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Food, Drug or Natural Health Product? - Choosing a Regulatory Framework

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Lance Hill, Regional Food Liaison Officer

Health Products & Food

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Outline

- Regulatory Roles
- Definitions
- Fortification
- Health Claims
- Product Classification
- Examples
- Choosing a Regulatory Framework
- Closing Remarks



Regulatory Roles

➤ Health Canada

- Standard Setting and Regulation
- Policy Development (food*, drug, NHP)
 - *Includes labelling when in regard to health and safety
- Health Product (Drug/NHP) Inspection (HPFBI)
- Product Safety (Cosmetic) Inspection (HECSB)

➤ Canadian Food Inspection Agency (CFIA)

- Food Inspection
- Food Labelling Policy – non-health and safety
- Enforce Food Safety, Labelling, Nutrition and Quality Standards



Who Regulates?

- HPFB regulates products between a number of directorates:
 - FD – food
 - TPD – drugs
 - NHPD – NHPs
 - MHPD – medical devices
 - BGTD – biologics
- HECSB regulates cosmetics
 - Note that some cosmetics may be drugs or NHPs



Product Definitions



Cosmetic

- includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.



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, abnormal physical state, or its symptoms, in human beings or animals,
 - b) restoring, correcting or modifying organic functions in human beings or animals, or
 - c) disinfection in premises in which food is manufactured, prepared or kept.



Food

- includes any article manufactured, sold or represented for use as a food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.



Novel Food

- a substance, including a microorganism, that does not have a history of safe use as a food;
- a food that has been manufactured, prepared, preserved or packaged by a process that
 - has not been previously applied to that food, and
 - causes the food to undergo a major change; and
- a food that is derived from a plant, animal or microorganism that has been genetically modified such that;
 - the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
 - the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
 - one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.



Natural Health Product

- means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is 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 humans;
 - b) restoring or correcting organic functions in humans; or
 - c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

- However, a natural health product does not include a substance set out in Schedule 2, or any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or traditional medicine that is or includes a substance set out in Schedule 2.



NHP Regulation - Schedule 1

An NHP includes:

1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2. An extract or isolate of a substance described in item 1.
3. A vitamin (named)
4. An amino acids
5. An essential fatty acid
6. A synthetic duplicate of a substance in items 2 to 5
7. A mineral
8. A probiotic



NHP Regulation - Schedule 2

➤ An NHP excludes:

1. A substance set out in Schedule C (radiopharmaceuticals)
2. A substance set out in Schedule D (biologicals)
3. A substance regulated under the the *Tobacco Act*
4. A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
5. A substance that is administered by puncturing the dermis (injectibles)
6. An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic



NHP Regulation - Section 3

- Except where otherwise indicated in these Regulations, the provisions of the *Food and Drug Regulations* do not apply to natural health products.



Functional Food vs. Nutraceutical

- Functional Food - marketing term coined in Japan in late 1980's.
- No consensus nationally or internationally on definitions of 'functional food' or 'nutraceutical'.
- Lack of easily-accepted definitions have regulatory implications and affect estimates of market scope and penetration.



Functional Food

➤ similar in appearance to, or may be, conventional foods, are consumed as part of a usual diet, and are demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions.

*excludes fortified or enriched foods

➤ Health Canada Working Definitions (Nutraceuticals/Functional Foods and Health Claims on Foods - November, 1998)

*no regulatory or legal standing



Nutraceutical

- a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease.
- Health Canada Working Definitions (Nutraceuticals/Functional Foods and Health Claims on Foods - November, 1998)
 - *no regulatory or legal standing



Risks and Benefits of Providing Functional Ingredients Through Food

Risks:

- Uncontrolled addition of functional components to food supply lead to adverse health effects
- Products with insignificant amounts of promoted ingredients and unhealthy amounts of other ingredients
- Magic bullet effect – potential for diet distortion

Benefits:

- Achieve goals of health promotion
- Lower financial burden of health care



Risk Reduction Claims

- Five health claims permitted on food products [B.01.603 FDR]
 - K⁺ / Na⁺ **and** high blood pressure
 - Calcium / vitamin D / physical activity **and** osteoporosis
 - Saturated / trans fats **and** heart disease
 - Fruits / vegetables **and** some types of cancer
 - Fermentable carbohydrates **and** dental caries
- Two additional disease risk reduction claims under consideration; consultation paper issued December 2006
 - vegetables, fruit and whole grains **and** reduced risk of heart disease
 - folic acid **and** reduced risk of neural tube defects



Expanded Health Claims for Foods

- recognized that an improved approach to authorizing health claims on foods essential to help create conditions for innovation and to sustain Canadian industry in a competitive market.
- seen as a way of enabling consumers to make informed choices
- proposed consultation - Spring 2007 (?) on development of a modernized framework for the management of health claims for foods



Existing Fortification Policy

- Correct a demonstrated nutritional deficiency:
 - Vitamins D to milk for rickets
 - Folic acid to flour for NTDs
 - Iodine to table salt
- Restore nutrients lost in processing:
 - Enrichment of white flour
- Ensure nutritional quality of substitute foods:
 - Fortification of simulated meats, soy beverages
- Ensure nutritional quality of products used a sole source of nourishment:
 - Infant formulas, formulated liquid diets, meal replacements



