Health Canada Santé Canada

Canada

Overview of the Regulation of Cosmetics and Modernizing the Regulation of Self-Care Products in Canada

November 24, 2017

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Agenda for Today's Session

1:00 – 1:05 pm	Welcome and Review of Agenda
1:05 – 1:25 pm	Part 1: Overview of the Regulation of Cosmetics
1:25 – 1:45 pm	Part 2: Modernizing the Regulation of Self-Care Products in Canada
1:45 – 1:55pm	Question and Answer Period
1:55 – 2:00pm	Closing Remarks

Part 1:
Overview of the Regulation of Cosmetics

Overview for Cosmetics

- Outline of the requirements to sell cosmetics in Canada:
  - Legislative authority
  - Definition of "cosmetic“ (classification)
  - Product labelling
  - Product notification
  - Safety of ingredients
  - Other requirements

- Working with Product Safety Inspectors

- References and Guidance for Industry

Legislative Authority

- Program's authorities come from
  - *Food and Drugs Act* (F&DA) and *Cosmetic Regulations*

Cosmetics also governed by:

- *Consumer Packaging and Labelling Act* (CPLA) and Regulations
  - Net weight declaration and false and misleading claims

- *Canadian Environmental Protection Act* (CEPA,1999)
  - New and existing cosmetic ingredients

Food and Drugs Act (F&DA)

- Defines cosmetic, drug, food and medical device (s.2)
- Provides general safety requirement for cosmetics (s.16)
  - No person shall sell any cosmetic that
    - has in or on it any substance that may cause injury to the health of the user
    - is adulterated
    - was manufactured, prepared, preserved, packaged or stored under unsanitary conditions

- Gives powers to the inspectors to search premises, take samples, seize products, stop sale, etc.

The *Cosmetic Regulations*

- *Cosmetic Regulations* outline requirements for:
  - Import
  - INCI ingredient labelling
  - Directions for safe use
  - Warnings/cautions
  - Notification
  - Some specific ingredient requirements

- Amended from time to time based on changing circumstances
  - Notification of cosmetics became mandatory in 1978
  - Mandatory disclosure of ingredients on product labels in 2006

Cosmetic vs Drug

- “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.
- To determine if a product is a cosmetic or a drug, one must look at:
  - the **representation of** the product
  - the **ingredients** present in the product
- Cosmetics do not treat/prevent disease, disorders or modify organic function of the body
  - Includes symptoms of a disease
- Cosmetic products must have an appropriate cosmetic function

** “Drug” means Therapeutic Product (non-Rx or Rx) or NHP*

Why are claims important?

- A large component of product classification under the F&DA is how it is represented for use i.e. the claims associated with the product.
- Representation includes what is on the label and all advertisement/promotion associated with the product
- Changing a claim could cause a cosmetic to be classified as a drug or vice-versa, and therefore subject to different regulations under the F&DA.

See: Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims

Labelling Requirements

- Cosmetic function
- Directions for safe use
- Warnings
- Requirements for cosmetics in pressurized containers
- Special packaging
- Product identity and the responsible company
- INCI Ingredient labelling

Directions for safe use (s. 24 of Cosmetic Regs)

(1) The label of a cosmetic that presents an avoidable hazard must include directions for safe use.

(2) For the purpose of subsection (1), “avoidable hazard” means a threat of injury to the health of the user of a cosmetic that can be

(a) predicted from the cosmetic’s composition, the toxicology of its ingredients and the site of its application;

(b) reasonably anticipated during normal use; and

(c) eliminated by specified limitations on the usage of the cosmetic.

Warnings

- Some ingredients or products require warnings to alert consumers of a special hazard
  - e.g. Cosmetics containing Alpha hydroxy acids (AHAs) require a warning to alert consumers about sun safety when using these products

- See the Cosmetic Ingredient Hotlist for ingredients that may require warnings

Pressurized Containers

- Must meet the requirements of the *Consumer Chemical Container Regulations* (CCCR) as they read on Sept 30, 2001.

