



**COSMETICS
ALLIANCE**
CANADA

The Voice of Canada's
Personal Care
Products Industry

celebrating **90** beautiful years
1928 - 2018

COSMETICS 101

OCT 2018



LEARNING OBJECTIVES



Learn the language of cosmetics in Canada
Understand the set-up of Canadian Law
Overview of the Cosmetic Regulations
Implication of other Acts and Regulations

DISCLAIMER



All information and presentations provided are intended as a service to paid registrants. This information should not be made public, nor should it be relied upon as legal advice. Companies should consult with legal counsel to verify the applicability of any information provided.

AGENDA



About CA

Course Delivery

Break

Q&A

Quiz



ABOUT US



COSMETICS ALLIANCE CANADA

THE VOICE OF CANADA'S
PERSONAL CARE
PRODUCTS INDUSTRY



ABOUT US



- Founded in 1928
- Principle trade association representing the cosmetic and personal care industry in Canada
- ~\$9.5 billion (retail)
- 150+ member companies (4 membership categories)
- Includes brand owners, manufacturers, importers, exporters, distributors, retailers and suppliers of goods & services to the industry in Canada

ABOUT US



COSMETICS and FRAGRANCES



SUNSCREENS
(primary and secondary)

ANTIACNE THERAPIES
ORAL CARE
DIAPER RASH / BABY CARE



ANTI DANDRUFF
MEDICATED SKIN CARE
ANTISEPTIC CLEANSERS

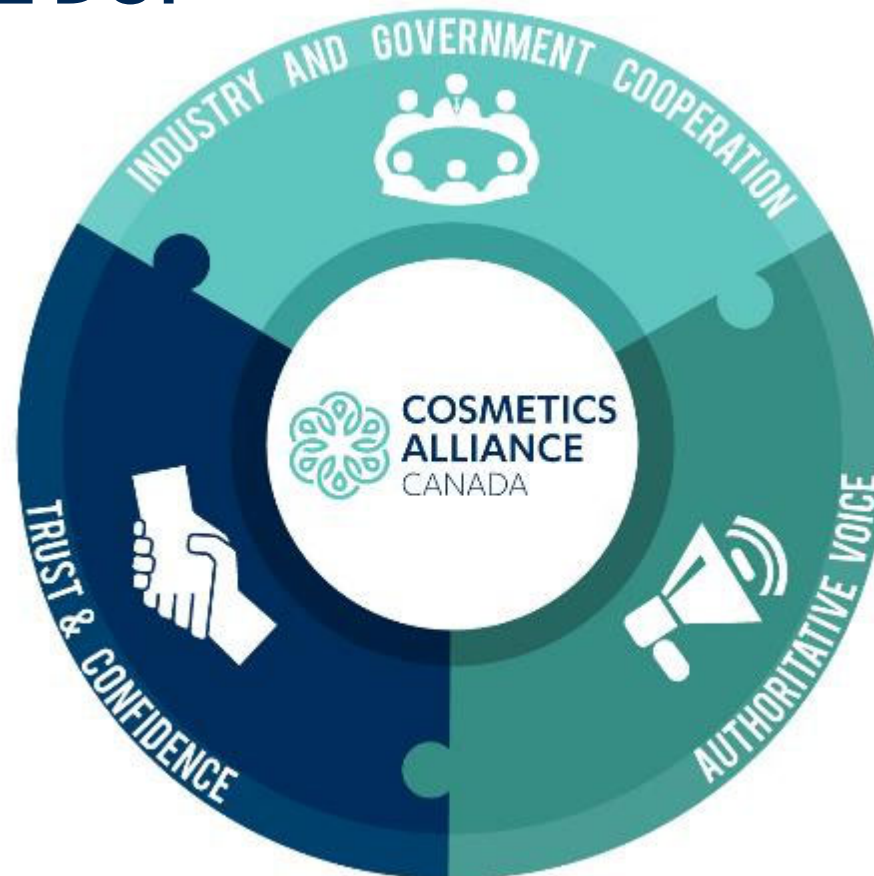
OUR MISSION:

- *To enhance and protect the ability of member companies to conduct business effectively in Canada;*
- *To foster industry and government cooperation;*
- *To provide an authoritative voice for communication to all stakeholders;*
- *To encourage trust and confidence in the industry and in the safety and efficacy of our products*

ABOUT US



WHAT WE DO:



POLL



#1: HOW MANY YEARS' OF EXPERIENCE DO YOU HAVE WITH COSMETICS?

#2: WHICH DEPARTMENT IN YOUR ORGANIZATION DO YOU WORK IN?

