NHP/FI Building Success Conference

A Reality Check:

Overcoming the challenge of changing regulations

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Current state of the dynamic regulations



Source: https://www.chfa.ca/files/regulatory_files/CHFA_Tradeshows/CHFA_East_Regulatory_Forum_SFCR.pdf



Regulatory Compliance, in all cases

- <u>Responsibilities of the</u> <u>manufacturer/importer:</u>
 - Safety/quality of product
 - Accurate positioning in the marketplace
 - Conform with applicable regulations
 - All food/supplement businesses should have awareness



Product Classification

- Classification of a product drives regulatory requirements (how and when you can sell)
- Products can fit in more than one category
 - Especially true for functional foods ("food-like NHPs")
 - Novel food
 - Non-compliant food
 - Natural health product
- Compliant food
- Supplemented food
- Food can be medicine, but the regulations differ.

Health Canada guidance: http://www.hc-sc.gc.ca/dhpmps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php



The first step in classification: (1) Product Composition

- All ingredients are considered
- Food ingredients
- Non-food ingredients
- Added amino acids, vitamins, minerals
- Novel ingredients
- Additives



Permitted Food Additives

List of Permitted Sweeteners

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.01	Acesulfame potassium	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) Carbonated beverages	(2) 0.025% in beverages as consumed
		 (3) Unstandardized beverage concentrates; Unstandardized beverage mixes; Unstandardized beverages; Unstandardized dairy beverages 	(3) 0.05% in beverages as consumed
		(4)	(4)

Health Canada reference: http://www.hc-sc.gc.ca/fn-an/securit/addit/list/index-eng.php



Classification: (2) Product representation

- Positioning
 - Health (therapeutic) claims?
 - Nutrition, satisfying hunger, thirst, desire for flavour?
- Directions of use
- Point(s) of sale



Classification: (3) Product format

Food-Like format → Food

• Beverages, candies, bars

Pharmaceutical/cosmetic format → Not a food

- Capsules, tablets, creams, lotions
- Powders, liquids → Ambiguous



Classification: (4) Public perception and history of use

- Historical pattern of use as food or therapeutic product
- Ready to drink liquids above/below 90 mL packages



Classification: (5) Owner preference and flexibility

- Sometimes more than one regulatory path is available
- Flexibility in formulation, marketing, packaging offers choice
- Knowledge of regulations allows conscious choices in composition, representation, brand name, and format of your products that can affect how your products are regulated



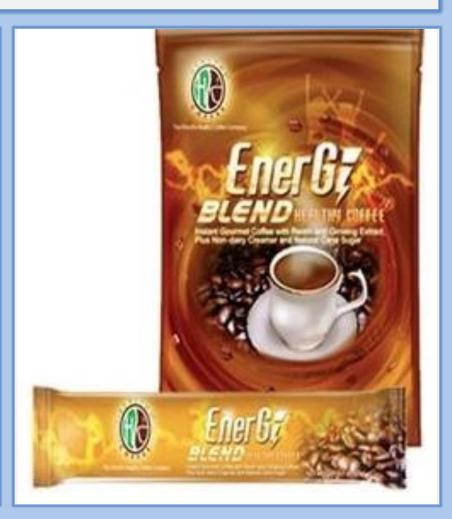
Example: Coffee + Reishi Mushroom

Ingredients

-Coffee bean -Reishi mushroom -Acesulfame-K

<u>Classification</u>

- Composition
- History of use
- Format
- Representation
- Owner preference





The categories: Compliant Food

- <u>All acceptable food ingredients</u>
 - Minimal processing
 - History of safe use as a food
 - Serve food purposes
 - Nourishment/Nutrition
 - Hydration
 - Satisfy hunger/thirst
 - Desire for taste, texture, flavour
- <u>All permitted Food Additives</u>



Apply: Compliant Food

- Simplest from a regulatory perspective
- No pre-market approval required
- No facility registration required, though this will be changing

- Prescriptive composition
- Limited claims
 - Nutrient-Function
 - General Health
 - Disease risk reduction

-Nutrient-Content -Function -Limited therapeutic



Regulations and Guidance: Compliant Foods

Canadian Food Inspection Agency http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/list-of-acts-and-regulations/eng/1419029096537/1419029097256 •

- Health Canada ۲ http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/acts-reg-lois-eng.php
- Food and Drugs Act ۲

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- Food and Drug Regulations (FDR) ۲
- Safe Food For Canadians Act (SFCA) •
- Consumer Packaging and Labelling Act •
- Food Labelling Guidance: http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/eng/1383607266489/1383607344939 •
- Nutrient Function Claims ۲ http://inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794?chap=8
- Therapeutic Claims_{http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/index-eng.php} •

The categories: Non-compliant Food

- Some aspect outside the FDR
 - New ingredient
 - Added vitamins, minerals, amino acids
 - New additive
- Supplemented foods often fall into this category
- "Non-compliant" food doesn't mean the product can never be sold, but additional regulatory steps are required