- These containers require a pressurized hazard symbol along with the appropriate signal word and hazard statement

- Also may need a flammability hazard symbol, depending on whether product is tested as flammable, the length of the flame and whether there is flashback, along with the appropriate signal word and hazard statement

Special Packaging

- Mouthwashes: require tamper-evident security packaging
- Security packaging is not required for any other cosmetic at this time
- Child resistant containers required for products that contain methyl alcohol, potassium bromate and sodium bromate

Product Identity and Manufacturer

- *Consumer Packaging and Labelling Act* and Regulations require:
  - Declaration of net quantity on inner and outer label
  - Common name of the product on outer label
  - Name and address of dealer on outer label

- *Cosmetic Regulations* complement this by requiring on inner label
  - Product identity and name and address of “manufacturer” (same as “dealer” under the CPLA)

Ingredient Labelling

- List of ingredients must be in INCI nomenclature and disclosed on outer label
- Descending order of predominance, except
  - Ingredients at concentration of less than 1%
  - Colouring agents
- In case of colour cosmetics, can use the term “May contain/Peut contenir” or “±”
- Incidental ingredients (not present in final formulation) do not need to be listed as ingredients
- See the Guide to Cosmetic Ingredient Labelling

Ingredient Labelling (2)

- Fragrance is denoted by the term “parfum” and flavour by the term “aroma”

- The term “Ingredients” or “Ingredients/Ingrédients” does not need to precede the list of ingredients.

- Botanicals listed by genus and species or exactly as named in the Cosmetic Ingredient Dictionary:
  - Acceptable terms for peach fruit extract would be “Prunus Persica” or “Prunus persica (Peach) Fruit Extract”
  - Unacceptable versions “Prunus persica (Peach)”

Ingredient Labelling (3)

- Where a product has only one label, all requirements must be on that label.

- Where product has an inner and outer label, ingredients not required on inner label.

- Where product has only one label and is too small to put on main label, can put ingredients on tag, tape or card that is affixed to the container of package.

- See Guide to Cosmetic Ingredient Labelling: **4.1 Small Containers**.

Bilingual Requirements

- For products sold anywhere in Canada, all labelling required by the *Cosmetic Regulations* (except INCI) must be in English and French

- Label would not be considered to meet the labelling requirements unless all required info is in both official languages

- More information on the Office québécois de la langue française (OQLF) website

Cosmetic Notification

- Post-market: within 10 days of first sale of the product in Canada (can be notified before as well)

- Required for new products, amendments to original notification such as formulation changes and discontinued products

- Notification information includes:
  - manufacturer(s)/importer
  - function
  - physical form
  - formulation

- No fee

Cosmetic Notification (2)

- Not a product evaluation or approval procedure

- Acceptance of the completed form or labels by Health Canada does not constitute, in any way, agreement that the product is a cosmetic or in compliance with all regulatory requirements.

- Manufacturer or Canadian distributor has the responsibility of ensuring that a cosmetic meets the requirements of the *Food and Drugs Act* and the *Cosmetic Regulations*.

Cosmetic Notification (3)

- Health Canada has an online Cosmetic Notification Form

- The Form allows you to:
  - Validate ingredients before submitting
  - See the status of the ingredients
  - Submit your notification form online

- Instructions on how to fill the form can be found in the Guidance document: How to complete a Cosmetic Notification Form, on the Health Canada website.

Cosmetic Ingredient Hotlist

- Currently 500+ substances on list. Not exhaustive.

- Originally based on EU's Cosmetics Directive's Annex II & III

- Composed of ingredients:
  - known to cause adverse health effects, or
  - which are limited to pharmaceutical applications

- Updated on a regular basis

How are ingredients identified for review?

- New scientific information
- New regulatory decisions (domestic or international)
- Consumer complaints/injuries
- Media
- Industry request
- Other concerns

Outcome of Assessment

- Add to Hotlist: **Prohibit**

- Add to Hotlist: **Restrict** through:
  - Concentration
  - Method of application (e.g. aerosol vs liquid)
  - Type of product used (e.g. rinse off vs leave-on product)
  - Addition of cautionary statement
  - Child-resistant packaging
  - Evidence of Safety

- No concern with current use in cosmetics

Next Steps of Hotlist Updates

- Notice to Stakeholders
- Consultation (60-day comment period)
- Evaluation period
- Hotlist update and Communication
- Compliance promotion and enforcement

- See the Cosmetic Ingredient Hotlist webpage for more details

Compliance & Enforcement (C&E)

Working with an inspector:

- Product Safety inspectors enforce the *Cosmetic Regulations* and cosmetic related sections in the *Food and Drugs Act*
- Powers are in the *Food and Drugs Act* and *Cosmetic Regulations*
  - Can inspect premises where cosmetics sold, manufactured or stored, and take samples for testing or photographs
  - Can recommend refusal of imports or allow a non-compliant product to be imported to be brought into compliance under their supervision
  - Can seize cosmetic products

C&E

Enforcement actions taken will depend upon:

- the risk to health or safety,
- the likelihood that the same problem will reoccur,
- the compliance history of the company,
- whether the company acted with indifference or premeditation,
- the degree of cooperation offered by the company,
- Branch and Programme priorities and available resources,
- the chances of success of the enforcement action being contemplated, and
- the need to maintain public confidence.

The HC Website: Guidelines to Help You

- Guidelines for Cosmetics Manufacturers, Importers and Distributors
- Guidance document: How to Complete a Cosmetic Notification Form
- Guidelines for the Labelling of Cosmetics
- Guide to Cosmetic Ingredient Labelling
- Labelling Requirements for Cosmetics in Pressurized Containers
- Guidance on the Classification of Products at the Cosmetic-Drug Interface
- Cosmetic Ingredient Hotlist
- Act and Regulations, etc.

https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics.html

Contact us

- Cosmetics Program:

  cosmetics@hc-sc.gc.ca

  cosmetiques@hc-sc.gc.ca

- Subscribe to the Cosmetics Mailing List:

  http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/subscribe-abonnement/index-eng.php

Part 2:
Modernizing the Regulation of Self-Care Products in Canada

What are self-care products?

Cosmetics
Used for cleaning, improving or altering the complexion, skin, hair or teeth (e.g., moisturizing creams, deodorants, shampoos)

Natural health products
Various uses including general health maintenance (e.g., mineral supplements, probiotics, traditional medicines)

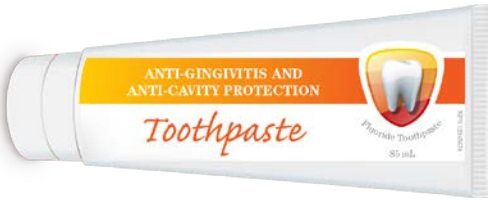
Non-prescription drugs
Commonly referred to as "over-the-counter drugs" (e.g., pain relief, cold & flu symptoms, allergy relief)

- Canadians use self-care products every day to maintain health, treat minor ailments and improve appearance.
- Self-care products are generally lower risk than other health products regulated by Health Canada, such as prescription drugs.
- However, they are not completely without risk as they can cause negative effects if combined with other medications or if not used as directed.

How are self-care products regulated now?

- Canada has rules in place that govern the safety, efficacy and quality of self-care products.
- All self-care products fall under one law in Canada – the *Food and Drugs Act* – but they are regulated under three different sets of regulations:
  - the *Cosmetic Regulations;*
  - the *Natural Health Products Regulations;* and
  - the *Food and Drug Regulations.*
- This means:
  - different rules for how to bring products to market;
  - different levels of evidence required for health claims made by manufacturers; and
  - different levels of post-market monitoring and compliance enforcement.

Product example: toothpaste

Similar products:			
These three toothpastes are sold side by side on store shelves	**Cosmetic** 	**Natural Health Product** 	**Non-prescription Drug** 
Different rules:			
Different pre-market rules	• No pre-market review • No inspection • No cost to industry	• Pre-market review based on claims • No inspection • No cost to industry	• In-depth pre-market review based on scientific evidence • Mandatory inspections • Significant cost to industry (fees up to $340,000)
Inconsistent powers	• No recall authorities • Maximum fine is $5,000	• No recall authorities • Maximum fine is $5,000	• Recall authorities exist • Maximum fine is $5,000,000

Why do we need change?

- The regulations have not kept pace with consumer expectations and with how self-care products are marketed by industry.
  - Under the current approach, products making similar claims (e.g., “relieves pain”) sit side by side on store shelves, even though they may be subject to different rules.
  - This makes it difficult for consumers to make informed choices.
- Health Canada does not have consistent powers (e.g., fines, recall authorities) to address safety concerns and non-compliance.
- The current framework results in an uneven regulatory environment for importers and manufacturers.

What are we working toward?

Self-care products would be **regulated according to risk to consumers**.

Self-care products making similar claims would **require similar evidence**.