FOOD AND DRUGS ACT

- FOOD AND DRUG REGULATIONS
- NATURAL HEALTH PRODUCT REGULATIONS
- COSMETIC REGULATIONS
- OTHERS

FOOD AND DRUGS ACT

- **TOP-LEVEL LAW**
- **57 PAGES**
- **CHANGED BY AN ACT OF PARLIAMENT**

- **COSMETIC REGULATIONS**
 - **REGULATIONS UNDER THE ACT**
 - **24 PAGES**
 - **GAZETTE PROCESS**
 - **APPROVED BY PRIVY COUNCIL**

IMPORTANT NOTE

- When reading the Food and Drugs Act, a natural health product (NHP) is covered under the term

DRUG

CANADIAN LEGISLATIVE PROCESS

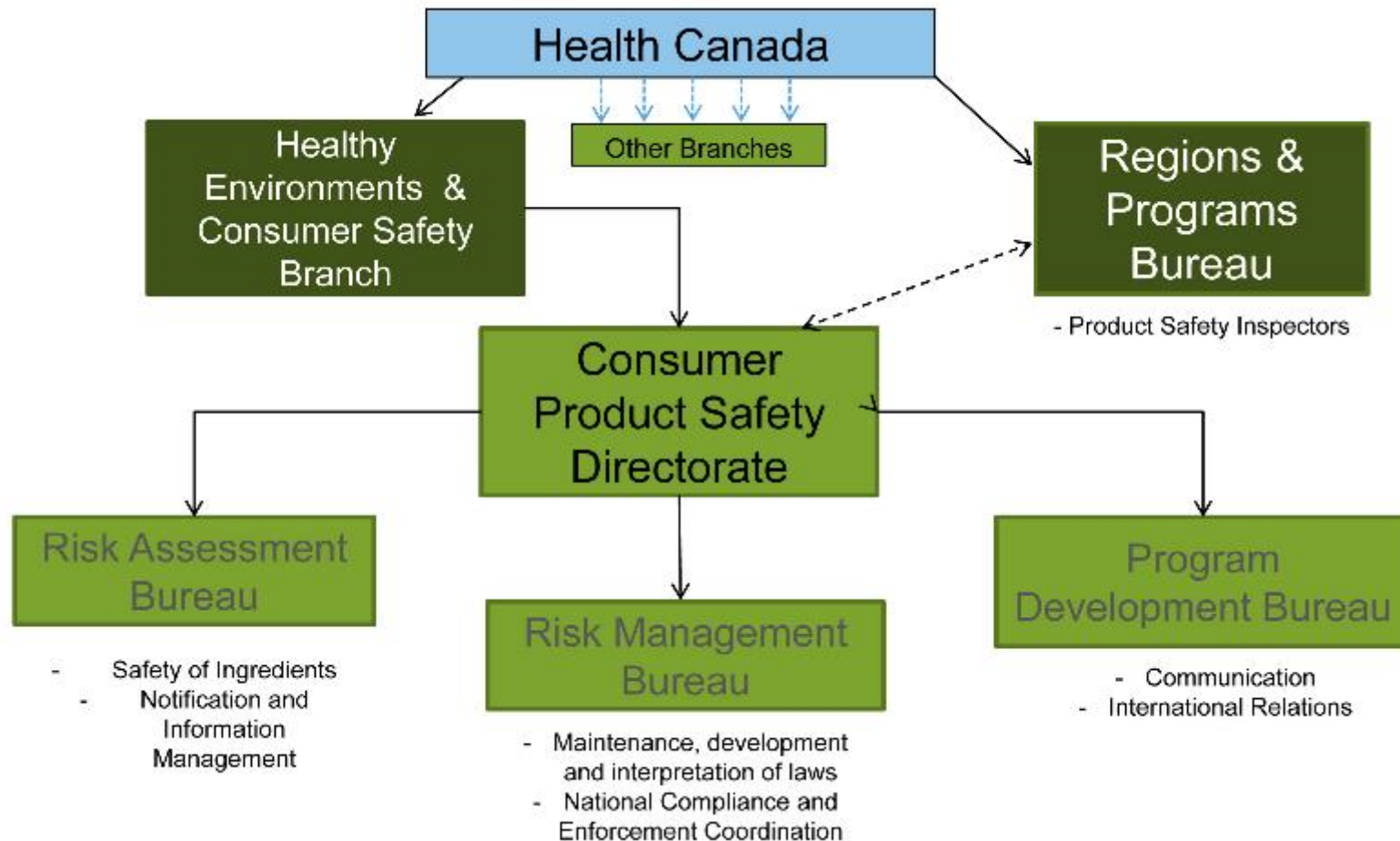
- **CHANGES TO THE *FOOD AND DRUGS ACT***
 - **PARLIAMENTARY PROCESS**
 - **INTRODUCTION OF A BILL INTO PARLIAMENT**
 - **APPROVAL BY ROYAL ASSENT (GOVERNOR GENERAL)**



CANADIAN REGULATORY PROCESS

- **CHANGES TO THE *REGULATIONS***
 - **GAZETTING PROCESS**
 - **CANADA GAZETTE PART I (PROPOSED REGULATIONS)**
 - **COMMENT PERIOD**
 - **PRIVY COUNCIL (CABINET) APPROVAL**
 - **CANADA GAZETTE PART II (ADOPTED REGULATIONS)**
 - **COMING INTO FORCE PERIOD**

HEALTH CANADA STRUCTURE



To maintain and improve the health of
the Canadian public by minimizing
health risks associated with the use of
cosmetics marketed in Canada

Mechanisms

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

DEFINITION OF A 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

PRODUCT CLASSIFICATION



PRODUCT CLASSIFICATION



PRODUCT CLASSIFICATION

TWO FUNDAMENTAL PRINCIPLES:

- INGREDIENTS
- CLAIMS (representation)

PRODUCT CLASSIFICATION

INGREDIENTS

- What are the ingredients in your product?
- Natural Health Product Ingredients?
- Drug Product Ingredients?
- Non-NHP Ingredients?
- Active/Medicinal versus Non-Medicinal/In-Active Ingredients?

