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# Health Canada Presentation to the Association of Food and Drug Officials

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# Outline

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## I. Canadian Regulatory Framework for Cosmetics

- *Food and Drugs Act (F&DA)*
- *Cosmetic Regulations (CR)*
- *Cosmetic Ingredient Hotlist (administrative tool)*
- *Regulations Amending Certain Regulations Concerning the Disclosure of Cosmetics Ingredients*

## II. Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

## III. Q&A

This document is not intended to substitute for or limit the requirements under the *Food and Drugs Act (F&DA)* and the *Cosmetic Regulations (CR)*. In case of any difference between this document and the legislation, the legislation will prevail.

# How cosmetics are regulated in Canada

## Health Canada's mandate is:

To maintain and improve the health of the Canadian public

*For cosmetics, it is accomplished by minimizing health risks associated with the use of cosmetics marketed in Canada*

Legislative authority to regulate cosmetics lies within:

- The ***Food and Drugs Act*** and
- The ***Cosmetic Regulations***

## Cosmetics are also subject to :

- *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

\*This legislation is not under the purview of the Consumer Product Safety Program (CPSP)

# *Food and Drugs Act*

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- Defines cosmetic, drug, food and medical device (s.2)
- Provides general safety requirement for cosmetics (s.16)
- Gives authority to the inspectors to enter premises, take samples, seize products, etc.
- Regulations under the Act:
  - *Cosmetic Regulations*
  - *Food and Drug Regulations\**
  - *Natural Health Products Regulations\**
  - *Others \**

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

# Ban on Cosmetic Animal Testing

- On December 22, 2023, amendments to the *Food and Drugs Act* came into force to prohibit:
  - testing cosmetics on animals in Canada;
  - selling cosmetics that rely on animal testing data to establish the product's safety, with some exceptions; and
  - false or misleading labelling pertaining to the testing of cosmetics on animals.
- Health Canada is adopting a **reactive compliance and enforcement approach** to these prohibitions, meaning any enforcement of these prohibitions will focus on complaints and incident reports.



# 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.

## Included\*:

- ✓ Soap
- ✓ Deodorants/antiperspirants
- ✓ Make-up
- ✓ Hair dyes
- ✓ Tattoo inks
- ✓ Tooth whiteners
- ✓ Mouthwash
- ✓ Nail adhesives
- ✓ Hotel amenities

## Excluded\*:

- ✗ Sunburn protectants  
(cosmetics can contain sunscreens if no sunscreen protection claims present)
- ✗ Anti-caries toothpastes
- ✗ Antidandruff shampoo
- ✗ Skin whiteners/lighteners
- ✗ Injectables (collagen, botox)
- ✗ Intentionally swallowed products (vitamins, etc.)

*\* = Not an exhaustive list*

# The general safety requirement for cosmetics

- Section 16 of the *Food and Drugs Act*
  - **No person** shall sell any cosmetic that
    - has in or on it any substance that may cause injury to the health of the user
    - contains any “filthy or decomposed” substance or foreign matter
    - was manufactured, prepared, preserved, packaged or stored under unsanitary conditions
- Section 18 of the *Food and Drugs Act*
  - **No person** shall manufacture, prepare, preserve, package or store for sale any cosmetic under unsanitary conditions.
- It is the responsibility of the companies to have quality control systems for impurities and micro-organisms, packaging and storing conditions
- Although there are no specific regulatory requirements for good manufacturing practices (GMP), Health Canada **encourages** the use of ISO Cosmetics GMP Standard: 22716

# Cosmetic Ingredient Hotlist

- The **Hotlist** is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the FDA, may contravene one or more provisions of the CR, or may otherwise be inappropriate for use in cosmetics.
  - Two tables: prohibited ingredients, restricted ingredients
  - Reviewed and updated as new scientific data becomes available
  - Not exhaustive – general prohibition applies at all times
- Consultation on proposed changes to the Cosmetic Ingredient Hotlist published in July 2023 can be found [here](#).
- The latest version of the Hotlist (May 17, 2024) can be found [here](#).
- Health Canada can take actions at any time to enforce the FDA and CR, regardless of whether a substance is included on the Hotlist.



