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Requirements for Manufacturing, Importing, Marketing, and Selling Cosmetic Products in Canada

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Canada

Purpose

- Overview of the requirements to sell cosmetics in Canada:
 - Legislative authority
 - Definition of "cosmetic"
 - Safety of ingredients
 - Product labelling
 - Product notification
 - Other requirements
- Working with Product Safety Inspectors
- Guidance for Industry



About the Cosmetics Program

Mandate

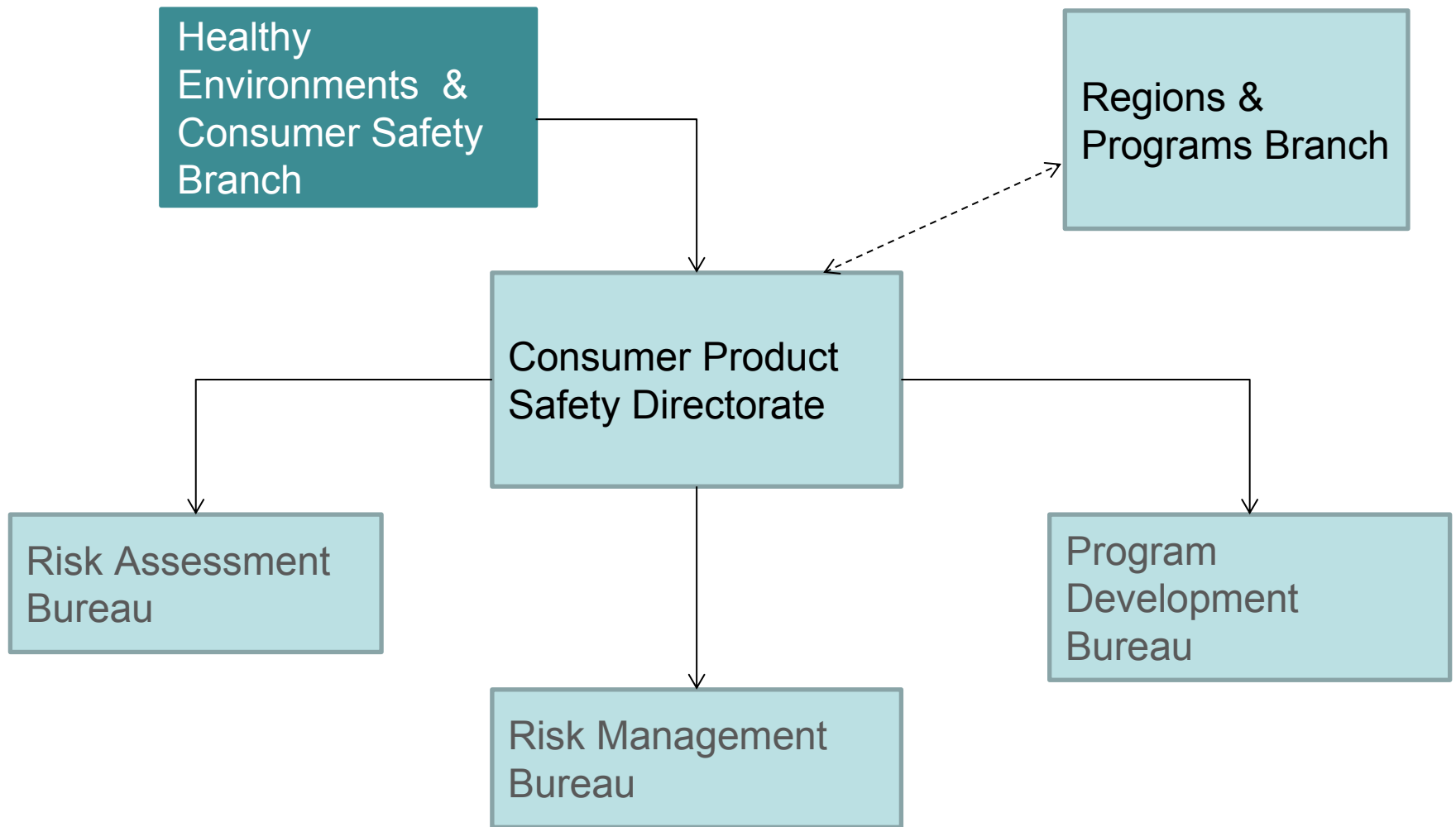
To maintain and improve the health of Canadians *by minimizing health risks associated with the use of cosmetics marketed in Canada.*

Met by:

- Defining and communicating requirements for cosmetic manufacture, labelling, distribution and sale
- Monitoring compliance



Organization



Legislative Authority

Program's authorities housed in:

- ***Food and Drugs Act (F&DA)*** and ***Cosmetic Regulations***

Cosmetics are 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



Legislative Authority: *Food and Drugs Act*

Food and Drugs Act (F&DA)

- Defines cosmetic, drug, food and device (s.2 F&DA)
- Provides general safety requirements for cosmetics (s.16 F&DA)
- Act defines the powers of inspectors' to search premises, take samples, seize products, stop sale, etc.

