have access to a domestic market and consumers have access to functional foods for which the manufacturers may make approved health claims.

Although also restrictive, the regulatory framework in the United States is more favourable to the development and marketing of functional food products. Specific legislation exists for approval, labelling and advertising of "dietary supplements" (*Dietary Supplements Health Education Act*), which may accommodate certain functional foods. Broader, basic food safety legislation governing approval of food products, additives and ingredients is also more adaptable to new products, technologies and advances in nutritional science. In addition, nutrition labelling requirements under the *Nutrition Labelling Education Act* serve to promote consumer awareness of the attributes of specific food types and products.

Our examination of the regulatory framework governing foods at the European Union level leads us to conclude that the limited body of regulation which does exist is less restrictive in practice than the written word would suggest. This is due to the fact that adoption and enforcement of EU directives of this nature by EU member states tend to be voluntary and vary widely among the 15 EU countries. As a consequence, the EU cannot currently be considered as one regulatory jurisdiction and the EU regulations applying to food products are only part of the picture for firms wishing to market food products in selected member states. When considering functional foods, the regulatory frameworks of the individual EU countries will be of greater concern in the near term.

The research findings of this project are summarized in a comparative analysis presented in condensed form in six tables found on pages 5 though 11 of the main body of the report. It is intended that this comparative analysis will:

- form the basis for a determination of the best regulatory system for Canada for the advancement of nutraceuticals and functional foods; and,

- lead to the establishment of a vehicle for industry-government collaboration to bring about the regulatory change required to establish the optimal system to achieve international competitiveness.

Based on our research and analysis, the authors wish to offer a number of recommendations for consideration and review by Agriculture and Agri-Food Canada and Health Canada in consultation with industry and the food research and development community.

Briefly stated, these recommendations are:

1. Develop a Regulatory Vision Which is Supportive of Functional Foods

A regulatory vision which is supportive of functional foods is one which acknowledges consumers' right of access to products which are recognized as safe and hold the potential to

promote or sustain health or improve wellness, even if only among some individuals in the population. The vision would also recognize consumers' right of access to information about such products, information including but not limited to health claims where such claims can be reasonably substantiated by "significant scientific agreement" or historical experience.

2. Strike an Industry-Government Task Force for Regulatory Reform

A joint industry-government task force should be commissioned by a committee of Cabinet Ministers (Health, Agriculture and Agri-Food, Industry and Treasury Board) and tasked with developing a new regulatory framework and a fast track (two year) agenda for its implementation.

This industry-government working group should be specifically tasked with exploring how Health Canada's regulatory guidelines applicable to the food and beverage sector can become enabling tools for food product development in Canada, rather than restrictive measures used as substitutes for regulation designed to control industry behaviour in the marketplace.

3. Establish the Equivalent of the Japan Health Food Association In Canada

One of the key elements of success of functional foods (FOSHU) in Japan has been the establishment of the Japan Health Food and Nutrition Food Association and the development of its legitimate and formal role in the functional food approval process. The equivalent of the JHFA represents the platform for private sector involvement in regulation of functional foods which is missing in Canada, yet of obvious importance to the establishment and future competitiveness of a functional food "industry" in Canada.

4. Differentiate Health Claims Associated with Diseases From Those Associated With Promotion of Health and Wellbeing

In the context of efforts to curb and reduce health care costs in Canada, one important element of regulatory reform would be to distinguish between health claims associated with the prevention and treatment of diseases (normally associated with drugs or pharmacological effects) from wellness claims which are more appropriate for promotion of health of individuals. This distinction would remove constraints to approval of functional foods where safety is not an issue and efficacy is recognized through "significant scientific agreement" or historical experience.

5. Harmonize Evaluation Protocols With Other Jurisdictions

As a way to place functional food products of Canadian companies on an equal footing with their counterparts in the United States, we recommend that health claims currently approved in the U.S. be allowed in Canada. As a condition to the adoption of U.S. health claims, we further recommend that Canadian regulatory authorities be allowed one year to make whatever adjustments that may be necessary to place the statements articulating the claims in the Canadian

context. If not amended within one year, it is recommended that the claims be allowed indefinitely as adopted from the U.S.

6. Consideration of Foreign Legislation As Models for Canada

There are at least three examples of foreign legislation and related systems which appear to be functioning and hold promise as the basis for designing and implementing new legislation in Canada. Within Japan, one of Canada's three leading trade, investment and research and development partners, the *Nutrition Improvement Act*, under which FOSHU licensing was created and is administered, stands as one example. Within the United States, the *Dietary Supplements Health Education Act* offers a functioning model for a system which could apply to dietary (nutrition) supplements brought to market and sold in Canada. The nutrition labelling requirements of the *Nutrition Labelling and Education Act* are also a useful model for communication of nutrition facts to consumers using label information on packaged foods and functional foods. Even the onerous requirements for health claims in the United States under NLEA are an improvement over the Canadian system. We recommend fast action to put in place similar legislation or regulations in Canada.

The above recommendations are offered in the sincere belief that time is of the essence in responding to these challenges, if Canada is to capture the economic benefits, including potential savings in future health care costs, which an internationally competitive functional foods industry has to offer.

I. Introduction

This project was commissioned by Agriculture and Agri-Food Canada in December of 1995 pursuant to two projects completed earlier in 1995. The earlier of the two projects, undertaken for Foreign Affairs and International Trade Canada , addressed Canada's potential for international (Canada-Japan) collaborative research, development and commercialization of functional foods. This work, entitled *Canada-Japan Collaborative Research and Development for Food Ingredients, Additives and Functional Foods: Identifying Potential Canadian Partners*, found that there are within Canada, significant numbers of private sector firms, academic institutions and public sector research organizations which hold both interest and capability in functional food R&D alliances at the international level. The project findings also revealed that there are very substantial differences in the regulatory frameworks governing approval and marketing of functional foods between Canada and Japan. These disparities suggest that while R&D alliances may succeed in the commercialization of new functional foods in Japan, the path to success in Canada is at best, unclear and at worst, impassable.

The second project, conducted for Agriculture and Agri-Food Canada, was an extensive sounding of the needs and impediments to success of 52 stakeholders in the Canadian nutraceuticals community. The report, entitled, *Nutraceuticals/Functional Foods Exploratory Survey on Canada's Potential*, identified Canada's regulatory framework for functional foods, as defined by the *Food and Drug Act and Regulations*, as being the major barrier to success in the Canadian nutraceutical market. Other barriers identified were related to marketing, product and research costs and lack of awareness (of nutraceuticals) among the public, industry and the medical profession. The study also revealed that Canadian stakeholders perceive international markets to be more accessible, and foreign government agencies to be more cooperative when developing a nutraceutical market than their Canadian counterparts. Canadian firms also perceive that easier market access in other countries offsets the higher cost of conducting R&D outside of Canada and that some foreign governments provide assistance in shortening the commercialization and regulatory approval process.

The findings of both studies pointed to the need for more detailed analysis of Canada's regulatory framework affecting functional foods as compared to those in other jurisdictions that are Canada's leading export markets for food products. Accordingly, this project was defined to yield a comparative analysis of the opportunities and constraints inherent in the existing regulatory frameworks affecting functional foods in Canada, the U.S. and the EU. It is intended that this comparative analysis serve two fundamental purposes. These are:

1. to form the basis for a determination of the best regulatory system for Canada for the advancement of nutraceuticals and functional foods; and,

2. to lead to the establishment of a vehicle for industry collaboration to work with government to bring about the regulatory change required to establish optimal system, to achieve international competitiveness.

In regard to the purposes stated above, it is important to define at the outset of this report what is meant by "best regulatory system" and "international competitiveness".

The "best regulatory system" is one which not only offers consumers reasonable assurance of the safety, efficacy and nutritional value of nutraceuticals and functional foods, but one that also:

- provides availability of products shown to offer strongly suggestive health and physiological benefits, to Canadian consumers with the least possible delay;
- is predictable and transparent in terms of evaluation and approval process and the associated timelines, costs and rights and the obligations of both regulators and those who are seeking product approval;
- recognizes and accepts the regulatory approval in selected jurisdictions as being the basis for approval or for accelerated evaluation of the same or like products and claims in Canada;
- functions with industry involvement in promoting self-regulation; and,
- provides clear and enforceable parameters permitting health claims which serve to encourage, rather than inhibit public awareness and health promotion.

"International competitiveness" of the Canadian firms, research organizations and institutions involved in the development, commercialization and marketing of nutraceuticals/functional foods means that:

- Canada's regulatory framework is also recognized by the United States, Japan and E.U. countries as preferred export markets for Canadian firms;
- regardless of ownership (domestic or foreign), firms are as likely or more likely to invest in and conduct nutraceuticals/functional foods research, development and commercialization in Canada as in other countries; and,
- Canadian nutraceutical and functional foods are recognized by consumers within Canada and in export markets as contributing to the promotion and maintenance of health and wellbeing.

A Word About Methodology

The authors of this report compiled the information contained herein and drew the findings and preliminary recommendations through an in-depth search, a review of existing legislation, regulations and guidelines and through interviews conducted in-person with industry and government contacts in Canada, Washington and Brussels and by telephone and correspondence

with contacts in Japan and the United States. Lists of reference materials and contacts are appended.

II. Guide to Interpretation of Tables: How to Use This Report

A large volume of legislation, regulations, guidelines and accepted practices was identified and reviewed in the research conducted for this report. The authors have opted to summarize the key components of the respective regulatory frameworks which lend themselves to comparison among the four jurisdictions. These are examined in a series of six tables dealing with the following subject matter:

- Table I: Terminology
- Table II: Applicable Legislation, Regulation and Guidelines
- Table III: Health Claim Approval Process and Mechanisms
- Table IV: Patent Protection and Confidentiality of Proprietary Information
- Table V: Product Labelling
- Table VI: Compliance, Enforcement and Penalties

The tables provide relatively extensive summary information respecting issues in all the jurisdictions. For more complete information, the reader should refer to the text numbered with the same table cell coordinates, contained in Section VII of this report.

For example, reference I.A.2 provides additional detail for:

Table I: Terminology,
A. Canada
2. Nutraceuticals

In cases where summary table boxes show “n/a”, the subject matter is either not applicable to the jurisdiction in question or no relevant information was identified.

III. Summary Tables

Table I: Terminology

Jurisdiction	1.Functional Foods	2. Dietary Supplements	3.Nutraceu-ticals	4. Medical Foods	5.Foods for Specified Health Use	6. Foods for Special Dietary Use	7. Health Food	8. Herbs & Botanicals	9. Novel Foods	10. Health Claims
A: Canada	No accepted regulated definition, governed by Food and Drug Act (Act) and Regulations. All ingestible products sold either as a food or drug as defined in Act.	In Canada, "nutritional supplement" is "a food sold or represented as a supplement to a diet that may be inadequate in energy and essential nutrients"	Commonly used in nutrition and science community.	Food and Drug regulations may be revised to define and regulate "foods for special medical purposes". Review pending as at 3/96.	11 categories are defined in Food and Drug regulations but generally apply only to processed and further processed foods. Regulatory review incomplete/pendin g.	Division 24, Part B of Food and Drug Regulations define 11 categories of Foods for Special Dietary Uses.	By definition, any food in compliance with F&D & Regs. should be free of any significant health or safety risk. No separate definition exists for "health food but it is a widely used term.	Refers toa large number of botanical substances which , while sold for medicinal or therapeutic purposes, default to legal definition of "food".	Refers to foods defined under new regulations being developed by Health Canada - foods produced by novel processes, including foods derived from biotechnology.	Section 5(1) of F&D Act generally prohibits false, misleading or deceptive claims in labelling or advertising. Schedule 3 prohibits claims for 46 specified diseases.
B: United States	No legal status or general acceptance in U.S. but accepted definition in dietetic profession.	Formal definition exists under the Dietary Supplements Health Education Act.	Accepted definitions in nutrition/science community but not embodied in law or regulation to date.	Regulated by FDA Office of Special Nutritionals on a case by case basis as enteral foods or foods for sick infants.	n.a.	n.a.	n.a.	n.a.	n.a.	Applies to disease-related claims only (FR vol.58,No. 3, 1/06/93. Claims related to essential nutrient disease are exempt within restrictions.
C: European Union	At EU level, currently no legal definition. Some member states have working definitions used by industry.	Products resembling those in U.S. are not subject to EU Directive.	This term has met with limited success in Europe and appears to be out of favour as a descriptive term.	n.a.	n.a.	n.a.	"Health Food" is a marketing, not a legal term, normally denoting product sold in specialty stores.	n.a.	n.a.	Directive 79/112 prohibits use of medical and health claims on labels; 15 states have varying enforcement.
D: Japan	Functional foods recognized as Foods for Specified Health Use in 1991 (FOSHU), replacing "functional foods".	n.a.	n.a.	n.a.	FOSHU are a sub-classification of "Foods for Special Dietary Uses" defined in Nutrition Improvement Act.	n.a.	"Health food" is a widely accepted term used by consumers and industry in Japan.	n.a.	n.a.	Health claims are permitted for foods licensed as FOSHU.
E: Codex	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	Proposed draft guidelines for use of health and nutrition claims to be reviewed by Codex Food Labelling Cttee in May , 1996.

Table II: Applicable Legislation, Regulation and Guidelines

Jurisdiction	1. Legislation	2. Regulations	3. Guidelines
A: Canada	Primary statute is Food and Drugs Act and Regulations, defining "food" and "drug" , prohibitions governing sale of foods.	Extensive regulations to the Food and Drug Act can be amended without reference to Parliament (amendment of the Act) as necessary to prevent deception (false or misleading information to consumer) or to "prevent injury to the health of the consumer". However, matters pertaining to health promotion and disease prevention are considered to be beyond the reach of the F&D Act, originally passed for, among other things, food safety and food integrity.	Guidelines exist which attempt to interpret Section 4 and 5 of Food and Drug Act: *Guide for Food Manufacturers and Advertisers*, *Guidelines for Nutritional Labelling*, *Guidelines for Safety Assessment of Novel Foods* and others (please refer to ....). Requirements also exist for pre-market review of food additives, infant formulae and irradiated foods.
B: United States	Nutrition Labelling and Education Act (NLEA), Public Law 101-535 of 1990 prescribes nutrition labelling for foods and other purposes. Separate law exists for dietary supplements - Dietary Supplement Health Education Act (DSHEA), P.L. 103-417, 1994.	7-page NLEA act is augmented by over 1000 pages of regulation published in the Federal Register accessible through Internet at (http: //www.access.gpo.gov/su_docs) Some allowable label claims under DSHEA remain to be defined.	Three publications exist, in addition to Federal Register to provide guidance to manufacturers. Further advice is available from the FDA Office of Food Labelling and the Office of Special Nutritionals in Washington.
C: European Union	Adopted Legislation agreed at EU level may not be implemented within member states (countries), published in "L" series of EU Official Journal. Proposal for a directive on claims has been under review for several years but appears stalled. At EU level, no legal definition exists for "food", also under review for several years.	Regulation exists (optional implementation by member states) exists in the form of directives (see Table VI).	n.a.
D: Japan	Sale of FOSHU ("functional foods") is governed by the Nutrition Improvement Act which also regulates conduct of a National Nutrition Survey, established a Nutrition Consultation Office and appointment/certification of Nutrition Instructors. Act provides for approval and labelling of Special Nutritive Foods, Enriched Foods and Foods for Special Dietary Uses.	FOSHU (Foods for Specified Health Use) exists under regulatory umbrella of "Special Nutritive Foods", enabling manufacturers to establish basis for functional (health benefit) claims.	Japan Health Food and Nutrition Food Association is authorized by Japan's Ministry of Health and Welfare to provide guidance to the food industry in assembling data for formal submission for licensing of new FOSHU to the MHW.

Table III: Approval Processes and Mechanisms, Including Health Claims As Applicable

Jurisdiction	1. Regulatory or Non-Regulatory	2. Defined and Transparent Process	3. Safety and/or Efficacy Requirements	4. Assessment Criteria
A: Canada	No approval process exists for health claims as they are currently prohibited. Regulatory pre-market review or approval is required for: all drugs, food additives, infant formulae and irradiated foods. Pre-market notification for novel foods pending when regs. are promulgated (1996). For foods that could be considered "functional foods", pre-market review is voluntary. Some guidelines exist for this purpose. Mandatory label review is not possible under Food and Drug Act because of its status as part of criminal law.	When pre-market review is mandatory and results in a regulatory amendment, (food additives, irradiated foods), requirement is reasonably transparent because of requirement for Part I & II Canada Gazette notices. The process is less transparent when it involves an administrative mechanism (licensing of drugs and notification about infant formulae) even though the pre-market requirement is mandatory.	Safety and efficacy requirements are spelled out in regs. dealing with pre-market review of food additives. *Guidelines for the Safety Assessment of Novel Foods* could be applied to certain types of "functional foods". In keeping with its criminal law status, responsibility under the Food and Drug Act for product safety rests with the manufacturer . Pre-market review by HPB is a method to control use and market introduction of foods and ingredients until safety can be scientifically evaluated to be assured.	The only published criteria relating to functional foods are found in *Guidelines for the Safety and Physiological Effect of Novel Fibre Sources and Food Products Containing Them*.
B: United States	Approval processes for health claims are regulated by FDA. Some structure function claims allowed following a simple notification process.	Process is fully transparent (submission contents disclosed to public), but as yet, inadequately defined in terms of requirements for health claim petitions (Fed.Reg.Vol.58, No. 3, 2535-2536).	Safety is addressed at other regulatory levels separate from health claim applications. Efficacy is key consideration for health claims, as assessed through scientific agreement on publicly available data.	Outline for health claim petitions (functional foods) is contained in Federal Register January 6, 1993, 2534-2536. Requirements are similar to other petition requirements for FDA.
C: European Union	Health claims are not permitted at the E.U. level although tolerance varies among member states of use of health claims on labels and in advertising. Concerned about inconsistency, the E.U. food sector is conducting a survey of definition, regulation, burden of proof for claims in use for functional foods and related products.	n.a.	n.a.	n.a.
D: Japan	Regulatory: 3 stage application process for licensing - technical screening, plus two committee reviews. Non-regulatory: Japan Health Food Association has parallel approval process for FOSHU. JHFA recommendation shortens MHW review process for domestic manufacturers who are members of JHFA.	Both regulatory and non-regulatory (private sector) aspects of review procedures and milestones are clearly defined and transparent through to final review by MHW Assessment and Discussion Committee for Foods for Specified Health Use.	The principle behind FOSHU is to discover active components having certain health benefits in ordinary foods which should be safe as judged by experience. Thus level of documentation/evidence respecting safety is lower than that applied to petitions dealing with food additives and pharmaceutical products.	FOSHU must satisfy 8 criteria, including demonstrable benefits from consumption as a food in ordinary dietary use.

Table IV: Patent Protection and Confidentiality of Proprietary Information

Jurisdiction	1. Patent Protection	2. Market Exclusivity	3. Confidentiality of Proprietary Information
A: Canada	No patent or equivalent protection is provided by virtue of mandatory pre-market clearance. However, the very specific nature of certain entries in the Tables of Food Additives (Division 16 of the Food and Drug Regulations) may afford an unintended measure of protection equivalent to a patent. No protection would be available for claims on functional foods (assuming the category and attendant claims were officially accepted at some future date) in that all such claims would be in the public domain.	No market exclusivity would exist in Canada if functional foods were to be recognized as a category of foods with recognized health claims.	n.a.
B: United States	No patent protection exists for health (functional food) claims made under the Nutrition Labelling and Education Act. Claims are allowable only on the basis of scientific agreement . Some patent protection exists for dietary supplements under DSHEA in that proprietary products are not required to disclose formulae (relative ingredient content) but are required to disclose nutrient content.	There is no market exclusivity for the use of health claims under NLEA. All products which contain a minimum (10% or more of the label reference value before fortification) may bear a claim for a previously approved benefit unless deemed ineligible as a consequence of undesirable nutritional attributes (Fed. Reg. Vol. 58, No. 3. 1/6/93, 2488).	Virtually no confidentiality of information under NLEA, other than names of individuals and respective medical practitioners and institutions which participated in studies submitted in support of petitions. Petitions become public information within 100 days of filing. In the case of DSHEA, petition information is confidential for 90 days only, unless certain information is recognized as a trade secret.
C: European Union	n.a.	n.a.	n.a.
D: Japan	n.a.	The licensing process for functional foods provides the applicant with a license for a specific product and the text for health claims that are approved by the Ministry of Health and Welfare. This would appear to provide market exclusivity for the product and the firm manufacturing the product once the license is granted.	Because of the cooperative nature of the review process involving both the government (MHW) and the private sector (JHFA), it would appear that there would be limits to the confidentiality of the information provided in a licensing application for a functional food.