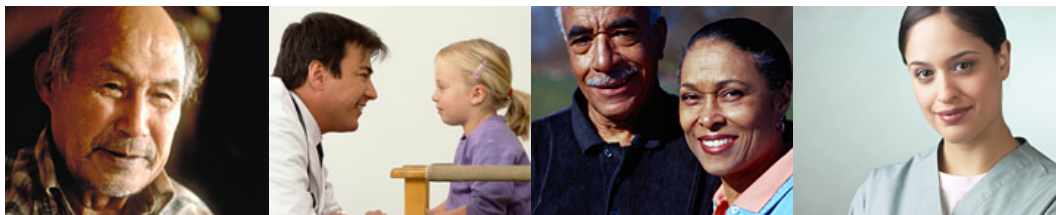
Discretionary Fortification

- Expanded Discretionary Fortification Proposal:
 - Addition of Vitamins and Minerals to Foods Policy Review and Implementation: Food Vehicles for Discretionary Fortification – June 23, 2003
 - At the "discretion" or "choice" of the manufacturer (within defined limits set by Health Canada) to meet a market demand.
- Pre-publish in Canada Gazette Part I – Spring 2007(?)
 - Cross Canada information sessions to be held during comment period

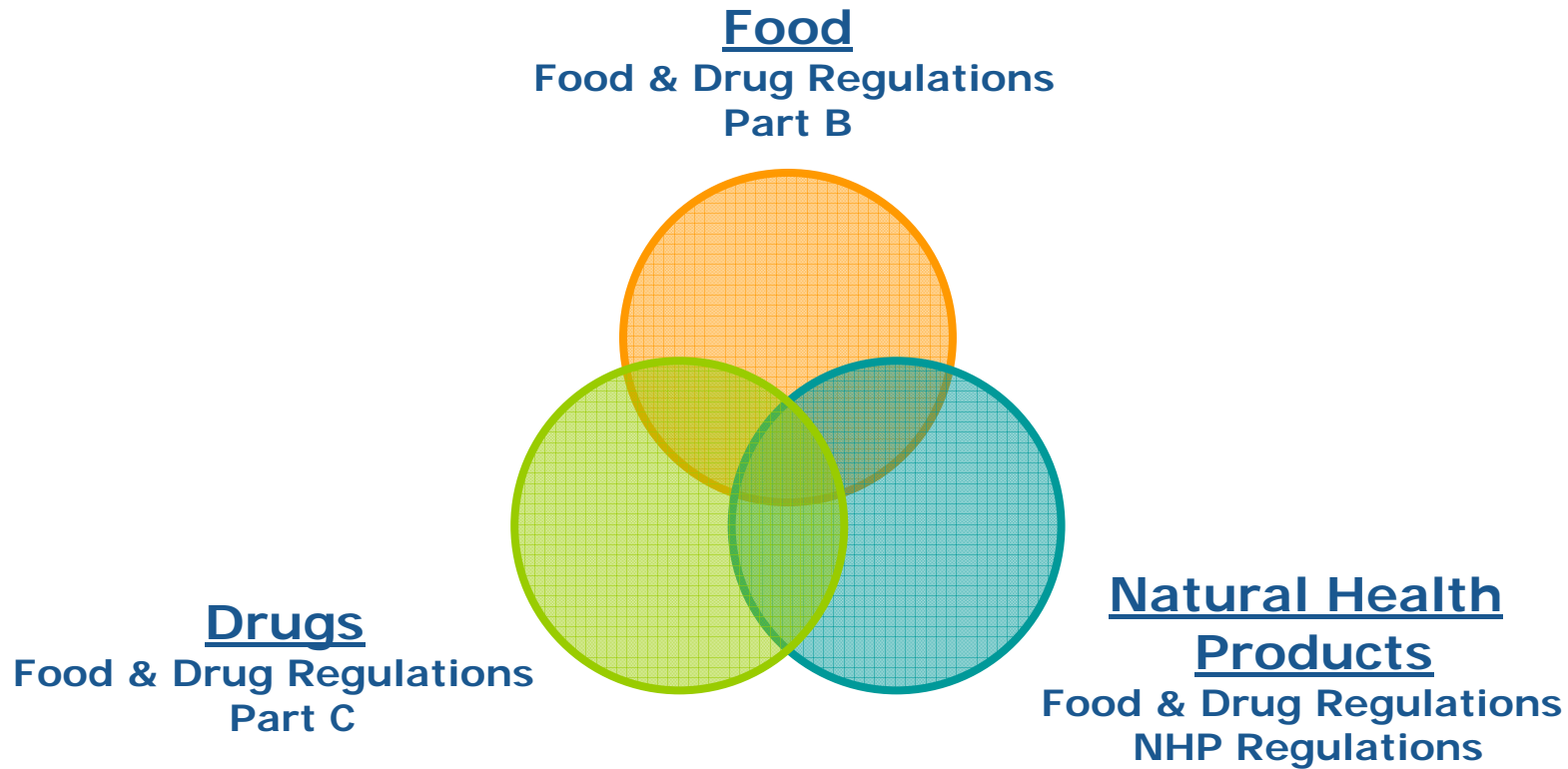


Product Classification – pre NHP

- Historically products were classified by the legislation that applied: either a food or a drug
- A product would be classified as a drug, when it contained a recognized medicinal ingredient at a therapeutic level **or** therapeutic or medicinal claims were made on the label or in advertising.
- No medicinal ingredients = '*A Food in Absence of Claims*' with onus on legal agent to ensure safety.



