



A Critical Analysis of Health Claim Management in Five Jurisdictions: Results and Recommendations

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Overview of Presentation

- **Background Information**
- **A comparison of scientific requirements for health claim substantiation**
- **Highlights of each jurisdictions' management of health claims**
- **A comparison of regulatory processes**
- **Recommendations for Canada**



Definition of “Health Claim”

- **Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and “health” (Codex, 1997 – revised 2004)**



Definition of “Health Claim” cont’d

- **Health claims do not refer to quantitative or qualitative declarations that state, suggest, imply or compare levels of energy and/or nutrients in food**
- **Health claims may or may not be legally defined in Acts/Regulations**
- **For our discussion, health claims will refer to health claims on food or food health claims**



Benefits of Health Claims

- **Permit the communication of food/health relationships to consumers (truthful and not misleading) with the hope of improving dietary eating patterns and health**
- **Encourage industry development of healthful food products**



Uncertainties Over Health Claims

- **Appropriateness of foods as vehicles of health claims**
- **Consumer interpretation of health claims, particularly of claims with different levels of substantiation**
- **Impact of health claims on consumer choice**
- **Impact of health claims on consumer behavior and health outcome**



Factors Affecting Regulatory Frameworks for Health Claims

- **Regulatory frameworks for health claim management are affected by a country's level of interest in:**
 - Health promotion (reflection of culture)
 - Public health
 - Consumer choice
 - Consumer protection
 - Civil rights / values (e.g., freedom of speech)
 - Economics, facilitation of trade
 - Enabling food research, innovation, product development, industry competitiveness



Factors Affecting Regulatory Processes for Health Claims

- **Regulatory processes for health claim management are affected by the organizational structure and operations of regulatory bodies and level of enforcement**
 - Human resources
 - Financial resources
 - Accountability
 - Communication



Scientific Requirements for Health Claim Substantiation

- **Efficacy**
- **Safety**
- **Quality Assurance**



Efficacy

- Intake of food X causes a change in health outcome Y (*i.e.*, causality)





Safety

- **No adverse nutritional or toxicological effects with intake of product**
- **No adverse nutritional or toxicological interactions between the food on which the claim is based with other foods**



Safety cont'd

- **Nutritional effects**
 - Assessed in humans
 - Assessment of changes in dietary intake patterns
 - Dietary intake modelling used for assessment
- **Toxicological effects**
 - Assessed in animals
 - Assessment of changes to tissues and organs with intake of food at different amounts (including very high doses)
 - Acute, short-, and long-term studies used for assessment



Quality Assurance

- **Assurance of:**
 - Methodologies
 - Use of validated analytical methods and accredited analytical laboratories
 - Quality control procedures
 - Good manufacturing/clinical/laboratory practices
 - Consistency
 - In amount of active ingredient
 - Stability
 - Shelf-life of bioactive ingredient and food
 - Purity
 - Starting ingredients and finished product meet pre-defined chemical, microbiological, and heavy metal specifications
- **Documentation is pivotal in the demonstration of quality assurance**



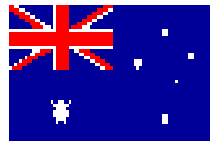
Health Claim Substantiation

- **Substantiation of quality assurance is objective**
- **Substantiation of safety and efficacy requires interpretation**
- **Communication of the “what” (*i.e.*, the scientific requirements) and the “how” (*i.e.*, how to meet the requirements) is fundamental to efficient and effective health claim substantiation**



Scientific Requirements in Health Claim Applications

	CA	AU/NZ	EU	Japan	US
Efficacy	√	√	√	√	√
Safety	√	*	*	√	√
Quality Assurance	√	*	√	√	√
* Addressed in novel food applications					





Evidence Requirements on Efficacy

	CA	AU/NZ	EU	US
Human studies (intervention and/or observational)	√	√	√	√
Effective Intake/Dose-Response	√	√	√	√
Consistency of findings across studies	√	√	√	√
Relevance of studies' findings/populations/diets to general population/target group of claim	√	√	√	√
Whether effective intake can reasonably be achieved under conventional use	√	√	√	√



Evidence Requirements on Efficacy cont'd

	CA	AU/NZ	EU	US
Alternative explanations/Independence of association	√ not essential	√	√	√
Magnitude of outcome	√	√	√	
Physiological relevance of magnitude of effect	√	√	√	
Statistical significance of outcome	√		√	√
Sustainability of effect	√	√	√	



