



# Lavender in Food, Cosmetics, Natural Health Products, and Drugs

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Susan Abel, Principal  
Food Preventive Control Services



# Classifying Products

- Canada has reasonably clear guidance on when a product is a:
  - Food, Supplemented Food
  - Cosmetic
  - Natural Health Product
  - Drug
- The distinction is based on **CLAIMS, INGREDIENTS, PRODUCT SIZE** and **HISTORICAL USE**
- Canada now regulates Natural Health Products under DRUGS
  - Guidance often groups over-the-counter drugs with Natural Health Products under the umbrella term, “drugs”

# Classification and Claims

- Food and Supplemented Food have severely limited claims
  - Health Claims – defined in regulation
  - Function Claims
- Cosmetics have restricted claims:
  - “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.”

# Classification and Claims

- Natural Health Products

- Natural Health Products are used for:

- (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.

- Monographs are Health Canada documents that define where a medicinal ingredient can be used, how much can be used, claims, as well as cautions, and warnings that must be adhered to on labels

# Classification and Claims

- Drugs

- Are used to **treat or prevent** diseases or symptoms
- Also have monographs
  - Category IV monographs for certain types of:
    - Acne
    - Sunscreen
    - Medicated skin care products
    - Diaper rash treatment
    - Anti-dandruff products
    - Antiseptic skin cleansers
    - Athletes foot treatments
    - Throat lozenges

# Health Canada Defines “CLAIM”

- A claim can be a word, a sentence, a picture, a symbol, a paragraph or an implication on product labels, package inserts or advertisements. Together, these claims are used to create a net impression of what the product is and does.
- The presence of an ingredient, or its concentration, may make the product unsuitable for classification as a cosmetic or as a drug/NHP.
- Products that are administered through **ingestion**, **inhalation**, or by **injection**, with the sole exception of tattoo ink, are not cosmetics.

# Health Canada Defines “INGREDIENTS”

It's not just what you say, but what you use in your product:

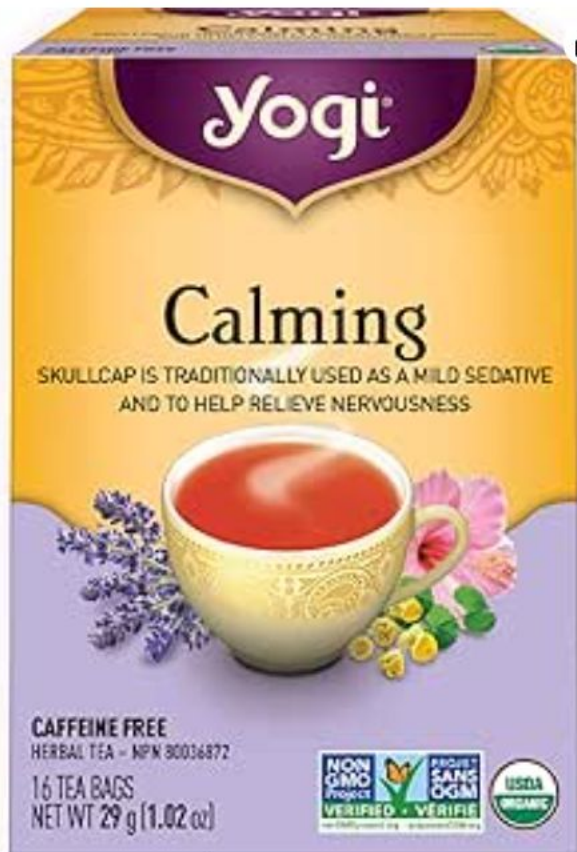
- Does the product's **composition** suggest it is an agent for treating, diagnosing, preventing, or curing disease; or restoring, correcting or modifying organic functions in human beings?

# Health Canada Defines “PRODUCT SIZE and HISTORICAL USE”

- A single dosage unit of less than 90 mL is a Natural Health Product rather than a food.
- A drink of more than 175 mL is perceived to be a beverage (food)
- A historical pattern of use as a food or if the public perceives the use of a product in the marketplace as a food is a food



# Claims – Natural Health Product vs Food



# Claims – Cosmetic vs Natural Health Product



## NON-THERAPEUTIC CLAIMS

- Protects/Relieves/Soothes dry skin
- Cools/Soothes skin after shaving/epilation
- Cleans/Cleanses skin
- Prevents/Protects against nicks / cuts/ irritation during shaving

## THERAPEUTIC/HEALTH CLAIMS

- Calms/Protects/Relieves/Soothes abrasions/bites/insect bites/ cuts/nicks/irritated skin/ inflamed skin/rashes/ sunburns\*
- Numbs
- Treats burns/infections
- Any impression or reference to pain or irritation

\*Refer to Health Canada's *Medicated Skin Care Products* Monograph:  
[http://webprod.hc-sc.gc.ca/nhp/nd-bdipsh/atReq.do?atid=skin\\_peau&lang=eng](http://webprod.hc-sc.gc.ca/nhp/nd-bdipsh/atReq.do?atid=skin_peau&lang=eng)

# Claims – Cosmetic vs Natural Health Product



  
**LAVENDER**  
Gentle & balancing

  
**ROMAN CHAMOMILE**  
Calming & relaxing

  
**CLARY SAGE**  
Supportive & euphoric



A gentle and purifying body wash crafted with organic botanicals invigorate and refresh the senses without leaving skin dry.



