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Regulation of Cosmetics in Canada

*Presentation by Emily Contreras
Senior Regulatory Officer, Cosmetics Division
Health Canada
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*Helping the people
of Canada maintain and
improve their health*

*Aider les Canadiens et
les Canadiennes à améliorer
leur état de santé*

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Presentation Outline

- Health Canada's Cosmetics Program
- Regulatory Authority
- Cosmetic (vs. drug)
- Classification & Claims
- Requirements of the *Food and Drugs Act* and the *Cosmetic Regulations*
- *CEPA* and the Chemicals Management Plan
- Tools for Industry
- Compliance & Enforcement
- Looking Ahead



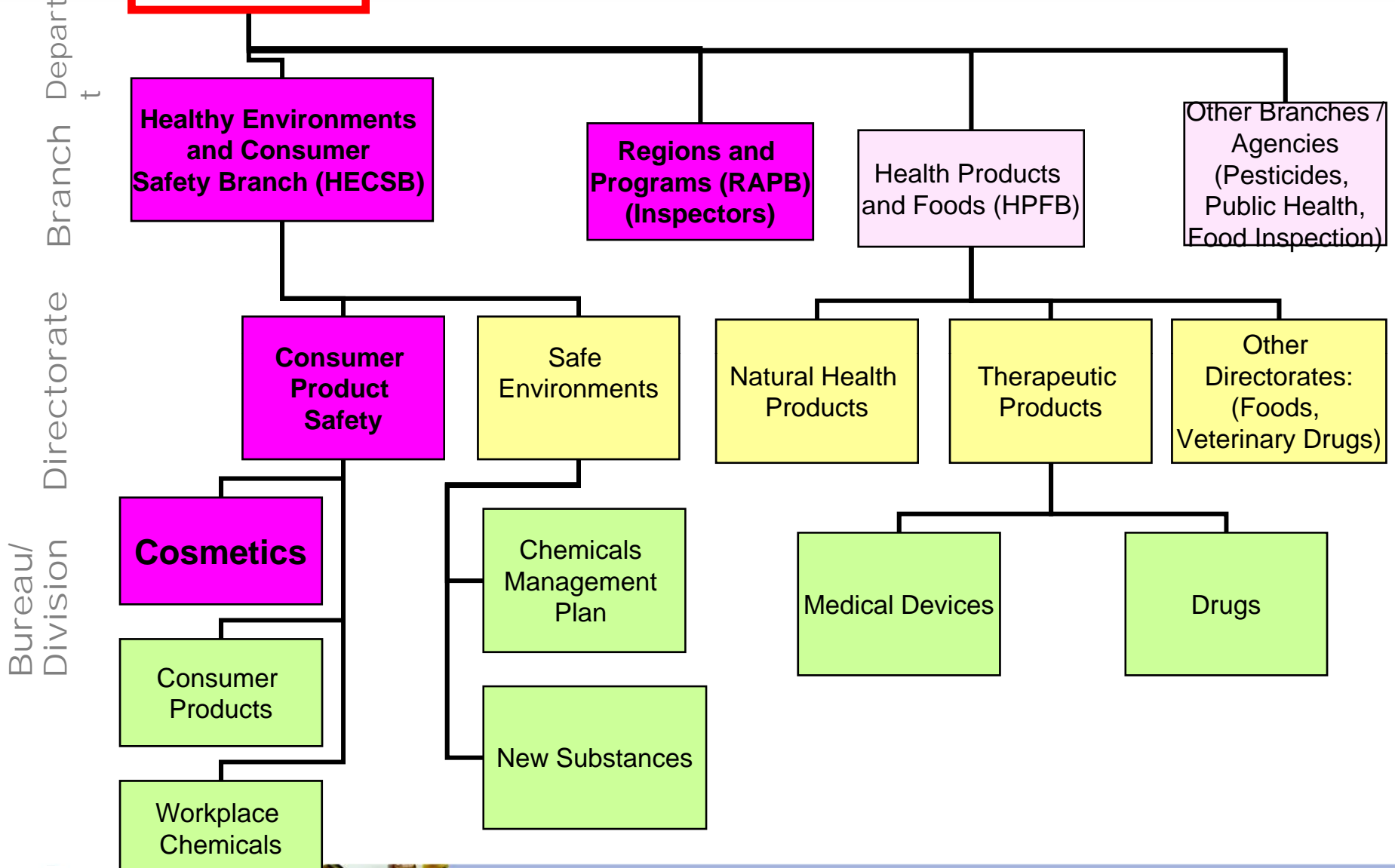


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Health Canada's Cosmetic Program