Evidence Requirements on Efficacy cont'd

	CA	AU/NZ	EU	US
Specificity of effect	√ not essential	√ secondary focus	√	
Biological plausibility	√ not essential	√ secondary focus	√	
Reversal of effect	√ not essential	√ secondary focus		
Temporal relationship	√	√		
TOTAL (# essential items/14)	10/14	10/14	12/14	7/14



Commonalities on the “how” across jurisdictions

- **Preliminary decisions on food-health relationship**
- **Literature retrieval**
- **Literature filtering**
- **Tabulation and synopsis of literature**
- **Study quality appraisal**
- **Evaluation of totality of evidence for causality and generalizability**



Evidence Requirements on Safety in Health Claim Applications

	CA	AU/NZ	EU	JAPAN (FOSHU)	US
History of safe use	√ ¹	*	*	√	*
Dietary exposure (current and increased due to claim)	√	*	*	n/a	√
Dietary/nutritional impacts	√	*	*	√	√
Adverse effects from human studies	√ ¹	*	√	√	√
Toxicological data from animal studies	√ ¹	*	*	√	*
TOTAL (required items/max. of 5)	2/5 to 5/5	0/5	1/5	4/5	3/5

¹Not required if food's safety previously reviewed by Health Canada; * Addressed in novel food applications (AU/NZ, EU) or GRAS/food additive applications (for US)



Evidence Requirements on Quality Assurance in Health Claim Applications

	CA	AU/NZ	EU	JAPAN (FOSHU)	US
Characterization of food (compositional analysis; physical/chemical characteristics; impurity profile)	√	*	√	√	√
Manufacturing Process	√ ¹	*	√ ²	√	*
Stability/shelf-life	√ ¹	n/a	√ ²	√	*
Compliance with specifications	√ ¹	*	√	√	*
Quality systems in place (Good clinical/laboratory/manufacturing practices)	√ ¹	n/a	√	√	√
TOTAL (max. of 5)	1/5 to 5/5	0/5	3/5 to 5/5	5/5	2/5

¹ Only required for modified foods; ² “Where applicable”

* Addressed in novel food applications (AU/NZ) or GRAS/food additive applications (US)



Conclusions on Scientific Requirements

- **Not all jurisdictions require efficacy, safety, and quality assurance to be comprehensively addressed in health claim applications; other routes exist for the assessment of safety and quality assurance - *e.g.*, novel foods, GRAS, food additive applications**
- **For scientific requirements on efficacy, Canada scored similarly to AU/NZ (10/14); its requirements are more comprehensive than US (7/14) and less comprehensive than EU (12/14)**



Recommendations for All Jurisdictions on Scientific Requirements

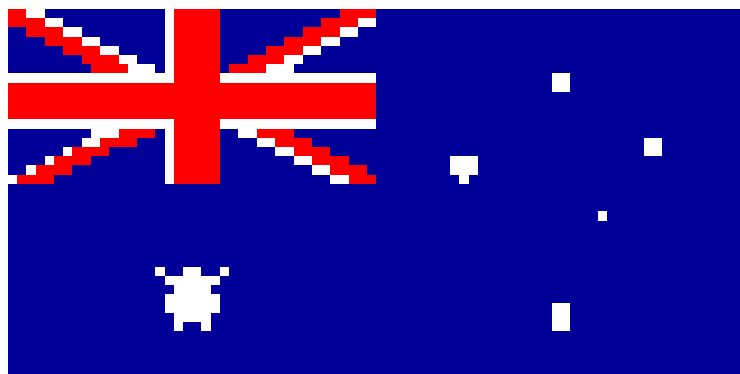
- **Provide clear expectations on demonstration of efficacy, safety, and quality assurance with advice on how to demonstrate them – *i.e.*, step-by-step approaches**
 - Examples for Safety
 - Recommendations on how to predict expected dietary intakes of foods with claim
 - Recommendation on how to assess interactions of bioactives with other foods, nutrients, and drugs
 - Examples for Efficacy
 - Ensure recommendations facilitate the comparability of research findings
 - Provide a systematic, actionable tool for study quality appraisal that facilitates differentiation of “good” from “poor” quality studies – *e.g.*, a checklist that scores a study for quality