Health Canada would have **appropriate powers** to address safety concerns and non-compliance.

Benefits for Consumers

- ✓ **Continued access** to a wide range of safe and effective self-care products
- ✓ **Better information** to support informed decision-making

Benefits for Industry

- ✓ More **predictable and consistent** rules for bringing products to market
- ✓ **Risk-based rules** that impose the appropriate level of regulatory oversight

How have we sought feedback to date?

Fall 2014: Consultation on a Framework for Consumer Health Products, proposing to modernize the oversight of health products intended for consumer use

Spring 2016: Public opinion research conducted with 2,500 Canadians to provide some baseline information on how Canadian consumers perceive and use self-care products

Fall 2016: *Consulting Canadians on the Regulation of Self-Care Products in Canada* – online consultation received over 3,500 responses from consumers, manufacturers, retailers, distributors, health professionals, researchers, and other regulators. *What We Heard* report released in March 2017.

April – June 2017: Online and in-person consultation sessions across the country to hear from Canadians on key components of a modernized framework.

MARKET ENTRY: What is Health Canada proposing?

- Classification would be based on risk, including product safety and harm of failed efficacy
- Lower-risk self-care products would be grouped into Category 1 & 2, and would come to market through a registration process
- Higher-risk self-care products would be in Category 3, and would come to market through an authorization process
- Given feedback during the first consultation, we are proposing a distinction between products making therapeutic claims and those that do not
- There would be similar levels of requirements for similar levels of claims
- Health Canada would have a more consistent application of user fees to recover costs of regulating self-care products
- There would be an appeals process (i.e., right to be heard) that is impartial and transparent

Self-care products would be regulated according to risk to consumers.

Proposal

	Category 1	Category 2	Category 3
Market Entry	Registration		Authorization
Claims	Non-therapeutic • Cleans & conditions hair • Reduces plaque • Whitens teeth	Therapeutic • Multi-vitamin/mineral • Source of antioxidant • Relieves cough	• Cold and flu • Weight loss • Lung infection
Evidence	Available upon request	Scientific (baseline) or historical	Clinical evidence (e.g. trials or observational studies)

INFORMATION FOR THE CONSUMER: What is Health Canada proposing?

- **Better labelling** to help consumers with product identification, selection and use, to support informed decision-making
- This would include **consistent content and format** that is easy to read and understand
- A **facts table** for self-care products making therapeutic claims
- Use of a **URL to provide additional information** for the consumer
- Stronger oversight and enforcement on **advertising**

Self-care products making similar claims would require similar evidence.

SITE LICENSING, COMPLIANCE & ENFORCEMENT, AND VIGILANCE: What is Health Canada proposing?

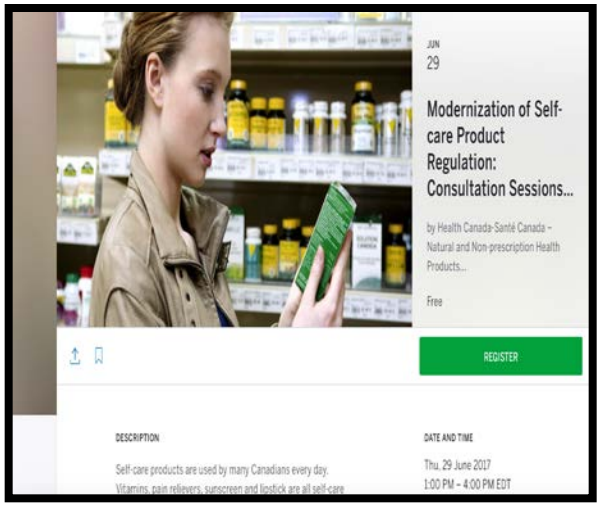
- Increase **proactive verification of compliance**, including inspections
- Require **site licences** for most categories of self-care products, including licensing for fabrication, packaging/labelling, importing, and testing
- Create a **baseline quality manufacturing standard** that is consistent across all product lines, with increased requirements as risk increases
- Continue to support the **issuance of trade certificates** for exportation purposes
- Establish a **risk-based approach to vigilance**
- Maintain a **risk-based response to health and safety issues**

Health Canada would have appropriate powers to address safety concerns and non-compliance.

Where can you find more information?

Health Canada self-care framework website:

www.canada.ca/selfcare-products



Contact the Health Canada self-care framework team:

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