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Regulation of functional foods in Canada

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Overview

- Canadian Regulatory Framework
- Need and Rationale for Change
- New regulations for Natural Health Products
- Implications of health claims for foods
- *Implications of functional foods with* bioactive additives
- Proposed regulatory framework for product-specific authorization of health claims
- Standards of Evidence for Evaluating Foods with Health Claims
- Current status
- Conclusions

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Regulatory Framework

- The Food and Drugs Act, 1954, defines "drugs"

""drug" includes any substance or mixture of substances manufactured, sold or represented for use in
(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or
its symptoms, in human beings or animals,
(b) restoring, correcting or modifying organic functions in human beings or animals..."

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The Act also prohibits the labelling or advertising to the general public, or the sale if so advertised, of drugs, foods, cosmetics or medical devices as a treatment, preventative or cure of many chronic diseases including:

- cancer,
- diabetes,
- heart disease,
- hypertension
- obesity

and others

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Legally, foods can also be drugs.

In practice this is rare

but that could change.

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In early '90s, we started to hear about "functional foods", designer foods", *"nutraceuticals", also, FOSHU, Food for Specific* Health Uses.

World was waking up to increasing understanding of how diets affect the incidence of disease.

Maybe foods can help prevent and cure disease.

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Demands of food industry grew for health claims to be allowed for foods.

Also, demands grew for consumers to have access to natural health care alternatives to mainstream medicine.

Demands grew for consumers to be able to have more choice of the types of therapeutic products they wanted.

Drug laws made it difficult and costly for natural health products to be sold as drugs

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Strong grass roots movement resulted a parliamentary review (1997) which led to a new *Natural Health Product Regulations.*

Come into force, January 2004.

The main components:
- definitions
- product licensing
- site licensing
- good manufacturing practices
- labelling and packaging
- clinical trials
- adverse reaction reporting

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NHP Definition

Function component:
- diagnose, treat, prevent disease
- restore or correct function
- maintain or promote health

Substance component:
- included substance list
- excluded substance list

Only OTC - prescription products would still be regulated as drugs

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Though foods also maintain and promote health, NHPs are not intended to include foods.

NHPs are a subset of drugs.

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Foods	Drugs & NHPs
Intended to provide nourishment, nutrition or hydration, or to satisfy hunger or thirst or a desire for taste, texture or flavour	Intended to diagnose, treat, mitigate, or prevent disease or abnormal physical states, and modify, restore or correct organic function
Foods: maintain and promote health	NHPs: maintain and promote health
Physiological actions, nutritional functions	Physiological/pharm-acologic actions

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Foods	Drugs & NHPs
Ad libitum consumption over life time	Regulated frequency, usually short term, can be long term
Unsupervised	Medical supervision or required drug labelling with contraindications, etc

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Foods with drug claims should be sold as foods, not drugs

Foods sold as drugs not subject to food controls intended to prevent harm to health

- Food additives
- Contaminants
- Pesticide residues
- Microbiological standards
- Novel food regulations
- Low acid canned food regulations

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Foods with drug claims should be sold as foods, not drugs (cont'd)

Foods sold as drugs not subject to composition and labelling standards intended to protect the consumer

- *Compositional standards*
- Ingredient lists, nutrition labelling & claims, allergen/labelling
- Food fortification (flour, salt, milk)
- Nutritional standards (infant formulas, meal replacements, medical foods)

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Foods with drug claims should be sold as foods, not drugs (cont'd)

- Food inspection systems designed to ensure safety and wholesomeness of foods may not be applied to foods sold as drugs: legal mandate of inspection agencies is food.
- Confusion in the market place with the same products labelled differently as drugs and foods

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To make drug claims for foods, requires new regulations in Canada

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Proposed Regulatory Framework for Product-Specific Health Claims - 2001

- Intended for "functional foods"
- Modeled on OTC drug framework
- Case-by-case basis
- Make application for a claim with supporting justification
- Receive Claim Identification Number instead of DIN
- Food regulations would apply
- Drug regulations would not apply