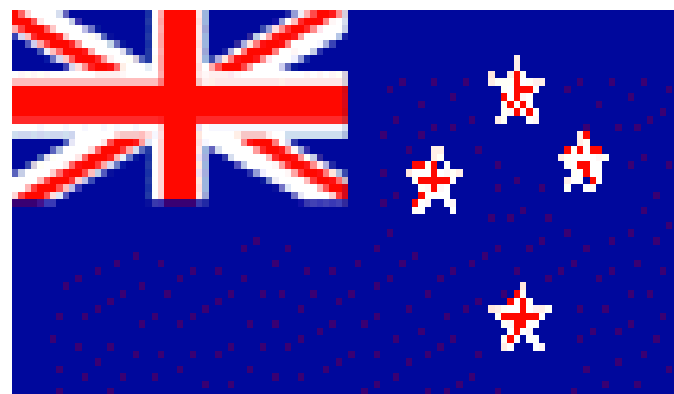
Profile of Claims Across Jurisdictions

Subject of Claim	CA	AU/NZ	EU	Japan	US
<p>• Required health effect (e.g., for growth, development)</p>	<p>Currently: Biological Role Claims (not considered health claims)</p> <p>Proposed: Function Health Claims</p>	General Level Health Claims	Article 13 Health Claims	FNFC	Structure/Function Claims (not considered health claims)
<p>• Health effect is not required but it can improve well-being</p>	<p>Currently: Structure/Function Health Claims*</p> <p>Proposed: Function Health Claims*</p>	General Level Health Claims	Article 13 Health Claims	FOSHU	Structure/Function Claims (not considered health claims)
<p>• Risk Reduction (mention of a disease or risk factor for disease)</p>	<p>Currently: Risk Reduction and Therapeutic Health Claims**</p> <p>Proposed: Disease Risk Reduction Health Claims**</p>	<p>General Level Health Claims (non serious disease)</p> <p>High Level Health Claims (serious disease)</p>	Article 14 Health Claims	FOSHU	<p>Authorized Health Claims</p> <p>Qualified Health Claims</p>

* If claiming to restore, correct or modify an organic function, considered a drug claim and requires a regulatory amendment ** Considered a drug claim and requires a regulatory amendment



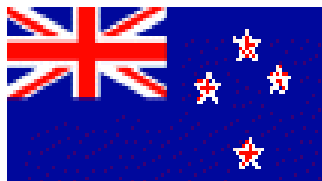
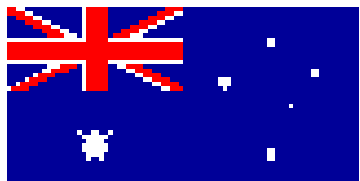
Australia and New Zealand





Current vs. Proposed Health Claim Management System

- **Current Food Standard 1.1A.2 prohibits all health claims - e.g., mention of a disease or physiologic condition prohibited**
- **Proposed Food Standard 1.2.7 to replace current Food Standard 1.1A.2**
- **Proposed Food Standard 1.2.7 will increase allowance of health claims**





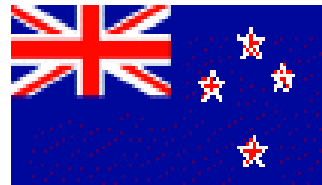
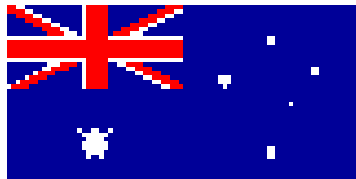
Proposed Profile and Regulation of Claims

	Nutrition Content Claim	General Level Health Claim	High Level Health Claim
Considered a Health Claim	No	Yes	Yes
Subject of Claim	Amount of nutrient, energy or <u>food component</u> (e.g., biologically active substance)	Function in body Modification of function beyond role in normal growth and development Performance benefits Well-being Reducing risk or helping to control a <u>non-serious</u> disease or condition	Reducing risk or helping to control (by reducing risk factors or improving health) a <u>serious disease</u> * or condition
FSANZ approval for claim use	No, but must be substantiated (i.e., proof of quantity)	No, but must be substantiated (i.e., proof of quantity and efficacy)	Yes, with a scientific dossier - Once approved, available for use by all
<p>* Serious disease: Disease, ailment, defect or condition that is not appropriate to diagnose, treat, or manage without consultation/supervision by a health care professional and includes obesity but not being overweight</p>			