Apply: Non-compliant Food

- Pre-market steps required
 - Temporary Marketing Authorization Letter (TMAL)
 - Novel food submission
 - Food additive submission
- Limited claims
- Prescriptive composition
- Can be reformulated into compliant foods to facilitate immediate market access



Regulations and Guidance: Non-Compliant Foods

- Canadian Food Inspection Agency
 http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/list-of-acts-and regulations/eng/1419029096537/1419029097256
- Health Canada http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/acts-reg-lois-eng.php
- Food and Drugs Act
- Food and Drug Regulations (FDR)
- Safe Food For Canadians Act (SFCA)
- Consumer Packaging and Labelling Act
- Food Labelling Guidance: http://www.inspection.gc.ca/food/labelling/food-labelling-forindustry/eng/1383607266489/1383607344939
- TMAL Guidance: http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/food-market-author-marche-aliment-eng.php
- Nutrient Function Claims http://inspection.gc.ca/food/labelling/food-labelling-for-industry/healthclaims/eng/1392834838383/1392834887794?chap=8
- Therapeutic Claims_{http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/indexeng.php}



Example: Super Cranberry



<u>Classification</u>

- Composition
- Representation
- Format
- History of use
- Owner preference



The categories: Natural Health Product

- Pharmaceutical format
- Therapeutic claims
- Non-food ingredients
- Specific directions of use
- Risk information
- Ingredients recognized by NNHPD



Natural Health Products Ingredients Database

Organism - Rhodiola rosea

NHPID Name: Reference: Proper Name(s): Common Name(s):	UNAVA
Category:	Approved Herbal Name
	Antioxidants (Under consultation), Cognitive function products (Under consultation), Rhodiola - Rhodiola rosea
Schedule 1:	Plant and plant material
Source Material(s):	
Preparations:	(Parts: <u>Whole plant</u>) Dry , <u>Fresh</u>

Roles

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Medicinal

 Rationale:
 Classified as an NHP under Schedule 1 item 1 (plant or plant material) of the NHP Regulations.

 Reference:
 NHPD

http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do

Apply: Natural Health Product

- Pre-market approval required
 - Claims
 - Formula
 - Directions of use
- Site licensing
 - Facility registration
 - Finished product (quality) testing
- Regulatory Tool: Monographs



Use(s) or Purpose(s)

Statement(s) to the effect of:

- Used in Herbal Medicine to help relieve inflammatory conditions of the gastrointestinal tract (<u>E</u> 2000, <u>Bradley 1992</u>)
- (Traditionally) used in Herbal Medicine to help relieve mild digestive disturbances (such as dysp flatulence, bloating, and belching) (<u>Mills and Bone 2005</u>, <u>ESCOP 2003</u>, <u>Bradley 1992</u>, <u>Ellingwo</u> <u>Felter 1983[1922]</u>, <u>Felter and Lloyd 1983[1898]</u>)
- (Traditionally) used in Herbal Medicine as a calmative and/or sleep aid (<u>Blumenthal et al. 2000</u> Bradley 1992, <u>Ellingwood 1983[1919]</u>, <u>Felter 1983[1922]</u>, <u>Felter and Lloyd 1983[1898]</u>)

Dose(s)

Children 2 - 4 years:

Preparation: Dry, Powder, Decoction & Infusion + All Non-Standardised Extracts

Dose(s): 0.3 - 4 Grams per day, dried flowers (Justice Canada 2008, Mills and Bone 2005, ESCOP 2003, Blumenthal et al. 2000, WHO 1999, Sch Bove 1996, Bradley 1992)

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http://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq.d%3Flang=eng

Regulations and Guidance: Natural Health Products

- Natural and Non-Prescription Health Products Directorate (NNHPD) – Health Canada
 http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php
- Natural Health Product Regulations (NHPR)
- Food and Drugs Act
- Food and Drug Regulations (FDR)
- Safe Food For Canadians Act (SFCA)
- Consumer Packaging and Labelling Act
- NHP Labelling Requirements Checklist http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/label-list-etiquet-eng.php
- Quality of Natural Health Products Guide http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php
- Site Licensing http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/slgd-drle-eng.php



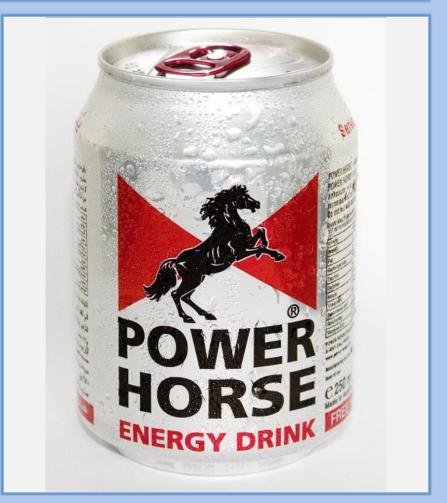
Example: Energy Drink

Ingredients:

- Carbonated water
- Whey protein
- Acesulfame potassium
- FD&C Red #40
- Green Tea
- Vitamin B12
- Taurine
- Caffeine

<u>Classification</u>

- Composition
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