Canadian Regulatory Modernization: Natural Health Products

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Presented via webinar to:

CAPRA ACPR

Canadian Association of Professionals in Regulatory Affairs

Association canadienne des professionnels en réglementation

July 16, 2013

SESSION OVERVIEW

- **Brief Overview of Canadian Regulations for NHPs**
- Repeal of UPLAR
- Revisions to Standards of Evidence for NHPs
- Regulatory Update: Transition of Food-Type Natural Health Products
- Regulatory Update - Site Licensing
- Regulatory Update - Clinical Trials for NHPs

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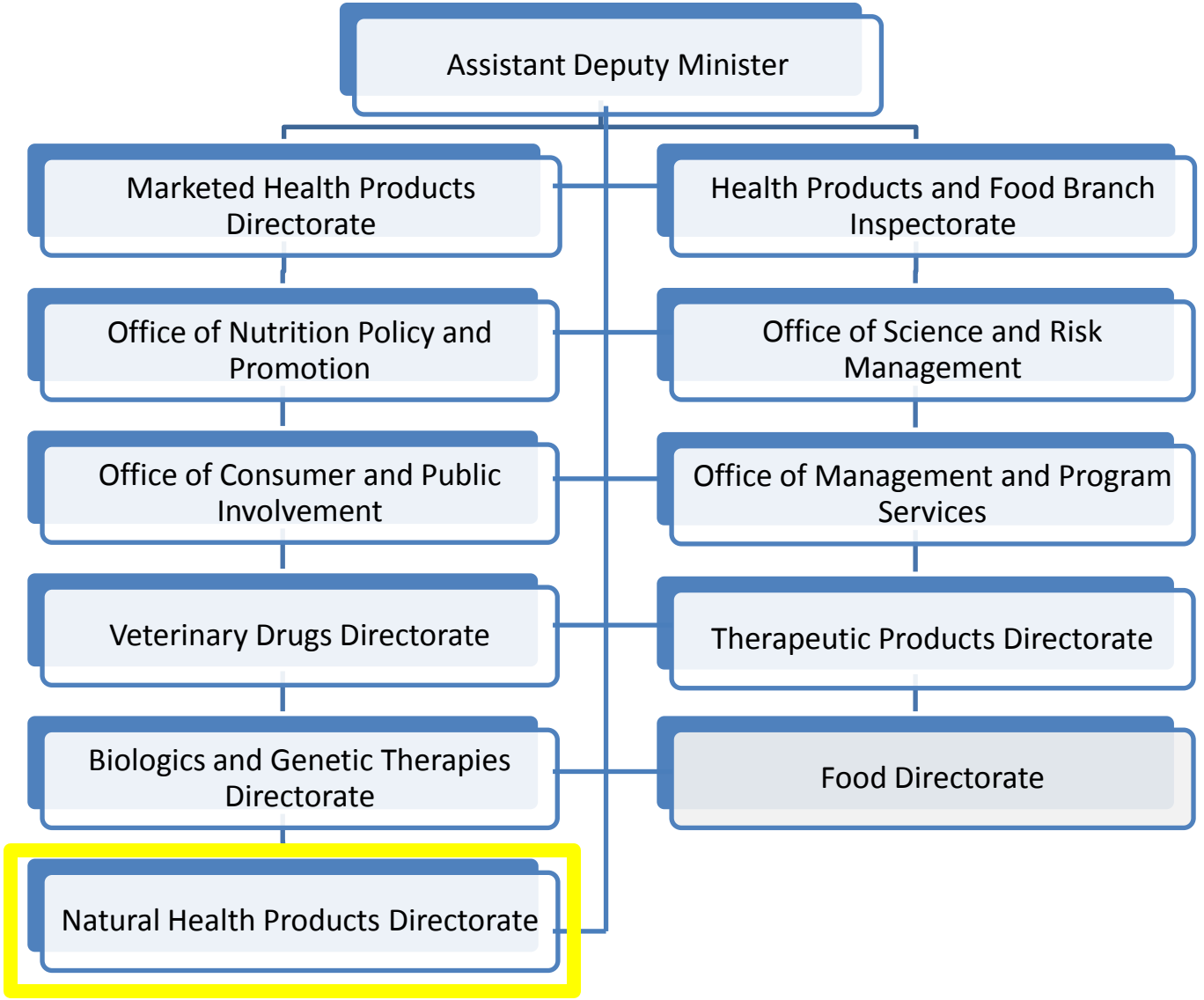
Brief Overview:

Canadian Regulations for NHPs

Health Products and Food Branch Overview



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Health Canada

NATURAL HEALTH PRODUCTS

- A **Natural Health Product (NHP)** contains one or more **medicinal ingredient(s)** responsible for a **physiological effect,** as outlined in **Schedule 1 of the *Natural Health Products Regulations (NHPR).***

Natural Health Products

- Vitamin and/or mineral supplements;
- Herbal and other plant-based health products;
- Animal-based health products;
- Probiotics
- Enzymes;
- Traditional medicines (ie/ TCM);
- Homeopathic medicines;
- Some personal care products which contain natural ingredients (ie/ shampoos, toothpastes).

KEY FEDERAL REGULATIONS - NHPS

- **NHPR** (***Natural Health Product Regulations***) (2004)

- **UPLAR** (***the Natural Health Product Unprocessed Product License Application Regulations***) (2010)

Repealed 2013

Regulatory Requirements

- Any finished NHP sold in Canada requires **pre-market approval**
- A **Product Licence Application (PLA)** must be submitted to Health Canada and reviewed by the NHPD.
- Issuance of a **Natural Product Number (NPN)** signifies market approval.

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REPEAL OF UPLAR

REPEAL OF NHP-UPLAR (2013)

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- **NHP-UPLAR** was repealed in February, 2013

- ✓ **Exemption Numbers (ENs)** will no longer be issued
- ✓ Moving forward, Canadian applicants will approach regulatory review using a **risk-based model**
- ✓ Product licensing decisions will be made in **180 days or less**

Repeal of NHP-UPLAR (2013)

3-Tiered Review System

- The development of more **Pre-Cleared Information (PCI)** means less time required for review
- Health Canada's goal is to have 99% of all applications reviewed ≤ 30 days
- 3-Tiered system based on the **level of certainty** associated with the product with a corresponding level of **pre-market review**

Repeal of NHP-UPLAR (2013)

3-Tiered Review System

Class 1

- **High** level of certainty
- Applicants fully supported by existing PCI
- **Current target**: 60 days
- **Proposed target**: 10 days
- Encompasses 75% of products

Class 2

- **Medium** level of certainty
- At least one claim and/or ingredient is supported by existing PCI
- **Current target**: 180 days
- **Proposed target**: 30 days
- Encompasses 20-24% of products

Class 3

- **Low** level of certainty
- None of the ingredients or claims are supported by existing PCI
- Current target: 180 days
- Proposed target: 180 days
- Encompasses 1-5% of products

Repeal of NHP-UPLAR (2013)

Risk-Based Approach to Health Claims

Low Risk

- NHPs used for the **treatment, cure, risk reduction or prevention of minor diseases or conditions**
- NHPs for **general health maintenance, support, or promotion that refer to modification or a biochemical or physiological function** of a nutritional nature or imply benefit to a minor disease or health condition.