Highlights

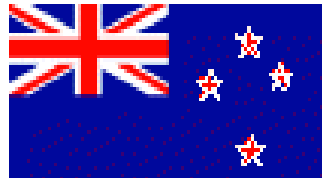
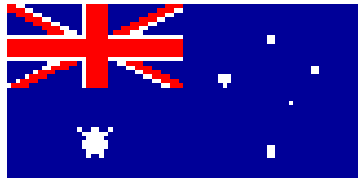
- **General level and high level health claims will not have the same route for authorization**
 - General level health claims will not require FSANZ approval; evidence to support substantiation must be available upon request
 - High level health claims will require FSANZ's review and approval and an application to “vary the Code”





Highlights

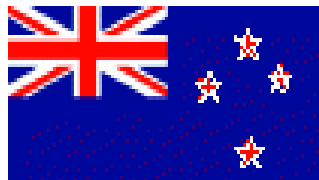
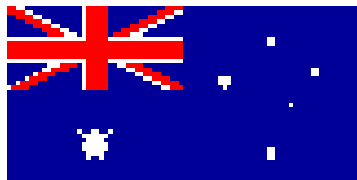
- **Health Claim Substantiation Criteria and Approval Process**
 - Different management system for general level health claims versus high level health claims pertaining to strength and types of acceptable evidence and approval process
 - General level: “Probable” rank of evidence; option exists to use generally accepted information sources for substantiation
 - High level: “Convincing” rank of evidence; requirement for appraisal of totality of evidence





Highlights

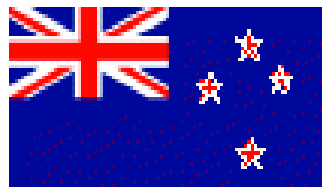
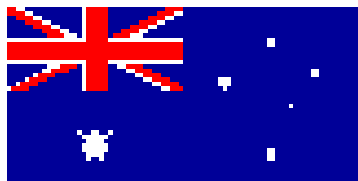
- **Eligibility criteria for health claims**
 - FSANZ is considering implementing a “nutrient profiling” criteria for general level and high level health claims
 - The nutrient profile of a food would be scored based on whether it is a fruit, vegetable, nut or legume and on levels of calories, saturated fat, sodium, sugars, fibre, and protein
 - A cut-off score would exist
 - A reference quantity of 100 g or 100 ml of the food would apply
 - An electronic calculator on FSANZ’s website to carry out calculation





Highlights

- **Use of existing authoritative reviews**
 - Simplified processes for health claim substantiation based on existing authoritative reviews; evidence must be of acceptable quality/rigor and findings must be relevant to populations and dietary patterns in AU and NZ
- **Execution of research**
 - Research conducted to resolve uncertainties or gaps in understanding of consumer perceptions

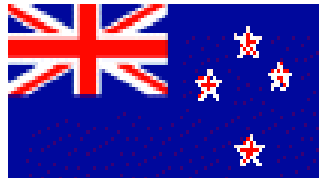
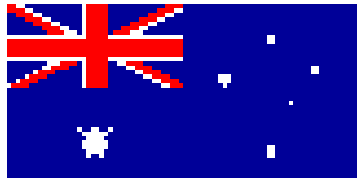




Highlights

- **Fees**

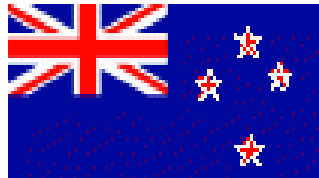
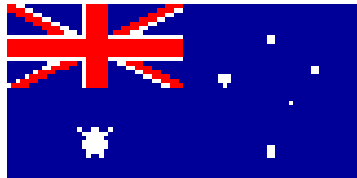
- A fee charged for assessing applications (to vary the Code) if: 1. Application has an exclusive commercial benefit or 2. Applicant would like the review expedited
 - Minor Procedure (175 hours of assessment): \$16,090 CA
 - General Procedure (500 to 850 hours): \$45,970 to \$78,149 CA
 - Major Procedure (1050 hours): \$96,537 CA + \$92 CA/each additional hour





Highlights

- **Transparency**
 - A publicly available “work plan” reviewed and updated by FSANZ at least every 3 months
- **Website**
 - FSANZ’s website exemplary





Canada





Relevant Developments

- **2007**
 - *Health Canada* proposes a modernized framework for management of food health claims
 - *Natural Health Products Directorate* informs stakeholders that natural health products in “food form” will be reviewed by the *Food Directorate*





Health Claim Definition

- **Current (condensed)**
 - No legal definition
 - Claims that relate to Canada's definition of a drug*
- **Proposed (condensed)**
 - A relationship between the consumption of foods or food constituents and health in the context of the total diet