## The *Cosmetic Regulations* outline requirements for:

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- Importation
- Labelling
- Specific requirements for certain cosmetics or ingredients
- Notification

# Labelling Requirements

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- Cosmetic function
- Directions for safe use
- Warnings
- Requirements for cosmetics in pressurized containers
- Special packaging
- Product identity and the responsible company
- INCI (International Nomenclature of Cosmetic Ingredients) ingredient labelling
- Bilingual requirements

# Cosmetic notification

- Notification within 10 days of first sale of the product in Canada
- Required for new products, amendments to original notification such as formulation changes and discontinued products
- No fee
- Online form: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/notification-cosmetics.html>
- Instructions on how to complete the form can be found in the [Guidance document: How to complete a Cosmetic Notification Form](#)

Submission of the Cosmetic Notification Form does not constitute approval for sale by Health Canada, agreement that the product is classified as a cosmetic nor that the product complies with all legislative requirements.

# Following notification...

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- You may be contacted by Health Canada for:
  - Classification issue (product is not a cosmetic)
  - Missing information
  - Clarification required (i.e. unknown ingredient)
  - Hotlist ingredient
  - Safety data request
  - Injury reports or complaints



# Information submitted to Health Canada

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- Health Canada collects and uses information provided in the cosmetic notification form for the purpose of protecting public health and safety.
- It is Health Canada policy to disclose information on individual products externally only to the notifier (identified in section 3 of the form).
- All information is protected by Canada's [Policy on Government Security](#)
- Personal information is protected under Canada's [Privacy Act](#)

# Advance Notice of Importation (ANI) – Regulatory context

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- S.5 of the CR and s.A.01.040 of the *Food and Drug Regulations* (FDR) prohibits the importation of non-compliant cosmetics and non-compliant drugs into Canada.
- S.9 of the CR and s.A.01.044 of the FDR allow for the importation of non-compliant products, when:
  - Advance notice of the proposed importation is provided
  - and
  - Product is brought into compliance within 3 months after importation
- More information can be found here: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/advance-notice-importation-process-cosmetics-drugs.html>

# Cosmetics sold online

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- The cosmetic provisions of the FDA and its CR apply to cosmetics manufactured, prepared, preserved, packaged, stored, imported, or advertised **for sale in Canada**.
  - Online sellers located within Canada must comply with the FDA and its CR.
- Online sellers located outside of Canada and selling **direct to Canadian consumers for their own personal use** are not subject to the FDA and its CR.
  - Health Canada encourages suppliers located outside of Canada and selling direct to Canadians for their own personal use to adhere to the **safety** and **labelling** requirements of the FDA and its CR.

# Helpful hints for exporting cosmetics to Canada

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- Ensure that your products are appropriately classified. Products considered cosmetics in some jurisdictions may not be regulated as cosmetics in Canada.
  - Health products – therapeutic claims, biological activity
  - Pest control products – insect repellents
- If you choose to notify on behalf of your importer(s), you may wish to provide them with the cosmetic number assigned to each of your products by Health Canada.
  - If you have not yet received your cosmetic number, you could provide a copy of the submission number for your notification to your importer(s)
  - You may wish to send a paper copy of these identifiers along with your shipments to Canada



# Recently published amended *Cosmetic Regulations*

- On April 24, 2024 the *Regulations Amending Certain Regulations Concerning the Disclosure of Cosmetic Ingredients* (SOR/2024-63) were published in the [Canada Gazette, Part II](#).
- This publication amends the *Cosmetic Regulations* to:
  - require the disclosure of fragrance allergens on cosmetic labels, when present above a specified limit;
  - introduce additional flexibility for the disclosure of ingredients of cosmetics sold in small packages;
  - improve regulatory oversight of cosmetics through clarifying terminology, strengthening cosmetic notification requirements, and enhancing compliance and enforcement tools; and
  - make changes of an administrative nature.
- The Regulations will come into force in two parts:
  - all amendments, with the exception of those related to the disclosure of fragrance allergens on cosmetic labels, will come into force 180 days after the day on which the Regulations were registered: October 9, 2024; and
  - the provisions regarding the disclosure of fragrance allergens will come into force two years after the day on which the Regulations were registered: April 12, 2026.

# Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

- **Objective:** To determine this sector's compliance with Sections 16 and 18 of the *Food and Drugs Act*.
- A total of 25 establishments were inspected resulting in the sampling of 30 different tattoo ink and permanent make-up pigment products.
- Chemical and microbial testing of the 30 samples was completed in 2022.
- The results for this compliance verification project and all other projects conducted by Health Canada on cosmetics and consumer products can be found at the following link:
  - <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/enforcement-summary-report.html>

# Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

- The 30 samples were tested to the heavy metal impurity limits set out in the [Guidance on Heavy Metal Impurities in Cosmetics](#):
  - Lead: 10 ppm
  - Arsenic: 3 ppm
  - Cadmium: 3 ppm
  - Mercury: 1 ppm
  - Antimony: 5 ppm
- The samples were also tested to the microbial limits set out in the standard ISO 17516:2014:
  - Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould):  $\leq 100$  CFU per g or ml
  - *Escherichia coli*: Absence in 1 g or 1 ml
  - *Pseudomonas aeruginosa*: Absence in 1 g or 1 ml
  - *Staphylococcus aureus*: Absence in 1 g or 1 ml
  - *Candida albicans*: Absence in 1 g or 1 ml



# Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

- **Results:**

- No samples were found to have heavy metal concentrations above the impurity limits.
- No samples were contaminated with the 4 pathogens listed in ISO 17516:2014 or any other human pathogen.
- 3 stop distributions due to microbial contamination.
  - 3 products had Total Aerobic Mesophilic Microorganism (Bacteria plus yeast and mould) levels above the 100 CFU/g limits set out in ISO 17516:2014.
- 23 trader commitments for non-compliance to the notification and/or labelling requirements.

# Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

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- **Results continued:**

- All 26 non-compliant products were non-compliant with the notification and/or labelling requirements.
  - 18 products did not meet the labelling and notification requirements.
  - 7 products did not meet the labelling requirements but met the notification requirements.
  - 1 product met the labelling requirements but did not meet the notification requirements.
  - 11 products had more than one labelling non-compliance.

# Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

- **Results continued:**

- Labelling non-compliances:

- 69% (18/26) non-compliant products did not meet the requirements of Subsection 18(a) of the *Cosmetic Regulations*. The information on the label required by the regulations was not present in both French and English.
  - Common issues:
    - Product identity was not bilingual
    - Warning statements were not bilingual
    - No French on label
- 31% (8/26) non-compliant products did not meet the requirements of Subsection 20(a) of the *Cosmetic Regulations*. The manufacturer's name and address were missing or incomplete.
- 31% (8/26) non-compliant products did not meet the requirements of Subsection 21.2(1) of the *Cosmetic Regulations*. The list of ingredients did not have INCI names for each ingredient.

# Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

- **Results continued:**

- Labelling non-compliances:

- 15% (4/26) non-compliant products did not meet the requirements of Subsection 20(b) of the *Cosmetic Regulations*. The labels were missing a product identity.
- 11% (3/26) non-compliant products did not meet the requirements of Subsection 18(b) of the *Cosmetic Regulations*. The labels were not legible.
- 4% (1/26) non-compliant products did not meet the requirements of Subsection 24(1) of the *Cosmetic Regulations*. The labels indicated a patch test should be performed prior to using the product but there were no patch test instructions.

# Compliance Verification of Tattoo Inks and Permanent Make-up Pigments

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- Overall, there was an 87% rate of non-compliance in this project.
- These results were not unexpected. Health Canada was aware that some tattoo ink and permanent make-up pigment stakeholders may not have known these products were classified as cosmetics in Canada.
  - This understanding was a contributing factor in planning and executing this project.
  - A mail-out was performed prior to the project to remind stakeholders that these products were cosmetics and needed to meet our requirements.
- A high non-compliance rate such as this typically informs recommendations that the project may be repeated within a shortened period of time.



# Guidelines to help you

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- [The Guide for Completing Cosmetic Notification Form](#)
- [Cosmetic Ingredient Hotlist](#)
- [Industry Guide for the labelling of cosmetics](#)
- [Guide to Cosmetic Ingredient Labelling](#)
- [Labelling Requirements for Cosmetics in Pressurized Containers](#)
- [Cosmetic advertising, labelling and ingredients](#)
- [Guidance on the Classification of Products at the Cosmetic-Drug Interface](#)
- [Guidance document: Animal testing ban on cosmetics](#) **"New"**
- [Act](#) and [Regulations](#), etc.
- [Selling consumer products and cosmetics online: Information for online marketplaces and online sellers](#)
- [Cosmetic Safety](#)



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<https://www.canada.ca/en/health-canada/services/cosmetics/subscribe.html>

**Contact information for the appropriate office may be found here:**

<https://www.canada.ca/en/health-canada/corporate/contact-us/cosmetics-program-regional-offices.html>

# Questions?

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