Vermeer Project for Safety evaluation: focus on international cosmetic regulatory framework

*Regulatory Framework Worldwide for Cosmetics/Ingredients*

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The definitions

Slightly different ways of regulating the cosmetic and personal care industry, different way to define what a cosmetic is according to its effects, and high degree of safety, are the main features of a compared cosmetic legislation among Europe, Asia, America and Australia.

This is valid also for cosmetic ingredients which can be considered under chemical laws or under cosmetic rules.
Cosmetic Regulations

Chemical Inventories

Cosmetics
Quasi Drugs
Functional
Natural
Ingredients
Substances
Polymers
Chemicals
Where

USA – Canada – Brazil
India
Australia
Cosmetics are defined in §201(i) of the Act as

“(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and

(2) articles intended for use as a component of any such articles; except that such term shall not include soap.” Cosmetics have been classified into several categories: skincare, fragrances, eye and other makeup, manicure products, hair coloring preparations, shampoos, deodorants, shaving products, baby products, bath oils and bubble-baths, toothpaste, mouthwashes (including breath mints or strips) and tanning products.
USA

Chemical Inventory basics:
How TSCA defines “chemical substance”

TSCA defines a “chemical substance” as any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.

Chemicals substances on the Inventory include: Organics; Inorganics; Polymers; and Chemical substances of unknown or variable composition, complex reaction products, and biological materials (UVCBs).

Chemical substances not on the Inventory are those with uses not regulated under TSCA. The use of these chemical substances is governed by other U.S. statutes on, for example: Pesticides, Foods and food additives, Drugs, Cosmetics, Tobacco and tobacco products, Nuclear materials, or Munitions.
The proposed Modernization of Cosmetics Regulation Act (MCRA) of 2018, will change the standards of cosmetics production and safety to that approximating food ingredients — a move that may be very costly and disruptive for some cosmetics companies.

**Special case – OTC (Drug)**

- Topical Antiseptic Products: Hand Sanitizers and Antibacterial Soaps
- Sunscreen Information
All cosmetics sold in Canada must be safe to use and must not pose any health risk. They must meet the requirements of the *Food and Drugs Act* and the *Cosmetic Regulations (C.R.C., c. 869)*

Cosmetics are defined as "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." This definition also includes cosmetics used by professional esthetic services, as well as bulk institutional products (e.g. hand soap in school restrooms).
Canada

Chemical Inventory in Canada:

DSL (Domestic Substances List)
NDSL (Non Domestic Substances List)

New Substances Notification Regulations (Chemicals and Polymers)
SOR/2005-247

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

No exemptions are indicated for cosmetic ingredients (only a reduced regulatory requirements based on structure or quantity)
ICL - In Commerce List of Food and Drugs Act Substances

It is an “additional” positive list: since September 2001, substances in products regulated under the Food and Drugs Act (FDA) have been subject to the New Substances Notification Regulations (NSNR) of the Canadian Environmental Protection Act, 1999 (CEPA 1999).

Substances which were in products that were regulated under the FDA and that were in Canadian commerce between 01 January 1987 and 13 September 2001 were placed on an administrative list, called the In Commerce List.

The In Commerce List contains substances found in pharmaceuticals, veterinary drugs, biologics and genetic therapies, cosmetics, medical devices and food additives. The In Commerce List consists of 4 sub-lists and is a static administrative list which will not change.

Chemicals in this list but not notified under CEPA (DSL) can be used in Canada ad Cosmetic Ingredients.
Canada

Cosmetic Ingredient Hotlist

List of Ingredients that are Prohibited for Use in Cosmetic Products
List of Ingredients that are Restricted for Use in Cosmetic Products

Cosmetic-Drug Interface

These are products that may share the characteristics of both "cosmetic" and "drug", as defined in the Food and Drugs Act, making them more difficult to classify. Such products may include, for example, acne therapy, anti-perspirants, anti-dandruff products, fluoride-containing anti-caries products, medicated skin products, diaper rash products, antiseptic skin cleansers, sunburn protectants, skin whiteners and tooth whiteners.

In Canada, a product at the cosmetic-drug interface (PCDI) can be regulated by one of three sets of regulations under the Food and Drugs Act, depending on their ingredients and on the claims they make:

- the Cosmetic Regulations
- the Food and Drug Regulations
- the Natural Health Products Regulations
Cosmetic is defined in Brasil as:

Toiletries (personal hygiene, personal care products), cosmetics and perfumes:
they are preparations consisting of natural or synthetic substances, for external use on various parts of the human body, skin, capillary system, nails, lips, external genital organs, teeth and mucous membranes the oral cavity, with the exclusive or main purpose of cleaning them, perfuming them, changing their appearance and or correcting body odors and or protecting them or keeping them in good condition.
4 lists

I- List of preservative action substances allowed for toiletries, cosmetics, and perfumes - Resolution - RDC No. 29 of June 10, 2012 and its updates;