* **Drug: represented in the diagnosis, treatment, mitigation, prevention of a disease, disorder or abnormal physical state or its symptoms; restoring, correcting, modifying organic functions**





Profile and Regulation of Health Claims

- **Since the Act states that foods cannot be represented as drugs, diet/disease claims on food require regulatory amendments from:**
 - Provisions of the Act and Regulations pertaining to drugs
 - Provisions of the Act pertaining to Schedule A





Current Profile and Regulation of Claims

	<ul style="list-style-type: none"> • Structure/Function (S/F) Claims • Risk Reduction (RR) Claims • Therapeutic (TH) Claims 	• Biological Role Claims	• Nutrient Content Claims
Classified as Health Claims	Yes	No	No
General Feature	Relate to Canada's definition of a drug	Do not relate to Canada's definition of a drug	Do not relate to Canada's definition of a drug
Subject of Claim	<p>S/F Claims*: Modifying, restoring or correcting an organic function or structure beyond normal growth and development or maintenance of good health</p> <p>RR Claims*: Alteration of a <u>risk factor</u> for a disease/adverse health condition</p> <p>TH Claims*: Prevention, treatment, management or mitigation of a <u>disease</u>, disorder, abnormal physical state or symptoms</p>	Nutritional function of energy or nutrients for good health or normal growth and development	Amount of a nutrient or energy
Health Canada's approval for claim use	Yes, but once approved, available for use by all (for generic claims)	No, allowable claims listed by Health Canada Yes, for new claims not on existing list	No, claims/specifications outlined by Health Canada

* Require regulatory amendments since considered drug claims



Proposed Profile and Regulation of Health Claims

	General Health Claims	Disease Risk Reduction Claims	Function Claims
Classified as health claims	Yes	Yes	Yes
Refer to a specific health effect, disease or health condition	No	Yes	Yes
Defining feature	Promote overall health, healthy eating or provide dietary guidance	Reduced risk of disease*	Restoring, correcting or modifying body functions* Maintenance or support of body functions for good health, performance or normal growth and development
*Will require regulatory amendments since would be considered drug claims			





Highlights

- **All health claims require the same strength of evidence for substantiation of efficacy**
 - Totality of evidence should substantiate efficacy with a “high level of certainty” – *i.e.*, reasonable assurance that the claim is unlikely to be reversed by new and evolving science





Highlights

- **Health Claim Substantiation Criteria and Approval Process**
 - Same management system for all health claims: all require approval and all must demonstrate a high certainty regarding efficacy





Highlights

- **Eligibility Criteria for Health Claims**
 - A generic eligibility criteria for all health claims does not exist in Canada
 - Of the five approved health claims, two claims (sodium /high blood pressure and fat/heart disease claims) must have the food contain 10% of a weighted recommended nutrient intake of a vitamin or mineral per reference amount and/or serving of stated size





Highlights

- **Type of evidence required for efficacy varies depending on whether the claim is “product-specific” or “generic”**
 - Generic: A combination of human intervention studies, observational studies, and systematic reviews can be used
 - Product-specific: Require controlled human intervention studies on specific food to be marketed





European Union





Relevant Developments

- ***Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food***
 - Applicable from July 2007





Profile and Regulation of Claims

	Nutrition Claim	Article 13 Claim	Article 14 Claim
Considered a health claim	No	Yes	Yes
Subject of claim	Amount of energy, nutrient or other substance (other than a nutrient that has a nutritional or physiological effect)	<u>Not</u> disease risk reduction or children's health/development Body function – e.g., in growth/development, psychology, behaviour, weight control, hunger/satiety	Disease risk reduction or children's health/development
Approval required by EFSA for claim use	No, a list of allowable claims/specifications	Yes, but once approved, available for use by all (if not based on proprietary data)	Yes, but once approved, available for use by all (if not based on proprietary data)





Highlights

- **Type of evidence for substantiation of efficacy differs between Article 13 claims and Article 14 claims**
 - Unlike Article 14 claims, Article 13 claims do not require that substantiation follow a guidance document; a comprehensive analysis and tabulation of the totality of evidence (all original research in humans) is also not required for Article 13 claims





Highlights

- **Review Process**
 - EFSA must review and approve all Article 13 and Article 14 claim applications
 - Scientific assessment is of the “highest possible standard”





Highlights

- **Transparency**
 - EFSA is legally obliged to be transparent
 - It must publish outcomes of its scientific work and management documentation (budgets, accounts, contracts) on its website
 - All approved and rejected claims are to be communicated in a “Community Register”