Medium Risk

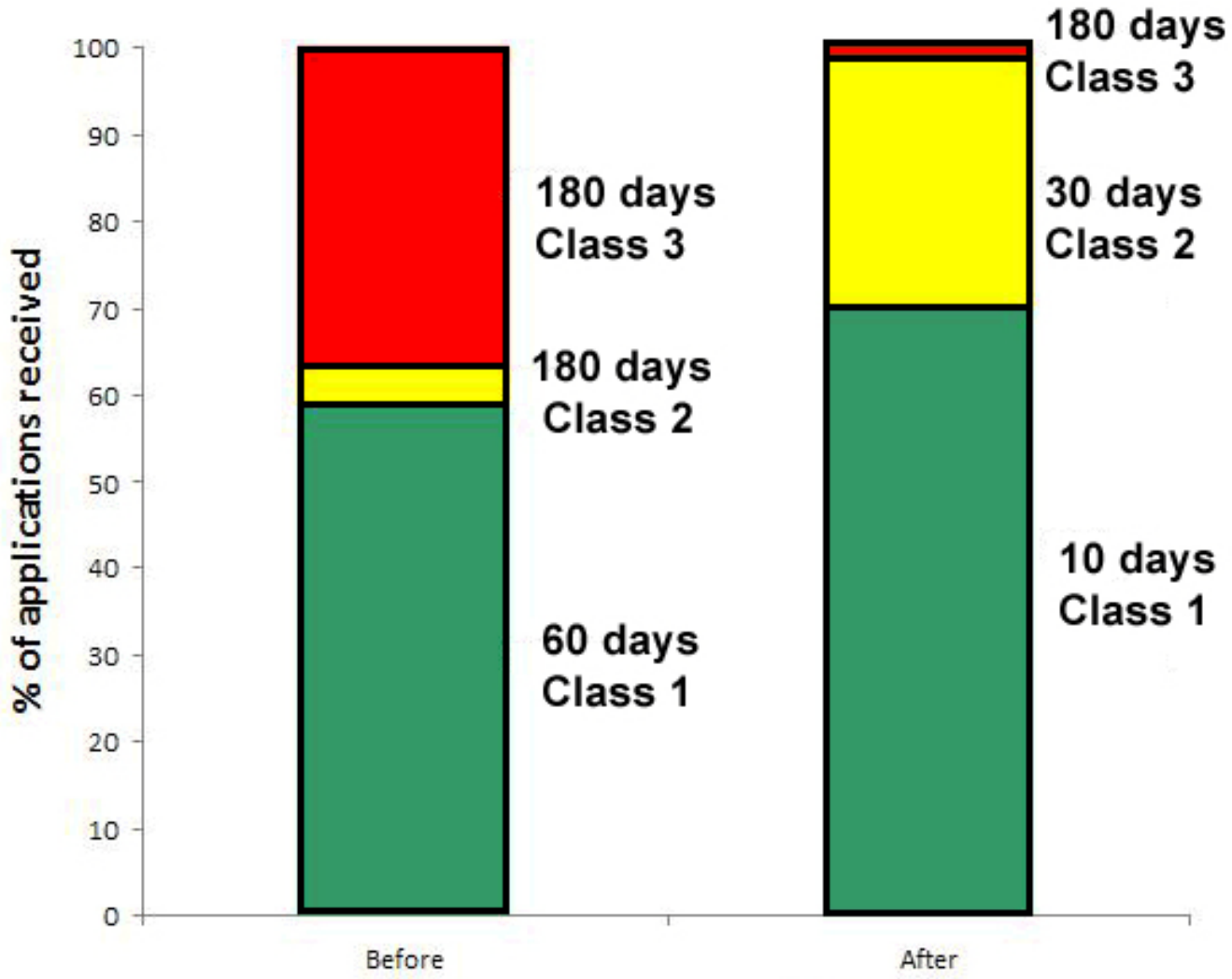
- NHPs used to **treat, cure, or prevent a major disease or health condition that is not naturally resolved in a timely manner** or could persist or worsen if not treated in a timely manner.

High Risk

- NHPs with the narrowest safety margin and effective dose range, as well as those used for the **treatment, cure and prevention of serious diseases**.

Repeal of NHP-UPLAR (2013)