INGREDIENTS

Tool

Natural Health Product Ingredients Database
(NHPID)

On-Line Database of Ingredients

<http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/search-rechercheReq.do>

CLAIMS

- **What are you saying about your product?**
 - **cleansing?**
 - **improving or altering complexion?**
 - **diagnosis, treatment, prevention?**
 - **restoring, correcting or modifying organic function?**

CLAIMS

Ad Standards

A national not-for-profit advertising self-regulatory body, committed to fostering community confidence in advertising and to ensuring the integrity and viability of advertising in Canada through responsible industry self-regulation.

<https://www.adstandards.ca/en/>

CLAIMS

Tools:

Guidelines for the Non-prescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims (2016)

Guidelines for Cosmetic Advertising and Labelling Claims – Interim (June 2010)

PRODUCT CLASSIFICATION



Skin Care/Makeup

NON-THERAPEUTIC CLAIMS

- Heals dry skin
- Repairs dry skin
- Replenish/Protect the skin's moisture barrier
- 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

- Heals (unqualified)
- Repairs (damaged) skin
- Repairs the skin's moisture barrier
- 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

PRODUCT CLASSIFICATION



Included*:

- ✓ Soap (non-therapeutic)
- ✓ Deodorants / antiperspirants
- ✓ Hair dyes
- ✓ Tattoo inks
- ✓ Tooth whiteners
- ✓ Mouthwash
- ✓ Nail adhesives
- ✓ Hotel amenities

SOME

Excluded*:

- ✗ Sunburn protectants (cosmetics can contain sunscreens if no sunscreen protection claims)
- ✗ Anti-caries toothpastes
- ✗ Antidandruff shampoo
- ✗ Skin whiteners/lighteners
- ✗ Injectables (collagen, botox)
- ✗ Intentionally swallowed products (vitamins, etc.)
- ✗ Devices and Articles (applicators, electrolysis machines, tanning beds, etc)

* = *Not an exhaustive list*

PRODUCT CLASSIFICATION



MERGING THE CONCEPTS

PRODUCT CLASSIFICATION



- When your product contains an NHP ingredient (Zinc oxide) and has a respective therapeutic claim (SPF), your product is a **NHP**.
- When your product contains a drug ingredient (Triclosan) and has a respective therapeutic claim (anti-gingivitis), your product is a **Drug**.
- When your product contains a drug and NHP ingredient (Octinoxate and Zinc Oxide) and has a respective claim (SPF), your product is a **Drug**.
- When your product contains Triclosan as an antimicrobial agent, is in-line with any hotlist restrictions and has only cosmetic claims, your product is a **Cosmetic**.
- **NUANCE: PHARMACEUTICAL INGREDIENTS ARE DRUG INGREDIENTS (ACETAMINOPHEN, ACETYLSALICYLIC ACID – NO RELATED NMI PROPERTIES)**

ASSESS YOUR LEARNING

#3: A CLEANSER FOR ACNE-PRONE SKIN IS A...

#4: A MOUTHWASH WHICH CLAIMS TO KILL ODOUR
CAUSING BACTERIA IS A ...

BREAK OR Q&A



5 MINUTE BREAK

OR

Q&A SESSION

YOUR CHOICE!



COSMETICS IN THE ACT



COSMETICS IN THE FOOD AND DRUGS ACT

PROHIBITED ADVERTISING AND SALE (§ 3)

PROHIBITED SALE OR ADVERTISING OF A COSMETIC TO THE GENERAL PUBLIC AS A TREATMENT, PREVENTATIVE OR CURE FOR ANY OF THE DISEASES, DISORDERS OR ABNORMAL PHYSICAL STATE REFERRED TO IN SCHEDULE A

SCHEDULE A: CANCER, ASTHMA, APPENDICITIS...

MAINLY DISEASES FOR WHICH THERE IS NO CURE

PROHIBITED SALE (§ 16)

GENERAL SAFETY PROHIBITION

NO SALE OF A COSMETIC THAT HAS IN IT OR ON IT, ANY
SUBSTANCE THAT MAY CAUSE INJURY TO THE HEALTH OF THE
USER WHEN USED:

- ACCORDING TO THE DIRECTIONS FOR USE, OR
- FOR SUCH PURPOSES AND METHODS OF USE THAT ARE CUSTOMARY OR
USUAL

PROHIBITED SALE (§ 16 & 18)

GENERAL SAFETY PROHIBITION

- NO SALE OF A COSMETIC THAT CONSISTS IN WHOLE OR IN PART OF ANY FILTHY OR DECOMPOSED SUBSTANCE OR OF ANY FOREIGN MATTER; OR
 - THAT WAS MANUFACTURED, PREPARED, PRESERVED, PACKAGED OR STORED UNDER UNSANITARY CONDITIONS.