Highlights

- **Marketing Opportunities**
 - Article 13 or 14 claims based on proprietary data are restricted for use to their applicant for 5 years (exceptions exist)
 - Expedited review of Article 13 claims based on newly developed science to stimulate product innovation





Highlights

- **Application Process**
 - An electronic, workable application form/template for health claim applications available





Highlights

- **Eligibility Criteria for Nutrition/Health Claims**

- By January 19, 2009, the European Commission is to establish specific nutrient profiles for which foods/categories of food must comply with to bear nutrition or health claims
- EFSA is to provide advice to European Commission by December 2007 on:
 - whether nutrient profiles should be set for food in general and/or categories of food
 - nutrients to be taken into account (e.g., fat, saturated fat, trans fat, sugars and salt/sodium)
 - choice of a reference quantity/basis for profiles
 - approach to the calculation of profiles
 - feasibility and testing of a proposed system





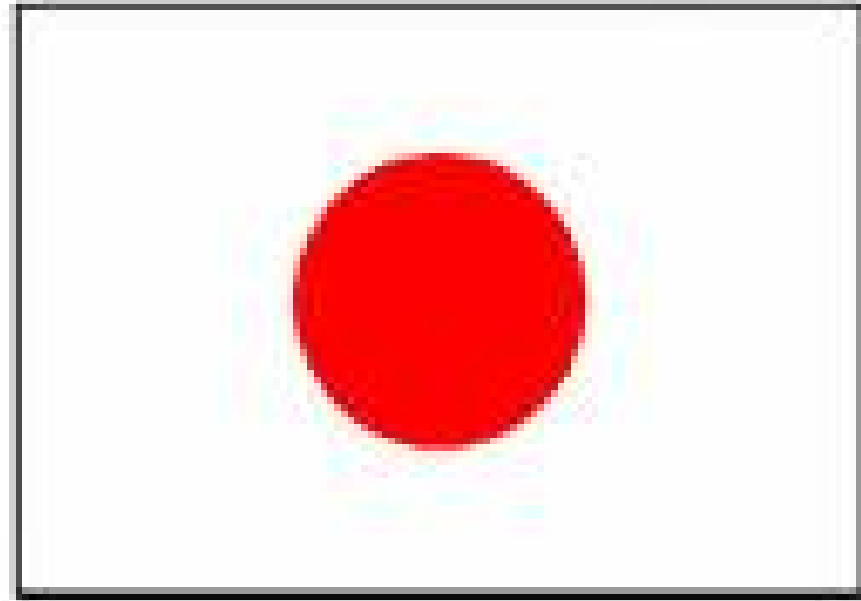
Highlights

- **Evaluation of impact of regulation**
 - Report to be submitted to European Parliament by the European Commission, by January 2013, that evaluates impact of nutrition/health claims regulation:
 - The evolution of the market with nutrition/health claims
 - Consumers' understanding of claims
 - Proposals for amendments, if necessary
 - Impact of regulation on dietary choices
 - Impact of regulation on obesity and non-communicable diseases





Japan





Relevant Developments

- **2003: Regulatory framework for “Foods for specified health uses” (FOSHU) expanded**
 - to allow claims based on weaker science (“qualified” route of approval)
 - to allow disease risk reduction claims





Profile and Regulation of Claims

	Foods with Nutrient Function Claims (FNFC)	Foods for Specified Health Uses (FOSHU)	So-called health foods
Subject of claim	Body structure or function	Body structure or function or disease risk reduction	Content of nutrients or ingredients
Approval by MHLW	No; pre-approved claims for 17 nutrients (12 vitamins, 5 minerals)	Yes	No; not regulated
Matrix commonly used	Conventional food form	Conventional food form	Dietary supplements (tablets, capsules)





Profile of FOSHU Claims

Profile of Approved “Specified Health Uses” for FOSHU (Ohama *et al.*, 2006)

Specified health use	Number of FOSHU products approved (%)
Intestinal condition	254 (44.6%)
Cholesterol/triglycerides	117 (20.6%)
Blood sugar	71 (12.5%)
Blood pressure	64 (11.2%)
Teeth	34 (6.0%)
Bone	26 (4.6%)
Iron supply	3 (0.5%)
Total	569 (100%)