Pre-Market Review

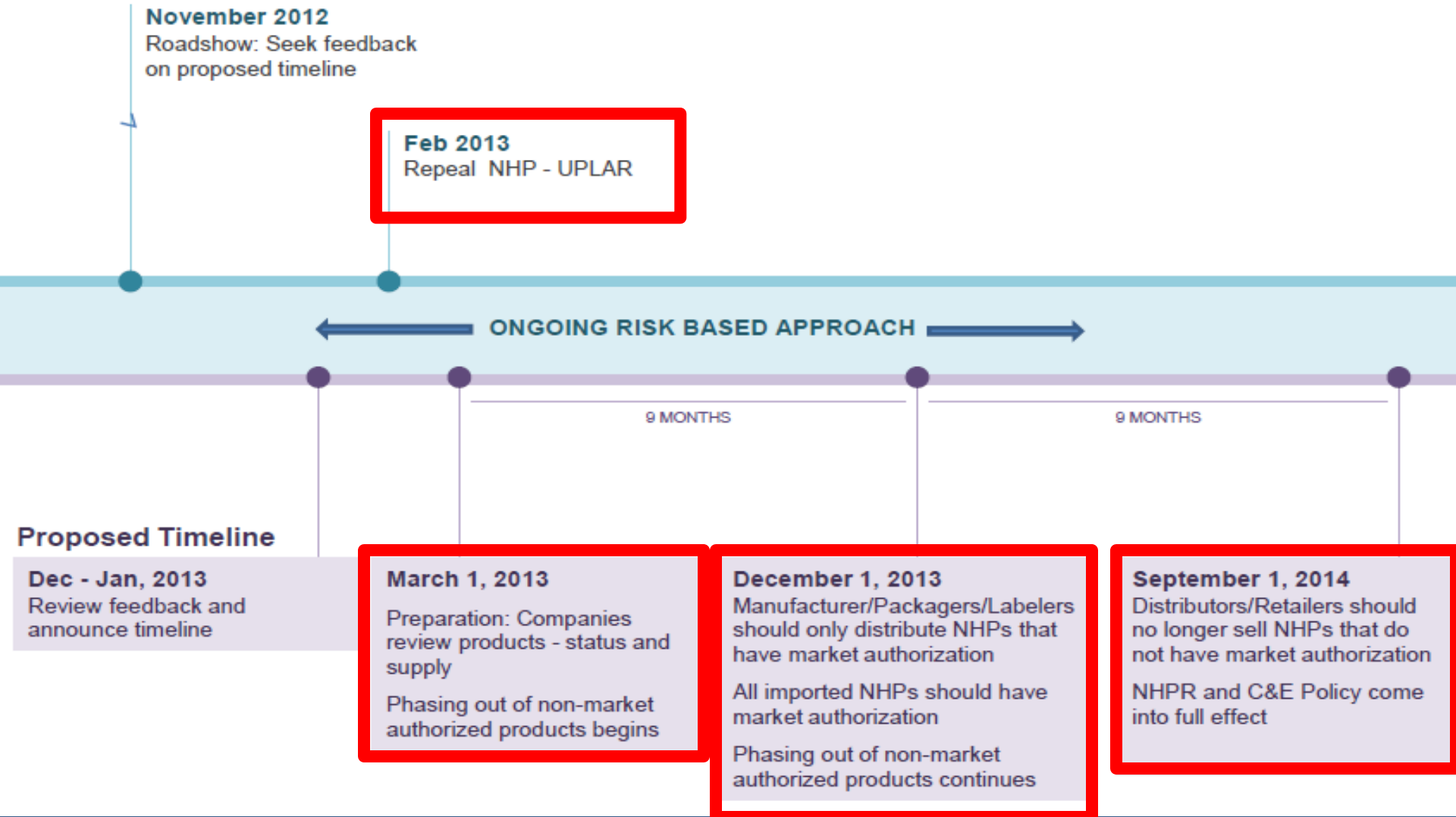


Compliance and Enforcement

- Natural Health Product **compliance** is enforced by the **Health Products and Food Branch Inspectorate [HPFBI]**

Repeal of NHP-UPLAR (2013)

Compliance and Enforcement



Repeal of NHP-UPLAR (2013)

Compliance and Enforcement

First Period

(March 1 – December 1, 2013)

- **Health Canada's goal #1**: to enhance awareness of the *NHPR* to ensure understanding and compliance
- **Health Canada's goal # 2**: to allow companies adequate time to phase out **non-market authorized products and non-compliant labelling**

Repeal of NHP-UPLAR (2013)

Compliance and Enforcement

Second Period

(December 1, 2013 – September 1, 2014)

- **Health Canada's goal**: all imported or manufactured NHPs should have **market authorization** and **compliant labelling**.
- Phasing out of non-market authorized products shall continue at the retail and distribution levels

Repeal of NHP-UPLAR (2013)

Compliance and Enforcement

Implementation

(September 1, 2014)

- **Health Canada's goal**: full completion of the transition period completed and all products should have **market authorization (NPN or DIN-HM)** and **compliant labelling**

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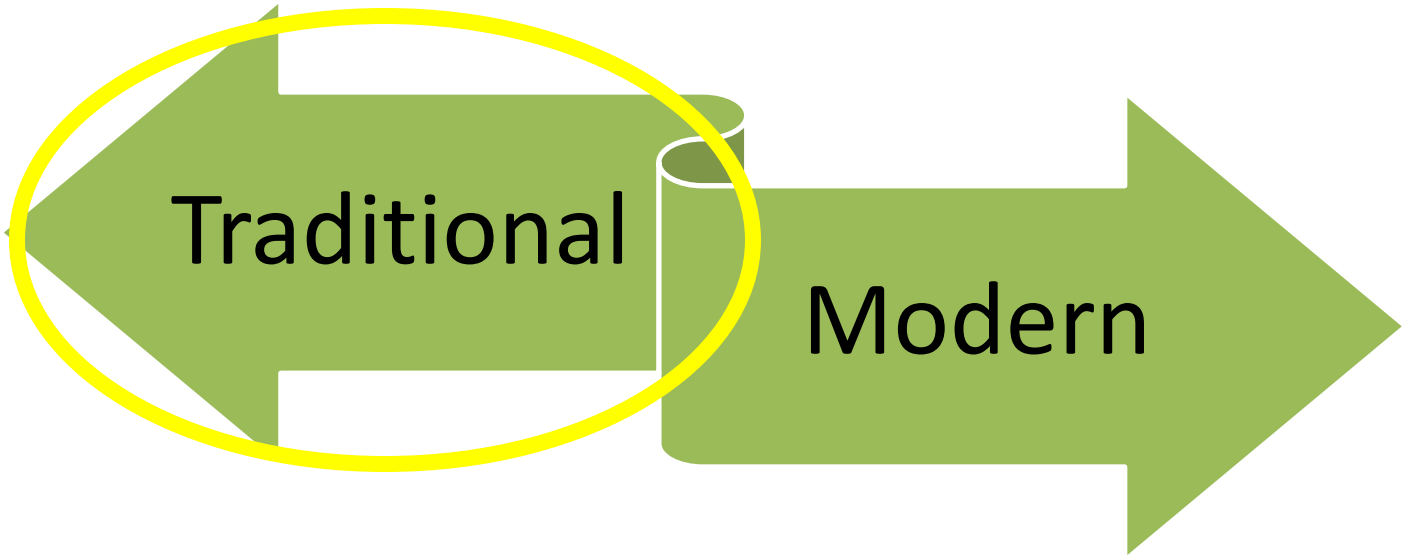
Revisions to Standards of Evidence for NHPs

Updated Regulatory Claims for Natural Health Products (2012)



World Health Organization [WHO]

Traditional Health Claims

Traditional Chinese Medicine [TCM]

Traditional Ayurvedic Medicines

Traditional Herbal [Eclectic] Medicines

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Pathway for Licensing Natural Health Products used as Traditional Medicines

*"**Provides information** to help product licence applicants **determine the evidence** (type and amount of data) **required** to support safety and efficacy of **Traditional medicines**."*

*"The intent of this document is to ensure that the levels of evidence are rigorous enough to **protect public health** and **maintain consumer confidence**, while providing industry with a **clearly defined pathway by which to bring NHPs formulated based on traditional principles to market**."*

Canada

Traditional Health Claims

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Demonstrates a long history of use
(e.g. two generations of safe traditional use)

Dose information and method of preparation must be exact to those traditionally used
(i.e., leaf, root, infusions, decoctions, tinctures, etc.)