Cosmetics Program

- **Cosmetics Division (HECS - Ottawa)**
 - Policies, regulations, scientific support, information kits, national coordination
- **Product Safety Inspectorate**
(RAPB - Six Regions across Canada)
 - Enforcement, first line of contact for most complaints and enquiries
 - Primary liaison with Customs (CBSA), Provincial Health Inspectors, US FDA, police (RCMP)





Cosmetics Program Mandate:

To protect and improve the health of the Canadian public 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





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Regulatory Authority





Authority

- Program's powers 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)
 - *New and existing cosmetic ingredients*





Food and Drugs Act

- Defines *cosmetic, drug, food and device*
- Provides general safety requirement for cosmetics
- Gives powers to the inspectors to search premises, take samples, seize products, stop sale, etc.
- Contains:
 - Cosmetic Regulations
 - Food and Drug Regulations
 - Natural Health Product Regulations, etc.





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.

- Scope in the above definition is not exhaustive because of the use of the term “includes”





What is a Cosmetic?

Included*:

- ✓ Soap
- ✓ Deodorants / Antiperspirants
- ✓ Hair dyes
- ✓ Tattoo inks
- ✓ Tooth whiteners
- ✓ Whitening chewing gum
- ✓ Breath strips
- ✓ Personal lubricants
- ✓ Nail adhesives
- ✓ Hotel amenities
- ✓ Professional products

Excluded*:

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

* = *Not an exhaustive list*





What is a Drug?

“Drug” includes any substance or mixture of substances manufactured, sold or represented for use in:

- a) the diagnosis, **treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms**, in human beings or animals,
- b) restoring, **correcting or modifying organic functions** in human beings or animals, or
- c) disinfection in premises in which food is manufactured, prepared or kept.





What is a Natural Health Product (NHP)?

- Defined in the Natural Health Products Regulations, not in the Act
- A subset of “Drug”, it is a therapeutic product whose active ingredients come from a “natural” source.
- Came into force January 1, 2004





Classification: Cosmetic vs Drug*

- To determine if a product is a cosmetic or a drug, one must look at:
 - the **claims** that appear on the product
 - the **ingredients** present in the product
- See *Guidance on the Classification of Products at the Cosmetic-Drug Interface*

* “Drug” means Therapeutic Product 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.
- Claims include 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 Food and Drugs Act.





Classification

Product	Purpose: Cosmetic or Drug ?
Skin Cream	<i>Cosmetic:</i> Moisturizes the skin
Diaper Rash Cream	<i>Drug:</i> Treats a skin disorder (rash)
Lipbalm	<i>Cosmetic:</i> Moisturizes the lips
Lipbalm with SPF 15	<i>Drug:</i> Protects the skin on lips from sun damage





To represent your product as a cosmetic

- Some claims can be modified so that they are qualified in a cosmetic sense (e.g. in terms of appearance/looks, via moisturization):
 - “reduces wrinkles” → drug claim vs.
 - “reduces the look of wrinkles” → cosmetic claim
 - “heals skin” → drug claim vs.
 - “moisturizing to heal dry skin” → cosmetic claim
 - “kills germs” → drug claim vs.
 - “kills bacteria that cause odour” → cosmetic claim





More about Claims...