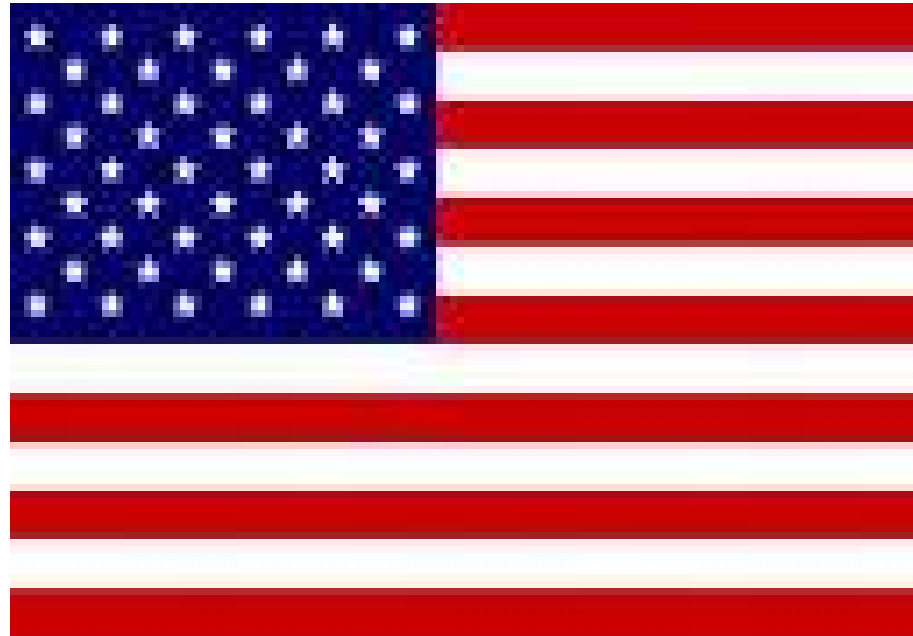
Highlights

- **FOSHU Substantiation Criteria and Approval Process**
 - Different strength of science accepted for FOSHU claims (*i.e.*, strong to weak science)
 - Rank A: Evidence is established
 - Rank B: Evidence is accumulating
 - Rank C: Evidence not established
 - Much of the responsibility for reviewing FOSHU applications has been turned over by MHLW to local authorities
 - Approved FOSHU products have a “seal of approval”; however, *Japan Health Food and Nutrition Food Association* also offers its own seal of approval





United States





Profile and Regulation of Claims

	<ul style="list-style-type: none"> • Qualified Claims • Authorized Claims 	• Structure/Function Claims	• Nutrient Content Claims
Classified as health claim	Yes	No	No
Subject of claim	Disease (damage to organ, part, structure, or system so that it does not function properly) or state of health leading to such dysfunctioning	Normal body structure/functions Well-being Nutrient deficiency disease (so long as disease prevalence stated)	Level of nutrient
FDA's approval for claim use	Yes	No	No
Notification to FDA for claim use	Qualified Claims: No FDA Authorized Claims: No Authoritative Statement Authorized Claims: Yes	No, for conventional foods Yes, for dietary supplements	No, for pre-approved claims Yes, for new claims based on authoritative statements



Highlights

- **Acceptable evidence for health claim substantiation varies for authorized versus qualified claims**
 - Authorized claims:
 - Randomized, controlled intervention studies
 - Prospective, observational cohort studies
 - Qualified Claims:
 - Randomized, controlled intervention studies
 - Prospective, observational cohort studies
 - Non-randomized intervention studies
 - Case control observational studies





Highlights

- **Difference strength of evidence permitted for authorized versus qualified claims**
 - Authorized
 - “Significant scientific agreement” (SSA)
 - Level of comfort for claim validity is “high”; substance/disease relationship not likely to be reversed by new and evolving science
 - Qualified
 - Level of comfort for claim validity can be “moderate”, “low”, or “extremely low”; consistency in findings across studies of similar or different designs ranked as moderate, low or extremely low





Highlights

- **All health claims require approval by FDA or notification to the FDA**
 - Authorized claims
 - Authorized by FDA or,
 - Authorized by a scientific body of the U.S. Government or National Academy of Sciences with notification to the FDA
 - Qualified claims
 - Receive “enforcement discretion”, if they are not rejected by the FDA – *i.e.*, specifications regarding language that must appear in claim





Highlights

- **Eligibility Criteria for Health Claims**
 - FDA specifies maximum levels of total fat, saturated fat, cholesterol, and sodium above which the food will be disqualified from making a health claim unless an exception is provided
 - Except for dietary supplements or where provided for in regulations, the food must also contain 10% or more of the Reference Daily Intake/Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein or fibre per reference amount customarily consumed prior to any nutrient addition