Claim wording must be prefaced with qualifiers such as "Traditionally used..."

Substantiating Traditional Health Claims

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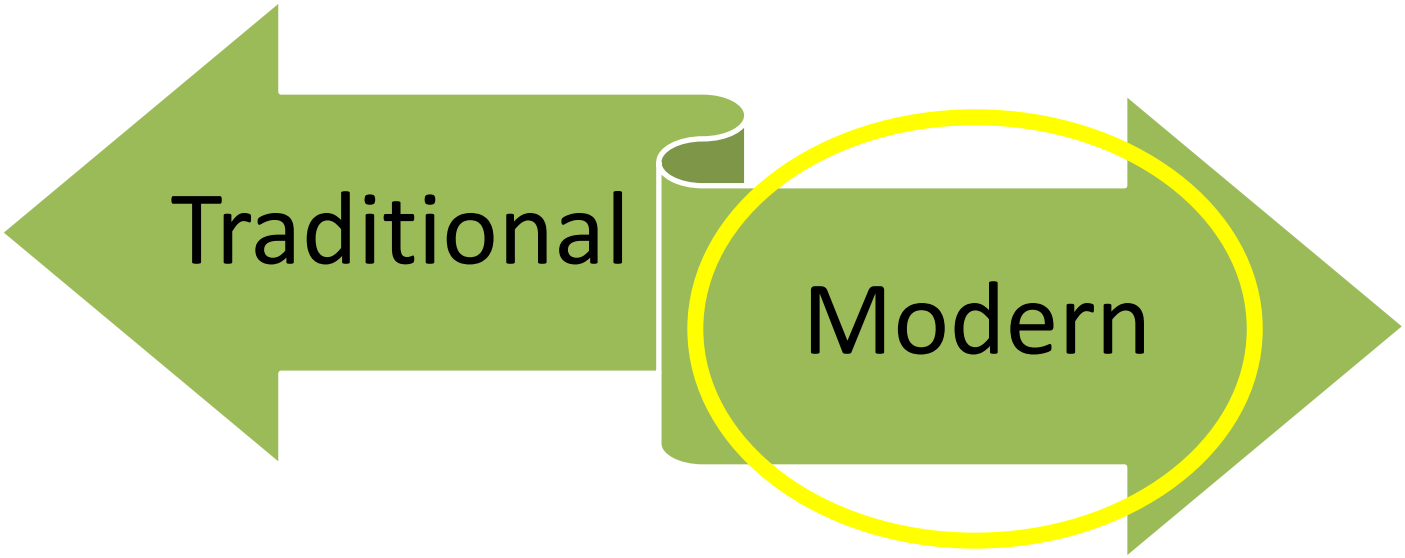
Safety

- **2 Independent references**
- History of use is important
- **Conditions of use in references should be comparable to those proposed**
- A search of the totality of evidence to ensure no new safety concerns are identified by findings outside of evidence for traditional use

Efficacy

- **2 Independent references**
- Pre-cleared information for traditional use; or
- Published peer-reviewed compilations
- Traditional claims divided into 2 sub-categories according to evidence
  - 1) Pharmacopoeial evidence alone
  - 2) Other types and/or combinations of references supporting traditional use

Updated Regulatory Claims for Natural Health Products (2012)



Modern Health Claims

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➢**Modern Health Claims** are based on evidence from a range of sources, including, but not limited to:

Clinical Studies

In vitro and **animal studies**

Pharmacopoeias

Textbooks

Peer-reviewed published articles

Regulatory authority reports

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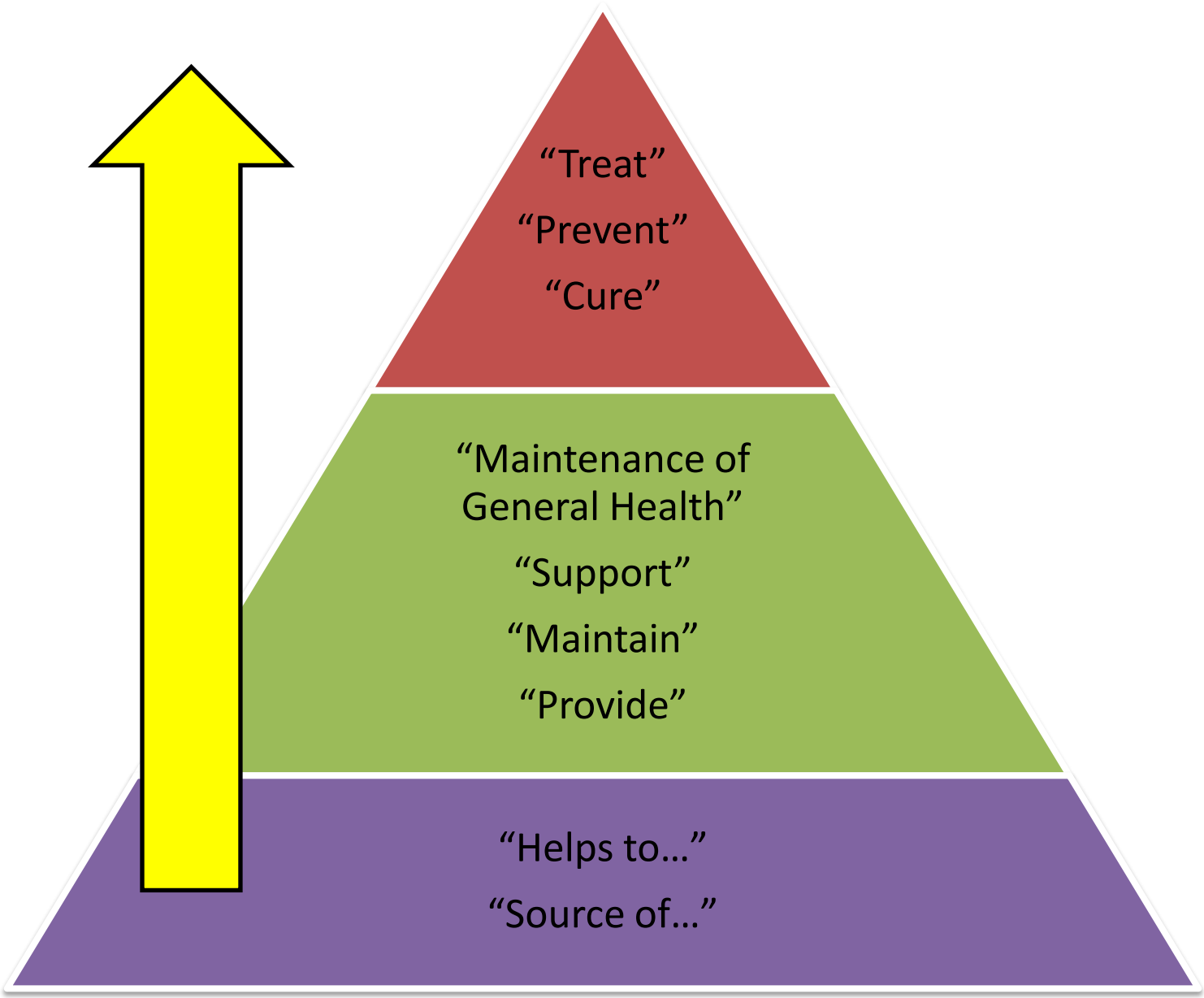
Pathway for Licensing Natural Health Products Making Modern Health Claims