- Cannot make reference to Health Canada, the Act or Regulations on labels or in advertising, and cannot suggest cosmetic is a prescription
- Cannot make false and misleading claims on label and advertisement under
 - The Consumer Packaging and Labelling Act, and
 - The Competition Act
 - These also prohibit deceptive packaging





History of Regulations for Cosmetics:

- Cosmetics first considered in 1939
- Regulations incorporated into the Food and Drug Regulations (FDR) in 1956
- Cosmetic Regulations split from FDR in 1977
- Amended from time to time based on changing circumstances
 - Notification of cosmetics became mandatory in 1978
 - Mandatory ingredient labelling in 2006
- Undergoing review/modernization over the next few years as part of the *Food and Consumer Safety Action Plan*





Summary of Authorities & Requirements:

Food and Drugs Act:

- Definition of cosmetic
- General Safety Requirements
- Powers of Inspectors

Cosmetic Regulations outline requirements for sale:

- Import
- Labelling
- Warnings/Cautions/Directions for safe use
- Specific products/ingredients
- Notification





S.16 of the Food and Drugs Act: The General Safety Requirement

- Basis for prohibition or control of ingredients (in the Cosmetic Regs and the Cosmetic Ingredient Hotlist)
- Also basis for need for quality control systems for impurities and micro-organisms, packaging and storing conditions
- Although there are no specific requirements for Good Manufacturing Practices (GMP), HC encourages use of ISO Cosmetics GMP Standard: 22716





Ingredient/Product Safety

- In addition to general safety requirement in the Act, the Cosmetic Regulations outline controls for:
 - Chloroform, estrogenic substances, mercury, PPD and coal tar hair dyes, methyl alcohol, potassium bromate and sodium bromate, genital deodorants. Prohibits products that remove stains from teeth with $< \text{pH } 4$
- All other ingredient controls are outlined in the Cosmetic Ingredient Hotlist





Labelling Requirements

- ✓ Appropriate cosmetic claims
- Directions for safe use
- Warnings
- Requirements for cosmetics in pressurized containers
- Special Packaging
- Product identity and the responsible company
- Ingredient Labelling
- Bilingual requirements





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

- The label of a cosmetic that presents an avoidable hazard must include directions for safe use.
- “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 and the site of application;
 - (b) 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
- 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

- Aerosol products in a metal pressurized container
 - Does not include pump sprays or those in plastic containers
- Must meet the requirements of the Consumer Chemical Container Regulations (CCCR) under the Hazardous Products Act as they read on Sept 30, 2001. This means the old version of CCCR.





Pressurized Containers

- These containers require an explosive symbol along with the appropriate signal word and hazard statement
- Also may need a flammability symbol, depending on whether product is tested as flammable, the length of the flame and whether there is flashback
- See *Labelling Requirements for Cosmetics in Pressurized Containers*





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 Methyl alcohol, potassium bromate and sodium bromate





Product Identity and Manufacturer

- Consumer Packaging and Labelling Act and Regulations requires
 - Declaration 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” (a.k.a. dealer)





Product Identity and Manufacturer

- Product identity is not required if identity is obvious (e.g. soap or lipstick)
- Manufacturer address needs to be detailed enough so that a letter mailed can reach manufacturer
 - In some cases this is just a postal code
 - 1-800 or email address only is not sufficient
 - Address does not need to be in Canada





Ingredient Labelling

- List of ingredients must be in INCI nomenclature and on outer label
 - Trivial names outlined in the Schedule of the Cosmetic Regs must either be in Latin, or in English and French.
Eg. “Aqua/Water/Eau” or “Water(Eau)”
 - If an ingredient has no INCI name, must use chemical name
 - Must be prominent and legible





Ingredient Labelling

- Descending order of predominance, except
 - Ingredients at 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 – Outer Label

- Where product has an inner and outer label, ingredients don't have to be on inner label
- Where a product has only one label, all requirements must be on that label
- Where product is too small/ornamental to carry a label, can put ingredients on tag, tape or card (affixed unless bulk)





Bilingual Requirements

- Any labelling requirement of the Cosmetic Regulations (except INCI) must be in English and French sold anywhere in Canada
- If you sell products in Quebec: under Bill 101, all must be in at least French (including any descriptions)
 - Exception is the ingredients when listed in INCI as per the Cosmetic Regulations
 - Bill 101 = Quebec Charter of the French Language





Notification

- Importer or manufacturer responsible for ensuring notification
- Post-market: within 10 days of sale
- Required for new products, formulation changes and discontinued products
- Notification for each product:
 - manufacturer(s)/distributor, purpose, physical form and formulation
 - No fee





Notification

- Product details entered in Cosmetic Notification System (CNS)
 - Name, purpose, contact info, formulations
 - A unique identifier (CNF#) is generated for easier reference
- Formulations entered are verified against the Cosmetic Ingredient Hotlist





Notification

- Not a product evaluation or approval procedure
- Acceptance of the completed form or labelling by Health Canada does not constitute, in any way, agreement that the product is in compliance with all regulatory requirements





Do I wait for a response?