Regulations under the Act:

- ***Cosmetic Regulations***
- *Food and Drug Regulations* **
- *Natural Health Product Regulations, etc* **

** *The products governed by these regulations are not under the purview of the Consumer Product Safety Program (CPSP)*



Definition of a Cosmetic

What is a cosmetic?

“**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.



Classification: Cosmetic vs Drug

- 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 (Hotlist)
- Cosmetics do not treat/prevent disease, disorders or modify organic functions of the body
 - Includes symptoms of a disease
- Products need an appropriate cosmetic function

* *“Drug” means Therapeutic Product or NHP*



Food and Drugs Act (F&DA)

General Safety Requirement under 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**
- Basis for control of ingredients (in the *Cosmetic Regulations* and the Cosmetic Ingredient Hotlist)
 - Also basis for need of quality control systems for impurities and micro-organisms, packaging and storing conditions
 - Although there are no specific requirements for good manufacturing practices (GMP), Health Canada encourages use of ISO Cosmetics GMP Standard: 22716



Cosmetic Ingredient Hotlist

- List of **prohibited and restricted ingredients** in cosmetics in Canada
- 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
 - that are limited to pharmaceutical applications



Cosmetic Ingredient Hotlist

How are ingredients identified and prioritized for review?

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



Cosmetic Regulations

Outlines requirements for:

- Labelling
- Import
- Notification
- Some specific ingredient requirements



Labelling Requirements

- Cosmetic function
- Directions for safe use (English/French) per s24 *Cosmetic Regulations*
- Requirements for cosmetics in pressurized containers (e.g. hazard symbols)
- Warnings and Special Packaging
- Product identity and manufacturer name and full mailing address
- Ingredient Labelling using INCI
- Other bilingual requirements



Directions for Safe Use

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

2. “**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 **specific 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](#) and [Cosmetic Regulations](#) for ingredients that require warnings
- If a warning is required, usually wording does not need to be word for word if the term “to the effect of” precedes the warning on the Hotlist.



Pressurized Containers

- See the guide: *Labelling Requirements for Cosmetics in Pressurized Containers*
- Aerosol products in a metal pressurized container
 - Does not include pump sprays or those in plastic containers
- Must meet the requirements of the *Consumer Chemicals & Containers Regulations (CCCR, 2001)*



Pressurized Containers

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



- Also, cosmetics 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” (dealer*)

* same as “dealer” under the CPLA.



Product Identity and Manufacturer

- Product identity is not required if identity is obvious (e.g. soap or lipstick)
- Manufacturer's address must be detailed enough so that a mailed letter would reach the manufacturer.
 - In some cases listing the city, province and postal code is sufficient. In other cases, the street name and number is also required.
 - 1-800 or email address is not sufficient, however, can be added as additional information.
 - Address does not need to be in Canada.



Ingredient Labelling

- See the [Guide to Cosmetic 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 that do not end up in final formulation do not need to be listed as ingredients



Ingredient Labelling

- **Fragrance** can be listed as either “parfum” or “parfum/fragrance”.
- 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

- Where product has an inner and outer label, ingredients are **not required** on the inner label.
- Where product has only one label and is too small, to put on the main label, the ingredients can be listed on **tag, tape or card** that is affixed to the container of the package
- See [Guide to Cosmetic Ingredient Labelling: 4.1 Small Containers](#)



Bilingual Requirements

- For products sold anywhere in Canada, **all** the labelling required by the *Cosmetic Regulations* (except INCI) must be in both English and French
- A label would not be considered to meet the labelling requirements unless all required information is in both official languages
- For products sold in the province of Quebec, all labelling (including descriptions, except INCI) must be in French (at minimum)
- Additional descriptive text does not need to be in French if the product not sold in Quebec



Cosmetic Notification

- **When?** Post-market: Within 10 days of the first day of sale of the product in Canada. Can be notified before sale too.
- Required for new products, as well as amendments for original notification such as formulation changes and discontinued products.
- Notification information includes:
 - manufacturer(s)/importer
 - function
 - physical form
 - formulation
- No fee



Cosmetic Notification

- Health Canada has developed a new online Cosmetic Notification Form
- The Form allows you to:
 - Validate ingredients before submitting
 - Save the completed form with data
 - Submit your notification form via the secure web page Health Canada - Submit a form.
- The form is available on the HC website along with a guidance document:

<http://www.hc-sc.gc.ca/cps-spc/cosmet-person/notification-declaration/index-eng.php>



Canadian Environmental Protection Act (CEPA, 1999)

- In Canada, all ingredients, including those in cosmetics, are subject to CEPA
- Two streams under CEPA treated differently:
 - New Substances
 - Existing Substances
 - Based on whether the substance is on the national chemical inventory (Domestic Substances List - DSL)



CEPA (cont'd)

New Substance” = Not on inventory (DSL)

- Subject to the *New Substances Notification Regulations*

“Existing Substance” = On DSL

- Substances screened, categorized and prioritized for assessment under the Chemicals Management Plan (CMP)
- High priority substances are subject to an information request and assessment under The CMP Challenge (see next slide)



The Chemicals Management Plan (CMP)

- 200 high priority substances on the DSL were part of “CMP I”
- Each batch had questionnaire for importers, manufacturers and end users.
- “CMP II” launched October 3, 2011, to assess approximately 1,500 DSL substances over next 5 years



In Practice

- What do I need to do in order to market a new cosmetic in Canada?
- Compliance and Enforcement: Working with an inspector



What is needed to market a new cosmetic in Canada?

- Definition – Is it a cosmetic under the Act?
- Formulation – Any Hotlist ingredients?
- Labelling
 - Ingredients
 - Purpose
 - Common name
 - Warnings/cautions/Directions for safe use
 - Bilingualism
- Notification



Following notification

Following notification, you may be contacted due to:

- Missing information
- Clarification required
- Product is not a cosmetic
- Hotlist ingredient
- Safety data request
- Injury reported or complaint



Compliance and Enforcement

Working with an Inspector

- Product Safety Inspectors **enforce** the *Cosmetic Regulations* and cosmetic related sections in the *Food and Drugs Act*
- Inspector **authorities** in the *Food and Drugs Act and Cosmetic Regulations*:
 - Can **inspect premises** where cosmetics are 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



Compliance and Enforcement

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.



Compliance and Enforcement

Importing Cosmetics into Canada

Section 9 of the *Cosmetic Regulations* says:

(1) Where a person seeks to import a cosmetic into Canada for sale and the sale would constitute a violation of the Act or these Regulations, that person may, if the sale of the cosmetic would be lawful in Canada after relabelling or modification of the cosmetic, import the cosmetic into Canada on condition that

(a) he gives to an inspector notice of the proposed importation; and

(b) the cosmetic will be relabelled or modified under the supervision of an inspector in such a manner as to enable the sale of the cosmetic to be lawful in Canada.

(2) No person shall sell a cosmetic that has been imported into Canada under subsection (1) unless the cosmetic is relabelled or modified in accordance with the Act and these Regulations within three months after its importation.



Compliance and Enforcement

New ANI Pilot Process to Invoke Section 9

1. Contact the Regional Product Safety office, **in advance** of importation of non-compliant cosmetic products
2. Complete a new ANI form and send it to Health Canada per instructions from the Regional Product Safety office
3. Proceed with the modifications or relabeling with regular updates to inspector
 - **Products must be quarantined**
 - Non-compliant product **cannot be sold** until these modifications are complete



Compliance and Enforcement

- Voluntary approach typically taken before inspectors use authorities under the Act
- If product can be brought into compliance, inspector may ask for a written commitment from you
 - In other cases, product may be refused from import or further sale, or may need to be recalled
- Lack of cooperation with an inspector can result in a customs target, advisory, seizure, or prosecution



References

<http://www.hc-sc.gc.ca/cps-spc/cosmet-person/index-eng.php>

- *Food and Drugs Act and Cosmetic Regulations*
- The Guide for Completing Cosmetic Notification Forms
- 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
- Good Manufacturing Practices (GMPs) for Cosmetic Products
- *Consumer Chemicals and Containers Regulations*



References

cosmetics@hc-sc.gc.ca

cosmetiques@hc-sc.gc.ca

- **Contact your designated Regional Product Safety Office:**
http://www.hc-sc.gc.ca/contact/cps-spc/hecs-dgsesc/pso-bsp_usa-eu-eng.php
or call: 1-866-662-0666
- **Subscribe to “Cosmetics @ Health Canada” :**
<http://www.hc-sc.gc.ca/cps-spc/cosmet-person/subscribe-abonnement/index-eng.php>
- **Latest Hotlist version published April 2014:**
<http://www.hc-sc.gc.ca/cps-spc/cosmet-person/hot-list-critique/hotlist-liste-eng.php>



Questions

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