*"**Provides information** to help product licence applicants **determine the evidence** (type and amount of data) **required** to support safety and efficacy of **NHPs making modern health claims**."*

*"The intent of this document is to ensure that the levels of evidence are rigorous enough to **protect public health** and **maintain consumer confidence**, while providing industry with a **clearly defined pathway by which to bring NHPs to market**."*

Canada

Health Claim Opportunities for NHPs



Risk-Based Approach to Health Claims

- Risks related to safety and efficacy include potential risks due to:
  - ✓ An ingredient's physical or chemical form
  - ✓ The **seriousness of the health claim** and the conditions of use implied; and
  - ✓ The health impact from lower than expected performance of the product
- Risk is **proportionate to the standard of evidence necessary** to support the safety and efficacy of the product

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Condition-Based Approach to Health Claims

Claims by Health Condition

Minor Disease/Condition (i.e., General Health Claims)

- **Products indicating treatment, prevention, risk reduction or cure of diseases/conditions or symptoms that:**
  - Are expected to naturally resolve in a timely manner
  - Or for which lower than expected performance of the product should not pose a major risk to the person taking it under the recommended conditions of use .

Examples:

✓*Helps to reduce recurrence of cold sores*
✓*Soothes sore throat*
✓*Helps relieve nervousness*
✓*Helps relieve minor burns including sunburn*
✓*Used as a mild sedative for jet lag*

Claims by Health Condition

Major Disease/Condition

- **Products indicating treatment, prevention or cure of diseases/ conditions that:**
  - Are not naturally resolved within a timely manner, *or*
  - Have potentially undesirable effects that may worsen or persist if proper treatment not pursued in timely manner.

Examples:

✓*Helps to enhance cognitive function /memory*
✓*Helps improve insulin sensitivity*
✓*Helps prevent macular degeneration*
✓*Helps maintain healthy blood/plasma cholesterol levels*
✓*Improves joint function in osteoarthritis of the knee*
✓*Helps reduce the risk of cardiovascular disease*

Claims by Health Condition

Serious Disease/Condition

- **For products indicating treatment, prevention or cure of diseases/conditions that:**
  - Require supervision by a health care practitioner, or are debilitating or potentially life threatening without effective treatment.
  - Treatment is vital to mitigate the health impact.

Examples:

✓*Helps prevent rheumatoid arthritis*
✓*For the treatment of high blood pressure*
✓*For the treatment of depressive disorders*
✓*For the treatment of cerebrovascular disease*

Claims by Health Effect

- General Maintenance of Health, Support &Promotion Claims
- Antioxidant Claims
- Treatment Claims
- Prevention Claims
- Risk Reduction Claims
- Cure Claims
- Diagnostic Claims

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SUBSTANTIATING MODERN HEALTH CLAIMS

Low Risk Category:	
Evidence type	**Considerations**
All acceptable minimum evidence requirements for the high and medium risk categories	N/A
Phase II clinical trials	One piece of evidence of equivalent ranking or higher is required to support efficacy. When the evidence provided to support the claim is methodologically weak, it should be supplemented to demonstrate consistency in results and plausibility.
Epidemiological studies	Evidence only meets minimum requirements for prevention and risk reduction claims. One pieces of evidence of equivalent ranking or higher are required to support efficacy.
Pilot and open label studies	Two pieces of evidence of equivalent ranking are required to support efficacy. The two different studies may be of equivalent or higher ranking. When the evidence provided to support the claim is methodologically weak, it should be supplemented to demonstrate consistency in results and plausibility.
Reputable textbooks	Textbook should reflect human in vivo data if the ingredient is an essential nutrient.
Demonstration of food use	Evidence can be used to support safety only.

Substantiating Modern Health Claims

Medium Risk Category:	
Evidence type	**Considerations**
All acceptable minimum evidence requirements for the high risk category	N/A
Systematic review other than meta-analysis	Conclusions should be based primarily on phase III trials, not phase II trials; primary evidence may be requested.
Published, peer-reviewed, detailed narrative reviews which cite detailed primary evidence	Detail should include: defining characteristics of the ingredient; primary endpoints/outcomes with statistical and clinical significance; the studied sub-population's age, gender, and health state; the dosing regimen and dosage form; the route of administration; the directions of use; any restrictions to study entry of participants based on interactions/risk; any identified adverse reactions
Phase II clinical trials	Two pieces of evidence of equivalent ranking or higher are required to support efficacy. When the evidence provided to support the claim is methodologically weak, it should be supplemented to demonstrate consistency in results and plausibility.
Epidemiological studies	Evidence only meets minimum requirements for prevention and risk reduction claims. Two pieces of evidence of equivalent ranking or higher are required to support efficacy.
Published compilations referring to traditional use	Evidence can be used to support safety only.

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Substantiating Modern Health Claims

High Risk Category:	
Evidence type	**Considerations**
NHPD published monographs	N/A
Phase III or phase IV clinical trials (randomized, controlled, well-designed)	For treatment, cure, and prevention claims or for health support claims when they imply treatment, cure, prevention, and risk reduction claims if the study is not multi-centred, at least two studies are required.
Meta-analysis (controlled and well-designed)	Conclusions should be based primarily on phase III trials, not phase II trials; primary evidence may be requested.
Prospective observational studies or combinations of one prospective study and one retrospective study	Evidence only meets minimum requirements for prevention and risk reduction claims. Two pieces of evidence of equivalent ranking or higher are required to support efficacy.
Evidence of a positive decision from another regulatory agency	Documentation in the form of an authorization letter or positive decision must be submitted that includes details on what was approved. A description of the regulatory requirements from the other regulatory agency should be provided.