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Proposed Regulatory Framework for Product-Specific Health Claims

Three pillars:

- Product safety
- Claim validity
- Quality Assurance

All detailed in
INTERIM GUIDANCE DOCUMENT: Preparing a Submission for Foods with Health Claims

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Interim Guidance document includes STANDARDS OF EVIDENCE FOR EVALUATING FOODS WITH HEALTH CLAIMS

Provides:
1) guidance with respect to the principles and criteria by which health claims for foods offered or advertised for sale in Canada will be evaluated;
2) details on the types of information to be submitted for health claim approvals.

http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_index.html

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Product Safety

In General
- The evidence should provide reasonable assurance of no adverse **nutritional, toxicological or microbiological** effects from ingesting the product as intended.
- The type and amount of data required to support safety will be proportional to the novelty of the product and the uncertainty regarding its safety.

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Product safety: Regulation of functional foods and ingredients as Novel Foods

- Novel Food regulations cover: foods with no history of safe use, foods significantly changed through a novel process including addition of a bioactive substance, genetically modified foods
- Apply to functional ingredients in food form
- Address safety assessment only; but product may need health claims to guide consumers on how to use product safely

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Claim Validity

Six underlying principles:
(1) use the totality of evidence relating to the claim, not just the evidence supporting the claim
(2) the evidence should support a causal relationship between the ingestion of the food and the claimed effect
(3) the evidence supporting the claim should be relevant and generalizable to the target population
(4) a systematic or structured approach should be used to ensure that all relevant evidence is considered and the conclusions are justified

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(5) a high level of certainty should be present for claim validity based on best practices in evaluating scientific evidence
(6) the studies must be of acceptable design and quality and conducted in accordance with current best scientific practices

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Types of evidence:
Product-specific claims authorization would require mainly controlled human experiments plus supportive observational studies and systematic reviews of the literature.

Diet-related disease risk reduction claims ("generic") could be based on of a combination of experimental studies, observational studies and systematic reviews

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Product-specific authorization

Proposed applicable foods:

A specific food or a biologically active substance added to or otherwise modified in a food that can be consumed in a reasonable amount as part of a healthy diet to achieve the claimed effect.

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Product-specific authorization (cont'd)

Proposed applicable claims:

- Correcting, restoring or modifying organic functions or body structures besides any generally accepted role in normal growth and development or maintenance of good health
- Dietary management of a disease or health-related condition

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Product-specific authorization (cont'd)

Proposed applicable claims (cont'd):

- Reduction of risk of a disease or health-related condition

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Product-specific authorization (cont'd)

Proposed conditions for authorization:

- Written submission for a "Claim Identification Number"
- Limits may need to be imposed on use of a bioactive substance in foods based on safety assessment
- Where a substance is added to or modified in a food to achieve the claimed effect, the composition of the food should not counteract the beneficial effect of the substance

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- The effect claimed should be achieved through physiological processes that are generally recognized to be associated with foods, rather than pharmacological processes.
- Applicant would be notified within a specified period from receipt of the submission regarding success, need for more information or rejection of application.

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Status of Product-specific health claims authorization proposals

The consultation on the proposed regulatory framework indicated only qualified support for the proposal with a large number of criticisms of many aspects.

As a result, further work on it has been delayed while other initiatives are completed.

The proposal will be revisited since interest remains high in marketing "functional foods" with health claims.

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Conclusions

5 generic, diet-related disease risk reduction claims are permitted for foods meeting criteria.

Others have been reviewed: decision pending.

Submissions for additional claims are being accepted.

Product-specific claims authorization for foods not yet available.

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For more Health Canada information on functional foods and health claims for foods:

http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_index.html

For information about natural health product regulations:

http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/index_e.html

For information about therapeutic products:
http://www.hc-sc.gc.ca/english/protection/drugs.html

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