Table V: Labelling

Jurisdiction	1. Status of Health Claims	2. Permissible Health Claims	3. Other Information Requirements Triggered by Health or Nutrition Claims	4. Labelling of Dietary Supplements	5. Status of General Nutrition Labelling
A: Canada	No health claims are permitted on foods sold in Canada. Thus, claims may not refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal				

Table VI: Compliance, Enforcement and Penalties

Jurisdiction	1. Jurisprudence	2. Level of Enforcement	3. Penalties
A: Canada	The body of jurisprudence established in Canada with respect to the Food and Drugs Act and Regulations is limited. Most prosecutions have involved the alleged adulteration of food products with prohibited substances (such as sulphur dioxide in ground beef to stabilize red pigment) and the manufacture of foods under unsanitary conditions. Since 1987, the compositional and identity standards for food products in the Food and Drug Regulations have been enforceable only when the standardized product crosses an interprovincial or international border. However, health-related portions of compositional standards (i.e. food additives and nutritional requirements) are "severable" from the standard and are thus enforceable anywhere in the country and not limited by having to move across a provincial border.	The approach taken in Canada by federal authorities is to encourage voluntary compliance with all food and beverage product pre-market notification, licensing labelling and advertising regulation and guidelines. Compliance is monitored by periodic field inspection and related product analysis. Enforcement is normally achieved through "voluntary " measures encouraged by federal authorities. Enforcement can be achieved through product recalls and seizures and in rare cases, prosecution under the Food and Drugs Act.	Penalties stipulated in the Food and Drugs Act states that persons violating provisions of the Act or Regulations are liable on summary conviction or on conviction upon indictment, for fines and/or imprisonment. Maximum fine is five thousand dollars per offence. Maximum term of imprisonment is three years (set in 1953).
B: United States	Pertinent court rulings and discussions of constitutional issues concerning the NLEA are contained in a number of Federal Register regulations (Volume 58, No. 3, 2524-2529, January 6, 1996) . The Federal Register of January 6, 1996 also contains state regulations and the process for state-requested exemptions.	FDA reports a high level of voluntary compliance, to be reassessed through a formal survey in 1997. Enforcement measures are not clearly declared by FDA, which relies primarily upon field inspections and consumer/industry complaints to identify non-compliant products.	Penalties for violation of the U.S. Food , Drug and Cosmetic Act may be found in Section 303 of the Act, prescribing basic penalties of imprisonment of up to one year and fines up to $1,000. Certain (drug-related) offences provide for civil penalties of up to $1,000,000.
C: European Union	A body of jurisprudence in many areas is evolving as a result of decisions made by the European Court of Justice. The court was created under the Treaty of Rome to ensure the correct interpretation and application of the provisions of Community law. A number of significant precedent-setting decisions have been made with respect to food composition and food labelling involving the denial of market access of a product from one member state to another.	Adopted legislation is in the form of Commission or Council directives or regulations which have been agreed upon at the Community level and published in the "L" Series of the Official Journal. Such legislation may or may not be implemented in all of the 15 member states. Challenges respecting implementation are ultimately resolved by the European Court of Justice.	No country-specific research was completed within the scope of this report.
D: Japan	n.a.	Enforcement is accomplished in Japan primarily through industry self-regulation as government has delegated the determination of standards, licensing of certain products and review of labelling, nutritional and health claims to industry bodies.	n.a.

IV. Implications for Functional Food Manufacturers: A Comparative Analysis of Opportunities and Constraints

Canada

Constraints

Among the four jurisdictions examined, Canada clearly has the greatest number of defined constraints to the approval and marketing of nutraceuticals/functional foods with declared health claims. While the E.U. also prohibits health claims, the tolerance among member states for health claims on foods appears to vary widely.

The principal constraint is clearly Canada's *Food and Drug Act and Regulations*, the most rigid components of which are Section III and Schedule A, which render it impossible to state and use a health claim in the marketing of a food product. In practical terms, even if a manufacturer has a health claim which is known to be true, the claim cannot be legally used in Canada.

The second greatest constraint, related to the *Food and Drug Act*, is the extensive use by Health Canada regulators of "Guidelines" developed over time on an ad hoc basis to provide guidance to manufacturers on acceptable manufacturing, advertising, packaging and labelling practices for food products. There are effectively no limitations within the Act or other legislation on the number and extent of "guidelines" which Health Canada and/or Agriculture and Agri-Food Canada may develop as interpretations of legislation and regulation in order to encourage industry "compliance". It is a common misconception in the private sector that guidelines have the force of law. In the absence of such limitations on regulators, manufacturers could be faced with a "moving target" which for some, will never be reached. The lack of predictability represents a formidable constraint.

Some advocates of regulatory reform in Canada hold the view that guidelines are, in fact, preferable to more definitive, restrictive regulations, provided that there is effective industry-government dialogue to develop guidelines which become enabling tools of product development, rather than substitutes for prohibitive regulation. The authors are in agreement with this school of thought but hold the view that the experience of the food industry to date would suggest that the forum for such dialogue does not yet exist.

The system has tended to be unsupportive of industry in developing and bringing functional foods to market. The industry is virtually unanimous in its view that the current regulatory system, as defined by the *Food and Drug Act and Regulations*, is inappropriate for the regulatory control of functional foods. HPB officials have stated within the last year that the current definitions of "foods" and "drugs" in the Act are not out-dated and that it is in the public interest to apply the present system of regulating foods and drugs to nutraceuticals/functional foods. In addition, HPB is on record with the view that the regulatory requirements respecting functional foods should mirror the same standards of evidence that apply to all other products for which health benefit

and disease prevention claims are made (i.e. drugs). This suggests to the authors that it is the policy of Health Canada to maintain the statutory prohibition of health claims for foods, effectively forcing all nutraceuticals/functional foods to be regulated as drugs.

In addition to the regulatory constraints which exist in Canada, researchers and manufacturers face the added and very practical constraint presented by Canada's relatively small market. This constraint becomes increasingly intimidating as the cost of food regulatory approvals escalates to those now associated with drug regulatory approval.

Opportunities

For those firms having the financial, scientific, technical resources and management expertise necessary to steer a product through the drug evaluation and approval process, approval of a food or food product intended for use as a nutraceutical or functional food can, in fact, represent an opportunity. The opportunity lies in the strong probability that very few products recognized by consumers as "functional foods" will ever come to market, in turn conferring a high degree of market exclusivity to those firms which do choose to "go the drug route" with their food products.

There are also characteristics of Canada's marketplace which may be seen and taken advantage of as "opportunities" by some manufacturers, and in turn by Canadian consumers who are willing to take additional steps to obtain products which they perceive to provide potential health benefits. These characteristics might be described as:

- low level of enforcement of regulatory provisions with respect to packaged foods and herbs and botanical preparations at the retail level within Canada;

- limited ability of Canadian authorities to prevent the importation of illegal food products, particularly by individual consumers through mail order and Internet purchases or through distributorships in direct network marketing companies;

- pervasive exposure to primarily American advertising in electronic and print media;

    - U.S. consumer magazines are in fact so widely distributed in Canada that an opportunity exists for Canadian companies to advertise their products,, bearing American health claims (permitted in U.S. but not in Canada) to Canadians.

- high mobility of Canadian consumers to and from the U.S. and other markets.

Examples of manufacturing firms, importers and retailers already taking advantage of these "opportunities" are widespread, in evidence on retail shelves across the country and at border crossings every day. Although such practices may not necessarily be putting Canadian consumers at risk, they are so widespread as to call into question the validity of the current regulatory system

which applies to foods and supplements which are perceived or sold as offering health benefits. Moreover, these opportunities to circumvent the regulatory system may also serve as deterrents to investment.

European Union

There is no apparent advantage at the jurisdictional level of the European Union to firms wishing to market nutraceutical and functional food products with reasonable certainty and the marketing benefits of having complied with regulatory requirements within a marketplace. Our research, albeit preliminary, further suggests that few, if any, competitive advantages exist within the jurisdictions of individual European Union member states.

Constraints

There are very real constraints to the commercialization and marketing of nutraceuticals/functional foods within the European Union within a climate of certainty of compliance. There is a EU Directive prohibiting the use of health claims, effectively rendering functional food products, which may be in compliance in single state jurisdictions, unmarketable outside that state. In the absence of a E.U. directive which has been voluntarily adopted by a member state, the laws of the member state are operative.

Within single EU members, such as the UK for example, regulation of the labelling and marketing of products such as functional foods resides at the national level but enforcement depends on the resources and interests at the country level. There does not appear to be a cohesive national policy with respect to enforcement..

The authors found no evidence to suggest that any significant degree of harmonization with respect to health claims exists among any of the member states of the EU. Health claims are prohibited by E.U. Directive. The food industry in the EU recognizes a need for harmonization before very disorderly marketing becomes further entrenched.

In summary, constraints at the European Union level are comparable to those in Canada, albeit less well defined in terms of legislation, compliance and enforcement practices adopted across all member states.

Opportunities

As in Canada, limited ability to coordinate compliance and enforcement measures affecting nutraceuticals/functional foods may present opportunities for firms willing to assume risk by marketing products with selective labelling and advertising or in selected regions.

Looking beyond regulatory loopholes, there may also be opportunities which reside in the culture of European countries such as is the case in Japan, where certain foods are recognized either by

reputation or experience as holding physiological or health benefits. In Japan, cultural acceptance and tradition formed a component of the current regulatory system which does provide for formal regulatory approval of foods with recognized health benefits.

United States

Constraints

Despite the existence of two pieces of legislation (NLEA and DSHEA) which can provide for certain health claims, many constraints remain to the development of a nutraceutical/functional foods industry having ready access to the marketplace.

As outlined in Section IV above, the Nutrition Labelling and Education Act, while a brief piece of legislation, is subject to a very great deal of interpretation by federal regulators, not unlike the situation in Canada with the Food and Drugs Act. As of early 1996, there are over 1,000 pages of interpretation of NLEA published in the Federal Register. In addition, the health claims which have been approved, are rather cumbersome to be practical as part of a food package label, particularly in the Canadian bilingual context. These allowed claims, coupled with the lack of exclusivity or patent protection, render the NLEA an obstacle rather than a conduit to the marketplace. However, it must be said that the American system has been shown to be somewhat workable with the recent approval of a variety of health claims.

Also seen as a serious constraint by the food industry is the sharp contrast in the clarity, simplicity and permissiveness of the *Dietary Supplements Health Education Act* as compared to the NLEA. The disparity in these two pieces of legislation has created an uneven playing field for firms wishing to bring specialized food products with even proven health benefits to market.

Opportunities

In contrast with regulators in Canada, regulators in the U.S. are motivated to make changes to a greater degree by top-down policy developed through extensive industry lobbying, litigation and transparent public consultation. There is also significantly more movement of senior bureaucrats between government, academia and industry positions which tends to bring more balance to the policy perspective. There is an important philosophy in place under which “significant scientific agreement” can diffuse bureaucratic accountability and sets up a climate that allows individuals with regulatory responsibilities to be less risk averse.

The Food and Drug Administration has also constituted a Food Advisory Committee (FAC) as a forum for expert dialogue and debate about the safety and regulation of new food products. In practice, the FAC has allowed interest groups, industry and professional organizations to present their views on new foods and food ingredients before an expert panel which offers its findings independently of FDA. In all cases to date, this has led to a consensus or strong majority of

opinion on products brought to the FAC for examination, allowing FDA to proceed with approval.

In some respects, the NLEA presents an opportunity for firms wishing to bring nutraceuticals/functional foods to market by virtue of the NLEA's nutrition labelling requirements (nutrition facts panel). There is an opportunity to build an awareness of the nutritional value of the food product even in advance of approval of associated health claims.

Finally, U.S. consumers are more ardent users of dietary supplements than their Canadian counterparts. The *Dietary Supplements Health Education Act* has established within a relatively short time frame (since 1990) very clear and permissive parameters under which manufacturers can bring new dietary supplements to market, while also defining labelling guidelines which allow commercially confidential/proprietary product formulae to remain confidential.

Japan

As is the case with some aspects of the U.S. regulatory system, aspects of the system governing functional foods in Japan pose constraints, as well as opportunities.

Constraints

Onlookers from the food R&D and manufacturing communities in other countries, including Canada, look to Japan as offering ready market access for nutraceuticals/functional foods. While the route to market access is clearly defined, some constraints remain.

The "Foods for Specified Health Use" (FOSHU) certification is not easily obtained. There is a 3-stage approval process and in the case of domestic manufacturers (petitioners) there is a process which amounts to a self-regulatory peer review by the Japan Health Food Association (JHFA). Although the JHFA also can serve to accelerate government regulatory review, this service is not currently available to foreign firms.

Access to FOSHU status is also somewhat limited by culture and past consumer behaviour in that FOSHU can be applied to foods only and not isolated nutrients or manufactured nutritional supplements and only those foods which have identifiable health benefits based on sound scientific research. Moreover, to achieve FOSHU status, food products must be of a type of food which is consumed in "ordinary dietary patterns" and have a composition which is not notably different in comparison with the nutrient composition of similar (types of) foods. What this implies is that FOSHU equates to traditional foods, safe for consumption as judged by experience and bearing recognizable and demonstrable health benefits. These criteria, coupled with the others (refer to Section VII, D) effectively act as constraints to health claims under FOSHU for many manufactured foods and derivatives.

Opportunities

The very concept of FOSHU represents an opportunity for the marketing and promotion of a wide range of foodstuffs which can be shown to meet the FOSHU criteria in that by definition, these will already have a significant degree of consumer acceptance as part of normal diets and household menus.

The industry participation through JHFA in the approval process represents an opportunity for new and existing firms to receive "accreditation" as functional food manufacturers by virtue of membership in the association and the association's recommendations for approval provided to the Ministry of Health and Welfare.

Offshore firms may be able to access the Japanese market and achieve FOSHU status for products through partnerships and strategic alliances with firms already members of JHFA, or alternately, seek independent membership in JHFA. Japan is the only jurisdiction where there is a process to allow health claims approved as part of the license granted to market the product. In effect, this provides a degree of market exclusivity to the manufacturer.

V. Implications for Canada's International Competitiveness

Having reviewed the regulatory frameworks within Canada, the U.S., Japan and at the level of the European Union, one would have difficulty in reaching any conclusion other than opportunities are limited and constraints are significant. In the United States and Japan, regulatory and industry initiatives have provided evolving health claim approval structures that currently and in the future will assist the marketing of functional foods.

In contrast, Canada and the European Union are far behind without even regulatory recognition that a process to approve a health claim should be possible.

If Canada does not improve its food and drug regulatory framework, there are quite predictable negative implications for Canada's international competitiveness and investment in food and nutrition research and development. At the very least, functional food research and investment in Canada will be restricted.

Without providing an alternate regulatory framework, the default mechanism is to require functional foods to be evaluated and licensed as drugs. The costs associated with this process would mean that only large pharmaceutical firms would have the necessary investment and human resources to enter this potentially lucrative field.

Even if a functional food were to be approved under the drug approval structure, market opportunities would be severely restricted in actual retail practice.

Adding to our inflexible regulatory environment, Canada's poor record in encouraging research and development investment in life sciences, including the food and pharmaceutical sectors,

suggests that future investment in functional food research and development may be severely limited, in addition to being heavily concentrated in the hands of a few organizations.

Preservation of the regulatory status quo could also lead to the erosion of consumer spending within Canada. Canadian consumers are neither in a cultural nor marketing vacuum. The government of Canada has embraced the "information highway" and with it a powerful new tool for marketers and for consumers. There are already hundreds of Internet sites accessible to Canadian consumers which offer nutrition advice as well as health related products. Canadian consumer spending will flow to these sources, if access to legitimate and licensed products available in other countries is denied in Canada.

An estimate of the net cost to the Canadian economy is beyond the scope of this study and the resources available to the authors.

VI. Adapting Canada's Regulatory Framework for Enhanced Competitiveness: Recommendations

Based on our research and analysis, the authors wish to offer a number of recommendations for consideration and review by Agriculture and Agri-Food Canada and Health Canada in consultation with industry and the food research and development community.

1. Develop a Regulatory Vision Which is Supportive of Functional Foods

A regulatory vision which is supportive of functional foods is one which acknowledges consumers' right of access to products which are recognized as safe and hold the potential to promote, sustain health or improve wellness, even if only among some individuals in the population. The vision would also recognize consumers' right of access to information about such products, information including but not limited to health claims where such claims can be reasonably substantiated by "significant scientific agreement" or historical experience.

Such a vision would acknowledge not only the potential health benefits to consumers, but the potential for reduced personal and government expenditures for health care.

The vision would also acknowledge the scientific expertise and integrity of regulatory systems within the jurisdictions of Canada's major trading partners. This should be an important criterion of conditional approval of functional foods already approved in these other jurisdictions.

The vision would ultimately incorporate and foster a mind set (corporate culture) within Canada's regulatory agencies which would seek to accelerate rather than impede the regulatory approval of functional foods, without compromising consumer safety.

2. Strike an Industry-Government Task Force for Regulatory Reform

Health Canada regulators have a strongly entrenched predisposition to resist regulatory reform in areas related to functional foods. This contrasts with the industry/research community consensus that regulatory reform is essential to the development and competitiveness of a Canadian functional foods industry. It is essential that the responsibility for regulatory review and reform not be left solely in the hands of Health Canada officials. Rather, a joint industry-government task force should be commissioned by a committee of Cabinet Ministers (Health, Agriculture and Agri-Food, Industry and Treasury Board) and tasked with developing a new regulatory framework and a fast track (two year) agenda for its implementation. The task force should be specifically asked to explore how Health Canada's guidelines applicable to the food and beverage sector can be developed to become enabling tools of food product development, rather than substitutes for prohibitive regulation.

The Interdepartmental Committee on Food Regulation, chaired by the Deputy Minister of Health, is an existing mechanism for transmittal of this recommendation to Ministers of these four departments.

3. Establish the Equivalent of the Japan Health Food Association in Canada

One of the key elements of success of functional foods in Japan has been the establishment of the Japan Health Food and Nutrition Food Association and the development of its legitimate and formal role in the functional food approval process. JHFA was formed with significant scientific expertise through the collaboration of several industry associations, research organizations and government departments. The equivalent of the JHFA represents the platform for private sector involvement in regulation of functional foods which is missing in Canada, yet of obvious importance to the establishment and future competitiveness of a functional food "industry" in Canada.

4. Differentiate Health Claims Associated with Diseases From Those Associated With Promotion of Health and Wellbeing

In the context of efforts to curb and reduce health care costs in Canada, one important element of regulatory reform would be to distinguish between health claims associated with the prevention and treatment of diseases (normally associated with drugs or pharmacological effects) from wellness claims which are more appropriate for promotion of health of individuals. This distinction would remove constraints to approval of functional foods where safety is not an issue and efficacy is recognized through "significant scientific agreement" or historical experience.

This regulatory change could be effected without amendment to the *Food and Drug Act* by introducing an appropriate amendment to the regulations as provided under Section 30 of the Act, to circumscribe the prohibition found in Section 3.

5. Harmonize Evaluation Protocols With Other Jurisdictions

Despite the exhaustive evaluations, clinical trials and public consultations which may lead to approval of functional foods and related health claims in other jurisdictions, notable the U.S. and Japan, Canada's regulatory system governing foods does not provide for the option of accepting these approvals, even on conditional terms, to allow marketing of the products in Canada.

As a way to place functional food products of Canadian companies on an equal footing with their counterparts in the United States, we recommend that health claims currently approved in the U.S. be allowed in Canada. As a condition to the adoption of U.S. health claims, we further recommend that Canadian regulatory authorities be allowed one year to make whatever adjustments that may be necessary to place the statements articulating the claims in the Canadian context. If not amended within one year, it is recommended that the claims be allowed indefinitely as adopted from the U.S.

6. Consideration of Foreign Legislation As Models for Canada

There are at least three examples of foreign legislation and related systems which appear to be functioning and hold promise as the basis for designing and implementing new legislation in Canada. Within Japan, one of Canada's three leading trade, investment and research and development partners, the *Nutrition Improvement Act*, under which FOSHU licensing was created and is administered, stands as one example. Within the United States, the *Dietary Supplements Health Education Act* offers a functioning model for a system which could apply to dietary (nutrition) supplements brought to market and sold in Canada. The nutrition labelling requirements of the *Nutrition Labelling and Education Act* are also a useful model for communication of nutrition facts to consumers within the label contents of packaged foods and functional foods. Even the onerous requirements for health claims in the United States under NLEA are an improvement over the Canadian system. We recommend fast action to put in place similar legislation or regulations in Canada.