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Regulatory Update:

Food-type NHP Transition

THE FOOD-NHP INTERFACE

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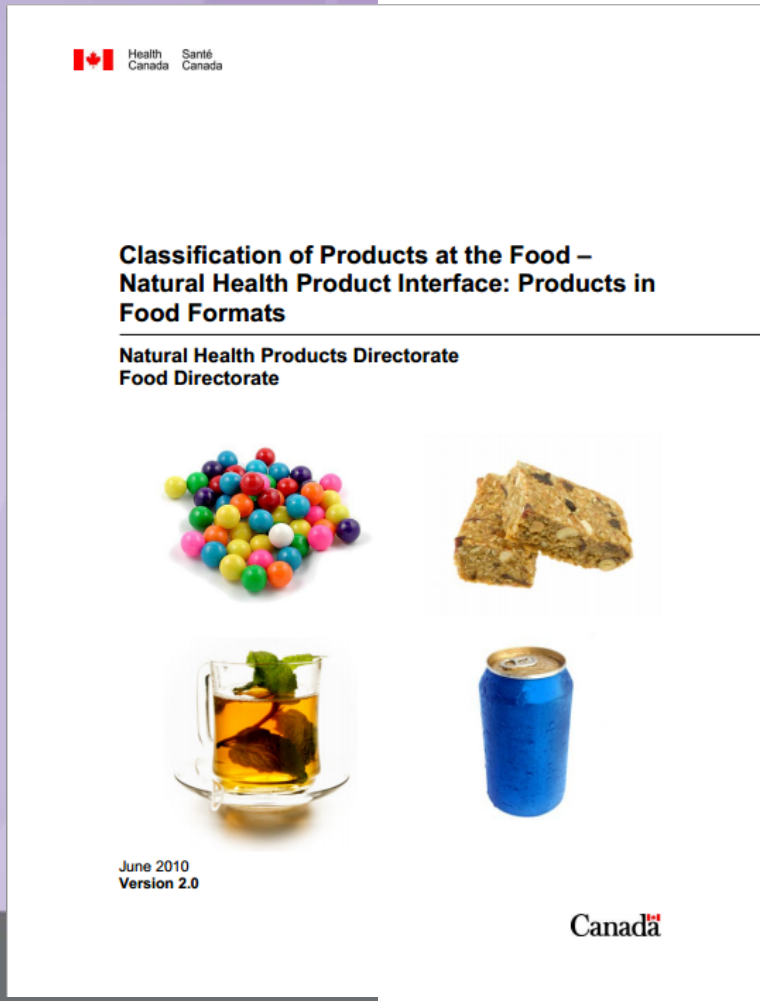
THE FOOD-NHP INTERFACE



- **Issues?**: The ***Natural Health Product Regulations*** were never intended to govern products in food format
- Classification of products at the **food-NHP interface** had become more tedious as innovation evolved.....many products appeared to have properties of both foods and of Natural Health Product!

The Food-NHP Interface

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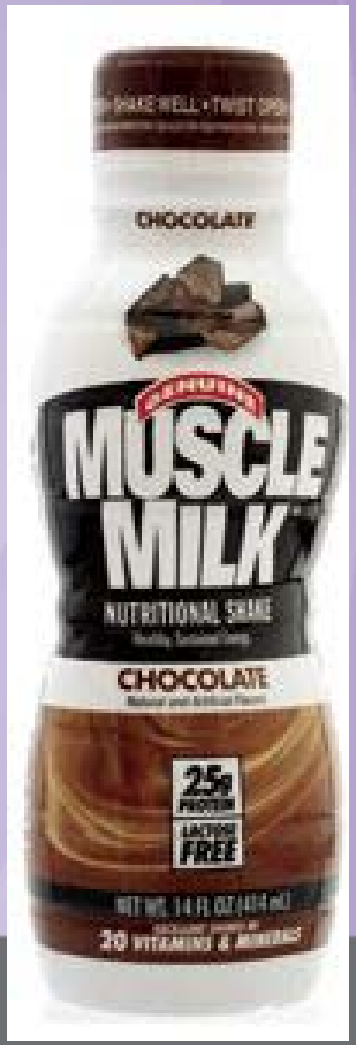


In deciding whether a product in food format was a natural health product, Health Canada took into account the following criteria:

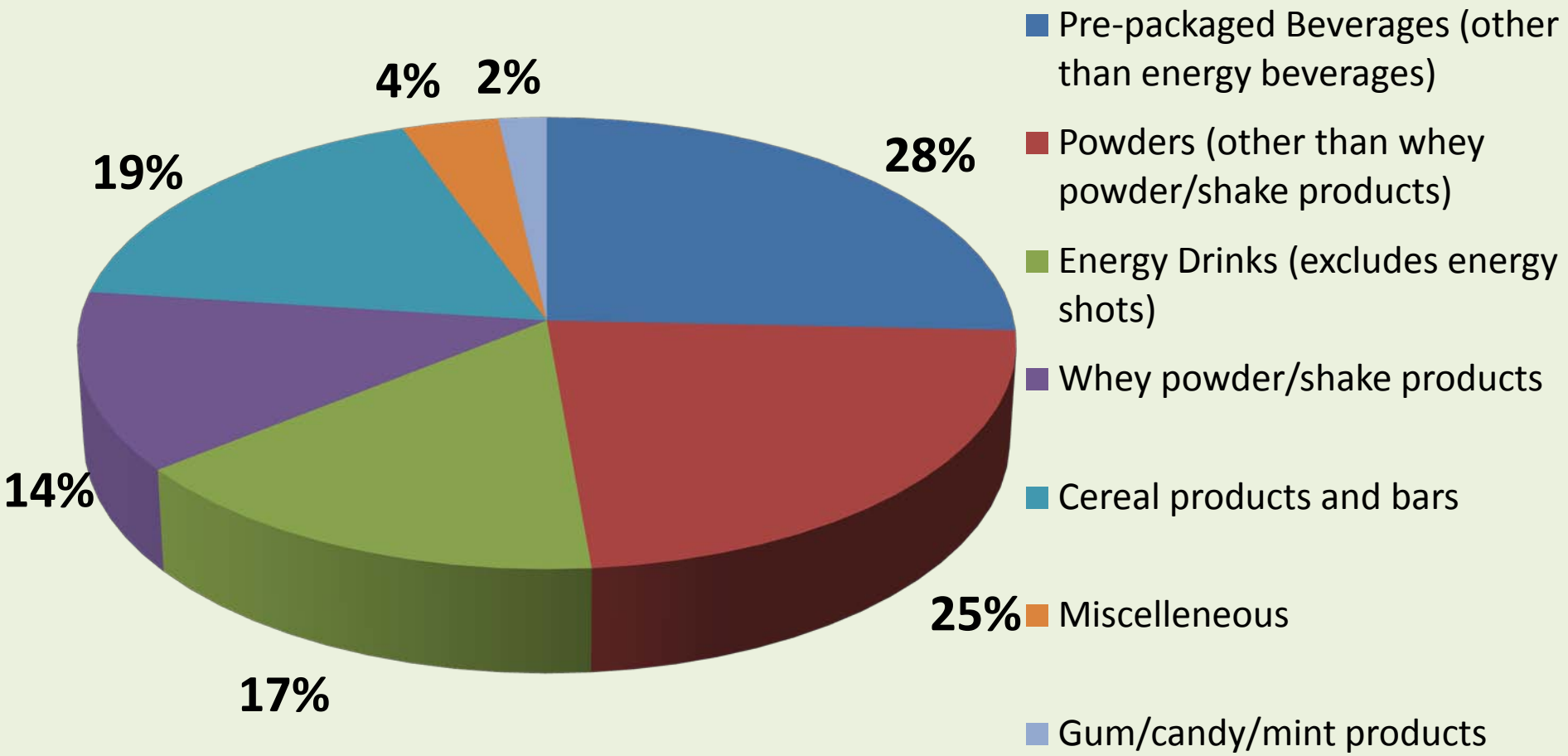
Product Composition	**Product Representation**	**Product Format**	**Public Perception and History of Use**