Highlights

- **Structure/Function Claims**
 - Although not considered health claims, these claims can be made on conventional foods without FDA approval or notification to FDA
 - Claims can be made on normal structures and functions in humans, well-being, *etc.* Examples include:
 - “Improves absentmindedness”
 - “Supports the immune system”
 - “Fiber maintains bowel regularity”





Highlights

- **Communication**
 - FDA maintains close communication with health claim petitioners
- **Transparency**
 - FDA maintains a high level of transparency regarding health claim-related activities





Regulatory Processes: Efficiency

	CA	AU/NZ	EU	JAPAN	US
Preliminary screening of health claim applications to ensure completeness	√	√			√
Outsourcing of expertise to help with health claim application evaluations		N/A FSANZ is an independent scientific body	N/A EFSA is an independent scientific body	√ Local authorities	√ Evidence-based Centers



Regulatory Processes: Transparency / Communication

	CA	AU/NZ	EU	JAPAN	US
Health claim application information available in public domain	√ Decision summaries of approved claims available	√ All information pertaining to applications (except confidential data) available	√ EFSA will make public a summary of health claim application and its scientific opinion on an approved claim	Not known	√ All information pertaining to approved and rejected claims (except confidential data) available
Formal obligation to communicate with applicant throughout review process		√	√	Not known	√
Easy accessibility of contact person/ telephone number for help		√	√		√



Regulatory Processes: Accountability to Timelines

	CA	AU/NZ	EU	JAPAN	US
Timelines for health claim authorization	None exist	Timelines to vary Code range from 3 to 12 months; timelines for high level health claims not yet established	9 to 10 months	~ 1 year	<p>Qualified claims: 9 months; extensions permitted with mutual agreement (FDA and applicant)</p> <p>FDA authorized claims: 1 yr, 9 months; extensions permitted with mutual agreement (FDA and applicant)</p>



Regulatory Processes: Market Advantage

	CA	AU/NZ	EU	JAPAN	US
Applicant has exclusive rights to health claim	√ For product-specific claims (generally based on proprietary data)		√ For claims approved based on proprietary data		
Options available to expedite review process		√ Application fee can be paid	√ EFSA will expedite review of claims based on newly developed science to stimulate product innovation		



Conclusions on Regulatory Processes

- **Canada did not perform similarly to other jurisdictions on factors related to efficiency; transparency/communication; accountability to timelines; market advantages**



Top Ten Recommendations for Canada

1) Document Revision

- Revise Canada’s Interim Guidance Document for food health claim Submissions so that it:
 - Clarifies criteria that differentiate claim categories (e.g., product specific vs. generic claims; different function claims)
 - Clearly articulates application requirements
 - Provides a “how to” approach to demonstrate efficacy, safety and quality assurance
 - Facilitates the comparability of research findings to evaluate efficacy
 - Includes a workable application template

2) Document Development

- Develop a handbook that describes the process and requirements for approval of novel foods, functional foods, health claims





Top Ten Recommendations for Canada

3) Authoritative Reviews

- Consider simplifying the process of health claim substantiation if critical reviews by credible authoritative bodies exist

4) Approval Process

- Consider a “step-up” or “tiered” process for the approval of different types of health claims





Top Ten Recommendations for Canada

5) Transparency/Communication

- Mandate communication with health claim applicants at specific timepoints during the health claim review process
- Make available an organizational chart that describes names, roles, telephone numbers of government employees involved in health claim application reviews
- Make accessible all information pertaining to health claim applications (minus proprietary data) in the public domain (e.g., applications received, approved, rejected)





Top Ten Recommendations for Canada

6) Accountability to Timelines

- Mandate an accountability to timelines for review of health claim applications

7) Outsourcing Expertise

- Outsource expertise, when necessary, to help review health claim applications

8) Market Advantages

- Consider a first-to-market advantage for health claim applicants





Top Ten Recommendations for Canada

9) Website

- Create a more user-friendly and organized website; see FSANZ's website (www.foodstandards.gov.au)

10) Research

- Execute research where appropriate and necessary to resolve uncertainties or gaps in the understanding of consumer perceptions of health claims



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Thank you!



Efficacy: Totality of Evidence Ranked

	CA	AU/NZ	EU	JAPAN	US
Totality of Evidence Ranked for Strength	n/a	√ convincing, probable, possible, insufficient	n/a	√ A, B, C	√ high, moderate, low, extremely low