VII. Notes to Summary Tables: Additional Detail by Jurisdiction

A. Canada

TABLE I.A.1. - FUNCTIONAL FOODS: In Canada there are no specific regulations dealing with functional foods even though examples of such products have appeared on the Canadian market. Such foods are governed by the existing legislative and regulatory framework; *The Food and Drugs Act and Regulations.*

Examples of functional foods seen in Canada include isotonic beverages for athletes, grain products containing purified fibre ingredients, fat substitutes based on modified starches, eggs enriched with n-3 fatty acids, herbs and botanical preparations and bifidobacteria cultures.

Under Canadian food and drug law, ingestible products must be either sold as a "food" or "drug". Food is defined in the *Food and Drug Act* as follows:

Any article manufactured, sold or represented for use as food or drink for man, chewing gum and any ingredient that may be mixed with food for any purpose whatsoever.

Drug is defined in the *Food and Drug Act* as follows:

Any substance manufactured, sold or represented for use in (a) the diagnosis, treatment,

under the Food and Drugs Act - Volume 3 includes a project with the objective of amending the *Food and Drug Regulations* to provide for the sale of foods for special medical purposes (FSMP) also known as "medical foods". Such amended regulations would augment current requirements dealing with formulated liquid diets.

This project states that a background document and proposals for regulatory amendments defining and setting out requirements for FSMP will be prepared for external consultation. While the starting date of this project is shown as July 1, 1994 and the date for pre-publication of proposed regulatory amendments in the *Canada Gazette Part I* as October 1995, it appears that this timetable has been set aside as the background document for public consultation has yet to be released.

TABLE I.A.5. - HERBS AND BOTANICAL PREPARATIONS: In 1984, the HPB initiated consultations aimed at developing minimal regulations to prevent potentially hazardous herbal preparations from being sold as foods.

As an ingestible substance must be classified under the Canadian *Food and Drugs Act* as either a "food" or a "drug", certain potentially hazardous substances were "defaulting" to the food classification as the products were sold without any explicit medicinal or therapeutic claims.

The regulatory concept involved with this initiative involved defining a list of natural substances called "herbs and botanical preparations" which were considered to be toxic on the basis of expert opinion and historical documentation.

Since 1984, the regulatory proposal has been published several times and has met with intense criticism each time. In order to build consensus, the proposal has been reviewed on tow occasions by an Expert Advisory Committee.

As a result of the protracted consultations there is now an emerging consensus on some 50 substances that should not be sold *per se* as food or added to food as an ingredient. Selling such a herb or botanical as a food would be considered as an act of adulteration. Final regulations are expected in 1996.

TABLE I.A.6 FOODS FOR SPECIAL DIETARY USES:

Regulations in Division 24, Part B of the *Food and Drug Regulations*
defines the following types of special dietary foods:

- carbohydrate reduced foods
- sugar free foods
- calorie reduced foods
- low calorie foods
- low sodium foods

- formulated liquid diets
- food for protein restricted diets
- food for low (naming the amino acid) diets
- foods for fat modified diets
- foods for gluten restricted diets
- meal replacements

The following is an excerpt from a background paper entitled *Review of Food Regulations Pursuant to the Food and Drugs Act* released by the HPB in February 1993 as part of the external consultation associated with regulatory review initiated by the Treasury Board of Canada in October, 1992.

4.8.2 Foods for Special Dietary Uses

a. Consumers with various metabolic problems, should be given direct, factual information useful to them in the dietary control of their condition.

b. The present regulations tend to institutionalize industrial gimmickry in the marketing of those products which qualify under the conditions which have been established. The bulk of the products which qualify, for example, as "recommended for calorie reduced diets" are generally peripheral products in the food supply. Examples include confectionery, dessert mixes and dressings for salads. The fact that these products carry a statement such as *recommended for calorie reduced diets* borders on being misleading in light of the fact that other products, such as skim milk or even fruits and vegetables, that might be useful in these diets, may not carry any label claims to the effect that they are recommended for any specific type of diet. This is because of the requirement that a calorie-reduced food must be processed to contain not more than 50% of the calories normally provided by that food. In essence, a 50% calorie-reduced version of a carrot or skim milk in not possible. Such manipulation is only possible when product characteristics can be artificially maintained in multi-component fabricated products - i.e. sweetness from an artificial sweetener and thickness by use of bulking agents such as vegetable gums.

   The requirement that these products use the term "recommended" as part of the dietary claim is very questionable. The connotation is that the government, through regulation, somehow endorses such products as having a useful place in dietary management".

   The regulatory review consultations which took place did not generate any specific recommendations respecting the observations about foods for special dietary uses contained in the background paper noted above.

TABLE I.A.7. - HEALTH FOODS: The term "Health Food", though widely used by industry and the consumer, is problematic for the Health Protection Branch (HPB).

The definition of "food" in the *Food and Drugs Act* makes no differentiation about types of food and states in another section that food must be free from poisonous or harmful substances. Thus, in legal terms, any food in compliance with the *Food and Drugs Act and Regulations* should assist in sustaining good health and should not present any appreciable hazard to the consumer.

"Health Foods" should not be confused with "organically produced" foods which represent, by international consensus, foods derived from organic agriculture and are part of the broad spectrum of methodologies supportive of the environment and the concept known as "sustainable agriculture". Organic foods are subject to non-regulatory certification procedures by a number of organizations around the world and are also currently under review by the Codex Committee on Food Labelling.

TABLE I.A.9. NOVEL FOODS: New regulations respecting "novel foods" and "novel food processes" are currently in the final stage of development by the HPB. These new regulations will define novel foods and require notification prior to the sale or advertising for sale of novel foods and foods produced by novel processes, including products of biotechnology. The proposal to regulate in this area has been published in both the 1994 and 1995 editions of the *Federal Regulatory Plan.* Final regulations are expected to be promulgated during 1996.

TABLE I.A.10 HEALTH CLAIMS: Section 5(1) of the *Food and Drugs Act* prohibits the selling or advertising of any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, composition, merit or safety.

This section of the Act has been used as the basis for developing guidelines which are contained in the Guide for Food Manufacturers and Advertisers, originally published under the authority of the Department of Consumer and Corporate Affairs (CCAC). When CCAC was abolished in 1993, this responsibility was transferred to the Food Production and Inspection Branch of Agriculture and Agri-food Canada where it currently resides.

It should be noted that the guidelines in the "Guide" are simply interpretations and, as such, do not have the force of law. Over the years there have been very few challenges in court about labelling and advertising claims, including health claims. Thus, there is very little jurisprudence in Canada in this area and there is a mistaken impression in parts of the private sector that the material in the "Guide" has regulatory status.

However, the *Food and Drugs Act* in the area of labelling and advertising does not deal only with a prohibition on false and misleading information. Section 3 of the Act and contains a prohibition against the advertising or labelling of a food or drug to the general public as a treatment, preventative or cure for any of the diseases or disorders listed in Schedule A to the Act. These include not only many chronic diet linked diseases such as cancer, diabetes, heart disease and obesity but also other diseases which are often the subject of claims for "folk medicine" such as alcoholism, hair loss and impotence. The rationale behind this prohibition (which was introduced

into the *Food and Drugs Act* in 1934) is that the 46 diseases listed in Schedule A require medical diagnosis or treatment and the general public should not be self-medicating for these conditions.

Another unfortunate reality about Section 3 of the *Food and Drugs Act* and Schedule A is that this section of the statute also prohibits claims that are true where a specific product is linked to a disease set out in Schedule A. For example, a claim that "a diet low in saturated fat may reduce the risk of heart disease" would be permissible only if no linkage were made to a specific product being offered for sale.

If the message is positioned on a food label or in a product-specific advertisement, it would be deemed to offend either Subsection 3(1) or 3(2) of the *Food and Drugs Act.* Section 3 of the *Food and Drugs Act* is as follows:

3. *(1) 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.*

   (2) No person shall sell any food, drug, cosmetic or device

   (a) that is represented by label, or

   (b) that the person advertises 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

Diseases Included in Schedule A

Alcoholism, Alopecia, Anxiety State, Appendicitis, Arteriosclerosis, Arthritis, Asthma, Bladder Disease, Cancer, Convulsions, Depression, Diabetes, Disease of the Prostate, Disorders of the menstrual flow, Dysentery, Edematous state, Epilepsy, Gall Bladder Disease, Gangrene, Glaucoma, Gout, Hernia, Hypertension, Hypotension, Impetigo, Kidney Disease, Leukemia, Liver Disease, Nausea and vomiting of pregnancy, Obesity, Pleurisy, Rheumatic Fever, Septicaemia, Sexual Impotence, Thrombotic and Embolic Disorders, Thyroid Disease, Tumour, Ulcers of the Gastro-intestinal tract, Vaginitis, Venereal Disease.

TABLE II.A.1. - LEGISLATION: The *Food and Drugs Act and Regulations* is the primary Canadian statute which governs the sale of foods, drugs, cosmetics and medical devices in Canada. This statute which is remarkably simple in concept, can trace its origins to an 1860 British law entitled *A Bill for Preventing the Adulteration of Articles of Food and Drink.* The Canadian law evolved from an 1874 statute to the current Act which was passed in 1953. First of all, the Act defines "food", "drug", etc. and then sets out prohibitions in Section 4 respecting the sale of food that:

- has in or on it any poisonous or harmful substance;
- is unfit for human consumption;
- consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
- is adulterated; or
- was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Section 5 deals with largely with deception and dishonest marketing and is as follows:

> *5(1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.*

Section 3 of the Act is adequately described in the notes dealing with Section A.10 of Table I-Health Claims. It is interesting to note that Section 3 of the *Food and Drugs Act* was introduced on July 3, 1934; making it an offense to import, offer for sale, or sell any remedy represented by label or advertisement to the general public as a treatment for any of the diseases, disorders or abnormal physical states named or included in Schedule A to the Act. During the same time period, American legislators also considered the inclusion of a similar provision in the *U.S. Food, Drug & Cosmetic Act*. This amendment which was proposed by Senator Copeland was extensively debated but was ultimately not accepted by Congress.

While certain minor amendments to the Act have been made during the past 43 years, it is the regulations pursuant to the Act which have been amended by the "Governor-in-Council" process hundreds of times in an effort to reflect social, technological and societal change. Section 30 of the Act authorizes the "Governor-in-Council" (i.e. the Governor-General of Canada) to "make regulations for carrying the purposes and provisions of this Act into effect, and, in particular but not so as to restrict the generality of the foregoing, may make regulations.....". Section 30 then lists a long list of areas that can be handled through subsidiary regulations which means that subordinate law in the form of regulations may be amended without direct reference to Parliament.

Some of the most used powers of Section 30 are as follows:

- declaring that any food or drugs or class of food or drugs is adulterated if any prescribed substance or class of substance is present therein or has been added thereto or extracted or omitted therefrom;

- prescribing regulations respecting the sale or condition of sale for any food, drugs, cosmetics and devices and the use of any substance as an ingredient in any food, drug, cosmetic or device to prevent the consumer or purchaser from being deceived or mislead as to its design, construction, performance, intended use, quantity, value, composition, merit or safety, or to prevent injury to the health of the consumer or purchaser.

A section of the regulation making power that is seldom used authorizes the Governor-in-Council to make regulations *"exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of such exemption".* It seems that this section could be invoked as a mechanism to bring relief to the inflexible structure created by Section 3 and Schedule A. Judicious use of this section could bring about some equivalency respecting advertising and conditions of sale between Canada and some of its major trading partners in the area of functional foods, nutritional supplements and related products that are emerging as a significant sector of the food industry.

TABLE II. A.2. REGULATIONS: The Food and Drugs Act, as a statute, is highly dependent on delegated legislative authority be means of regulations. Such power given to the Governor-in Council is typical of Canadian legislation in technical fields where a high degree of flexibility is required to keep pace with changing technology. In contrast to ever-changing regulations, the basic statutes tend to deal with broad principles and thus remain relatively stable.

It is important to note that the authority to make regulations is limited to that necessary to prevent deception, or to prevent injury to the health of the consumer. The promotion of health is not included as part of the authority given to the "Governor-in-Council" in terms of prescribing "condition of sale" requirements or regulations respecting the use of substances within the ambit of the Act.

It seems that the matter of promoting health is outside the bounds of the *Food and Drugs Act.* Under the terms of the Act that creates the Department of Health, the duties, powers and functions of the Minister extend to matters of preserving and improving public health, as carried out in cooperation with provincial authorities.

While the role of nutrition and health promotion is recognized as a vital component of public health, this matter is not really addressed in the *Food and Drugs Act* which was drafted to ensure food safety and integrity. Nutrition regulations promulgated for the prevention of injury (even potential injury) and deception would appear to be on solid legal grounds. Examples of these include regulations specifying limitations on vitamin and mineral nutrient addition; control of critical products such as infant formulae which are used as a sole source of nutrition; and deception-related regulations for substitute foods.

On the other hand, authority to promulgate regulations in the area of public health intervention and promotion of health as opposed to the prevention of injury and fraud, is questionable. Examples in this area include regulations dealing with the format and content of nutritional information; mandatory requirements for the addition of certain nutrients to food, when the food is principally a carrier for these nutrients (e.g. mandatory addition of Iodine to Salt and Vitamin D to Milk and Milk Products); and minimum protein requirements for prepared meat products.

In the same vein, HPB's authority to regulate wellness claims for functional foods and dietary supplements may also be subject to challenge.

TABLE II.A.3. GUIDELINES: As an alternate to regulations, a number of guidelines have been introduced which attempt to interpret the basic provisions found in Section 4 and 5 of the *Food and Drugs Act*. As outlined in the notes to Table I.A.10 - Health Claims, guidelines are simply interpretations and, as such, do not have the force of law. Despite disclaimers that appears in all Guidelines issued by the HPB and AAFC, the regulated industries tend to think that these guidelines have actual regulatory status.

Guidelines have been developed because they can be amended easily as they are not subject to the lengthy process associated with actual regulatory amendments. However, there is a tendency for guidelines to become extremely complicated over time because of the relative ease of amendment and the fact government has resources dedicated to this activity. Another characteristic associated with guidelines is that history of application tends to become the policy of the department or agency applying the guidelines in the absence of actual jurisprudence.

The following is a list of Guidelines that affect the sale of food products sold in Canada:

- *Guide for Food Manufacturers and Advertisers (originally published by Consumer & Corporate Affairs Canada [CCAC] in 1988 but now under review by Agriculture and Agri-Food Canada who assumed responsibility for food labelling with the demise of CCAC in 1993);*

- *Guidelines for the Nomenclature and Classification of Externally Visible Defects in Metal Containers of Canned Foods - Issued by the Food Directorate, HPB, October 10, 1989;*

- *Guidelines on Nutritional Labelling - Issued by the Food Directorate, HPB, November 30, 1989*

- *Guidelines for Developing Pesticide Residue Data in Foods as Consumed - Issued by the Food Directorate, HPB, May 31, 1990;*

- *Guidelines for Incidental Additive Submissions - Issued by the Food Directorate, HPB, May 31, 1990;*

- *General Principles for Labelling and Advertising Claims that Relate to the Nutrition Recommendations - Issued by the Food Directorate, HPB, March 1, 1991;*

- *Guidelines for Health Information Programs Involving the Sale of Foods - Issued by the Food Directorate, HPB, March 1995 (revised version);*

- *Guidelines for the Production, Distribution, Retailing, and Use of Refrigerated Prepackaged Foods With Extended Shelf-Life - Issued by the Food Directorate, HPB, December 9, 1991;*

- *Guidelines for the Safety Assessment of Novel Foods, Volume I - Preamble and Guidance Scheme for Notification - Issued by the Food Directorate, HPB, September, 1994;*

- *Guidelines for the Safety Assessment of Novel Foods, Volume II - Genetically Modified Microorganisms and Plants - Issued by the Food Directorate, HPB, September, 1994;*

- *Guidelines Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them - Issued by the Food Directorate, HPB, February 1988 (revised slightly and Appendix 2 added, November 1994).*

Another area where a certain degree of confusion exists involves the regulatory authority for pre-market review. Currently, the *Food and Drug Regulations* contain specific authority for pre-market review of the following:

- All drugs
- Food Additives
- Infant Formulae
- Food Irradiation

The final regulations dealing with "Novel Foods" will also contain authority for pre-market review. However, until these regulations are actually promulgated, no legal requirement exists for pre-market review despite the existence of the Guidelines for the Safety Assessment of Novel Foods.

Pre-market review requirements for food additives were introduced in 1964 and Section B.16.002 of the Regulations sets out the safety and other criteria that must be met in order to have a modification made to one of the Tables of Division 16. The Tables in the Regulations which list the food additives permitted for use in Canada use the concept of "positive listing". In other words, if a substance does not appear in a table for use in a certain food at a specified level of use then that substance is not permitted as a food additive in Canada.

Division 25 of the Regulations sets out criteria respecting notification of the "Director" (i.e. the Assistant Deputy Minister, HPB) before a new human milk substitute may be introduced into the marketplace as well as when a human milk substitute has undergone a major change. These requirements were introduced in 1990.

Until 1989, food irradiation was considered to be a food additive and thus subject to the requirements set out in B.16.002. It was recognized that food irradiation was not a "best fit" in the table of food additives and in March, 1989 a new Division (Division 26) was established

specifically for food irradiation. The pre-market approval criteria established were very similar to those required for safety approval of a food additive.

In terms of regulatory requirements for the pre-market approval of the safety and physiological effects of novel fibre sources, such requirements do not exist. However, a detailed guideline is in existence which in the "Introduction" section states the following:

> *If a novel fibre source or novel fibre-containing product is not safe for human consumption, it may be in violation of Section 4 of the Food and Drugs Act. Similarly, if a product is represented as containing dietary fibre, but does not have the effects the public has come to expect of dietary fibre, the product may be in violation of Subsection 5(1) of the Act. This guideline has been developed, therefore, to assist manufacturers in identifying the procedures which will be considered to verify the safety and physiological efficacy of new products which they wish to represent as dietary fibre sources and dietary fibre-containing food products.*

It should be very clear that as part of the criminal law, the *Food and Drugs Act* is not a "reverse onus" statute. In other words, it is the responsibility of the Federal Government to prove beyond a reasonable doubt that a person violated a specific section of the Act. If a person or a firm decides, for example, to sell a novel fibre or a food containing a novel fibre without any consultation with the HPB, no violation of the *Food and Drugs Act* would have taken place. It would be the responsibility of the HPB to build a case that the sale of the novel fibre was a violation of either Section 4 (safety) or Section 5(deception and fraud) or both. It is only when regulatory pre-market review requirements have been established that a person is potentially guilty for not complying with the conditions that have been established by regulation.

TABLE III. A.1 - APPROVAL PROCESS: As outlined in the notes to *TABLE II A.III GUIDELINES*, regulatory pre-market review or approval is currently restricted to four classes of substances; all drugs, food additives, infant formulae and food irradiation.

In order to preclude perceived compliance problems which could occur without a pre-market review by the HPB, many manufacturers voluntarily provide information about new products not falling into one of the four classes noted above. In the case of "functional foods" most of the voluntary pre-market review tends to involve nutritional issues. The cooperation of the private sector in this voluntary system has resulted in the elaboration of detailed guidelines in certain areas which have proved to be more difficult to deal with than actual regulations. When a regulation does not exist, the demands for information tend to be "open ended" and the submission of one set of data often precipitates more questions and the request for additional information or a new study.

The review of labels for food products, including "health and functional foods", also tends to be somewhat misunderstood. With the exception of labels used in plants registered by AAFC, there is no mandatory label review requirement in Canada. Once again, many food manufacturers and

importers simply provide a label for pre-market review as a precautionary measure against compliance problems that could result from a trade complaint or the occasional interception of a product by a field inspector. As noted earlier in this report, a large volume of non-regulatory interpretations about label statements and claims has grown up over the years and is the subject of a 140 page *Guide for Manufacturers and Advertisers* which constantly seems to be under review and revision.

TABLE III.A.2. TRANSPARENCY OF THE APPROVAL PROCESS: In those areas where the pre-market approval process is mandatory, a certain degree of transparency is built into the process. For example, making changes to the Tables of Division 16 of the Regulations (Food Additives) is a regulatory procedure and thus, HPB is obligated to follow the standardized regulatory process which involves pre-publication in the *Canada Gazette Part I* and final publication in the *Canada Gazette Part II* when the final regulation is promulgated. Such transparency is necessary for Canada to fulfil its international obligations under the *Agreements on Sanitary and Phytosanitary Measures* found in both the WTO and NAFTA Agreements.

Changes to the tables permitting new or modified uses of food irradiation use the regulatory process in a manner analogous to that used to change one of the food additive tables and thus external transparency is part of the process.

By contrast, the notification procedure specified in the infant formula regulations is administrative in nature and thus, there is no obligation for transparency. The new regulations being developed for "Novel Foods" will also use the notification concept and thus transparency will be minimal, except if there is an administrative requirement for the approval letter from the "Director" to be published in the *Canada Gazette Part I.*

In the case of voluntary submissions such as those dealing with the safety and physiological effects of novel fibre sources, no external transparency exists as the transaction is entirely between the petitioner and the official in the HPB. If a petitioner receives a "letter of no objection" to the sale of the novel fibre source, that information is the exclusive property of the petitioner.