- No. We do not send an acknowledgement since we receive over 20,000 notifications every year.
- You must specifically request one if you want one
- Acknowledgement letter is not necessary to continue sale in Canada (assuming you've met all of the regulatory requirements)





If you don't hear from us, that's usually a good thing

We may contact you for:

- Missing information/Clarification
- Not a cosmetic
- Hotlist ingredient
- Unacceptable claims
- Safety Data
- Complaint





Common Notification Errors

- Illegible writing (small font, poor handwriting)
- Concentrations missing
- Unknown ingredients (use INCI or another standard reference where possible)
- Not signed
- Unsure whether this relates to multiple products or one





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Canadian Environmental Protection Act (CEPA) and the Chemicals Management Plan





CEPA: The Canadian Environmental Protection Act

- In Canada, all ingredients, including those in cosmetics, are subject to Canadian Environmental Protection Act (CEPA)
- Two Streams under CEPA treated differently:
 - New Substances
 - Existing Substances
 - Delineation based on whether the substance is on the national chemical inventory (Domestic Substances List)





A “New Substance” means..

- Not on chemical inventory (Domestic Substances List)
 - Subject to the ***New Substances Notification Regulations***
 - Trigger is 100 kg annual import or manufacture
 - Exception for substances on In Commerce List (ICL): will be reviewed under future environmental assessment regulations





“Existing Substance”

- On Domestic Substances List
 - 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)
- Cosmetics Division works with the CEPA programs to share information and to communicate risk management approaches
 - Can use the Hotlist to risk manage ingredients assessed under CEPA if concern to human health





The Chemicals Management Plan (CMP)

- 200 high priority substances on the DSL are part of The CMP Challenge
- 12 Batches of 15-25 substances launched in *Canada Gazette*, Part I every 3 months, Feb 2007-Dec 2009
- Each batch has questionnaire for importers, manufacturers and end users.
- Each substance undergoes a screening level assessment by Health Canada and Environment Canada
 - Recommend risk management approaches if designated as “Toxic” to humans or the environment
 - See Hotlist slides





CMP – Medium Priorities

- 631 Medium health priorities for CMP
- 2000 Medium eco priorities
- Search of CNS revealed 42% in CNS
- Developing criteria for prioritization
- Will engage industry regarding issues of prioritization, data gathering and assessment





Industry Tools

- Hotlist
- Guidance Documents and the HC Website





The Cosmetic Ingredient Hotlist

- List of prohibited and restricted ingredients in cosmetics in Canada
- Created in 1995 based on policies regarding certain ingredients used in cosmetics
- Cosmetic Regulations contained some prohibited or restricted ingredients, but did not capture other ingredients that should not be used in cosmetics





The Cosmetic Ingredient Hotlist

- Currently 700+ 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





The Cosmetic Ingredient Hotlist

- Not entrenched in the regulations
 - Changes do not undergo extensive regulatory amendment process
 - Updated once or twice per year
- List is considered to be an elaboration of s. 16 of the *Food and Drugs Act* which states that

No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user





How are ingredients nominated for review?

Come to Program's attention through:

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





How are ingredients nominated for review?

Prioritized for assessment based on:

- Available evidence
- Injury complaint
- Synchronization with other decisions in GoC (e.g. proposed changes to *Food and Drug Regulations* by HPFB)
- Perceived risk
- etc.