PROHIBITED SALE (§ 16 & 18)

“GOOD MANUFACTURING PRACTICES (GMPS)”

- **NO ESTABLISHED** STANDARD IN THE REGULATIONS
- HEALTH CANADA ALONG WITH **ICCR** ENDORSES THE USE OF

ISO 22716: GUIDELINES ON GOOD MANUFACTURING PRACTICES
FOR COSMETICS

THE REGULATIONS **DO NOT** CONTAIN INFORMATION ON **HOW** TO
ENSURE YOUR COSMETIC WAS MANUFACTURED, PREPARED,
PRESERVED, PACKAGED OR STORED UNDER SANITARY
CONDITIONS

INTERNATIONAL COOPERATION ON COSMETICS REGULATION

Established in 2007, the International Cooperation on Cosmetics Regulation (ICCR) is a **voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan and the United States**. This group of regulatory authorities meet on an annual basis to discuss common issues on cosmetics safety and regulation, as well as enter into a constructive dialogue with relevant cosmetics industry trade associations.



"Source: ICCR, <http://www.iccrnet.org/>"

PROHIBITED SALE (§ 16 & 18)

GUIDANCE ON HEAVY METAL IMPURITIES IN COSMETICS

- LEAD: 10 PPM
- ARSENIC: 3 PPM
- CADMIUM: 3 PPM
- MERCURY: 1 PPM
- ANTIMONY: 5 PPM

Many heavy metals are not acceptable as ingredients in cosmetic products sold in Canada as they may cause injury to the health of the user, which is in contravention of the general prohibition found in § 16 of the *F&DA*. Yet they may still be found in cosmetics as impurities due to the persistent nature of these substances and the fact that they are found in the natural environment.

ADMINISTRATION AND ENFORCEMENT, ANALYSIS, POWERS (§ 22 - 36)

AUTHORITY TO:

- INSPECT
- TAKE SAMPLES AND MAKE COPIES OF DOCUMENTS
- ISSUE WARRANTS
- SEIZE ARTICLES

COSMETIC REGULATIONS INSPECTORS & SAMPLING ((§ 3, 6, 7, 8, 11)



- INSPECTORS HAVE AUTHORITY TO
 - Carry out responsibilities under the act
 - Take photographs of a cosmetic or a place of manufacture, preparation, preservation, packaging or storage
 - Any labelling or advertising material
 - Examine and take samples
 - Submit for analysis
 - Notify the importer or collector of customs

EXPORTS (§ 37)

EXEMPTION TO THE ACT FOR EXPORTED PRODUCTS:

- MANUFACTURED OR PREPARED IN CANADA
- NOT FOR CONSUMPTION IN CANADA AND INTENDED FOR EXPORT
- EXPORT CERTIFICATES
- MEETS ANY OTHER PRESCRIBED REQUIREMENT
- NOT EXEMPT FROM § 16 & 18 (ADULTERATED/UNSANITARY)

COSMETICS IN THE REGULATIONS



**COSMETICS IN THE COSMETIC REGULATIONS
AND
OTHER IMPLICATED REGULATIONS**

COSMETIC REGULATIONS AND OTHER LEGISLATION



COSMETIC REGULATIONS

CONSUMER PACKAGING & LABELLING ACT & ITS REGULATIONS

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)

COMPETITION ACT

**CONSUMER CHEMICAL CONTAINER REGULATIONS (FROM SEP 30,
2001) (CCCR, 2001)**

CHARTER OF THE FRENCH LANGUAGE (QUEBEC ONLY)

**IMPORTATION
ADVANCE NOTICE OF IMPORTATION
INSPECTORS & SAMPLING
PROHIBITED INGREDIENTS
CHILD-RESISTANCE & SECURITY PACKAGING
LABELLING
RESTRICTIONS
AVOIDABLE HAZARDS
PRESSURIZED CONTAINERS
SAFETY
NOTIFICATION**

COSMETIC REGULATIONS IMPORTATION (§5)



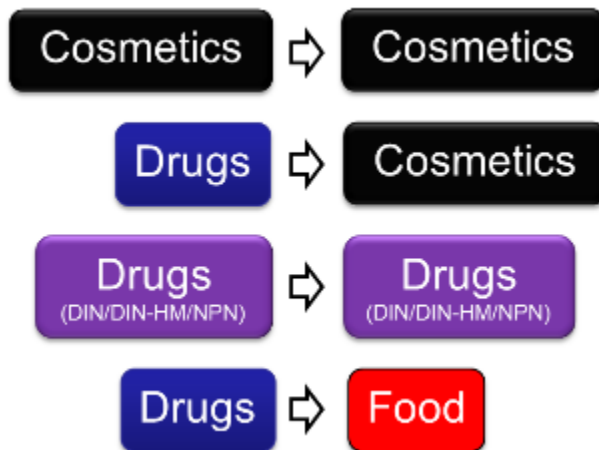
- No person shall import into Canada for sale a cosmetic the sale of which in Canada would constitute a violation of the act or regulations

ADVANCED NOTICE OF IMPORTATION (ANI)

EXCEPT

- IMPORTATION OF NON-COMPLIANT COSMETICS IS ALLOWED IF:
 - The importer provides advance notice to Health Canada of the proposed importation
 - The product is relabelled or modified as required to enable its sale to be lawful
 - The product is required to be relabelled or modified **within three months** of its importation.