A significant difference exists between the transparency of the petitioning process in the United States and that used in Canada. In the USA, when a petition for a food additive is filed it becomes a matter of public record and the existence of the petition is announced via the *Federal Register*. When a food additive petition is filed in Canada it is considered to be of a proprietary nature and strictly between the petitioner and the HPB until such time as the scientific evaluation has been completed. At that time the regulatory process requires details to be pre-published for comment in *the Canada Gazette Part I.* If a petition is withdrawn or does not pass successfully through safety evaluation, this never becomes a matter of public record.

TABLE III. A.3. - SAFETY AND EFFICACY REQUIREMENTS: Safety and efficacy requirements are part of the regulatory regime for food additive pre-market approval described in Section B.16.002 of the *Food and Drug Regulations.* In the case of food additives there is

considerable international consensus about Acceptable Daily Intakes (ADIs) and the nature of toxicological studies that must be carried out in order to demonstrate safety.

In areas other than food additives, there is much less international consensus about safety and the type, duration and end points needed for a safety evaluation. For example, the *Guidelines for the Safety Assessment of Novel Foods* could be invoked to deal with a number of food products that are considered by the private sector to be "functional foods". As "Novel Food" regulations will be promulgated shortly, these guidelines will take on a new regulatory status.

It is interesting to note that three of the four "decision trees" in Volume I of these Guidelines include a box which says "consult Food Directorate respecting notification requirements". This makes the notification system unclear as there appears to be no published standard against which a petitioner will be assessed. This type of bureaucratic discretion frequently leads to situations where there is no "end point" with the petitioner constantly being asked for additional data. Thus, if these novel food petitions are not well managed, the end result could be a tangle of bureaucratic data requests (chemical safety as well as nutrition) against a backdrop of regulatory authority which can be used to prevent the sale of a product.

In those cases where regulatory authority does exist not in terms of pre-market review or approval of a food product, manufacturers should always bear in mind that responsibility for product safety and quality rests with the manufacturer or importer. If the HPB challenges a product in terms of safety or an allegedly false or misleading label claim then it is the responsibility of the federal government to develop appropriate evidence, proceed with charges under the appropriate section or sections of the *Food and Drugs Act* and ultimately have a court of law adjudicate the facts of the case.

TABLE III .A.4. - TEST CRITERIA: The only published Guideline containing detailed test requirements of the type that would be required for "functional foods" are found in the *Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them.* This Guideline contains the following:

- General Principles Relating to Product Testing
- Information Necessary to Evaluate the Acceptability of a Novel Fibre Source as a Potential Dietary Fibre Ingredient:
- Form, Manufacture and Intended Use
- Physico-chemical Specifications
- Microbiological Specifications
- Safety
- Physiological Efficacy Evaluation
- Annex 1 - Proposed Guidelines for Clinical Studies
- Annex 2 - Guidelines for Planning and Statistical Review of Clinical Laxation Studies for Dietary Fibre

The "Regulatory Interpretation" section of Annex 2 states the following:

> *This study protocol may also be used to demonstrate the efficacy with respect to laxation of a reasonable daily intake of a specific product, such as a bread or breakfast cereal, in support of a claim for "promotes regularity" or "promotes laxation" on the label or in the advertising of that product.*

TABLE IV.A.1. - PATENT PROTECTION: No patent or equivalent protection is intended for any food product. However, in the case of food enzymes (subject to pre-market approval as a class of food additive), the extreme specificity of certain entries in Table V of Division 16 of the *Food and Drug Regulations* may well provide a type of unintended product protection equivalent to patent protection. This occurs because only the petitioner has access to the particular microorganism used in the production of the particular enzyme. Extreme specificity of regulations or even administrative decisions in other areas could also provide protection to a manufacturer equivalent to that afforded by a patent. The big advantage to a manufacturer of this unintended protection is that such protection is without a time limitation and is provided without cost.

There is no area where even unintended protection would be afforded to claims relating to nutrition or functional or physiological properties of a food. All such claims are in the public domain by virtue of appearing in regulations or guidelines.

TABLE IV.A.3. - CONFIDENTIALITY OF PROPRIETARY INFORMATION:
Information submitted to government agencies in Canada such as the HPB is subject to the rules and procedures of the *Access to Information Act (ATI).* Proprietary information contained in submissions requesting regulatory amendment is protected if it contains trade secrets or information, if released, that could prejudice the economic position of the manufacturer. Scientific evaluations and records relating to such evaluations carried out by public servants are generally available once the regulatory amendment has been made.

TABLE V.A.1. - LABELLING - STATUS OF HEALTH CLAIMS: As outlined in previous sections of this report, health claims are not permitted on foods sold in Canada. A health claim is generally interpreted as being an explicit or implicit claim relating a specific food to its use as in the treatment, prevention or cure of a disease or abnormal physical state. Wellness claims, such as “promotes a good night’s sleep”, “helps relieve fatigue”, “encourages energy during the day”, or other physiological states not associated with a disease, would be reviewed on a case by case basis. Under the current system, in most cases the use of such claims would be discouraged.

TABLE V.A.2. - PERMISSIBLE NUTRITION CLAIMS AND STATEMENTS:
(the following information has been extracted from pages 87 - 89 of the *Guide for Food Manufacturers and Advertisers}*

While health claims are not permitted, claims are permitted for the action or effects of the following nutrients:

- protein, fat, carbohydrates, sugars (all monosaccharides and disaccharides), sorbitol, mannitol, xylitol, starch, dietary fibres, amino acids, linoleic acid, cis - methylene interrupted polyunsaturated fatty acids, cis - monounsaturated fatty acids, saturated fatty acids, vitamins and mineral nutrients listed in Tables 1 and 2 of Part D of the Regulations.

The claims are subject to the following conditions:

i. the claim may not refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or symptoms or same, nor may it refer directly or indirectly to correcting, restoring or modifying organic functions;

ii. the claim may not refer directly or indirectly to the treatment, prevention or cure, of diseases listed in Schedule A or the Food and Drugs Act;

iii. the claim must be limited to the generally recognized function(s) of the nutrient which is a factor in or aids in maintaining food health and normal growth and development.

The generally recognized function of nutrients may be found in the Recommended Nutrient Intakes for Canadians issued by Health Canada

Examples of acceptable claims include:

- Thiamine helps release energy from carbohydrates.
- Vitamin C helps to keep teeth and gums healthy.
- Iron aids in red blood cell formation.

Examples of unacceptable claims include:

- Calcium fights bone disease such as osteoporosis.
- Protein builds muscles and makes you stronger.

iv. the claims for the action or biological role of the nutrients should not imply that consumption of the food, by itself, will have the effect attributed to the nutrient.

An example of an acceptable claim is:

Milk is an excellent source of calcium which helps build strong bones and teeth

An example of an unacceptable claim is:

Milk helps build strong bones and teeth

v. No claim should be made regarding the fibre content of a food unless the food contains at least 2 g of dietary fibre per serving. Foods containing a minimum of 2 g of dietary fibre per serving may be described as a "source" or dietary fibre or as containing "moderate" amounts of dietary fibre. A minimum of 4 g per serving permit the food to be described as containing "high" amounts of dietary fibre. Foods containing at least 6 g of dietary fibre per serving may be described as containing 'very high" amount of dietary fibre.

TABLE V.A.4. - OTHER INFORMATION TRIGGERED BY A NUTRITION CLAIM:

The claim triggers a declaration of the nutrient content in a serving of stated size of the food. Furthermore, a minimum level of nutrient must be present in the food; in the case of protein, a reasonable daily intake (RDI) must have a protein rating of at least 20; in the case of vitamins and mineral nutrients, a serving of stated size must contain at least 5% of a RDI of the nutrient.

TABLE V.A.5. - STATUS OF GENERAL NUTRITION LABELLING: A voluntary (non-triggered) nutrition labelling scheme was introduced in Canada in 1988 following several years of consultation with the food industry and other interested parties. Three basic labelling formats are possible:

Core List

Energy	Fat
Protein	Carbohydrate

Core List + Carbohydrate Constituents, Sodium & Potassium

Energy	Carbohydrates
Protein	Sugars
Fat	Starch
Polyunsaturates	Dietary Fibre
Monounsaturates	Sodium
Saturates	Potassium
Cholesterol	

Core List + Vitamins and Minerals

Energy	Fat
Protein	Carbohydrate

The following vitamins and minerals declared on the basis of % of RDI

Vitamin A	Vitamin B12

Vitamin D		Pantothenic Acid
Vitamin E		Calcium
Vitamin C		Phosphorus
Thiamine		Magnesium
Riboflavin	Iron	
Niacin		Zinc
Vitamin B6		Iodine
Folacin		

It is not necessary to declare all the micronutrients noted above, only those that pertain to a particular product. The list of micronutrients is based on the availability of a reference standard for use in nutrition labelling. Complete details of the nutrition labelling scheme may be found in the *Guidelines on Nutrition Labelling.*

TABLE VI.A.1. JURISPRUDENCE: The amount of jurisprudence that has been established over the years with respect to the *Food and Drugs Act* has been somewhat limited. In the 1960's many of the prosecutions involved the illegal use of sulphur dioxide in ground meat as an agent to prevent discoloration. The combination of relatively vigourous enforcement, new packaging techniques, improvements in refrigeration and a reduction in the number of "corner butcher shops" appears to have virtually put a stop to this once prevalent practice.

In the 1950's, 1960's and 1970's considerable effort was also directed at bringing charges against manufacturers and distributors who were considered to be operating unsanitary manufacturing premises in violation of Section 7 of the Act. These cases were important in underscoring the responsibility of the manufacturer in having adequate quality control and sanitation procedures in place to preclude the possibility of producing, packaging or storing food under unsanitary conditions. As many of those charged pleaded guilty, there was little testing of the basic law in this area.

The introduction of mandatory fortification of milk and milk products with Vitamins A and D resulted in a number of prosecutions in the 1970's. These cases were significant as they served notice to the dairy industry about the importance of having adequate quality control measures at the processing level.

The most important legal challenge in terms of impact on the *Food and Drugs Act* resulted from a Supreme Court of Canada decision in 1979 respecting "Labatt's Lite Beer". The Supreme Court rendered a judgment to the effect that the inclusion of compositional standard, such as those for beer, in a criminal law statute (*the Food and Drugs Act and Regulations)* did not represent a justifiable exercise of the criminal law. As a result, the beer standards (and presumably all other compositional standards such as strawberry jam, ice cream, bread, etc.) were invalid.

In order to rectify this situation, an amendment was made to Section 6 of the Act in 1987 which re-validated the standards on the basis of the constitutional power dealing with trade and

commerce. The effect of this amendment was that standards for food products which reside in the *Food and Drug Regulations* cannot be enforced unless the product crosses an international or provincial border. Prior to this pivotal Supreme Court of Canada decision, it was always felt that food standards could be enforced regardless of the nature or level of the transaction.

The Supreme Court decision did not really address the "health-related" aspects of standards such

TABLE VI.A.3. - PENALTIES: The "Penalties" section of the *Food and Drugs Act* state the following:

> *Every person who violates any of the provisions of this Act or the regulations is guilty of an offence and is liable*
>
> *a. on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months, or to both, and for a subsequent offence to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months, or both; and*
>
> *b. on conviction upon indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years, or to both.*

The relatively low fines contained in the penalties section reflect the fact this section of the Act has not been amended since 1953.

B. United States of America

TABLE I.B.1. - DEFINITION OF A FUNCTIONAL FOOD: The term functional food has no legal status or general acceptance in the United States. In addition, the organization of the FDA regulatory groups does not allow for consideration of 'functional foods'. Since functional foods do not exist as legal entities in the U.S., marketers have to assess the product and terms under which they want to market the product and then decide whether they will label as a food or dietary supplement. Dr. Clare M. Hasler the director of the Functional Food for Health Program of the University of Illinois uses the following definition attributed to the Institute of Medicine, " Functional foods encompass potentially healthful products including any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains" (Hasler and Huston, 1995).

TABLE I.B.2. - DIETARY SUPPLEMENT: The following definition was established as part of the Dietary Supplements Health Education Act. "A dietary supplement is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb, or other botanical, an amino acid, a dietary supplement for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract or combination of these ingredients". A dietary supplement is intended for ingestion in pill, capsule, tablet or liquid form; is not represented for use as a conventional food or as the sole item of a meal or diet; is labelled as a dietary supplement. A dietary supplement includes such products as an approved new drug, certified antibiotic or licensed biologic that was marketed as a dietary supplement or food before approval, certification or license (unless the Secretary of Health and Human Services waives this provision.)

TABLE I.B.3. NUTRACEUTICAL: The following definition was coined by Dr. Stephen DeFelice of the Foundation for Innovative Medicine, a New Jersey based industry group. A nutraceutical is: "A food derived from naturally occurring substances which can and should be consumed as part of the daily diet, and which serves to regulate or otherwise affect a particular body process when ingested." Food Technology (April, 1992) expanded this definition to, "A nutraceutical is any substance that may be considered a food or part of a food and provides medical or health benefits, including prevention and treatment of disease. Nutraceuticals may range from isolated nutrients, dietary supplements, and diets to genetically engineered 'designer' foods, herbal products and processed products such as cereals, soups and beverages."

TABLE I.B.4. - MEDICAL FOODS: Medical foods are regulated by the FDA Office of Special Nutritionals and include enteral foods (oral liquid diets or liquid diets designed for delivery through stomach tubes). Foods for sick infants are considered medical foods, although formulas and other foods for infants are regulated under Infant Formula Act of 1980 (amended in 1986). Parenteral foods or diets (designed for intravenous use) are regulated as drugs.

TABLE I.B.10 - HEALTH CLAIM: A health claim is any claim made on the label that either expressly or through implication (through the use of endorsements, written statements, symbols or vignettes), characterizes the relationship between any substance to a disease or health related condition. Implied health claims include only those forms of communication that a manufacturer intends or would likely to be understood to assert a directly beneficial relationship between any substance and a health or disease related condition. (Fed. Reg. Vol.58, No.3. 1/6/93. 2479). FDA has clearly indicated that two elements must be present in a health claim - reference to a substance, and reference to a health or disease condition. A substance is a food or ingredient. A health or disease condition refers to damage to an organ, part, structure or system of the body such that it does not function properly. It can also be a state of health leading to a disfunction.

Claims related to essential nutrient diseases are not included in this definition and are not considered health claims. In keeping with regulations for foods for special dietary uses, a food may be labelled with such words as 'hypoallergenic, lactose-free, wheat-gluten free, and dietetic' without being considered to be labelled with a health claim. FDA cautions however that additional information beyond that allowed by regulation for foods for special dietary uses may be interpreted as a health claim (Fed. Reg. Vol 58. No. 3. January 6, 1993, 2482).

The term health claim as used in the United States is really a disease-related claim, since wellness issues, (those statements or claims not related to a disease and are not a structure function claim) are not well covered. This presents difficulties in interpretation for manufacturers who want to present their products as useful for a wider variety of uses not covered by a disease related claim. FDA has indicated, however, that phrases such as 'invigorating, relaxing, stimulating, feeling better, or perform at your best,' are not health claims (Fed. Reg. Vol 58. No.3. 1/6/93 2482). When using these claims, FDA has indicated they may be regulated under the general restriction of truthfulness in labelling and/or as a structure function claim. This situation has no doubt left some confusion among manufacturers. Consumers interested in products that may provide more

general benefits are left with little or no information. This leads to reliance on less reliable forms of information. This insufficiency was one of the reasons the dietary supplement industry saw a need for a separate Act to govern their products.

The health claim situation is further complicated by the changing understanding and definition of a structure function claim. Structure function claims that simply explain the physiological effect of a substance in the body are allowed. But, it the structure function claim is considered to be associated in the minds of the public with a disease, it becomes a health claim and is not allowed without petitioning. For example, saying an ingredient lowers cholesterol was once considered a structure function claim; it was therefore allowed. Since FDA believes, however, that the public believes low cholesterol is associated with decreased heart disease, such a claim has become a health claim requiring a petition for use.

TABLE II.B.1. & 2. - LEGISLATION AND REGULATIONS: The *Nutrition Labelling and Education Act (NLEA)*, Public Law 101-535, November.8. 1990 is an act to amend the Food, Drug and Cosmetic Act to prescribe nutrition labelling for foods and for other purposes. While only 7 pages long, it is the least clearly written Act ever seen by this author. Evidence for its lack of clarity is given in the need for FDA bureaucrats having to have already published more than 950 pages (triple column) of Federal Register regulations interpreting this Act. The Federal Register regulations and explanations of interpretations are listed in the references.

Copies of Federal Registers, acts and legislation and can be obtained from depository libraries. The American Embassy library in Ottawa can deliver hard copies of Federal Registers and will accept phone requests. (The Federal Register of January 6, 1993 most pertinent to nutrition labelling and health claims is, however, out of print, and at 900 pages can not be obtained in hard copy. Interested readers should contact the authors to use the reference copy.) The Federal Register can be accessed through Internet (http: //www.access.gpo.gov/su_docs).

The dietary supplement industry was very dissatisfied with some aspects of NLEA and gathered political support for a separate act dealing with nutrition labelling of dietary supplements. The *Dietary Supplement Health Education Act (DSHEA)* Public Law 103-417, October 26, 1994 amends the *Food, Drug and Cosmetic Act* to establish standards with respect to dietary supplements and for other purposes. By contrast, this is a very clear act, although some details, such as allowable label claims, were left to be decided after the recommendations of a Presidential Commission established by DSHEA.

TABLE II B. 3. - GUIDELINES: In the United States, the official FDA guidance to understanding a regulation and the official interpretations of controversial issues is published in the Federal Register. In addition, FDA has published three good publications to assist food manufacturers to understand and ensure compliance with NLEA. They are listed with the references. In Washington, FDA officials with the Office of Food Labelling and the Office of Special Nutritionals are also available to answer questions.

TABLE III.B.1. - REGULATORY AND NON-REGULATORY APPROVAL PROCESS: Approval processes for health claims are regulated by FDA, although as indicated in Table 5. B. IV some structure function claims for dietary supplements are allowed following a simple notification process.

TABLE III.B.2. - DEFINED AND TRANSPARENT PROCESS: As indicated in Table III. B. 1, 2 and 3. the process is very transparent, so transparent that innovation and investment are discouraged. Relative to the size of the food processing and dietary supplements industry in the United States, very few health claim petitions have been submitted for consideration. Industry associations and academic bodies involved in this field indicate that research investment has been poor and/or insufficient because of the transparency and lack of exclusivity of the health claims approval process.

The lack of definition of the requirements for the preparation and submission of successful health claims has also been noted as a reason for insufficient investment and petitioning. FDA has, however, written outlines of its petition requirements. The availability of written guidelines does make the process easier, particularly for non-American manufacturers. In this instance, it may be more fairly said that the industry does not understand the requirements and finds them too onerous as well as insufficiently defined.

The Federal Register of January 6, 1993 gives the outline and basic requirements for petitions for new nutrient content claims, synonymous terms, claims implied in a brand name, and descriptive claims that are neither nutrient or health claims (such as those concerning the term ‘fresh’) (Vol. 58, No. 3. pp 2423-2426). The outlines seem reasonable and, when seen in the context of food additive or food irradiation petitions, they seem somewhat more straightforward and easier to use.

Our evaluation of the process for petitioning for health claims can not be quite as positive. Beginning with a good and concise summary of FDA decisions on the definitions and basis for health claims (Fed. Reg. Vol. 58, No. 3. 2533-5234) FDA outlines the rather onerous petition requirements for health claims (2535-2536).

In spite of the level of detail given in some instances, we believe many manufacturers would still have many unanswered questions, particularly about the parameters FDA will use to evaluate the research. This is an important point, since without this information, petitioners who wish to conduct research intended to provide FDA with needed information may not know how to proceed and may therefore become discouraged from research investment in studies that FDA may later decide are not suitable. (Other information on this subject is given in Table III. B. 4 and 5). To give a recent example, in the petition for the claim that oatmeal and oat bran as contributing to lowering blood cholesterol, FDA decided they wanted studies using humans representing the US healthy population (defined as those with <300mg/dL cholesterol). The FDA did not, however, use as evidence a study using American human females with low serum cholesterol levels since this population group was seen to be not at risk for heart disease. (Fed. Reg. January 12, 1996) This decision is not in keeping with medical research recommendations

that more data on female research subjects be used, particularly in heart and stroke research. The FDA also did not accept research with non-Caucasian subjects, as not representing the US population. This could be viewed as a questionable decision given immigration patterns and changing population demographics.