II- List of permitted colorants for toiletries, cosmetics, and perfumes - Resolution - RDC No. 44 of August 9, 2012 and its updates;

III- List of substances that personal hygiene products, cosmetics, and perfumes should not contain except in the conditions and restrictions set for Resolution – RDC No. 03 of January 18, 2012 and its updates;

IV- List of ultraviolet filters allowed to toiletries, cosmetics, and perfumes - Resolution - RDC No. 47 of March 16, 2006 and its updates;

V- List of substances that cannot be used in personal hygiene products, cosmetics and perfumes - Resolution - RDC No. 48 of March 16, 2006 and its updates.
2 risk group

GRAU 1
Definition Products Grade 1: toiletries (personal hygiene, and personal care products), cosmetics, and perfumes are those products whose formulation complies with the definition adopted in item I of Annex I of his resolution and that are characterized by having basic or elementary properties, the proof of which is not initially required and do not require detailed information on their mode of use and its use restrictions, due to the intrinsic characteristics of the product

GRAU 2
Definition Products Grade 2: toiletries (personal hygiene, and personal care products), cosmetics, and perfumes whose formulation complies with the definition adopted in item I of Annex I of this resolution and that they have specific indications, whose characteristics require proof of safety and/or effectiveness as well as information and care, mode and restrictions of use
No Chemical Inventory

No Notification of cosmetic ingredients

But…

Imported cosmetic needs a notification to the ANVISA (Agência Nacional de Vigilância Sanitária) for GRAU 1 and a registration for GRAU 2 cosmetics.

Chemicals cited in Portaria 71/96 - Anexo XV are considered to define risk.
India

Import and Registration of Cosmetics on May 19th, 2010.
Drugs and Cosmetics Act, 1940, and amend.(Act 22, 1995 e 2007).
Drugs and Cosmetics Rules, 1945 , and amend.(III Amendment 1994).
Poisons Act, 1919.
Indian Standards - Bureau of Indian Standards (BIS).
Ministry of Health and Family Welfare Notification no. GSR 11(E) del 07/01/91.
Indian Packaging Commodities Regulation Order (1975)
Trade and Merchandise Marks Act (1958) and Rules (1969), as amended
Guidelines for cosmetic claims on packs
Code for self regulation in advertising

As per the Drug and cosmetic act 1940, “cosmetic” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.
Registration of Import of Cosmetics

A Gazette Notification G.S.R 426(E) dated 19th May 2010 has been issued by the Government of India for amending the Drugs & Cosmetics Rules, 1945 providing for registration of import of cosmetics into the Country. This provision was to come into effect from the 1st April, 2011. But in view of the various possible difficulties apprehended by the stakeholders, its implementation was deferred till the 31st March, 2013.

All cosmetic products that are imported for sale in India now need to be registered with the Central Drugs Standard Control Organisation (CDSCO) which has been appointed as the licensing authority for the purpose of these rules. This new ‘registration’ requirement is primarily to regulate indiscriminate import of beauty and personal care products by traders with no accountability for contents and no mechanism to fix responsibility in case a consumer is not satisfied with the quality. The new regulation is an attempt to check the sale of sub-standard cosmetic products and also to harmonise import requirements with products manufactured in India.
In INDIA no chemical inventory

Only a generic notification of hazardous chemicals for specific substances

No specific notification for cosmetic ingredients

Bureau of Indian Standards (BIS) has provided the specification for some group of cosmetics (i.e. for Skin Creams and Lipstick in the Indian Standards (IS) 6608:2004 and 9875:1990 respectively)

Some restrictions for heavy metals in raw materials, dyes colors (pigments lakes) if used in the manufacture of skin creams and lipstick, Synthetic Organic Colors and Natural Organic Colors used in the Cosmetic
Cosmetic is defined in Australia as a substance or preparation (product)

A cosmetic is a substance that is designed to be used on any external part of the human body—or inside the mouth—to change its odours, change its appearance, cleanse it, keep it in good condition, perfume it or protect it.

Cosmetics in Australia are classified under the scope of industrial chemicals
All importers of cosmetics or cosmetic ingredients and/or manufacturers of cosmetic ingredients must be registered with NICNAS.

All ingredients in a cosmetic product must be listed on the Australian Inventory of Chemical Substances (the Inventory) or notified to NICNAS for pre-market assessment unless an exemption applies.

All ingredients not on the AICS and notified to NICNAS will be subject to public health, work health and safety (WHS), and environmental risk assessment.

All ingredients not on the AICS and introduced under an exemption from notification and some permit categories are subject to annual reporting and record keeping requirements.
NICNAS regulates the importation and manufacture of chemicals for 'industrial' use, which includes cosmetics and soaps. Chemicals for human therapeutic use, such as medicines, are regulated by the [Therapeutic Goods Administration](https://tgaustralia.gov.au) (TGA).