ADVANCE NOTICE OF IMPORTATION (ANI) PILOT PROJECT



IMPORTERS SUBMIT:

SINGLE ADVANCE NOTICE OF
IMPORTATION FORM

FOR MULTIPLE PRODUCTS

VALID FOR A MAXIMUM PERIOD OF 3
MONTHS

ADVANCE NOTICE OF IMPORTATION (ANI) PILOT PROJECT

BORDER-CONTROLLED (CANADIAN BORDER SERVICE
AGENCY) (CBSA)

FORM IS AVAILABLE IN THE MATERIALS LIBRARY

ADVANCE NOTICE OF IMPORTATION (ANI) PILOT PROJECT

DOES NOT APPLY TO:

- DRUGS/NHPS WITHOUT A DIN OR NPN
- PRODUCTS ALREADY IN CANADA
- COSMETICS CONTAINING PROHIBITED INGREDIENTS
- PRODUCTS IMPORTED FOR RE-EXPORTATION
- MEDICAL DEVICES
- PRODUCTS NOT IMPORTED FOR SALE IN CANADA

ASSESS YOUR LEARNING

#8: WHEN YOU IMPORT A PRODUCT UNDER THE ANI...YOU ARE REQUIRED TO RE-LABEL ...

#9: THE ANI PILOT DOES NOT APPLY TO ...

COSMETIC REGULATIONS CERTAIN PROHIBITED AND RESTRICTED INGREDIENTS (§ 14, 15, 22.1, 28.2, 28.3)



- CERTAIN PROHIBITIONS AND RESTRICTIONS ON INGREDIENTS
 - EYE AREA & COAL TARS
 - CHLOROFORM
 - ESTROGENIC SUBSTANCES
 - MERCURY
 - METHYL ALCOHOL
 - CERTAIN BROMATES

SECURITY PACKAGING (§ 28.1)

- Required for mouthwashes that are available to the public in an open self-selection area or distributed as a sample
- The inner label of the security package must carry a statement or illustration that draws attention to the security feature of the package and, if the security feature is part of an outside package, the outer label must also carry the statement or illustration.
 - Unless the security feature of a security package is self-evident and is an integral part of the immediate container

CHILD-RESISTANT CONTAINERS (§ 15.2)

REQUIRED FOR:

- 28.2 – CERTAIN METHYL ALCOHOL CONTAINING PRODUCTS WITH CONDITIONS
- 28.3 – CERTAIN BROMATES CONTAINING PRODUCTS WITH CONDITIONS

COSMETIC REGULATIONS

DIRECTIONS FOR SAFE USE / AVOIDABLE HAZARDS (§ 24)



- Some ingredients or products require warnings to alert consumers of a special hazard
- These are outlined in
 - **prescribed** hazards in the Regulations themselves,
 - **non-prescribed** identified in the Cosmetic Ingredient Hotlist, **or**
 - may be based on safety information you have for your product and/or ingredients
- Pressurized containers have **prescribed** warnings per the CCCR (from Sep 30, 2001) (See Labelling Requirements for Cosmetics in Pressurized Containers)

COSMETIC REGULATIONS SAFETY (§ 29)



The minister may request a manufacturer submit evidence to establish the safety of a cosmetic under the recommended or the normal conditions of use.

If you do not have this evidence, you may need to cease to sell the cosmetic after the date specified in a request from the Minister.

Health Canada does not publish safety standards.

“It is the manufacturer’s responsibility to ensure that the products meet the requirements for cosmetics under the F&DA and Cosmetic Regulations”

INTERNATIONAL COOPERATION ON COSMETICS REGULATION

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"Source: ICCR, <http://www.iccrnet.org/>"

ICCR



INTERNATIONAL COOPERATION ON COSMETICS REGULATION

THE ICCR REVIEWS AND LOOKS TO ENDORSE VARIOUS SAFETY TEST METHODS AND TOOLS TO ASSESS COSMETIC PRODUCTS AND INGREDIENTS

[HTTPS://WWW.ICCR-COSMETICS.ORG/TOPICS/](https://www.iccr-cosmetics.org/topics/)

COSMETIC INGREDIENT HOTLIST

An **administrative tool** that helps industry satisfy
Section 16 of the Act and
Section 29 of the Regulations

Contains prohibited and restricted ingredients
“that may contravene section 16”

COSMETIC INGREDIENT HOTLIST

A science-based document that is reviewed and updated as new scientific data becomes available.