Product Classification - Post NHP



Food vs. Novel Food vs. Drug vs. NHP ?

- Nature of claim, process, matrix, form, extraction of naturally occurring constituents, etcetera are important criteria;
- Enforcement considerations – HPFB Inspectorate (Drugs/NHPs), CFIA (foods);
- No mechanism to analyze, develop, and uniformly apply classification criteria, and provide scientific, technical and policy advice;
- Bridging Mechanisms – Interim Marketing Authorizations / Temporary Marketing Authorization Letters may or may not be available.



Categorization Committee

- Original Health Canada response on a branch level
 - Included representatives of all program areas:
 - Food (including CFIA), Therapeutic Products, NHPs, Cosmetics, Medical Devices, Biologics
- Initial discussions centred on energy drinks
 - Legal authority needed to make classification decisions; not possible simply through policy
- Made recommendations to senior management.



NHPs in Food-Formats

- “...NHPD has received a number of product licence applications for products presented in food-formats and food-mediums (e.g. juices, cakes, drinks, yogurts, butters, etc.). The increasing presence of these products has raised certain concerns regarding potential risk to consumers, confusion amongst the public and the industry, and the true intent and scope of the *Natural Health Products Regulations*”. (July 26, 2006)



Food-Like NHPs

- HPFB has initiated a regulatory review:
 - Discussion paper available on-line, *“Charting A Course: Refining Canada's Approach to Regulating Natural Health Products,”* March 2007
 - How best to regulate these products in a way that reduces risk and reflects the manner in which they are used.
 - On-line questionnaire will be used to collect input, Spring 2007 (?)
- Pending:
 - NHPD will continue to accept, review and assess applications for food-like NHPs provided:
 - Meet both substance and function components of the NHP definition.
- Company's receiving an NPN will be informed that the product may be required to fit a different set of regulations in the future.



Example #1

- Addition of calcium to orange juice did not meet the fortification policy for foods:
 - A company obtains a DIN to sell the calcium fortified OJ as a calcium supplement;
 - Calcium fortified OJ marketed in Canada as a drug.
 - Criteria established by the Food Directorate under which it would permit calcium addition to OJ vis a vis a TMAL;
 - IMA provided for calcium fortification of OJ as a food.



Example #2

- Large number of Energy drinks on the Canadian market:
 - Meet both food and NHP definitions
 - Ingredients have physiological effects
 - Marketed in a manner similar to foods
 - Many contain ingredients not permitted in food products: vitamins, taurine, caffeine, etcetera.
 - Consumed in a manner similar to food, *'ad libitum'*
- In the interim, products being accepted as NHPs pending regulatory review.



Example #3

- Addition of calcium to apple juice:
 - A company applies for an NPN for calcium fortified AJ as a calcium supplement:
 - Company receives Site Licence;
 - Application for NPN placed in queue with submission number;
 - No action against product on market under compliance policy.
 - Second company applied for TMAL to market a calcium fortified AJ as a food:
 - Application denied by Food Directorate;
 - TMALs for fortification of foods not being accepted pending movement on proposal for expanded fortification of foods.



Committee on Product Classification (CPC)

- new committee established to bring together senior level staff and scientific experts:
 - to meet monthly to make science-based decisions on complex classification issues



Choosing a Regulatory Framework

- If a product meets both the food and NHP definitions:
 - a company **may choose** how the product will be marketed;
 - once marketed it will be expected to comply with the relevant regulations.



Some questions to ask?

- Is the product intended to be consumed ad libitum?
- Is it in a dosage form?
- What are the directions for use or intended use?
- Is this a product of biotechnology, a new process or is a non-traditional food in Canada?
- Do you want to make a claim(s)?
- Does your marketing division want to make claims?
- Do you have clinical studies supporting claims?
- Do you have the infrastructure to obtain a site licence?
- How do you want the consumer to perceive your firm?



In Closing

- Products readily recognized as food by consumers should be regulated as a food and should not be issued a DIN, DIN-HM or NPN;
- For the interim, until NHP regulations are amended, “food-like NHPs” will continue to be regulated as NHPs;
- Recognize that regulatory review may require changes to your product positioning & labelling;
- SOPs are being developed for NHPD, FD & CFIA interaction but enforcement will continue to be an issue.
- **Choose a framework with which you can comply?**



Contact Information

Lance Hill, Regional Food Liaison Officer

Health Products & Food

Phone: (604) 666-7534

Fax: (604) 666-3149

e-mail: lance_hill@hc-sc.gc.ca

400 – 4595 Canada Way

Burnaby, BC

V5J 1P1