TABLE III.B.3. - SAFETY AND EFFICACY REQUIREMENTS: Safety requirements are not major considerations in the approval processes for health claims for foods. Safety is dealt with at other regulatory levels, for example, through food additive petitions or GRAS declarations, though regulations on adulteration of foods, through food standards or through USDA regulation.

Unlike any other food regulation, the DSHEA specifically indicates dietary supplements are safe and places the burden of proving otherwise on the FDA. If the Secretary of the Health and Human Services Department believes the product presents a significant or unreasonable risk of illness under ordinary or labelled conditions of use, or if the product is thought to be adulterated, or if the information associated with or the label is considered to be false or misleading the Secretary can withdraw the product pending court action. This situation allows for the sale of dietary supplements unless shown by FDA to be unsafe or adulterated or labelled in a misleading fashion.

The health claim procedures for foods entirely concern efficacy. Health claims are only allowed following the submission of a petition containing publicly available valid scientific research and only if an FDA review agrees the claim represents significant scientific agreement. The situation for dietary supplements is not as clear. Health claims for dietary supplements are currently regulated under NLEA, but there has been a Presidential Commission appointed tasked with recommendations concerning allowable health claims on dietary supplements. The role of this commission was established under DSHEA. This commission under the leadership of Dr. Ken Fisher, containing scientists, industry representatives, alternative medicine experts and others, has only recently begun deliberations.

The dichotomy in the relative strictness of NLEA for health claims for foods and the relative laxness of DSHEA for health claims for dietary supplements was noted by several people as a cause for concern, legally and from the point of view of fairness to the food industry.

TABLE III.B.4.- PETITION REQUIREMENTS: The outline for health claim petitions is included in Fed. Reg. January 6, 1993 pg. 2534-2536.

Most of the requirements are similar to those required for other petitions to FDA. Petitions must include copies of all cited references, computer literature searches and English translations of foreign language research and must be submitted in duplicate (or as original and diskette). All research and scientific reviews have to be submitted in quadruplicate. Non-clinical lab studies must include statements the research was conducted as per good lab practice regulations. Clinical tests must include statements the research was conducted under compliance with institutional review and informed consent regulations.

The following petition elements are critical to a health claim petition. The petitioner has to establish the substance is a food, a component of a food, is GRAS, or is listed as a food additive. The list of specific ingredients that supply the nutritive substance (the subject of the health claim) must be included. Next comes a scientific review of all information supporting (and not supporting) the health claim. The data submitted and the review must "establish significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims that the claim is supported". The public health benefit resulting from the health claim must be established. The FDA's interest in this issue is described in the questions FDA indicates should be answered. Is there an optimum level of intake of the nutritive substance? Is there a level of consumption at which adverse reactions for any segment of the population are seen? Are there certain population segments that must receive special consideration? What other nutrition or health factors (positive or negative) should be considered when consuming the substance?

Besides individual health impacts, the FDA wants to know the effects on food consumption and other nutrient intake and status will result from approval of the health claim. They also want information on the incidence of the disease or health condition the claim is supposed to affect. If the claim is directed at a population subset, the data and analysis must include the dietary habits and nutrition status of the subset (note that claims for healthy infants under two years old may be very difficult or impossible to obtain. Claims for sick infants will result in the product being considered a drug.)

The petitioner has to include analytical data (preferably using AOAC methods) of the amount of substance in the food intended to bear the health claim.

In the United States, petitioners for food additives, animal feeds or food irradiation have to draft the new regulation for consideration of FDA. In this instance, the petitioner has to provide the model health claim for FDA. The model claim has to capsulize the relevant conclusions of the summary and explain how the consumer will attain a total dietary pattern goal associated with the health benefit. For currently allowed claims, refer to Table V. B.2.

Making public health decisions based on nutrition research when the nutrient is found in whole foods and the research is conducted on human subjects who consume whole diets is a difficult task. FDA has noted difficulty in determining which nutrient in foods is responsible for the health benefit. For this reason, FDA denied the health claim relating dietary fibre to a reduced risk of cancer (Fed. Reg. January 6, 1993. Vol. 58. No. 3. 2537-2551) and denied the health claim relating dietary fibre to reduced risk of cardiovascular disease (Fed. Reg. January 6, 1993. Vol. 58. No.3. 2552-2605). In explaining the rejection FDA indicated while there was a wealth of research suggesting that various fibre containing foods reduced the risk of some cancers and cardiovascular disease, FDA could not say with certainty that it was the fibre component that was responsible for the beneficial result. In addition it was noted that the American Cancer Society did not agree with the claim. This is not consistent with the need for the claim to have general scientific agreement. (Note that FDA did allow health claims for these subjects. Refer to Table V.

B.2.) From this result we can recommend that a more focused food and health benefit model claim would have a better chance of success.

All petitions to FDA have to include an environmental impact assessment or a claim for a categorical exclusion. The petition outline for environmental impact assessment is included in the *Food and Drug Act* (CFR 21, Part 25). FDA noted in the decision to Quaker Oats concerning their oatmeal and oat bran petition that a health claim petition did not result in an environmental impact and so a statement was not required. Similar health claims can now presume a similar result, but this should be ascertained through correspondence with FDA.

Signing is an important element. Petitions to FDA must be signed by the preparer, indicating the petition is representative and balanced and includes all pertinent and known favourable as well as unfavourable information. This level of signing is for the scientific authority(s) in charge of the petition. (From past experience, the authors recommend petition preparers include personal resumes of their qualifications and experience. This is recommended for all scientific authorities who prepare research reviews, petitions segments, and/or are the signing scientific authority of a petition. This means of establishing credibility is particularly recommended for non-American petitioners whose qualifications may be less known to FDA reviewers.) Petitions are then signed by the petitioner, meaning an authorized signing officer or attorney of the manufacturer.

TABLE III.B.5. - TEST CRITERIA: The recent, successful, health claim for oatmeal and oat bran as contributing to reduced risk of heart disease (Fed. Reg. January 12, 1996), gives an example of the criteria used by FDA to evaluate research. This is a particularly useful approach since the test criteria were not identified in earlier regulations. FDA has noted the criteria used to evaluate fibre effects included: reliability and accuracy of the methods used in nutrient intake analysis including measurements of total soluble fibre and total dietary fibre; available information on the soluble fibre or beta-glucan contents of the oats and control foods; measurements of end points (total cholesterol, LDL-cholesterol and HDL-cholesterol); and general study design characteristics. General study design includes such factors as randomness of subjects, attrition rates (including reasons), potential for misclassification of individuals (with regard to dietary intakes), presence of recall bias and interviewer bias, recognition and control of confounding factors, appropriateness of statistical tests and statistical power of the studies.

FDA further wrote that studies had to present data and adequate descriptions of the study design and methods (and therefore they did not consider abstracts); be available in English; include estimates of enough information to estimate soluble dietary fibre intakes; include direct measurement on blood cholesterol and other blood lipids related to coronary heart disease; be conducted with persons who represent the general US population (defined as adults with total blood cholesterol levels <300mg/dL). They noted human dietary studies should be longer than three weeks in duration to give valid results. The FDA considered it highly desirable to have the study include data on total dietary soluble fibre content of baseline, treatment and control diets and on the nutrient intakes of the subjects during the study.

These criteria, while lengthy, onerous and probably expensive to follow, appear rather straightforward, but FDA later did not consider a published study on healthy, young US females saying they were not at risk for heart disease. Some studies on special population groups (as defined by health status such as diabetics and those with previous heart attacks) were also not weighed heavily. One study on Asian subjects was not considered because FDA did not consider this group as representing the US population. While FDA does give much greater weight to human nutrition studies, they did consider animal studies in their investigation of the role of foods containing fibre in reducing the risk of heart disease.

TABLE IV.B.1. - PATENT PROTECTION: The lack of patent protection for health claims made under the NLEA is a serious problem. Under NLEA health claims can not be considered unless the claim represents significant scientific agreement. Companies are very reluctant to invest in the research required to submit a health claim knowing the research must all be published, or made public and knowing the health claim, if allowed, will be available to any company who wishes to use it. This system works to disadvantage for most food processors, although it could work to advantage to a processor who has most of the market share for a certain product or range of products. For example, while Quaker Oats can not be said to be the sole processor and marketer of oat based products, they are certainly a very prominent provider of this range of products. As such they may have determined there would be sufficient returns from their efforts to obtain a health claim for oat bran and oatmeal.

Dietary supplements are allowed some patent protection under DSHEA. Proprietary blends do not have to list all ingredients, but they must list the total quantity of all dietary ingredients in the blend.

TABLE IV.B.2. - MARKET EXCLUSIVITY: There is no market exclusivity for the use of health claims under NLEA. Once a claim has been approved, any food having sufficient quantities of the nutrient (sufficient is defined as being 10% or more of the label reference value before fortification.) and not disqualified by reason of having too much total fat, saturated fat, cholesterol or sodium, may use the health claim. Foods bearing the oat bran or oatmeal health claim must have no less than 20 g oatmeal or 13 g oat bran that provides without fortification at least 1 gram of b-glucan soluble fibre per reference amount commonly consumed. In addition, the food must meet the requirements for a low saturated fat, low cholesterol and low fat food as defined in Fed. Reg. Section 101.62. A food having any one of either 11.5 g fat, 4.0 g saturated fat, 45 mg cholesterol, or 360 mg sodium per reference amount commonly consumed, per label serving size, may not be labelled with a health claim; they are disqualified. (Fed Reg. Vol.58. No.3. 1/6/93. 2488).

While most health claims allowed thus far seem to be broad enough for use on many foods, there are some problem areas. For example, the disqualifying levels indicated above do not allow for whole milk to be labelled as a being a source of calcium, even though whole milk is the only type of cow's milk recommended for young children. Currently health claims directed to children are not allowed. Furthermore, a health claim intended for a milk or formula for healthy infants would

be regulated under the *Infant Formula Act of 1980* (amended in 1986). (Foods for sick infants would, however, be regulated as medical foods.)

The industry has discussed a need for exclusivity, at least for a short term, or tax credits to allow it to recuperate the money it would have to spend trying to comply with the claims process. The Foundation for Innovative Medicine has called for a seven year exclusivity for health claims based on approved proprietary research as is the case in the Orphan Drug Act. That act has resulted in a significant increase in investment in drugs for unusual or rare diseases and is considered to be a strong demonstration of the benefits to the public when proprietary information is used and intellectual property rights are respected.

TABLE IV.B.3. - CONFIDENTIALITY OF INFORMATION: There is no virtually confidentiality of information under NLEA. The one exception is that the names of people who participated as research subjects and their doctors and medical institution will not be released to the public. When a petition is filed for consideration by FDA it becomes public information within 100 days of filing. If a Freedom of Information request was submitted to FDA before the 100 day time limit, FDA would release the petition. Petitions for health claims under NLEA must either include published information, or if proprietary research is included, it will be made public by FDA. There are some confidentiality provisions under DSHEA. Information submitted to FDA pertaining to new dietary ingredients will be kept confidential for 90 days. After that time, the information will be made public unless the information is considered a trade secret, or otherwise confidential commercial information.

TABLE V.B.1. - STATUS OF HEALTH CLAIMS: Only health claims that have been reviewed and approved by FDA are allowed in the United States. Several health claims have been allowed, and they are listed in Table 5. B. II. Unfortunately, the allowed statements are very lengthy, would require a very high level of reading skill and vocabulary. When it is considered that information on Canadian food labels has to be present in English and French, these statements might not fit on many food packages. Although symbols work better for a diverse population with various language skills, the use of symbols (such as a heart symbol) are only allowed when placed in immediate proximity of the allowed health claim. Unfortunately the statements allowed can not be said to have much marketing flair.

FDA has tried to address this problem with some shorter versions of the health claims, but they are still not very attractive, and the label must still include the longer claim. They are listed with the model health claims in Table 5. B. II.

TABLE V.B.2. - PERMISSIBLE HEALTH CLAIMS: Foods qualify to be labelled with health claims if they contain more than 10% of the nutrient or substance in question (before fortification) and are not disqualified because they are overly high in fat or sodium. A food having any one of either 11.5 g fat, 4.0 g saturated fat, 45 mg cholesterol, or 360 mg sodium per reference amount commonly consumed, per label serving size, may not be labelled with a health claim; they are disqualified. (Fed Reg. Vol.58. No.3. 1/6/93. 2488).

Recent changes have been made to this regulation allowing fruits and vegetable products composed solely of fruits and vegetables and enriched grain products conforming to standards of identity in CFR 21, parts 136, 137 or 139 and enriched breads made with whole wheat are allowed to be labelled with health claims (Fed. Reg. December 21, 1995, 66224).

Foods bearing the oat bran or oatmeal health claim must have no less than 20 g oatmeal or 13 g oat bran that provides without fortification at least 1g b-glucan soluble fibre per reference amount commonly consumed. In addition, the food must meet the requirements for a low saturated fat, low cholesterol and low fat food as defined in Fed. Reg. Section 101.62. (Fed. Reg. January 12, 1996)

Dietary supplements are currently only allowed to be labelled with the approved health claims. This situation may change following the release of the recommendations of the Presidential Commission appointed to review this subject.

Several model health claims are given in the various Federal Register decisions. In the preamble to the decisions, FDA also outlines the components necessary for adaptations if a manufacturer would wish to alter the FDA model. A manufacturer can add any language clarifying or simplifying the concepts, but the regulated language must still be present. The model claims as noted below are the minimum; allowable alterations would probably not make the label claim shorter.

FDA has listened to the problems manufacturers have with the lengthy label claims, noting they are not very attractive from a marketing perspective. At the moment, for nutrient claims only, FDA will allow a 'romance' or promotional language on the front panel as long it is 'anchored' with the correct term and the consumer is directed to the side or back panel where the full health claim statement is given. For example, a product may say on the front panel that is 'only contains a little bit of fat', but this must be anchored with the correct term 'low fat' and the health claim must be made on a side, back or easily accessible panel. FDA has published notice, in a proposed rule, to allow similar label provisions for some health claims. Refer to Fed. Reg. December 21, 1995, 66206-66227.

The following model health claims (Fed. Reg. January 6, 1993, January 12, 1996 and March 5, 1996)) and proposed model health claims (Fed. Reg. December 21, 1995) are allowed, or proposed, under NLEA.

Fibre containing foods and cancer

1. Low-fat diets rich in fibre containing grain products, fruits and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

2. Development of cancer depends on many factors. Eating a diet low in fat and high in grain products, fruits and vegetables that contain dietary fibre may reduce your risk of some cancers.

Fibre containing foods and heart disease

1. Diets low in saturated fat and cholesterol and rich in fruits, vegetables and grain products that contain some types of dietary fibre, particularly soluble fibre, may reduce the risk of heart disease, a disease associated with many factors.

2. Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables and grain products that contain fibre may lower blood cholesterol levels and reduce your risk of heart disease.

3. Proposed health claim: Diets low in saturated fat and cholesterol and rich in fibre containing fruits, vegetables and grain products may reduce the risk of heart disease.

4. Proposed health claim: A diet low in saturated fat and cholesterol and high in fruits and vegetables and grain products that contain fibre may lower blood cholesterol levels and reduce your risk of heart disease.

Fruits and vegetables and cancer

1. Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fibre, vitamin A and vitamin C), may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C and is a good source of dietary fibre.

2. Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A and vitamin C, and dietary fibre may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fibre and vitamin C.

3. Proposed health claim: Low fat diets rich in fibre containing grain products, fruits and vegetables may reduce the risk of some types of cancer.

4. Proposed health claim: A diet low in fat and high in grain products, fruits and vegetables that contain fibre may reduce your risk of some cancers.

5. Proposed health claim: Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fibre, vitamin A and vitamin C) may reduce the risk of some types of cancer.

6. Proposed health claim: A diet low in fat and high in certain fruits and vegetables, foods that are low in fat and that may contain vitamin A and vitamin c may reduce your risk of come cancer.

Calcium and osteoporosis

1. Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce the risk of osteoporosis later in life. (Note, FDA noted this statement is appropriate for most conventional foods. Also note, the inclusion of the races of people most likely to benefit is not optional, although a manufacturer may instead identify middle-aged, menopausal, older, or persons with a family history as also likely to benefit. We suggest the inclusion of a label statement pertinent to only some racial origins is not likely to meet with marketing and/or political approval in Canada's diverse population.)

2. Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above about 2,000 mg are not likely to provide any benefit. (Note FDA considers this appropriate for foods exceptionally high in calcium and for most calcium supplements.)

3. Proposed model health claim: Especially for teens and young adult women, adequate calcium in a healthful diet may reduce the risk of osteoporosis later in life.

4. Proposed health claim: A healthful diet with adequate calcium and regular exercise help teen and young adult white and Asian women maintain good bone health and may reduce their risk of osteoporosis later in life.

5. Proposed health claim: Exercise and a healthful diet with enough calcium may teen and young adult women reduce their high risk of osteoporosis later in life. Adequate calcium in important for everyone (women and men of all ages) but daily intakes above 2,000 mg (200% of the DV) may not provide added benefit. See (location of panel) for more information.

6. Proposed health claim: Adequate calcium in a healthful diet may reduce the risk of osteoporosis. See (location of panel) for more information.

Low fat foods and heart disease

1. While many factors affect heart disease, diets low in fat and cholesterol may reduce the risk of the disease.

2. Development of heart disease depends on many factors, but its risk may be reduced by diets low in fat and cholesterol and health lifestyles.

3. Development of heart disease depends on many factors including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking. lack of exercise and type of dietary pattern. A healthful diet low in saturated fat, total fat and cholesterol, as part of a healthy lifestyle may lower blood cholesterol levels and may reduce the risk of heart disease.

4. Many factors such as family history of the disease, increased blood and LDL-cholesterol levels, high blood pressure, cigarette smoking, diabetes and being overweight, contribute to developing heart disease. A diet low in saturated fat, cholesterol and total fat may help reduce the risk of heart disease.

5. Diets low in saturated fat, cholesterol and total fat may reduce risk to heart disease. Heart disease is dependent on many factors, including diet, a family history of the disease, elevated blood and LDL-cholesterol levels and physical inactivity.
6. Proposed health claim: Diets low in saturated fat and cholesterol may reduce the risk of heart disease.

7. Proposed health claim: Your risk of heart disease might be reduced by a diet low in saturated fat and cholesterol and a healthy lifestyle.

Low fat foods and cancer

1. Development of cancer is dependent on many factors. A diet low in fat may reduce the risk of some cancers.

2. Eating a healthful diet low in fat may help reduce the risk of some types of cancer. Development of cancer is associated with many factors, including a family history of the disease, cigarette smoking and what you eat.

3. Proposed health claim: A low fat diet may reduce the risk of some cancers.

Sodium and hypertension

1. Diets low in sodium may reduce the risk of high blood pressure, a disease associate with many factors.

2. Development of hypertension or high blood pressure depends on many factors. (This product) can be part of a low sodium, low salt diet that might reduce the risk of hypertension of high blood pressure.

3. Proposed health claim: A low sodium diet may reduce the risk of high blood pressure.

4. Proposed health claim: (The product) can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

Sugar alcohols and dental caries

1. Proposed health claim: Tooth decay is a disease caused my many factors including frequent consumption of sugary foods. (Name of sugar alcohol) does not promote tooth decay.

2. Proposed health claim for packages containing less than 15 sq in label area: Does not promote tooth decay.

Oat bran or oatmeal and heart disease

1. Diets high in (oat bran or oatmeal) and low in saturated fat and cholesterol may reduce the risk of heart disease.
2. (Note the following shortened claim may be made on the front panel, if the consumer is directed to read the full claim on the side or back panel.) Front panel: Eating (oat bran or oatmeal) daily may reduce heart disease risk. See side or back panel for more information.

Foods containing psyllium and coronary heart disease (new as of February, 1998)

1. "The soluble fiber from psyllium seed husk in this product, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease."

2. Foods carrying the health claim must provide at least 1.7 grams of soluble fiber from psyllium seed husk per reference amount customarily consumed of the product. This single-serving size, multiplied by four eating occasions per day, totals the 7-gram per day intake of controlled studies.

Folate and Neural Tube Defects

1. Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

2. Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

3. Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

4. Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV (1,000 mcg). (Note: This statement is to be used when the food contains more than 100 percent of the DV of folate per serving or per unit.)

TABLE V.B.4. - LABELLING OF DIETARY SUPPLEMENTS: Dietary supplements must bear ingredient labels that include the quantity of each ingredient. Proprietary blends can instead give the total quantity of all dietary ingredients (excluding inert ingredients). The label must include the words 'dietary supplement' . A supplement that indicates conformance with specifications in an official compendium, must conform to those specifications. Otherwise, the product must be as represented on the label and in the strength indicated. The part of the plant from which the herb or botanical was derived must be indicated.