Restricted and prohibited ingredients can **also** be found in the Cosmetic Regulations

COSMETIC INGREDIENT HOTLIST

The Hotlist is not exhaustive
Currently ~ 500 substances
Originally based on EU Annex II & III

Why does the EU Annex II list ~ 1400 restricted ingredients and the Hotlist lists ~ 500 restricted substances ?

COSMETIC INGREDIENT HOTLIST

How ingredients are identified for review:

- New scientific information
- New regulatory decisions (domestic or international)
- Consumer complaints/injuries
- Media, industry request, other concerns

COSMETIC INGREDIENT HOTLIST

- A copy of the current Hotlist is contained in your materials
 - Open the document

RESTRICTED versus PROHIBITED

REVIEW OF THE HOT LIST DOCUMENT

COSMETIC REGULATIONS SAFETY (§ 29)



**Subscribe to List Serve for Updates on Hotlist and Any Other
Communications and Updates**

[http://www.hc-sc.gc.ca/cps-spc/cosmet-person/subscribe-
abonnement/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/cosmet-person/subscribe-abonnement/index-eng.php)



ASSESS YOUR LEARNING

#5: Dextromethorphan hydrobromide is a

#6: Nitrosamines are

#7: Benzethonium chloride is an acceptable ingredient in lipsticks

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



SECTION 16

NO PERSON SHALL SELL A COSMETIC UNLESS IT IS LABELLED IN
ACCORDANCE WITH THESE REGULATIONS

LABELLING

Inner Label – a label on or affixed to the immediate container
(Bottle Label, Tube Label)

Outer Label – a label on or affixed to the outside package of a
cosmetic
(Carton, Blister Card)

Some have both,
Some only have an inner label – termed the outer label in this case

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



Outer and Inner Label



*Inner Label Only
(i.e. Outer Label)*



GUIDANCE DOCUMENTS

LABELLING OF COSMETICS (2006)

GUIDE TO COSMETIC INGREDIENT LABELLING (2009)

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



SECTION 17

NO REFERENCE TO THE ACT OR REGULATIONS TO BE MADE ON ANY LABEL OR
ADVERTISING, UNLESS AS REQUIRED IN THE ACT OR REGULATIONS

I.E. APPROVED BY HEALTH CANADA

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



SECTION 18

INFORMATION SHOWN IN ENGLISH & FRENCH,
EXCEPT FOR THE INCI NAME

CLEARLY LEGIBLE
REMAIN SO THROUGHOUT THE LIFE OF THE PRODUCT, UNDER NORMAL
CONDITIONS OF SALE AND USE.

COSMETIC REGULATIONS
LABELLING (§ 16, 17-21)



COSMETIC REGULATIONS
LABELLING
SECTION 19, 20, 21

Product Identity
Name and Address of Manufacturer
Avoidable Hazards & Cautions
Ingredients

OTHER ACTS AND REGULATIONS REQUIRED FOR LABELLING

CONSUMER PACKAGING & LABELLING ACT & ITS REGULATIONS

COMPETITION ACT

**CONSUMER CHEMICAL CONTAINER REGULATIONS (FROM SEP 30, 2001)
(CCCR, 2001)**

CHARTER OF THE FRENCH LANGUAGE (QUEBEC ONLY)

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



CONSUMER PACKAGING & LABELLING ACT & REGULATIONS LABELLING

PRESCRIBES THE MANDATORY INFORMATION THAT MUST APPEAR ON THE
LABEL OF A PRE-PACKAGED PRODUCT

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



CONSUMER PACKAGING & LABELLING ACT & REGULATIONS LABELLING

Product Identity
Net Quantity
Name and Address of Manufacturer
False & misleading
Container standardization

ONLY APPLIES TO THOSE PRODUCTS SOLD TO CONSUMERS

DOES NOT GOVERN COSMETICS APPLIED BY COSMETICIANS,
HAIRDRESSERS, AND SO ON, TO THEIR CLIENTS UNLESS SUCH PERSONS
SELL THE COSMETICS TO THEIR CLIENTS AS PREPACKAGED PRODUCTS

CONSUMER PACKAGING & LABELLING ACT & REGULATIONS LABELLING

Net Quantity

Although the Cosmetic Regulations do not require a declaration of net quantity, there are several specific requirements in the CPLA&R

Character heights correspond to the area of the Principal Display Surface

For Example:

PDS not more than 32 cm² : Minimum character height = 1.6 mm (1/16 ") for the **numerical part** of the declaration of net quantity

The numerical part of the net quantity must appear in bold face type.

16 mL

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



CONSUMER PACKAGING & LABELLING ACT & REGULATIONS LABELLING

Net Quantity

Non-metric declaration may be provided, and are supplementary

Tolerances on amounts per Schedule 1 of the CPLR

**CONSUMER PACKAGING & LABELLING ACT & REGULATIONS
LABELLING**

Readability and Character Height

All information that is required to appear on a label, other than the declaration of net quantity must be in letters not less than 1.6 mm in height.

When the area of the PDS is less than 10cm², the information may be in letters of not less than 0.8 mm in height

For further details, consult sections 14, 15, and 16, of the Consumer Packaging and Labelling Regulations.