Sources of Information

- Opinions of EU's Scientific Committee on Consumer Products (SCCP)
- Cosmetic Ingredient Review (CIR)
- Assessments/reviews conducted by other groups within Government of Canada
- Scientific literature





Review Process

- Substance undergoes **Screening Review**
 - Compilation of scientific and regulatory information into a Cosmetic Ingredient Profile
 - This usually provides sufficient evidence to make a decision





Review Process

- If there are still questions/concerns, the substance will undergo a more **in-depth Risk Assessment** (Cosmetic Policy Decision Document)
 - Considers Margin of Safety and Risk/Benefit
- Power to ask companies for information under the Cosmetic Regulations





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
- Insufficient information
- No objection to current use in cosmetics





Next Steps for Hotlist Update

- Affected companies informed
- Draft Hotlist published to Web
- 60-day comment period
- Any submitted supporting data reviewed
- Final Hotlist published to Web





Hotlist Update

- Last update September 2009
<http://www.healthcanada.gc.ca/hotlist>
- CMP Batch 1&2 of Hotlist:
 - Draft underwent consultation until Dec 23
 - Hydroquinone: Further restrictions – same as EU
 - Methyloxirane monomer - prohibition
 - Naphthalene - prohibition
 - Toluene Diisocyanates - prohibition
 - CEPA-related housekeeping issues (SNAC substances), and minor cosmetic amendments





Hotlist: Coming Soon

- Comments reviewed
- Removing references to CEPA actions (SNAc)
 - Possibly listed in a separate document
- Next edition will reflect CMP Batches 3-5 (all prohibitions):
 - **Batch 3** - DEGME, Methoxyethanol acetate, PGME, PGMEA, 2-Methoxypropanol, 2-MEA, Pigment Red 3
 - **Batch 4** - 1,3-Butadiene, DES, DMS
 - **Batch 5** - Acrylamide (monomer)





The HC Website: Guidelines to Help You

<http://www.healthcanada.gc.ca/cosmetics>

- Guidelines for Cosmetics Manufacturers, Importers and Distributors
- The Guide for Completing Cosmetic Notification Forms
- Guidelines for the Labelling of Cosmetics
- Guide to Cosmetic Ingredient Labelling
- Labelling Requirements for Cosmetics in Pressurized Containers
- Guidelines for Cosmetic Advertising and Labelling Claims
- Guidance on the Classification of Products at the Cosmetic-Drug Interface
- Cosmetic Ingredient Hotlist
- Act and Regulations, etc.





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Compliance and Enforcement: Working with an inspector





Compliance and Enforcement: Working with an inspector

- Product Safety inspectors enforce the *Cosmetic Regulations*
- Powers are in the *Food and Drugs Act* and *Cosmetic Regulations*
 - Can inspect premises where cosmetics sold, manufactured or stored, take samples for testing or take 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 a cosmetic





Circumstances under which an inspector might contact you

- Non-compliance in regard to cosmetic that:
 - is being imported (referral from Canadian Border Services)
 - was found on the market, as a result of
 - an inspection on the market
 - sampling performed during a routine market survey
 - a trade/consumer complaint
 - notification screening
 - is being advertised to Canadians (internet, broadcast, etc)
 - was found during an inspection of the manufacturing plant
- Investigation of an injury complaint





Working with an inspector

- Under the law, anyone on premises must assist the inspector if necessary. Cannot falsify information, hinder or obstruct the inspector as they are doing their duty. Cannot remove or alter anything seized by the inspector.
- Follows the HECSB Compliance and Enforcement Policy





Actions taken will depend on:

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





Working with an inspector

- Don't panic! Provide assistance where possible.
- Voluntary approach always taken before inspectors use their powers 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
- Inspectors will not do all the work for you. Hire a consultant if you do not know how to comply.