Dietary supplements must also conform to some aspects of the Nutrition Labelling and Education Act. Nutrients present in significant amounts for which FDA has established daily consumption recommendations must be listed first, followed by ingredients for which no daily recommendations have been set. Ingredients that are not present in significant amounts do not have to be listed. Nutrient listing must precede ingredient listings; ingredients listed in the nutrient listing do not have to also be listed as ingredients. Quantity per serving must be given; the source of the nutrient is optional.

Health claims may be made for dietary supplements only in accordance with the allowed health claims, and only in the wording allowed, under NLEA. Dietary supplement manufacturers who wish to make a health claim not yet approved by FDA must provide sufficient information in a petition.

While dietary supplements may not claim to diagnose, mitigate, treat, cure or prevent disease, there are some nutritional statements that are allowed without a petition process. A manufacturer may make a statement that claims a benefit of a classical nutrient deficiency and discloses the prevalence of such diseases in the United States, describes the role of the product in affecting the structure of function of the product in humans, and describes the mechanism of action of the product in the body. Claims relating to general well-being from consumption of the product are also allowed. These statements must be accompanied by the following statement on the label, "This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

The process required to allow such statements is simple. The manufacturer has to have substantiation that the statement is truthful and not misleading. The manufacturer has to notify FDA within 30 days of the first marketing of the product that a statement of nutritional support has been made.

TABLE VI.B.1. - JURISPRUDENCE: There have been many pertinent court rulings and discussions of constitutional issues concerning the NLEA; these are outlined in the many Federal

Register regulations (particularly January 6, 1996 Vol 58. No. 3. 2524-2529). Additionally, state regulations and the process for a state to request exemptions are included in Federal Register January 6, 1996. We do not see any indication that court challenges on the regulations will have any significant bearing on the regulations. We do think the issue of a court challenge by food processors, wishing the level of freedom granted dietary supplements under DSHEA, bears watching.

TABLE VI.B.2. - COMPLIANCE AND ENFORCEMENT: FDA would not indicate their level of enforcement. Food Processing (January 1995) indicated the FDA was committed to enhanced enforcement of nutrition labelling requirements, including enhanced enforcement of products bearing unauthorized health claims. The authors believe mislabeled products might be identified by FDA inspectors as part of their other duties. FDA officials in the Office of Food Labelling also appeared to take a very active interest in product labels, especially on new and unusual products. Competitors of offending products are another contributor to enforcement; they regularly complain to FDA to ensure action is taken.

FDA, in a retail survey, found by the end of May 1995 more than 80% of the domestic and imported products checked were in compliance with the regulations (Food Technology, December 1995). It also noted substantial compliance with the regulations for voluntary nutrition labelling of raw fruits, vegetables and seafood. More than three-fourths of the stores surveyed provided nutrition labelling information. FDA's next survey will be in 1997. If it does not find substantial compliance at that time, FDA will propose nutrition labelling of these products.

TABLE VI.B.3. - PENALTIES: Penalties are found in Section 303 of the Act and may be levied up to $1,000,000 for certain drug-related offences. Lesser offences may call for one year imprisonment and fines of up to $1,000.

C. European Union

TABLE I.C.1 FUNCTIONAL FOODS: There is currently no legal definition in Europe for the term "functional foods" despite the fact that the term is used relatively frequently within the food industry and by consumers. Regulation of such products falls into the grey area between foods and drugs. Authorities in a number of the member states of the E.U. reject the term on the basis that all foods serve some functional purpose.

In August, 1995, the U.K. Ministry of Agriculture, Fisheries and Foods (MAFF) developed a working definition which states that a "functional food" is:

> *A food that has a component incorporated into it to give a specific medical or physiological benefit, other than a purely nutritional effect.*

This working definition helps to distinguish functional foods from products such as breakfast cereals which are fortified with vitamins and minerals to enhance their nutritional benefits. It also

makes a distinction between functional foods and supplements which are marketed primarily for the purpose of ensuring an increased intake of beneficial nutrients.

In a June 1994 briefing paper, the British Nutrition foundation stated the following about functional foods:

> *The definition of "Functional Foods" is vague, and probably reflects the marketing and legislative origins of the concept. The term is used to describe food products that contain components that can affect some physiological function. Functional Foods are ascribed a potency greater than foods consumed principally for particular nutrient features (health foods), but less than assumed for products classed as medicines. Common features of products described as Functional Foods are:*
>
> - *product in "food form" (not a capsule or powder)*
> - *"naturally-occurring" components although perhaps in unnatural concentrations or in foods that would not normally supply these components*
> - *safe for unsupervised consumption as apart of a daily diet*
> - *provision of a "health benefit", usually described on labels or in advertising*
>
> *While many fortified foods or nutritionally modified foods possess the features attributed to Functional Foods, in practice the term implies products with attributes able to affect (and improve) physiological function beyond the possible repletion of nutrients.*

TABLE I.C.2. - DIETARY SUPPLEMENTS: Dietary supplements in the North American, specifically the U.S. context, are regulated by the member states of the E.U. and are not subject to a specific legal directive.

However, E.C. Directive 89/398/EEC contains rules relating to foodstuffs for particular nutritional uses. This directive will be described in further detail in the section dealing with Applicable Legislation, Regulations and Guidelines.

TABLE I.C.3. - NUTRACEUTICALS: This term has not met with any significant success in Europe and appears to be out of favour as a descriptive terms.

TABLE I.C.7. - HEALTH FOOD: In member states of the E.U. the term "health food" is a marketing rather than a legal or scientific terms. It generally describes products which are available from particular specialist retail outlets (so-called health food stores). Such products generally claim nutrient or health benefits although in many cases there is little variation in composition between these products and similar foods sold in mainstream retail outlets.

TABLE I.C.9. HEALTH CLAIMS: The framework directive dealing with Labelling, Presentation and Advertising of Foodstuffs (79/112) implemented in all member states in 1982, prohibits the use of medical and health claims on the label or in advertising of foods. However, the tolerance for such claims appears to vary considerably among the 15 member states of the E.U.

In an effort to provide greater clarity to the issue of claims, the Commission of the E.U. has been working for a number of years to establish community rules covering claims on food labels and health and nutrition claims, in particular. In July 1993 a *Draft proposal for a Council Directive on the Use of Claims Relating to Foodstuffs (Doc. SPA/62/Rev.3Orig.FR)* was released as the basis for a framework directive that would eventually be debated by the European Parliament. This proposal dealt with claims such as "high or rich", "Low, weak or poor", "Increased", "Reduced", "Without", "Without added", "Contains x% more" and "Contains x% less".

This draft has been withdrawn as a result of lack of interservice consensus and the Commission is reviewing both the need and appropriateness of proceeding with a specific proposal on claims in light of the requirements found in the adopted Framework Directive (79/112) which deals with Labelling, Presentation and Advertising of Foodstuffs.

TABLE I.C.9.- NOVEL FOODS: Novel food regulations are currently undergoing second reading in the European Parliament. After a year of debate, E.U. Ministers finally succeeded on 23 October 1995 in adopting a Common Position on proposed regulations about the marketing and labelling of genetically engineered and other novel foods. However, the Common Position failed to find the support of Germany, Austria, Denmark and Sweden who felt that the compromise text was too weak.

It is expected that most members of the European Parliament will favour tougher labelling requirements and strict controls on the marketing of novel food. The strongest critics of the novel foods proposal are member of the socialist and green parties.

The regulations would require manufacturers to obtain pre-market approval for a novel food by a member state government but only after the Commission and other member states had been consulted and given the opportunity to object.

Second reading is likely to take place during the plenary session the week of 11 March. If the position of the Parliament and Council remain divergent after 2nd reading, a Conciliation Committee will be established. If conciliation fails, the Council of Ministers may adopt the text unilaterally but it will not become E.U. law if Parliament rejects it within six weeks.

TABLE II.C.1. - LEGISLATION: The development and passage of legislation in the E.U. is a complex process and beyond the scope of this report. However, in simplified form, the process is as follows:

ADOPTED LEGISLATION (AL): Such legislation is in the form of a commission or Council directive or regulations which have been agreed at the Community level and published in the "L" series of the Official Journal. Such legislation may or may not be implemented in the 15 member states.

PROPOSED LEGISLATION (PL): A proposal to legislate by the Commission with the draft text being published in the "C" Series of the Official Journal. Such proposals are in the process of being reviewed, approved and commented upon by the European Parliament, the Council and the Economic and Social Committees.

DRAFT PROPOSALS (DP): Are initial texts prepared by the various Directorates-General of the Commission for adoption as a Commission proposal. Consultation with stakeholders takes place during the course of preparation.

The following is a list of E.U. food legislation that relates to the sale of foods in the E.U.

1. Framework Directive on the Labelling, Presentation and Advertising of Foodstuffs (AL)[Ref: 79/112]. This directive provides general labelling rules and among other things, prohibits the use of health claims on food labels and in advertising. Dates of implementation 22/12/80 and 22/12/82.

2. Nutrition Labelling Rules for Foodstuffs for Sale to the Consumer (AL) [Ref: 90/496]. Dates of implementation 01/04/92 and 01/10/93.

   This directive provides for voluntary nutrition labelling on foods but is "triggered" by a nutritional claim which then requires the declaration of the certain specified information. The

nutritional uses have been identified but action has been taken only on foods for infants and foods intended for weight control or energy restricted diets. The nine groups of foods for particular nutritional uses listed in an appendix to the Directive are as follows:

i. Infant formulae
ii. Follow-up milk and other follow-up foods
iii. Baby foods
iv. Low-energy and energy-reduced foods intended for weight control
v. Dietary foods for special medical purposes
vi. Low-sodium food, including low-sodium or sodium-free salts
vii. Gluten-free foods
viii. Food intended to meet the expenditure of intense muscular effort, especially for sportsmen
ix. Foods for persons suffering from carbohydrate metabolism disorders (diabetes)

Discussions at the Edinburgh Council (12/12/93) confirmed the decision to continue work on infant food and energy-reduced foods as well as the drafting of a proposal on medical foods. There is a lack of consensus among member states respecting the need for directives on low sodium foods, gluten free foods, foods for sportsmen and foods for diabetics.

The last week of February 1996, the Commission adopted a Directive on Foods Intended for energy-restricted diets. This Directive establishes protein and fat content of low-calorie foods. It also sets minimum dietary fibre and energy values per daily ration or meal and sets minimum quantities for minerals. As of 1 April 1999 only products which comply with the Directive may be marketed.

Under the Directive, the energy provided by a daily ration must be between 800 and 1200 kcal. The dietary fibre content of the daily ration must be between 10 g and 30g, minimum and maximum.

The Directive was unanimously endorsed by the Scientific Committee for Food and thus takes account of the latest scientific knowledge in the area of low energy diets.

5. Proposal for a Council Regulation on Novel Foods and Novel Food Ingredients (PL): As noted in I.C.VIII, this issue is currently before the European Parliament and passage as adopted legislation is far from being a certainty.

A Footnote About Food Legislation at the European Union Level

It is interesting to note that there is no legal definition for "food" at the E.U. level. While discussions about a definition have been ongoing for a number of years, no consensus has yet been reached.

At the E.U. level, food law has been built piece by piece through Directives relating to specific issues or subjects. The absence of a definition for food is symptomatic of the lack of an integrated "top-down" policy framework which is needed to provide cohesion and to enhance the harmonization of the food legislation found in the 15 member states.

The issue of claims provides a good example of how the absence of a Directive can lead to a certain amount of disorder among the member states. When adopted legislation at the E.U. level does not exist, member states are thus at liberty to express national views.

Proposed Draft Guidelines for the Use of Health and Nutrition Claims at Step 6 of the CODEX Procedure

The above-noted guidelines will once again be discussed when the 24th Session of the Codex Committee on Food Labelling convenes in Ottawa, Ontario 14-17 May, 1996.

The draft document provides definitions for nutrition claim, nutrient content claim, comparative claim, nutrient function claim and health claim. It should be noted that the definition for health claim in square brackets which means that the text is tentative and subject to further review and amendment. However, the draft definition for "health claim" in Section 2.2 is as follows:

> [Health claim means any representation that states, suggests or implies that a relationship exists between a food or a nutrient or other substance contained in a food and a disease or health-related condition.]

Section 7 of the draft guidelines then deals more specifically with the issue of health claims as follows:

7.1 Without prejudice to Section 8, a health claim that a food or nutrient or substance contained in a food has an effect on an adverse health-related condition in the body should not be permitted.

7.2 A claim that the consumption or reduced consumption of a food, nutrient or substance contained in a food, as part of a total dietary pattern, may have an effect on a [disease] or health-related condition [should/should not] be permitted subject to the following conditions:

7.2.1 There is scientific consensus supported by the competent authority that a relationship exists between the food, nutrient or substance and the disease or adverse health-related condition;

7.2.2 The wording of the claim is within the context of a total dietary pattern;

7.2.3 The food for which the claim is made should be:

i a significant source of the nutrient or substance in the case where increased consumption is recommended or,

ii "low" in or "free" of the nutrient or substance in the case where reduced consumption is recommended

7.2.4 The claim should not state or imply that the consumption of a particular food would cure, prevent or treat a disease; and

7.2.5 [The claim should not be made if the consumption of the food would result in the intake of a nutrient or substance in an amount that would increase the risk of a disease or health-related condition.]

Section 8 of the draft guidelines deals with claims relating to dietary guidelines or healthy diets.

Research on Functional Foods in Europe

Directorate General XII, Directorate E is responsible for the assessment of projects involving biotechnology, food and agricultural research and to provide funding in cooperation with industrial and academic partners. A project entitled "Functional Food Science in Europe" has been approved which involves workshops and strategic collaboration between the European agriculture and food industry and the European research community.

The goal of the workshops will be to define and understand the interaction between specific dietary components and particular physiological functions related to health.

The International Life Science Institute (Europe)[ILSI Europe] will coordinate this activity by organizing a series of plenary meetings and establishing thematic working groups.

The first plenary meeting is scheduled for 2-4 April 1996 in Nice, France and will involve more than 50 participating scientists from the food industry and academia. The meeting will review the following six areas:

- Gastro-intestinal Functions
- Behavioural and Psychological Functions
- Conception and Development
- Modulation of Lipid Metabolism
- Impact of Food Technology
- Control of Redox Status

Following the April meeting, the thematic working groups will carry out in-depth reviews of the issues and prepare consensus papers on each theme. This will form the basis for a general consensus document which will be entitled "Concepts in Functional Food Science and Science

Based Requirements for Functional Constituent Applications". The results will be communicate to industry and the scientific community at large.

The following schedule for implementing the program outlined above has been adopted:

- April 1996 — First Plenary Meeting - Function Food Science: State of the Art
- April-November 1996 — Thematic Working Group Sessions - Drafting of theme papers on issues identified during the First Plenary Meeting
- January 1997 — Second Plenary Meeting - Review of the theme papers
- April-September 1997 — Drafting of a general consensus document on "Concepts in Functional Food Science and Science-Based Requirements for Functional Constituent Applications"
- December 1997 — Third Plenary Meeting - Review of the general consensus document
- January 1998 — Publication of the theme papers
- December 1998 — Publication of the general consensus document

In addition to the project described above, the following projects which relate to functional foods have also been approved by DG XII:

Project 0894 - Phenolic phytoprotectants - role in preventing initiation, promotion and progression of cancer

Project 0813 - Effect of copper in the food chain on human health

Project 0809 - The impact of dietary fat/carbohydrates ratio and simple/complex carbohydrate changes on long term weight control in overweight subjects

Project 0653 - Understanding the biological effects of dietary complex phenols and tannins and their implications for the consumer's health and well-being.

Project 0594 - Nutritional and health impact of trans-polyunsaturated fatty acids in European populations

Project 0574 - Understanding and improving the selection and acceptance of foods and health promotion

Project 0158 - Improving the quality and nutritional value of processed food by optimal use of natural food antioxidants

Project 0085 - Nutritional studies on dried functional ingredients containing N-3 polyunsaturated fatty acids

D. Japan

TABLE 1.D.1. - DEFINITION OF FUNCTIONAL FOOD: From 1984 - 86 in Japan, a systematic evaluation of the physiological function of foods was carried out by university groups and the Ministry of Agriculture, Forestry and Fisheries. These studies revealed that foods have functions controlling homeostasis in the body, as well as nutritional and sensory functions.

From 1988 - 1990 similar studies were carried out in terms of evaluating the bio-regulatory functions of foods. During 1992 - 1994, studies focussed on the analysis of functional foods and molecular design.

The studies which were initiated in 1984 resulted in the Ministry of Health and Welfare (MHW) introducing "functional foods" in 1991 and the system for licensing "Foods for Specified Health Use".

sugar including prevention of diabetes mellitus; regulation or control of cholesterol content; prevention of gallstone formation; prevention of obesity and hypotensive effects.

ii.

Once the conceptual framework for "functional foods" was in place in 1991, the MHW established a system for licencing "Foods for Specified Health Use" The term FOSHU replaced the term "functional food".

"Foods for Specified Health Use" (FOSHU) are a sub-classification of "Foods for Special Dietary Uses" (FSDU). The four categories of FSDU that have been established in Japan are:

i. **Foods for the Sick** - (e.g. Low Sodium Foods, Low Protein Foods, Foods for Allergic Diseases, Lactose Free Foods, Assorted Foods for Diabetes, Assorted Foods for Liver Disease, etc.)

ii. **Milk Powder for Pregnant and Lactating Women**

iii. **Formulated Milk Powder for Infants**

iv. **Foods for Specified Health Use**

Allergen-free rice and low phosphate content milk were the first foods approved by MHW as FOSHU. Allergen free rice is effective for patients with atopic dermatitis. Low phosphate milk is effective for patients with chronic renal diseases who are instructed to reduce their intake of phosphates.

When the first functional foods were introduced in Japan in 1988)prior to the MHW licensing scheme), 57% of all such products were soft drinks. This proportion declined to 15% by 1995. Milk drinks, lactic acid bacteria drinks and yogurt are now at least as important as soft drinks in terms of market share. There is now an increasing significance of other food categories including confectionery, biscuits, cheese, snack food, processed meats and table-top sweeteners.

TABLE I D.10. - HEALTH CLAIMS: The concept of "Foods for Specified Health Use" (FOSHU) has been introduced in Japan for the purpose of providing the consumer with a food that has strongly suggestive health benefits based on sound, scientific research data. The label of the food will thus be permitted to include a label claim that a person who uses the product for specified health use may expect to obtain the health benefit through the consumption of the product. The following is an example of the type of labelling that has been recommended by the final report of the advisory group on FOSHU to the Ministry of Health and Welfare:

Food: Bread	**Component: XYZ**
Name of the Product	XYZ containing bread
Specified Health Use	This product contains XYZ which is expected to have a health benefit: ABC

Cooking precautions	This product should not be heated
Precautions for Use	Do not take more than 100 g per day. Ask your doctor for advice when intending to use the product for XYZ deficiency. This product is a dietary treatment, not a cure.
Precautions for Storage	Avoid direct rays from the sun
General Messages	Good health can be attained by eating a variety of foods. For good health you should consume more than 30 different kinds of foods each day

TABLE II D.1. - LEGISLATION: The sale of "functional foods" in Japan is governed by an Act entitled the *Nutrition Improvement Act.* The overall purpose of the Act is to contribute to the public welfare by fostering greater awareness of nutrition improvement in the general population, explaining good nutrition and promoting good health through improved nutrition. The term "functional food" has now been replaced by a new term, "Foods for Specified Health Use" (FOSHU).

This Act regulates the conduct of the National Nutrition Survey, the establishment of a Nutrition Consultation Office and the appointment of Nutrition Instructors and the supervision of nutrition in dining facilities. This Act also provides authority to make regulations respecting the approval and labelling of foods for special dietary and nutritive uses. The broad, collective category known as Special Nutritive Foods branches out into Enriched Foods and Foods for Special Dietary Uses.

- The Enriched Foods category includes foods such as vitamin enriched rice and vitamin enriched bread. The Foods for Special Dietary Uses category includes the following sub-categories:

- Foods for the Sick (Low Sodium Foods, Low Calorie Foods, Assorted Foods for Low Sodium Diets, Assorted Foods for Diabetes, etc.)

- Milk for Pregnant or Lactating Women

- Formulated milk powder for infants

- FOODS FOR SPECIFIED HEALTH USE

Article 12 of the Nutrition Improvement Law states the following:

"When one wishes to indicate on the food product that the particular food will provide certain nutrition elements or is suitable for specific purposes, for babies, for infants, pregnant women, invalids etc., one must obtain permission to do so from the Minister of Health and Welfare".

TABLE II D.2. - REGULATIONS: The FOSHU category has been established under the regulatory umbrella of "Special Nutritive Foods". As a result of this decision, high-cost approval for making claims should not be necessary. The agreement on this new category represents more than a decade of cooperation among government, academia and industry associations.