REGULATORY MODERNIZATION

- In 2011, Health Canada's Food Directorate began steps to transition the majority of **NHPs in food format** over to the **food regulatory framework.**

- This decision was deemed to be consistent with the intent of the ***Natural Health Product Regulations,*** which were **never meant to include food products**.

Food-type NHP Transition: Affected Product Types



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Food-type NHP Transition

- **Three Principles** have guided Health Canada's collaborative approach to affected industry members during this transition:

Categories of Products at the Food-NHP Interface

Category #1:

Compliant Foods

Category #2:

Products which require regulatory change to accommodate long-term

Category #3:

Products Which are Unsuitable to be Sold as a food

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General Guidance Document for Temporary Marketing Authorization for Foods

February 2012

Food Directorate

Health Products and Food Branch





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Category Specific Guidance for Temporary Marketing Authorization

Caffeinated Energy Drinks

March 2012

Food Directorate

Health Products and Food Branch





Canada

ENERGY BEVERAGES

- **Stipulations:**

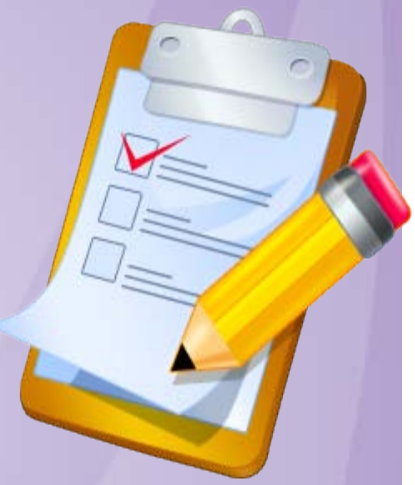
  - ✓ Established **minimum *and* maximum limits** for **caffeine content;**
  - ✓ Set **limits for inclusion of other ingredients** (ie/ vitamins and minerals) and develop a list of acceptable and unacceptable ingredients
  - ✓ **Requirement of all general food labelling provisions** (NFT, ingredient labelling, allergen labelling etc).
  - ✓ **Stipulated mandatory labelling statements**:
    - *Not recommended for children*
    - *Not recommended for pregnant or breastfeeding women*
    - *Not recommended for individuals who are sensitive to caffeine*
    - *Do not mix with alcohol*

Product Classification Decisions

- Following the transition of **Caffeinated Energy Drinks**, affected foods undergoing transition have been categorized as follows:

Pre-packaged, ready-to-consume drinks	• Juices • Waters
Conventional foods	• Bars • Cereals
Granulated and powdered products added to food or drinks	• Protein Powders • Drink mixes

Temporary Marketing Authorization (TMA)



- Foods sold in Canada must meet requirements set out in the ***Food and Drugs Act*** **(FDA)** and the ***Food and Drug Regulations*** **(FDR)** as they pertain to foods

- To permit sale of a food that **does not** meet the FDR normally requires a **regulatory amendment** (as in the case for Caffeinated Energy Drinks, or other food-like NHPs now classified as foods)

Health Canada's Approach to the Food-NHP Transition

Caffeinated Energy Drinks	Other Food-NHP Categories
Category-based classification	Same (behind the scenes)
Category-based assessment and TMAL issuance	Bulk, parallel assessment and non-serial TMAL issuance
Full assessment	Risk-based rapid triage screening (burden on FD to justify specific, identified health risk, triggering reformulation)
5-year TMAL	2-year TMAL
Full research protocol	Streamlined research protocol
Category-specific guidance ("monograph") before TMALs	Category-specific guidance ("monograph") to follow TMALs

KEY TRANSITION DATES

For products which did not require reformulation:

PROJECTED DEADLINE	
April 17, 2012	No new food products will be accepted into the NHP queue after this date.
April 26, 2012	Information Update Letters sent to Companies.
June 15, 2012	Deadline for companies to submit TMAL application.
Ongoing – Winter 2012	Simultaneous issuance of TMALs and NHP status revocation to eligible products.
March 2014	Deadline for meeting all food labelling requirements.

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www.hc-sc.gc.ca

"The end goal of the transition was to ensure that products that look like foods and are consumed as foods are regulated as foods. In doing so, Canadians are able to make more informed choices due to consistent nutrition information and labelling requirements."

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Regulatory Update:

Site Licencing

NHPD Site Licensing

- Health Canada's **Site Licensing process** helps to assure Canadians that all NHPs available on the market are of high quality.
- A NHPD Site License is required prior to the legal **manufacturing, packaging or labeling** of finished NHPs domestically produced for sale in Canada
- A NHPD Site License is also required prior to the **import** of finished NHPs produced outside of Canada (ie/ the U.S., China, India) and imported for sale.