# Case Study – Brand Names, Puffery, and Fraud

## **Tonic foods**

The term "tonic" has been used in the past to describe a class of foods believed to have the power to restore a normal degree of vigour or to restore good health. Today, this term should not be used, as no food can be described as an effective tonic. However, exceptions may be made due to long term use, such as "tonic water".

# Brand Names, Puffery, and Fraud

If a representation could influence a consumer to buy or use the product or service advertised, it is material. To determine whether a representation is false or misleading, **the courts consider the "general impression" it conveys, as well as its literal meaning.**



Remedy Organic Kombucha Cherry Plum

puffery often includes a value word that is a matter of opinion

a false ad contains a deliberate falsehood.

Don't make a performance claim unless you can prove it, even if you think it is accurate. Testimonials usually do not amount to adequate proof.

# Case Study – Wellness Beverages

Brewed Botanical Blend (Purified Sparkling Water,  
Organic Tea Blend (Moringa Oleifera Leaf\*, Ashwagandha  
Root\*, Licorice Root\*, Turmeric Root\*), Orange Extract,  
Citric Acid \*Certified Organic Ingredient

2013-11-27	Horseradish tree ( <i>Moringa oleifera</i> ) leaf powder	A powder made from horseradish tree leaves	Ingredient has a history of safe use as a food
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Ashwagandha root extract	Not permitted for use in Supplemented Foods	the data insufficient to establish acceptable conditions for use as a supplemental ingredient in supplemented foods there is no history of use as an ingredient added to food
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# Case Study – Aromatherapy Monograph



## What the RULES

Topical

Inhalation

Topical and inhalation

Used in aromatherapy as a nervine/calming.

Used in aromatherapy to help relieve headache.

Used in aromatherapy as a carminative/antispasmodic for symptomatic relief of digestive discomfort.

Used in aromatherapy to help relieve colds/cough.

## What the PACKAGE says:

Just a few drops in your diffuser infuse your surroundings with a calm

Beyond its captivating fragrance, Pure Lavender Essential Oil offers a wealth of therapeutic benefits, from promoting relaxation and reducing stress to soothing skin irritations.

nūvō  
wellness





- Food
  - CFIA Licence if you sell outside Ontario
  - No notification or registration of the food
  - Limited Claims
- Supplemented Food
  - CFIA Licence if you sell outside Ontario
  - Special rules for ingredients and labelling and CLAIMS
  - No notification or registration required
- Natural Health Product
  - Needs site licence to manufacture it
  - Needs product registration
  - No fees – YET
  - Slow – up to 2 years
  - Defined claim options
- Cosmetics
  - No licence or registration needed
  - Limited claims
  - Health Canada notification required

# Cosmetics are for topical use only

## **Cosmetic**

- Topical use:
  - Cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes

## **Natural Health Product**

- Topical (local application and body massage): Cream; Gel; Liquid; Lotion; Ointment; Solution
- Topical (bath and compresses): Liquid (in a dropper bottle)
- Inhalation: Liquid (in a dropper bottle)
- Topical and Inhalation: Liquid (in a dropper bottle)

# Cosmetics Notification

- **All** cosmetics sold in Canada must be notified to Health Canada.



Cosmetics can be applied to the skin around the eyes but products applied directly into the eyes are not cosmetics.

With the sole exception of tattoo ink, products that are administered through ingestion, inhalation or injection (such as, intramuscular, subcutaneous or intravenous) **are not classified as cosmetics.**

# Cosmetics Notification

- Manufacturers and importers must notify Health Canada **within 10 days after they first sell** a cosmetic in Canada.
- Failure to notify may result in a product being denied entry into Canada or removed from sale.

# Cosmetics Notification

- Online form:

- <https://healthycanadians.gc.ca/appraisal/radar/CPS-SPC-0007.08.html>

- Relatively user-friendly, but each ingredient is manually entered

- You MUST know the formula

- Only need to notify ONCE or if there are CHANGES

Enter one ingredient per line using the International Nomenclature of Cosmetic Ingredients (INCI) where possible. Click the "Search Ingredient" button to validate the ingredient. The status of the ingredient will appear in the "Search Result" field. Any condition that applies to the ingredient will appear in the "Condition of Use" field. If the status of the ingredient is "Unknown" or "Not found" check the spelling, punctuation, and for extra spaces. If entering the exact concentration, enter the same value in both the "Lower Concentration %" and "Upper Concentration %" fields. You may also select a range code from the drop-down list and the lower and upper concentrations will be automatically entered. Check "May Contain" if the ingredient is variable.

Ingredient 1

\* Name (required)

May Contain ☐

Range Code

Select Range Code

\* Lower Concentration % (number between 0 and 100, format: 99 or 99.999999) (required)

\* Upper Concentration % (number between 0 and 100, format: 99 or 99.999999) (required)

Search Result

Condition of use

Add Ingredient



Here to help!  
Susan Abel, Principal  
905 373 2288  
[Susan.abel@food-safety.ca](mailto:Susan.abel@food-safety.ca)