In July, 1991, a mechanism for the development of food with health claims was legalized in Japan although products in this FOSHU category have been somewhat slow to appear on the market because of the rigour of the examination process by government authorities.

In bringing the FOSHU concept to fruition in Japan there was extraordinary cooperation among government, academia and the food industry; each with its own reasons or special interests. The Government was interested in health care cost reduction, academia in new research and the food industry in new business opportunities.

Because many consumers are not well informed with respect to nutrition and health care, it was decided that there must be a mechanism for protecting consumers against improper usage and unacceptable risk. The Ministry of Health & Welfare has chosen to educate the public nutritionally by offering the new category of foods with health claims, i.e. FOSHU.

From a regulatory viewpoint, FOSHU is a food which is based on knowledge concerning the relationship between foods or food components and health, is expected to have certain health benefits, and has been licensed to bear a label which may make the claim that a person who uses the product for specified health use may expect to obtain the health benefit from such consumption. It must be made clear that a FOSHU is a food (not an isolated nutrient or dietary supplement) which has strongly suggestive health benefits based on sound, scientific research data. As the regulatory regime dealing with FOSHU is relatively new and few products have been licensed, many experts believe that it will be difficult to obtain many promotional health claims, mainly because of the "food vs drug" argument.

TABLE II D.3. - GUIDELINES: The Japan Health Food & Nutrition Food Association has been authorized by the Japanese Ministry of Health and Welfare to provide guidance to the food industry in terms of assembling and arranging sound data for examination prior to submitting a formal licencing application to the MHW.

TABLE III.D.1. - APPROVAL PROCESS: *The non-regulatory aspects of the approval process* - The MHW works cooperatively with the Japan Health Food Association in processing applications for licensing a FOSHU. The Japan Health Food Association represents about 1300 "health food" producers and has a strong lobbying influence on government policy. The

Association provides a twofold function: to advise the government on public policy issues and to facilitate official applications for licensing by member firms.

In order to facilitate the official application, and to keep the duration of the procedure down to an expected minimum of two months, the Association has established its own approval system, parallel to, but separate from that of the MHW. Within the Association there are three groups or committees concerned with FOSHU:

- Working Groups;
- Specialist Groups;
- Academic Groups

Role of the Working Groups:

Member firms of the Association collaborate in the working groups which are responsible for collecting scientific evidence used for considering the 11 identified categories of functional components.

Role of Specialist Groups

The specialist groups evaluate the scientific evidence delivered by the working groups and will conduct research on new functional components. Because of the good research facilities of the member companies and their close relationship with government, the scientific evidence is regarded as being reliable, and is generally accepted by the MHW. The data provided by the working groups and the specialist groups have a strong influence on official approval of a FOSHU. There are some 24 associate professors affiliated with the specialist groups.

Role of the Academic Committee

The Academic Committee of the Japan Health Food Association is responsible for the recommendations to the MHW. This Committee consists of three senior professors who will evaluate the compiled information provided by the specialist groups. Once the evidence is satisfactory, the Committee will complete the application form and send it to the food producer along with a recommendation by the Association for official filing with the MHW. With such a recommendation, the official application procedure is expected to clear the Ministry within a period of two months.

The Official or Regulatory Aspects of the Approval Process: The licensing system for FOSHU's distinguishes foreign applicant from domestic applicants. Overseas applicants must apply directly to the Ministry (Office of Health Policy on Newly Developed Foods, Environmental Health Bureau) while domestic producers first apply to the local government (Prefecture, city or special ward having jurisdiction) before applying to the MHW. This distinction is made to reduce the application period and to relieve the Ministry from resource intensive paper burden. It is the

responsibility of the local government to see that the application form is correct and complete. Once the application form is correct, the Ministry will further process the application.

Within the MHW the official application passes through 3 stages. The first stage involves the technical screening of the food product and its components. Tests are conducted by five sub-committees which are affiliated with the National Institute of Health and Nutrition. Each sub-committee is responsible for one group of functional components:

- Lipid
- Protein
- Carbohydrate
- Minerals and Vitamins
- Fibre

In the second stage the sub-committees report the technical results to the General Committee at the MHW. The General Committee evaluates the test results against the new regulation and if the results are positive, this committee will give a recommendation for licensing to the "Assessment and Discussion Committee for Foods for Specified Health Use". In the final stage this latter Committee reviews the recommendation and a positive review results in granting the license for the FOSHU.

TABLE III.D.4. - NATURE OF DATA REQUIRED: A FOSHU must satisfy the following criteria before a license can be issued:

1. Contribution to the improvement of dietary habits and the maintenance and enhancement of health.
2. The health benefits for the food or relevant component should have a clear medical and nutritional basis.
3. Appropriate consumption should be definable for the food or relevant component based on medical and nutritional knowledge.
4. The food or relevant component should be safe as judged from experience.
5. The relevant component should be well-defined in terms of a)physicochemical properties and test methods b) methods of qualitative and quantitative determination.
6. The composition of the product should not be notably defective in comparison with the composition of nutritive components which are normally contained in similar types of food.
7. The product should be the type of food that is consumed in ordinary dietary patterns, rather than consumed on an occasional basis.
8. The product should be in the form of ordinary food, not in pill, capsules, or other dosage form.

The level of research required for the license of the FOSHU is different from that applied to a drug or pharmaceutical product. *The principle behind the FOSHU concept is to discover active*

components having a certain health benefit in an ordinary food material which should be safe as judged from experience.

The application for licensing by the MHW must be in written form and must be accompanied by a product sample. The following is a list of minimum requirements that must be covered in an application:

i. Brand name of the food
ii. List of ingredients by percentage
iii. An explanation of the manufacturing procedure
iv. Analysis of the ingredients
v. Matters for which permission or approval is requested
vi. Name, address and date of birth of the applicant
vii. Name and address of the main office of the applicant
viii. Reason for seeking permission or approval
ix. Statement of caloric value
x. List of nutritive components by quantity
xi. instructions for storage, preparation, and administration, and any other cautions which must be observed in using the food

TABLE V.D.1. - STATUS OF HEALTH CLAIMS: LABELLING: The label of an approved FOSHU must declare the following information on the label:

- name of the food product (brand name)
- location of factory, name of manufacturer
- name and address of distributor
- health use
- nutritive components and relevant components
- raw material and food additives
- new contents
- storage instructions
- date of production
- date of expiration
- instructions respecting consumption
- method of cooking and consumption
- information respecting dietary guidance in terms of health promotion

TABLE V.D.2. - PERMISSIBLE HEALTH CLAIMS: As noted earlier in this report, one of the reasons that the MHW established the FOSHU licencing system was to permit the licensed product to bear a label claim respecting the benefits that will be derived from consuming the food.

Attached as Appendix III is a List of Foods for Specified Health Use that have been issued a license. The health claims licensed by the Minister of Health and Welfare are provided in the

table. The translation from Japanese into English produces some rather curious statements. In any event, the health claims currently permitted appear to be relatively modest although the claims relating to the prevention of cholesterol adsorption would not likely be permitted in Canada as such a claim would likely be interpreted as having a relationship to heart disease and thus would offend Section 3 of the Food and Drugs Act.

Appendix I

Nutrition Labeling Health and Education Act of 1990

Guiding Principles

The *Nutrition Labeling Health and Education Act of 1990 (NLHEA)* is an amendment to the Food Drug and Cosmetic Act. Its intent was to require nutrition labeling on all foods and dietary supplements and to ensure nutrition claims are made according to approved definitions. The intent was both to provide consumers with information intended to help maintain health dietary practices and to protect consumers from unfounded health claims. The Act covers processed foods and dietary supplements; raw agricultural foods and fish are included on a voluntary basis as long as there is substantial voluntary compliance with nutrition labeling. Restaurant foods or foods sold for restaurant use are not included.

Compliance Timeframe

NLHEA is currently effective. The labeling situation for dietary supplements is in a state of flux.

Administration

The Act is administered by the Office of Food Labeling in the Food and Drug Administration. The regulations interpreting the Act and explaining FDA decisions have been published in the Federal Register, notably, but not restricted to, January 6, 1993.

Provision for Consumer Education

The Act required that consumers be informed by government about the availability of nutrient labeling and the importance of nutrition labeling in maintaining health dietary practices.

Summary for Nutrient Labeling

The regulations cover nutrient labeling in detail, including such issues as determining serving size and the number of servings in package. Amounts of the following nutrients must be indicated: calories, fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, total protein. FDA has defined the presentation style for the nutrition labeling (the Nutrition Facts panel). The requirement for labeling of minerals and vitamins are less clear: if they were required to be on the label before 1990, or if the Secretary of Health determines they should be on the label, they will have to be on the label.

Summary for Health Claims

Several health claims have been approved; they connect in a general way, the relationship between the food (or ingredient, or supplement) and a disease. The claims are quite lengthy, although there is some latitude for adjustments by the manufacturer. To obtain approval for a health claim to be used on a label or elsewhere, the manufacturer must petition FDA and provide sufficient publicly available (and preferably published) research to allow FDA to agree the claim meets with significant scientific agreement.

Appendix II

Dietary Supplement and Health Education Act of 1994

Guiding principles

The *Dietary Supplement Health Education Act of 1994 (DSHEA)* is an amendment to the Food, Drug and Cosmetic Act. It removes dietary supplements with the labeling provisions of the Nutrition Labeling and Health Education Act. DSHEA grew out of several identified needs and understandings beginning with an acknowledging that certain nutrients, dietary supplements and diets can prevent disease and improve public health. These improvements were seen as necessary for public health and to reduce health care costs. Dietary supplements were viewed as safe, in general. These points set the tone for the regulation and are an important aspect to understanding the view of the American government. In some aspects, DSHEA exempts dietary supplements from the *Nutrition Labeling and Education Act of 1990*.

The value of the dietary supplement industry to the American economy (seen to be worth $4 billion) was also considered. The introduction to the Act summarized the government's position that while it should take swift action against unsafe or adulterated products, it should not take any action to impose unreasonable regulatory barriers that would limit or slow the flow of safe products and nutrition information.

Compliance Timeframe

Since the *Dietary Supplements Health Education Act (DSHEA)* removes dietary supplements from some aspects of NLHEA, and since DSHEA was enacted before the deadline for NLHEA compliance, the FDA has published a further delays in compliance. Since the two acts legally cover the same issue in different ways, FDA has not yet made a final rule on the exact requirements of labeling for dietary supplements. It is not clear to manufacturers how they will be allowed to label their products. Dietary supplements do not have to comply with nutrition labeling provisions until Dec 31, 1996. It should be noted, however, that some manufacturers have voluntarily brought their labels into compliance with either NLHEA or DSHEA.

Administration and Organizations Created by the DSHEA

Policy, enforcement and compliance issues on this regulation are managed by the Food and Drug Administration. The Office of Food Labeling carries the responsibility for labeling; the Office of Special Nutritionals is responsible for policy issues and regulatory development.

The regulation also established and funded the Office of Dietary Supplements in the National Institutes of Health, under the direction of Dr. Bernadette Marriott, to explore the role of dietary supplements in improving health and reducing health care costs and to promote research into the role of dietary supplements in maintaining health and preventing disease. The DSHEA gives this

office the science advisory role for advice to Secretary of Health, Directors of National Institute of Health, and Laboratory Center for Disease Control, and the Commissioner of Food and Drugs. Their prime purpose is to enhance the science on the effect of dietary supplement on health. Their work will be accomplished through sponsoring symposiums and, later, through funding research.

The provision of information on dietary supplements, what information would be allowed on labels, and advice on how best to present correct information will be decided based on recommendations of a Presidential commission set up by this regulation. Of interest is that the Commission was directed to be formed of people involved in manufacture of dietary supplements, of scientific backgrounds qualified to evaluate the health benefits of these products, and of people involved in herbal medicine, medical botany or related sciences. The Commission, under the direction of Dr, Ken Fisher, is charged with producing a report with recommendations to government for regulatory changes. To ensure that regulatory changes are made, the FDA is charged with publishing proposed regulatory changes based on the recommendations within 24 months of the report submission, or the recommendations of the Commission become law.

Definition of Dietary Supplement

A dietary supplement was defined as:

- Containing one or more nutrients, herbs, botanicals, or a concentrate, metabolite or constituent extract from the ingredients previously mentioned;
- In the form of a supplement (meaning tablet, capsule or powder);
- Is not represented as a food or sole item of a meal or the diet;
- Includes a similar new drug or biologic approved under previous legislation and not currently being investigated.

Burden of Proof

Of particular importance is that the burden of proof of product safety and the truthfulness of the information rests with the Food and Drug Administration. If the Secretary of the Health and Human Services Department believes the product presents a significant or unreasonable risk of illness under ordinary or labeled conditions of use, or if the product is thought to be adulterated, or if the information associated with or the label is considered to be false or misleading the Secretary can withdraw the product pending court action. This situation allows for the sale of dietary supplements unless shown by FDA to be unsafe or adulterated or labeled in a misleading fashion.

Labeling

Labeling is not yet in force but some manufacturers have voluntarily complied. Nutrient content labeling if done, must comply with NLEA (the Nutrition Facts panel). Health claims in keeping with those already approved by FDA are allowed, if the manufacturer wishes to use them (and if the product is then labeled as required under NLEA). Other health claims and labeling issues are the subject of a Presidential Commission whose work is not yet complete.

Several kinds of information were considered to be exempt from labeling, for dietary supplements (note the situation is different for foods). Articles and book chapters, when not false or misleading, not associated with a particular manufacturer or brand name, when displayed apart from the dietary supplements or with other information to present a balanced viewpoint and when there is no sticker or added information are not considered to be labeling.

The following types of label statements can be made:

- Benefits related to classic nutrient deficiency disease and disclosing the prevalence of the disease
- Description of the nutrient or dietary ingredient intended to affect the structure or function
- Characterizes the mechanism of action
- Describes general well-being from consumption of the nutrient or dietary ingredient.

There are two provisos to the labeling approvals. The manufacturer must have substantiation that the label is truthful and not misleading (but there is no indication that this information has to be provided to FDA). Also, the following information must be prominently displayed, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure of prevent any disease.” Labels may not claim to diagnose, mitigate, treat, cure, prevent a specific disease or class of diseases.

There are additional labeling requirements for dietary supplements including the name and quantity of the ingredient, or total quantity of all ingredients in a blend, wording to indicate the product for sale is a dietary supplement. Other requirements can be described as basic weight and measures similar to food or over the counter drug products.

Approval process

Unlike pre-marketing clearances needed under other circumstances, the manufacturer of a dietary supplement with a label containing allowed statements has to inform FDA of the sale of the product within 30 days of the first marketing.

Appendix III

List of Food for Specified Health Use in JAPAN

	Product Name	Applicant	Type of foods	Functional Component	Health Claims Licenced by the Ministry of Health and Welfare	Date of Licence
1	FINE RICE	SHISEIDO Co. Ltd.	Processed Rice	(Rice globulin)	FINE RICE, a rice in which the rice globulin content is reduced, is suitable as a replacement ofnormal rice for people allergic to rice globulin consumption of which would result in atopic dermatitis.	Jun 1 1993
2	MORINAGA LOW PHOSHORUS SPECIALIZED FORMULA L.P.K.	MORINAGA MILK INDU-STRY CO., LTD.	Foods contain-ing milk and milk products as principal ingredients	(Phosphorus)	LOW PHOSPHORUS SPECIALIZED FORMULA L.P.K. as it contains less phosphorus (1/5 of that commercial milk) and less potassium/sodium, while it contains other necessary nutrients such as protein (easily digestible whey protein), calcium, iron and vitamins, is suitable for chronic renal failure patients who require theraputic low phosphorus diets.	
3	YOGHURINA	SUNTORY Ltd.	Lactic Acid and bacteria drinks	Xylo-oligosaccharide	This drink acts to increase intestinal Bifidobacteria and maintain a good GI condition	Oct 1 1993
4	CALCIUM PARLOR	TAKARA SHUZO Co., Ltd	Soft drink	CCM (Citric Acid, Malic Acid, and Calcium)	It contains calcium with higher bioavailability and is suitable for supplementing calcium intake which tends to be insufficient in normal diets.	
5	CALCIUM 160	TAKARA SHUZO Co., Ltd.	Soft drink	CCM (Citric Acid, Malic acid, and Calcium)	It contains calcium with higher bioavailability, and is suitable for supplementing calcium intake which tend sto be insufficient in normal diets.	
6	MEIOLIGO (Granule)	MEIJI SEIKA KAISHA, LTD	Table sugar	Fructo-oligosaccharides	This food acts to increase intestinal Bifidobacteria and maintain in a good GI condition	
7	MEIOLIGO (Syrup)	MEIJI SEIKA KAISHA, LTD	Table sugar	Fructo-oligosaccharides	This food acts to increase intestinal Bifidobacteria and maintain in a good GI condition	
8	NICHIREI ACEROLA EXTRA BLEND	NICHIREI Corp.	Soft drink	Soybean oligosaccharides	This is suitable for those who are concerned about their GI condition, as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment	
9	OLIGO CC	THE CALPIS FOOD INDU-STRY Co., Ltd.,	Carbonated beverage	Soybean oligosaccharides	This is suitable for those who are concerned about their GI condition, as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment	
10	SOYBEAN OLIGO-SACHARIDE SYRUP	THE CALPIS FOOD INDU-STRY Co., Ltd.	Table sugar	Soybean oligosacchardies	This is suitable for those who are concerned about their GI condition, as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment	
11	GOODENT	LOTTE Co., Ltd.	Gum	Palatinose Maltitol	Thi is a low cariogenicity gum	

	Product Name	Applicant	Type of foods	Functional Component	Health Claims Licenced by the Ministry of Health and Welfare	Date of Licence
12	ELTOS (Syrup)	TAISHO PHARMA-CEUTICAL Co., Ltd.	Table sugar	Soybean oligosacchardies	This is suitable for those who are concerned about their GI condition, as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment	
13	ELTOS (Granule)	TAISHO PHARMA-CEUTICAL Co., Ltd.	Table sugar	Soybean oligosacchardies	This is suitable for those who are concerned about their GI condition, as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment	
14	OLIGO COFFEE	MEIJI SEIKA KAISHA Ltd.	Refreshing drink	Fructo-oligosaccharide	This food is made with Fructooligosaccharides, so increases intestinal Bifidobacteria and helps well regulate a GI condition	Apr 22 1994
15	OLIGO TIME (Syrup)	SHOWA SANGYO Co., Ltd.	Table sugar	Isomalto-oligosacchardies	This is suitable for those who are concerned about their GI condition, as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment.	
16	PROTEIN GAMMO	FUJI OIL Co. Ltd.	Gammodoki (Fried tofu with vegetable)	Soy protein	This product is helpful for people with high blood cholesterol to improve their diet pattern, as it is made with isolated soy protein which helps inhibit absorption of cholesterol and is designed to be a form for easier intake.	
17	MS MEIOLIGO (Syrup)	MEIJI SEIKA KAISHA Ltd.	Table sugar	Fructo-oligosaccharides	This food is made with Fructooligassachrides, so increases intestinal Bifodobacteria and helps well regulate a GI condition	
18	DAIZU KARAAGE	FUJI OIL Co., Ltd.	Frying without coating of soy protein	Soy protein	This product is helpful for people with high blood cholesterol to improve their diet pattrns, as it is made with isolated soy protein which helps inhibit absorption of cholesterol, and is designed to be a form for easier intake.	
19	ALL-BRAN	KELLOGG (JAPAN) K.K.	Cereal	Wheat bran	ALL-BRAN is a food which helps well regulate a GI condition as it is made with wheat bran which is rich in dietary fibre. Permits maintenance of a comfortable GI condition with a tasty food.	Oct 17 1994
20	G-9 (G-NINE)	KANESA Co., Ltd.	Fermented soy protein drink	Soy protein	This product is helpful for people with high blood cholesterol to improve their diet pattern, as it is made with isolated soy protein which helps inhibit absorption of cholesterol and is designed to be a form for easier intake.	
21	SOYBEAN OLIGO-SACCHARIDE SYRUP	DAI-NIPPON SUGAR MFG. Co., Ltd.	Table sugar	Soybean oligosacchardies	This is suitable for those who are concerned about their GI condition as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment.	
22	OLIGO YOHGULET	MEIJI SEIKA KAISHA Ltd.	Tablet candy	Fructo-oligosaccharides	This food contains Fructooligoshaccarides so increases intestinal Bifidobacteria and helps well regulate a GI condition	
23	OLIGO CANDY	MEIJI SEIKA KAISHA Ltd.	Candy	Fructo-oligosaccharides	This food contains Fructooligosaccharides so increases intestinal Bifidobacteria and helps well regulate a GI condition	