SITE LICENSING.....PROPOSED CHANGE

- ✓ **Mandatory on-site inspection** for companies demonstrating **critical deficiencies** in GMP compliance;
- ✓ **Optional on-site inspection** by a recognized 3rd party to obtain a "seal of approval" for export and/or marketing purposes

A concept paper outlining the proposed approach to Site Licensing is **anticipated for consultation** in the summer of 2013.

International Trade Certificates (ITCs)

- An ITC speaks to the regulatory status of a NHP in Canada and/or the Canadian manufacturing, packaging, and/or labeling site
- An ITCs is meant to facilitate the export process for the Canadian NHP by assuring a **foreign regulatory authority** that an NHP exported to their country is legal for sale in Canada and meets the requirements under the NHPR
- Two types of ITCs are offered by the CHFA (Canadian Health Food Association):
  - ITCs for **Natural Health Products (NHPs)**
  - ITCs for **Good Manufacturing Practices (GMP) Compliance**

CHFA, 2013; Health Canada, 2013

INTERNATIONAL TRADE CERTIFICATES (ITCS)

- **Previously**: Health Canada voluntarily issued ITCs as a service to regulatees

- **Currently**: Health Canada has developed criteria for the issuance of ITCs by a 3rd party

http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/itc-attestation-cci-eng.php

Health Canada, 2013; CHFA, 2013

International Trade Certificates (ITCs)

- **3rd Parties authorized to issue ITCs** (as of June 1, 2013):

  - ✓ The **Canadian Health Food Association (CHFA)**;
  - ✓ The **Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA)**;
  - ✓ The **Consumer Health Products Canada (CHP Canada).**

Health Canada, 2013

International Trade Certificates (ITCs)

- The CHFA will strive to issue an ITC within a **30 day standard target**
- The CHFA may request additional documentation to confirm the information provided in the ITC application form
- Delays in providing this information may result in longer delivery timelines
- Appropriate fees must accompany the application form

Fee Structure	CHFA Member*	CHFA Non-Member
Regular Service (up to 30 days)	$179	$299

CHFA, 2013

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Regulatory Update:

Clinical Trials for NHPs

CANADIAN REGULATORY FRAMEWORK

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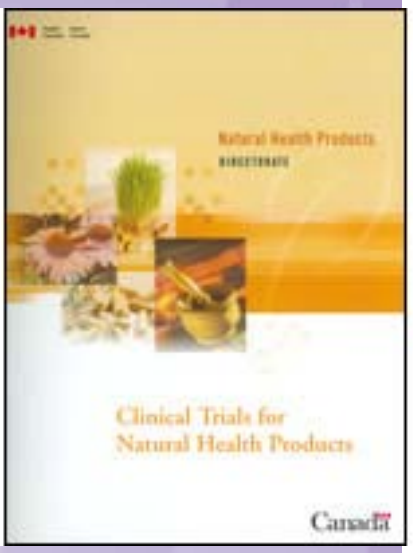
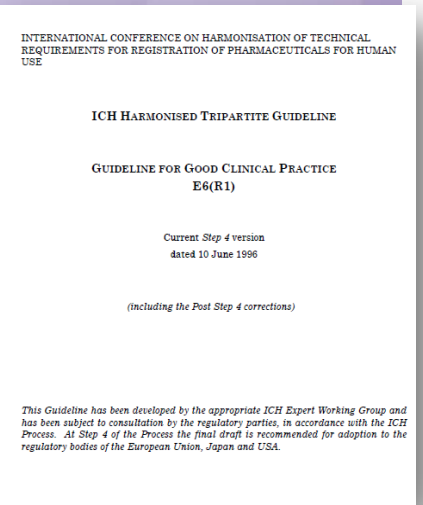


- In 2005, Health Canada issued a Guidance Document for ***Clinical Trials for Natural Health Products***.
  - ➢ This Guidance document was intended to provides directive to stakeholders to ensure compliance with the regulations.



INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE
E6(R1)

Current *Step 4* version
dated 10 June 1996

(including the Post Step 4 corrections)

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

- These guidelines defer to international standards for clinical trials, namely the **International Conference on Harmonization** **[ICH]** guidance for ***Good Clinical Practices*** **[*GCPs*]**.

Clinical Trials for NHPs

Clinical Trial Applications [CTAs]

- **Health Canada** requirements for a NHP-CTA include elements of the **Common Technical Document [CTD]**

- **3 modules to the CTA:**
  - **Module 1:** Administrative Info
  - **Module 2:** Quality Overall Summary (QOS)
  - **Module 3:** Quality Data (investigational product and placebo)

Clinical Trials for NHPs

New Self-Care CTA Classification

- **Currently**, Clinical Trial Application (CTA) applicants send regulatory submissions to Health Canada's NHPD, who will then forward it if necessary to the appropriate directorate (BGTD or TPD) if necessary;

- **In the future**, applicants will classify their CTA according to self-care status

Clinical Trials for NHPs

New Self-Care CTA Classification

- As of August 1st 2012, CTAs investigating NHPs for a purpose that is **not consistent with self-care** will **not be reviewed** at NHPD

  ✓ Biologics not appropriate for self-care will be directed to Health Canada's **BGTD (Biologics and Genetic Therapies Directorate)**:

  ✓ All other NHPs not appropriate for self-care will be directed to Health Canada's **TPD (Therapeutic Products Directorate)**

- Transition of a CTA to TPD or BGTD does **not change the regulatory oversight or evidence requirements for the CTA**

Clinical Trials for NHPs

New Self-Care CTA Classification

Self-Care	Non Self-Care
✓Insomnia	✓Cancer
✓Digestive health	✓Cystic fibrosis
✓Fatigue	✓Angina
✓Weight-loss	✓Major depression
✓Common cold	✓Huntington's disease
✓Seasonal allergic rhinitis	✓HIV
✓Peri-menopausal symptoms	✓Alzheimer's disease
✓Atopic dermatitis	✓Cirrhosis
✓Osteoarthritis	✓Parkinson's disease
	✓Muscular dystrophy

Clinical Trials for NHPs

Transition of SAE Reporting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ADVERSE REACTION REPORT FORM FOR CLINICAL TRIALS
Natural Health Products Directorate

- As of November 2012, the NHPD will no longer accept Serious Adverse Event (SAE) reports
- SAE reports must be sent to the appropriate directorate (TPD or BGTD, respectively)

Clinical Trials for NHPs

Clinical Trials Database

- Launched May 29, 2013
- Information on the database:

Medical condition	Protocol title	Drug name	Sponsor's name
Study population	Trial status	No objection letter date	Study end date
	Study start date	Protocol and control number	

nutrasource diagnostics inc.

THANK YOU!

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