

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

- **Responsibilities of the manufacturer/importer:**
 - 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/dhp-mps/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

- **Classification**

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



The categories: Compliant Food

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

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
<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-for-industry/eng/1383607266489/1383607344939>
- Nutrient Function Claims
<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-for-industry/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/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>

Example: Super Cranberry



- **Classification**

- 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: Rhodiola rosea
Reference: [UNAVA](#)
Proper Name(s): [Rhodiola rosea](#)
Common Name(s):

- [Hong jing tian](#)
- [King's-crown](#)
- [Rhodiola](#)
- [Roseroot](#)

Category: Approved Herbal Name
Monograph(s): [Antioxidants \(Under consultation\)](#), [Cognitive function products \(Under consultation\)](#), [Rhodiola - Rhodiola rosea](#)
Schedule 1: [Plant and plant material](#)
Source Material(s): [Rhodiola rosea](#)
(Parts: [Whole plant](#))
Preparations: [Dry](#), [Fresh](#)

Roles

Medicinal

Rationale: Classified as an NHP under Schedule 1 item 1 (plant or plant material) of the NHP Regulations.
Reference: [NHPD](#)

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 ([B](#) [2000](#), [Bradley 1992](#))
- (Traditionally) used in Herbal Medicine to help relieve mild digestive disturbances (such as dyspepsia, flatulence, bloating, and belching) ([Mills and Bone 2005](#), [ESCOP 2003](#), [Bradley 1992](#), [Ellingwood 1983\[1919\]](#), [Felter 1983\[1922\]](#), [Felter and Lloyd 1983\[1898\]](#))
- (Traditionally) used in Herbal Medicine as a calmative and/or sleep aid ([Blumenthal et al. 2000](#), [Bradley 1992](#), [Ellingwood 1983\[1919\]](#), [Felter 1983\[1922\]](#), [Felter and Lloyd 1983\[1898\]](#))

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](#), [Schiff 1996](#), [Bove 1996](#), [Bradley 1992](#))

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>

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