Looking Ahead

- International Cooperation (ICCR)
- Nanomaterials and Cosmetics
- GMPs
- Modernization of the Cosmetic Regulations
- Classification of Products at the Cosmetic-Drug Interface
- CosMos – online notification system





International Cooperation on Cosmetic Regulation

- Canada part of regulatory dialogue with regulatory representatives of US, EU and Japan, as well as industry counterparts
- Meet once a year face to face and have quarterly teleconferences
- Issues include: alternatives to animal testing, sunscreens, GMP, ingredient safety, labelling/packaging and nanotechnology
- Next meeting July in Toronto





Cosmetics & Nanomaterials

- Current regulatory framework has capacity to effectively deal with potentially harmful substances in cosmetics
- However, the standard nomenclature used for cosmetics (INCI) does not identify nanomaterials (same with CAS, IUPAC, etc)
- Therefore currently unable to identify which products contain nanomaterials





Cosmetics & Nanomaterials

- Updated EU Cosmetics Regulation addresses nanomaterials via labelling, notification and safety substantiation
- At this time, the information for nano in cosmetics is not compelling enough for HC to take this level of action





Current Activities: Nanomaterials

- Focus is on international committee work:
 - Member of the International Cooperation on Cosmetic Regulation (ICCR) with the US, EU and Japan
 - International meeting in July 2009 on Nano in cosmetics that shared the current state of play and issues in regards to regulation of nano in cosmetics
 - Dec 2009 formation of the ICCR Nano Working Group
 - First step: Develop nano criteria relevant to cosmetics to be used by regulators
 - Second: Establish a set of safety principles that will guide the collective assessment of nanomaterials in cosmetic products





Next Steps: Nanomaterials

- ICCR Nano WG outcomes will be used to develop a Industry Guideline for nano in cosmetics under the HC Interim Working Definition framework
 - Interim working definition published for consultation March 2010
 - http://www.hc-sc.gc.ca/sr-sr/consult/_2010/nanomater/index-eng.php
- Possible regulatory approach will focus on identification of nano in the Cosmetic Notification Form





GMPs

- Canada has committed through ICCR to adoption of ISO 22716: Cosmetics – Good Manufacturing Practices
- GMP not mandatory, however strongly suggested given legal requirements for manufacture and storage under sanitary conditions
- GMP page on HC Cosmetics website in early 2010
- No immediate intent to change level of compliance and enforcement activity for cosmetics GMP, though possibility of mandatory GMP may be explored in the future





Cosmetics Modernization - Why Now?

- Key deliverable under the Government of Canada's *Food and Consumer Safety Action Plan*
- Some jurisdictions, in particular the EU, have been enhancing the way they regulate cosmetics.
- Some provisions in the *Cosmetic Regulations* were simply cut and pasted from the *Food & Drug Regulations*; uncertain of their relevance to cosmetics
 - A full analysis and review required





Cosmetic Modernization Work

Split into three main categories:

1. Legislative Modernization:
Food and Drugs Act
2. Regulatory Modernization:
Cosmetic Regulations
3. Administrative Modernization:
Policy and Guidance to deal with Interface Challenges





Approach to Regulatory Modernization

- Policy analysis and a comparison of domestic and international regulatory frameworks to determine best practices in the following areas:
 - compliance/enforcement
 - notification/assessment
 - packaging and labelling
 - ingredients
 - miscellaneous





Products at the Cosmetic-Drug Interface

- Guidance on the Classification of Products at the Cosmetic-Drug Interface issued in 2008
- Provides clear criteria for determining what is a cosmetic versus drug:
 - Representation
 - Composition
 - Level of Action
 - Other:
 - Inherent risk-benefit balance
 - Precedents and past decisions
 - Classification schemes of other regulatory authorities





Products at the Cosmetic-Drug Interface

- To date 3 product categories have been assessed against this criteria: diaper rash creams, medicated skin care and antiperspirants
- Only antiperspirants reclassified to cosmetics
- Companies affected by transition will be given until end of 2011 to change their labels
- New antiperspirants must comply with cosmetic requirements immediately





Online Notification: COSMos

- Currently: All notification forms entered into system by hand
- Developing an online tool for better management and easier notification for companies
- IT development part of project still going slower than expected





CosmOS – Cosmetics Online System

- **New Cosmetic Notification Form Version 1** was tested by industry volunteers; went very well
- Still refining form and user requirements
- Targeted CosMOS project completion April 2011(?)
- Interested in contributing your thoughts on the notification form?
 - Contact Christopher Pollard at christopher.pollard@hc-sc.gc.ca





Questions?

For More Information:

Cosmetics Program Website:

- www.healthcanada.ca/cosmetics

Contact Us:

- cosmetics@hc-sc.gc.ca