**Consumer Chemicals and Containers Regulations
(from Sep 30, 2001)**

Symbols and warnings statements for pressurized containers (i.e.)



INCI

International Nomenclature of Cosmetic Ingredients

published in the International Cosmetic Ingredient Dictionary and
Handbook

Available on-line from the Personal Care Products Council

US INCI !!!

EU Trivial Name

English & French Equivalents

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



INCI

- Ingredient listing must appear at the point of purchase
- When the immediate container or outside package is too small, they may appear on a tag, tape or card affixed to the container or package (tear-away tags or leaflets accompanying the product at point of sale are not acceptable)
- For ornamental containers that have no outside package and it is impractical to affix the information to the container, a leaflet must accompany the product at the point of sale

COSMETIC REGULATIONS LABELLING (§ 16, 17-21)



INCI

- Listed in descending order of predominance,
- Incidental ingredients (not present in the final formulation) do not need to be listed as ingredients
- Quantities less than 1% concentration, may appear in any order
- Shade and Colour Ranges
- “±” or “may contain/peut contenir”

ASSESS YOUR LEARNING

#10: The CPLA&R only applies to products sold to a consumer

#11: Readability and character height for cosmetic labelling is found in

All information on the label is required to be translated into French, using:

EQUAL PROMINENCE

Exception is the listing of ingredients (INCI) for cosmetic products

There are exceptions for company names and trademarks.

COSMETIC REGULATIONS NOTIFICATION (§ 30-31)



NOTIFICATION (§ 30 & 31)

Manufacturers and importers must notify Health Canada within 10 days after they first sell a cosmetic in Canada.

When there is a change affecting the information in the notification, an amended notification shall be made. Changes can include:

- Modification of the cosmetic formulation
- Change of product name
- Discontinuation of Sale
- New Company name, address or contact information

NOTIFICATION (§ 30 & 31)

- “New” electronic (HTML) based form
- Instructions on Health Canada’s website
- New, amended or discontinuation of sale
- Embedded ingredient validation system that cross-references entries with the Cosmetic Hot List – CURRENTLY NOT WORKING
- Cosmetic ingredient concentrations use ranges/range codes
- Option for “may contain” (i.e. colour variants/fragrances)
- No Fees
- NOT A PRIOR APPROVAL SYSTEM

NOTIFICATION (§ 30 & 31)

- Where labels are required to be submitted (e.g. avoidable hazards), they can be uploaded
- Cosmetic Number (CN) is a unique 7-digit identifier assigned once the CNF is processed. They will be assigned and sent to the notifier via email.
- Case and Submission number: internal tracking numbers, inserted directly into the CNF when submitted online. These numbers assist Health Canada in identifying the correct products.
- Save all these numbers for reference purposes.

NOTIFICATION (§ 30 & 31)

- The same form is required to indicated product discontinuations (one of the fields on the form)

POST-MARKETING SURVEILLANCE



The Consumer Product Safety Directorate deals with reports of **consumer product-related** health or safety concerns from industry and consumers.

Industry reports are required under section 14 of the Canada Consumer Product Safety Act (CCPSA) and may be received **voluntarily** for cosmetics under the Cosmetic Regulations made under the Food and Drugs Act.

Cosmetics are specifically exempt from this CCPSA.

Health and safety reports involving consumer products and/or cosmetics can be submitted by telephone or e-mail.

POST-MARKETING SURVEILLANCE



- Voluntary Reports on health and safety issues related to cosmetics (and consumer products) – received from consumers and industry
- Quarterly reports published and include cosmetic reporting

POST-MARKETING SURVEILLANCE



- No routine cosmetic inspections
- Cyclic enforcement sampling
 - to verify compliance of cosmetic products which are subject to the CR
 - 2014/2015 – CE Project: Labelling & CNF
 - 2016/2017 – CE Project: MI/MCI
 - 2017/2018 – CE Project: Fragrances
 - Results are published on the Consumer Product Safety portion of Health Canada’s website

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/enforcement-summary-report.html>

BREAK OR Q&A



5 MINUTE BREAK

OR

Q&A SESSION

YOUR CHOICE!



CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)



- Compliance for new and existing substances in products regulated under the Food and Drugs Act
 - Pharmaceuticals, radiopharmaceuticals, veterinary drugs, biologics
 - Cosmetics, food additives, medical devices, natural health products
 - Novel foods
- Ensures substances in Food and Drug Act regulated commodities are assessed from a human health and environmental safety perspective

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)



- Lists
 - DSL (Domestic Substances List)
 - NDSL (Non-Domestic Substances List)
 - ICL (In-Commerce List)
 - FDA-DSL (Food and Drugs Act-DSL)

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)



- DSL
 - Substances in Canadian commerce between 1984-1986, or that were added to the DSL in accordance with CEPA 1999
- NDSL
 - Substances assessed by the US EPA by listing on the Toxic Substances Control Act (TSCA)
 - Substances added to the NDSL **one** year after being listed on the TSCA Chemical Substances Inventory. Update **which is** done twice a year
 - Subject to fewer information requirements for notification under NSNR
 - Substances not on DSL or NDSL – notify 5 days before exceed 100 kg/yr
 - Substances not on DSL but on NDSL – notify 30 days before exceed 1000 kg/yr