<table>
<thead>
<tr>
<th>Cosmetics</th>
<th>Therapeutic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deodorant</td>
<td>Anti-perspirant</td>
</tr>
<tr>
<td>Soothes dry skin</td>
<td>Relieves rashes</td>
</tr>
<tr>
<td>Covers pimples</td>
<td>Heals pimples</td>
</tr>
<tr>
<td>Smooths wrinkles</td>
<td>Aids in repair of skin tissue</td>
</tr>
</tbody>
</table>

A group of countries follow EU cosmetic regulation principles where the cosmetic definition is aligned with the EU’s and countries follow the EU ingredients annexes within cosmetics regulation 1223/2009.

Looking back to the colonial past, countries including Kenya follow a "heritage from the Commonwealth" for regulation, which has also been inspired by India's cosmetics controls. This is based on a standard for cosmetic finished products, which prevents innovative products reaching the market.

Thirdly, Cameroon, for example, adopts a system promoted by the World Trade Organisation (WTO) to help emerging countries control their imports. Delegation of services and public health responsibilities are given to third party certifiers.

In general for Ingredients for Cosmetics:

- No Chemical Inventory
- No Cosmetic Ingredients Inventory
- Refer to local and existing cosmetic rules
Regulation (EC) N° 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products when placed on the EU market. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector. The Regulation simplifies procedures to the extent that the internal market of cosmetic products is now a reality.

The Regulation replaces Directive 76/768/EC, which was adopted in 1976 and had been substantially revised on numerous occasions. It provides a robust, internationally recognised regime, which reinforces product safety while taking into consideration the latest technological developments, including the possible use of nanomaterials. The previous rules on the ban of animal testing were not modified.
Europe

Strengthened safety requirements for cosmetic products
Manufacturers need to follow specific requirements in the preparation of a product safety report prior to placing a product on the market.

Introduction of the notion of “responsible person”
Only cosmetic products for which a legal or natural person is designated within the EU as a “responsible person” can be placed on the market. The new Cosmetics Regulation allows the precise identification of the responsible person is and clearly outlines their obligations.

Centralised notification of all cosmetic products placed on the EU market

Manufacturers will need to notify their products only once – via the EU Cosmetic Products Notification Portal (CPNP).
Europe

New rules for the use of nanomaterials in cosmetic products

Colourants, preservatives and UV-filters, including those that are nanomaterials, must be explicitly authorised. Products containing other nanomaterials not otherwise restricted by the Cosmetics Regulation will be the object of a full safety assessment at EU level if the Commission has concerns. Nanomaterials must be labelled in the list of ingredients with the word “nano” in brackets following the name of the substance, e.g. “titanium dioxide (nano)”.
Europe

REACH Regulation (1907/2006) applicable for cosmetic ingredients (only substance)

Exemption for quantity and natural substances

For the registered substances important the cosmetic use clearly indicated in the registration dossier
The European Commission cooperates with its partners on cosmetic products at both the EU and international level. Cooperation at the international level is focused on enhancing trade with non-EU countries.

What is ICCR?

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.

https://ec.europa.eu/growth/sectors/cosmetics/international_en
Five Regulatory Authorities

Brazil, Canada, the European Union, Japan and the United States

entered into a constructive dialogue, aiming at investigating possibilities of regulatory convergence for cosmetic/personal care products

International Cooperation on Cosmetics Regulation (ICCR)
International Activity

Main agenda items

- Good Manufacturing Practices
- Validation of Alternative Methods to Animal Testing
- Nanomaterials in Cosmetics (science input)
- Safety of Ingredients
- Traces
- Expansion to other countries
International Activity

Why ICCR?

- Dealing with cosmetics safety does not stop at national borders
- An ‘aspiration’: A global response to a global concern
- Ultimately a convergence of regulations among key partner economies
International Activity

How ICCR works?

- Management by objectives (limited number of topics)
- Decisions by consensus
- No changes in national legislations required
- Regular teleconferences with Regulators
- Annual meeting hosted by chairing member
- Press releases and information on websites
Tic-Tac-Toe
<table>
<thead>
<tr>
<th>Country</th>
<th>Chemical Inventory Required</th>
<th>Ingredient notification required in cosmetic rules</th>
<th>Chemical Cosmetic limitation</th>
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</thead>
<tbody>
<tr>
<td>USA</td>
<td>N</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>CAN</td>
<td>Y</td>
<td>N (ICL)</td>
<td>Y</td>
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<tr>
<td>BRA</td>
<td>N</td>
<td>N</td>
<td>Y</td>
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<tr>
<td>IND</td>
<td>N</td>
<td>N</td>
<td>Y</td>
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<tr>
<td>AUS</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>EUR</td>
<td>Y (substance)</td>
<td>N</td>
<td>Y</td>
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Remember

The cosmetic ingredients need a toxicology profile

This is our commitment to ensure the safe use of final cosmetic products

Thanks for you attention