	Product Name	Applicant	Type of foods	Functional Component	Health Claims Licenced by the Ministry of Health and Welfare	Date of Licence
24	ONE A NIGHT PLAIN	OTSUKA PHARMA-CEUTICAL Co., Ltd.	Soft drink	Lactosucruose	ONE A NIGHT PLAIN is suitable for those who are concerned about their GI conditions as it increases Bifidobacteria living int he Gi and helps maintain a good intestinal environment	May 25 1995
25	ONE A NIGHT BITTER	OTSUKA PHARMA-CEUTICAL Co., Ltd.	Soft drink	Lactosucruose	ONE A NIGHT BITTER is suitable for those who are concerned about their GI conditions as it increases Bifidobacteria living int he Gi and helps maintain a good intestinal environment	
26	ONE A NIGHT GINGER	OTSUKA PHARMA-CEUTICAL Co., Ltd.	Soft drink	Lactosucruose	ONE A NIGHT GINGER is suitable for those who are concerned about their GI conditions as it increases Bifidobacteria living int he Gi and helps maintain a good intestinal environment	
27	ORIGO-NO-ASA	ENSUIKO SUGAR REFINING Co., Ltd.	Table sugar	Lactosucrose	“ORIGO-NO-SUGAR” is a food designed to help maintain a good GI condition as it contains Lactosucrose as the major ingredient and acts to increase intestinal Bifidobacteria	May 25 1995
28	NYUKA-ORIGO	ENSUIKO SUGAR REFINING CO., Ltd	Table sugar	Lactosucrose	“NYUKA-ORIGO” is a food designed to help maintain a good GI condition, as it contains Lactosucruose as the major ingredient and acts to increase intestinal Bifidobacteria.	
29	NYUKA-ORIGO (GRANULE)	ENSUIKO SUGAR REFINING CO., Ltd	Table sugar	Lactosucrose	“NYUKA-ORIGO (GRANULE)” is a food designed to help maintain a good GI condition, as it contains Lactosucruose as the major ingredient and acts to increase intestinal Bifidobacteria.	
30	FROZEN YOGHURT SOKOYAKA KAZOKU	EZAKI GLICO Co., Ltd.	Frozen yoghurt	Lactosucrose	FROZEN YOGHURT SOKOYAKA KAZOKU is a food designed to help maintain a good GI condition as it contains Lactosucrose and acts to increase intestinal Bifidobacteria	
31	MEIJI OLIGO PUDDING	MEIJI MILK PRODUCT Co., Ltd.	Ready to eat pudding	Fructo-oligosaccharide	This food contains Fructooligosaccharide and is deisgned to help maintain a good GI environment	
32	FRUCTO-OLIGO-SACCHARIDES by NIHON OLIGO	NIHON OLIGO Co., Ltd.	Table sugar	Fructo-oligosaccharide	This food is made with Fructooligosaccharides and is designed to help maintain a good Gi environment	
33	BEFORE	KANEBO Ltd.	Soft drink	Gasein Dodeca peptide	This food contains “Casein Dodeca peptide” and is helpful for peole with acidity hypertension to improve their diet pattern	
34	TEKKOTSU INRYOU	SUNTORY Ltd.	Soft drink	CPP(Casein Phospho peptide)	TEKKOTSU INRYOU is suitable for supplementing Calcium intake which tends to be insufficient in normal diets, as it is formulated with CPP and is designed to improve absorption of its calcium content.	
35	CALCIUM PARLOR Ca.	TAKARA SHUZO Co., Ltd.	Soft drink	CCM (Citric Acid, Malic Acid, Calcium)	As it contains calcium with higher bioavailability it is suitable for supplementing calcium intake which tends to be insufficient in normal diets.	

	Product Name	Applicant	Type of foods	Functional Component	Health Claims Licenced by the Ministry of Health and Welfare	Date of Licence
36	SUTTO	TOKIWA CHEMICAL INDUSTRIES Ltd.	Soft drink	Soybean oligosaccharides	This is suitable for those who are concerned about their GI condition as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment.	Oct. 25, 1995
37	PISES	TOKIWA CHEMICAL INDUSTRIES Ltd.	Soft drink	Soybean oligosaccharide	This is suitable for those who are concerned about their Gi condition as it increases intestinal Bifidobacteria and helps maintain a good intestinal environment	
38	MARUSHIGE GENKISU	MARUSHIGE UEDA Co., Ltd.	Seasoning vinegar	Xylo oligosaccharide	This seasoning vinegar acts to increase intestinal Bifidobacteria and maintain a good GI condition	
39	MAIASA-SOHKAI	MORINAGA MILK INDUSTRY Co., Ltd.	Soft drink	Lactulose	This drink is made with Lactulose so acts to increase intestinal Bifidobacteria and maintain a good GI condition	
40	ORIGO-NO-OKAGE	ENSUIKO SUGAR REFINING Co., Ltd.	Table sugar	Lactosucrose	This food contains Lactosucrose as the major ingredient so acts to increase intestinal Bifidobacteria and maintain a good GI condition	
41	ORIGO-NO-OKAGE EX	ENSUING SUGAR REFINING Co., Ltd.	Table sugar	Lactosucrose	This food contains lactosucrose as the major ingredient so acts to increase intestinal Bifidobacteria and maintains a good GI conditions	
42	PICK OLIGO CANDY	EZAKI GLIGO Co., Ltd.	Candy	Lactosucrose	PICK OLIGO CANDY is a food designed to help maintain a good GI condition as it contains Lactosucrose and acts to increase intestinal Bifidobacteria	
43	PICK OLIGO BISCUIT	EZAKI GLICO Co., Ltd.	Biscuit	Lactosucrose	PICK OLIGO BISCUIT is a food designed to help maintain a good GI condition, as it contains Lactosucrose and acts to increase intestinal Bifidobacteria	
44	OLIGO55	HAKUBUN Co., Ltd.	Table sugar	Fructo-oligosaccharides	This is amde with Fructooligossacharide and is designed to help well regulate a GI condition	
45	CUP OLIGO SWEET EXTRA	NISSIN SUGAR MFG. Co., Ltd.	Table sugar	Galacto-oligosaccarides	Thi sweetener contains Galactooligosaccharides which acts to increase intestinal Bifidobacteria and is designed to help maintain a good GI condition	
46	ASAHI POWER GOLD	ASAHI BREWERIES Ltd.	Carbonated beverage	Isomalto-oligosacchardies	This is suitable for those who are concerned about their GI condition as it is made with Isomaltooligosaccharides it increases intestinal Bifidobacteria and is designed to help maintain a good GI condition	
47	HEALKET	NIPPON KAYAKU Co., Ltd.	Biscuit	Chitosan	“HEALKET” is a biscuit formulated with a specific amount of chitosan which helps inhibit absorption of cholesterol and so is helpful for people with a high cholesterol value or for those who are concerned about it to improve their diet	
48	HEALTH SUPPORT FOOD “MARIN” INCLUDING CRITOSAN	ITO HAN FOODS Inc.	Fish cake (Kamaboko)	Chitosan	HEALTH SUPPORT FOOD `MARIN`INCLUDING CHITOSAN is helpful for people with a high cholesterol value or for those who are concerned about it to improve their diet pattern as it is designed for easier intake of chitosan which helps inhibit absorption of cholesterol	

	Product Name	Applicant	Type of foods	Functional Component	Health Claims Licenced by the Ministry of Health and Welfare	Date of Licence
49	HEALTH AND BALANCED LIFE PORK WEINER	ITO HAM FOODS Inc.	Vienna sausage	Indigestible dextrin	This product contains water-soluble dietary fibre (Indigestible dextrin) made from potato startch and so helps well regulate a GI condition. Permits maintenance of a coomfortable GI condition with a tasty food.	
50	FIBE-MINI	OTSUKA PARMA-CEUTICAL Co., Ltd.	Carbonated beverage	Polytextrose	FIBE-MINI is a dietary fibre drink which helps well regulate a GI condition by conveniently providing the dietary fibre which tends to be insufficient in normal diets.	Oct. 25, 1995
51	SUNFIBER 55	TAIYO KAGAKU Co., Ltd.	Powered soft drink	Partially bydrzed guar gum	This product is a food (powdered soft drink) which is made with partially hydrolyzed guar gum as the major ingredient and is designed to help maintain a good GI condition. Permits maintenance of a comfortable GI condition with a tasty food.	
52	ONE TWO PELOTTY	EZAKI GLICO CO., Ltd.	Chocolate	Palatinose Green tea polyphenols	ONE TWO PELOTTY is a low cariogenicity chocolate as it uses platinose and green tea polyphenols as ingredients which are not cariogenic.	
53	NUTULOVE	EZAKI GLICO CO., Ltd	Chocolate	Maltitol Palatinose Green tea polyphenols	NATULOVE is a low cariogenicity choclate as it uses platinose and green tea polyphenols as ingredients which are not cariogenic.	
54	KISS MINT GUM WHITE	EZAKI GLICO Co., Ltd.	Gum	Maltitol Palatinit Erythritol Green Tea polyphenols	KISS MINT GUM WHITE is a low cariogenicity gum as it uses saltitol. hydorgenated palatinose, erythritol and green tea polyphenols as ingredients which are not cariogenic.	
55	BALANCE SUPPORT PORK FRANK	NIPPON MEAT PACKERS INC.	Frankfurt sausage	Soy protein	This product is designed to help inhibit absorption of cholesterol. It is thus helpful in improving the diets of meat lovers who are concerned about cholesterol	
56	BALANCE SUPPORT PORK FRANK	NIPPON MEAT PACKERS INC.	Vienna sausage	Soy protein	This product is designed to help inhibit absorption of cholesterol. It is thus helpful in improving the diets of meat lovers who are concerned about cholesterol	
57	HEWE IRON DRINK fe	ASAHI CHEMICAL INDUSTRY Co., Ltd.	Soft drink	Heme iron	This is suitable for those who suffer from a mildly anemic condition which may require an iron supplement	
58	KOTSU KOTSU CALCIUM	ASAHI BREWERIES Ltd.	Soft drink	CPP (Casein Phospho peptide)	This product is suitable for supplementing calcium intake which tends to be insufficient in normal diets, as it is formulated with CPP and is designed to improve absorption of its calcium content.	
59	OLIGOSUGAR 39	HAKUBUN Co., Ltd.	Table sugar	Fructo oligosaccharides	This food is made with Fructooligosaccharides, so increases intestinal Bifidobacteria and helps well regulate GI condition.	May 31, 1996
60	TAKANASHI DRINK YOGURT ONAKA-HE-GG!	TAKANASHI MILK PRODUCTS Co., Ltd.	Drink yogurt	Lactobacillus GG	This drink is produced by fermentation with Lactobacillus GG which reaches one's intestines in an active state to help increase intestinal Bifidobacteria and Lactobacilli, to maintain a good intestinal environment and to regulate GI condition.	

	Product Name	Applicant	Type of foods	Functional Component	Health Claims Licenced by the Ministry of Health and Welfare	Date of Licence
61	KENJIN SARON	KINKI COCA-COLA BOTTLING Co., Ltd.	Soft drink	Indigestible dextrin	This drink is helpful for those who are concerned about their blood glucose level, as it contains dietary fiber (Indigestible dextrin) which helps moderate absorption of sugars.	
62	FIBER JELLY	POKKA CORPORA-TION	Soft drink	Polydextrose	This product contains dietary fiber (Polydextrose) to supplement intake which tends to be insufficient for people at present, so permits maintenance of a comfortable GI condition. It is suitable for those who are concerned about their GI condition.	
63	L-ONE	ENZAMIN LABORATORY Inc.	Soft drink	Xylo oligosaccharides	L-ONE contains an ample amount of dietary fiber (Polydextrose), and so helps well regulate GI condition.	
64	SUKKIRI KAICHO	LOTTE Co., Ltd.	Chocolate	Lactosucrose	SUKKIRI KAICHO is a chocolate made with Xylooligosaccharides which act to increase intestinal Bifidobacteria, and so helps maintain a good intestinal environment and well regulated GI condition.	
65	OLIGO 2400. APPLE	TAISHI FOOD Inc.	Soft drink	Lactosucrose	OLIGO 2400. APPLE is a food which contains Lactosucrose as the major ingredient and acts to increase intestinal Bifidobacteria, and so helps maintain a good GI condition.	
66	OLIGO 2400. CARROT	TAISHI FOOD Inc.	Soft drink	Lactosucrose	OLIGO 2400. CARROT is a food which contains Lactosucrose as the major ingredient and acts to increase intestinal Bifidobacteria, and so helps maintain a good GI condition.	
67	OLIGO 2400. GRAPE	TAISHI FOOD Inc.	Soft drink	Lactosucrose	OLIGO 2400. GRAPE is a food which contains Lactosucrose as the major ingredient and acts to increase intestinal Bifidobacteria, and so helps maintain a good GI condition.	
68	ORIGO-NO-OKAGE EX (GRANULE)	ENSUIKO SUGAR REFINING Co., Ltd.	Table sugar	Lactosucrose	This food is designed to help maintain a good GI condition as it contains Lactosucrose as the major ingredient, and so acts to increase intestinal Bifidobacteria.	
69	TOCHU 120	HITACHI ZOSEN Corp.	Soft drink	Glycoside from Eucommia Leaves	This drink contains Glycoside from Eucommia Leaves and is suitable for people with mild hypertension.	
70	CASEIN DP	KANEBO Ltd.	Soft drink	Casein Dodeca peptide	This food contains “casein Dodeca peptide”, and is helpful for people with mild hypertension to improve their diet pattern.	Oct. 7, 1996
71	MENARD CHOLE-TORU BAR	NIPPON MENARD COSMETIC Co., Ltd.	Biscuit	Chitosan	“MENARD CHOLE-TORU BAR” is a biscuit formulated with a specific amount of chitosan which helps inhibit absorption of cholesterol, and so is helpful for people with a high cholesterol value or for those who are concerned about it to improve their diet pattern.	
72	HEALTHY AND BALANCED LIFE MEAT LOAF	ITO HAM FOODS INc.	Bologna sausage	Indigestible dextrin	This product contains water-soluble dietary fiber (Indigestible dextrin) made from potato starch, and so helps well regulate GI condition. Permits maintenance of a comfortable GI condition with a tasty food.	

	Product Name	Applicant	Type of foods	Functional Component	Health Claims Licenced by the Ministry of Health and Welfare	Date of Licence
73	HEALTHY AND BALANCED LIFE PORK FRANK	ITO HAM FOODS Inc.	Frankfurt sausage	Indigestible dextrin	This product contains water-soluble dietary fiber (Indigestible dextrin) made form potato starch, and so helps well regulate GI condition. Permits maintenance of a comfortable GI condition with a tasty food.	

Appendix IV

Contact List

United States

1. Yetley, Beth Food and Drug Administration. Office of Special Nutritional, 200 'C' St. S.W. Washington, D.C.

2. Cordaro, John President Council of Responsible Nutrition 1300 19th Street, Suite 310 Washington, D.C.

3. Fisher, Ken Director Presidential Commission 200 Independance Avenue Washington, D.C.

4. Satchell, Felicia Food and Drug Administration. Office of Food Labelling 200 'C' Street S.W. Washington, D.C.

5. Campbell, Betty Food and Drug Administration. Office of Food Labelling. 200 'C' Street S.W. Washington, D.C.

6. Wilkening, Virginia. Food and Drug Administration. Office of Food Labelling. 330 'C' S.W. Washington, D.C.

7. Hathcock, John. Director Nutritional and Regulatory Science. Council for Responsible Nutrition. 1300 19th Street, Suite 310 Washington, D.C.

8. Marriott, Bernadette. Director. Office of Dietary Supplements. National Institutes of Health. Bethesda Maryland.

9. Hasler, Clare Director Functional Foods for Health Program, Department of Food Science, University of Illinois, Urbana-Champaign. 737 Beaver Hall. 905 South Goodwin Avenue. Urbana, Illinois.

10. Witwer, Rhonda. Industry Liaison Department of Food Science, University of Illinois, Urbana-Champaign. 737 Beaver Hall. 905 South Goodwin Avenue. Urbana, Illinois.

European Union

1. Binns, Dr. N., Nutrition Manager, Coca Cola International, European Community Group, 1 Queen Caroline Street, London W6 9HO (Tel: 081 237 3380; FAX: 081-237-3719)

2. Breslin, Dr. Liam , European Commission, Directorate-General XII - Science, Research and Development, Square de Meeus 8 - 1040 Brussels, Belgium (Tel: 32 - 2 - 295.04.77; FAX: 296.43.22)

3. Edmondson, Dr. Maureen, Scientific & Regulatory Affairs Manager (Europe), Mars Incorporated; Mars Confectionery, Dundee Road, Slough Berks. SL1 4JX, U.K. (Tel: 44 - 1753 514791; FAX: 44 1753 514775)

4. Feral, R., European Commission, Directorate-General XXIV - Consumer Service and Policy, Rue de la Loi 200, B-1049 Brussels, Belgium (Tel: 32-2 295.84.15; FAX: 296.32.79)

5. Guler, Dra. Irma G., Scientific & Regulatory Affairs, Confederation of the Food and Drink Industries of the EU (CIAA); Rue de la Loi 74, B-1040 Brussels, Belgium (Tel: 32 2 230 81 45; FAX: 32 2 230 85 69)

6. Knowles, Dr. M.E., Director, Scientific & Regulatory Affairs, Coca-Cola International, Chausee de Mons 1424, 1070 Brussels (Tel: 32 2 529.15.00; FAX: 32 2 529.18.51)

7. McAlpine, Rory A., Counsellor (Agriculture) Mission of Canada to the European Union, Avenue de Tervuren, 2 1040 Brussels (Tel: 32 2 741 06 10; FAX: 02 741 06 29)

8. Rapp, Dr. E.G., Director, Food Law & Safety, CPC Europe Consumer Foods Ltd., Avenue de Tervuren 300, Bte, B-1150 Brussels (Tel: 32 2 761.09.11; FAX: 32 2 761.09.18)

9. Taeymans, Dr. D., Manager, Scientific & Regulatory Affairs, CIAA, Rue de la Loi, 74 B-1040 Brussels; (Tel: 32 2 230 81 45; FAX: 32 2 230 85 69).

Japan

1. Kojima, Dr. Kohei, Professor Emeritus, College of Envvironmental Health, Azabu University, Fuchinobe 1-17-71, Sgamihara-Shi, 229 Japan

2. Lapsley, Dr. K., Program Chair, Food; Centre for Food and Animal Research, C.E.F. Building No. 55 Ottawa K1A OC6 (Tel: 613 759-1436; FAX: 613 759 1465)

3. Loken, M., Japan Division (PJP), Asia & Pacific Branch, Department of Foreign Affairs and International Trade, Lester B. Pearson Building, 125 Sussex Drive, Ottawa K1A OG2 (Tel: 613 996-2467; FAX: 613 943-8286)

4. Murray, Alison M., Senior Science & Technology Program Officer, Science and Technology Section, Canadian Embassy, 3-38, Akasaka 7-Chome, Minato, Tokyo 107 (Tel: 03 3408-2101 EXT. 3327; FAX: 03 3403-8119)

5. Nakagawa, Dr. Kunio, Manager, Department of Foods for Specified Health Use, Japan Health Food and Nutrition Food Association, 6-1, Jingumaei 2-chome, Sibuya-ku, Tokyo 150 (Tel: 03 5410 8321; Fax: 03 5410 8235

6. Rust, G., Trade Commissioner, Investment, Science & Technology (RENI), Department of Foreign Affairs and International Trade, Europe Branch, Lester B. Pearson Building, 125 Sussex Drive, Ottawa K1A OG2 (Tel: 613 995 8296; FAX: 613 995 6319)

Canada

1. Cheney, Dr. Margaret, Chief, Nutrition Evaluation Division, Food Directorate, Health Protection Branch, Health Canada, Health Protection Building, Tunney's Pasture, Ottawa, Ontario, K1A 0L2 (Tel: 613 957 0352; Fax: 613 957 1574)

2. Lapsley, Dr. K., Program Chair, Food; Centre for Food and Animal Research, Agriculture and Agri-Food Canada C.E.F. Building No. 55 Ottawa K1A OC6 (Tel: 613 759-1436; FAX: 613 759 1465)

3. Lee, Nora, Nutrition Evaluation Division, Health Protection Branch, Health Canada, Frederick Banting Building, Tunney's Pasture, Ottawa, Ontario K1A 0L2 (Tel: 613 957 1740; Fax: 613 941 6636)

4. Stewart, Lynn, Senior Market Analyst, Food Bureau, Agriculture and Agri-Food Canada, Sir John Carling Building, 930 Carling Avenue, Ottawa, Ontario K1A 0C5 (Tel: 613 759 7551; Fax: 613 759 7480)

Appendix V

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