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)



- FDA-DSL (Domestic Substances List)
 - Substances in products regulated under F&DA that were in-commerce in Canada between 1984 and 1986
 - For substances not on the DSL, HC identified substances that were in the HC databases but did not have enough information to add to the DSL. These became the FDA-DSL.
 - A non-statutory, policy list

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)



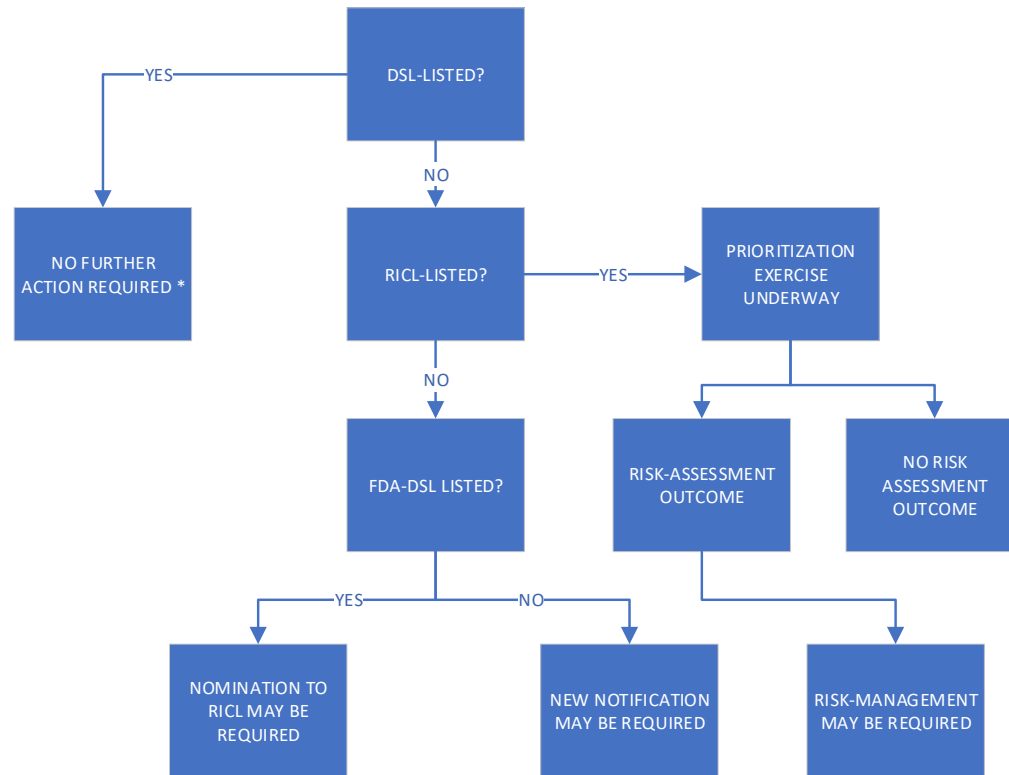
- There are two ICLs (Current and Revised)
 - Compiled from HC records for those substance in-commerce between 1987-Sep 13, 2001.
 - Revised ICL – substances are considered to be “existing” as present under administrative policy and are not subject to NSNs FOR NOW
 - “Existing” substances are undergoing a prioritization and screening program under CMP to ensure they are assessed for human health and environmental concerns

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)



- Search engines available on ECCC website
 - Chemicals and polymers
 - Organisms

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA, 1999)



* IF ON DSL AND NO RISK MANAMENT PLAN MEASURES IMPOSED (I.E. SNAC) THEN FREE TO IMPORT/MANUFACTURE FOR ANY USE

Competition Bureau

Administers four laws:

- The Competition Act**
- The Consumer Packaging and Labelling Act**
- The Textile Labelling Act**
- The Previous Metals Marketing Act**

Competition Bureau

Investigates anti-competitive activities,
Protect consumers and
Promotes competitive markets

Covers many items
Ensure truth in advertising

The Bureau promotes truth in advertising in the marketplace by discouraging deceptive business practices and encouraging the provision of sufficient information to enable informed consumer choice.

UPCOMING TRAINING SESSIONS

**Nov 13th – Cosmetics Labelling 101
Introduction to Cosmetic Labelling for Canada**

**Dec 11th – Introduction to Natural Health
Products**

Contact: regulatory@cosmeticsalliance.ca

or

See Regulatory Essentials

Q&A



Q&A SESSION





QUIZ

- **OPEN BOOK**
- **15 QUESTIONS, MC & MC²**
- **CAN HANG UP PHONE LINE NOW (CHAT)**
- **HAVE UNTIL 2:30, BUT IF YOU NEED MORE TIME....**
- **ONCE SUBMITTED, YOU CAN LEAVE SESSION**
- **FOLLOW-UP EVALUATION**

GOOD LUCK

