OVERVIEW OF GLOBAL COSMETICS REGULATORY ENVIRONMENT

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INTRODUCTION

- Businesses must comply with international cosmetics regulations for a successful global market presence
- An important step in producing a compliant cosmetic product is understanding the regulatory status of its ingredients
- Additional non-regulatory requirements such as company specific restrictions may further impact ingredient selection
AGENDA

▪ How is cosmetic ingredients selection dictated by legislation in EU, ASEAN, US, and Australia

▪ Amendments and expected changes, examples

▪ Beyond regulatory?
  • Retailer restrictions on cosmetic product ingredients

▪ Q&A
EU – LEGISLATION

  - Main regulation for cosmetic products marketed in the EU
  - Sets specific requirements for certain ingredients in cosmetic products

  - Certain substances restricted in cosmetic products e.g. D4, D5

- CLP Regulation (EC) No 1272/2008
  - Raw material classification
Cosmetics definition:

- Substances or products used on external parts of the body, teeth, oral cavity
- In order to clean, perfume, change appearance, correct body odor, protect, and keep in good condition
- Sunscreens and antiperspirants are defined as cosmetics
EU – COSMETICS REGULATION (EC) NO 1223/2009 (2)

- Ingredient requirements:
  - Carcinogenic, mutagenic, reprotoxic substances (CMR) prohibited with few exceptions
  - Annexes II – VI includes prohibited, restricted and authorized substances
  - Provisions for use of nanomaterials
## CMR SUBSTANCES & NANOMATERIALS

**CMR Substances prohibited except when following conditions met**

<table>
<thead>
<tr>
<th>Condition</th>
<th>CMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant with EU Food Safety Regulation 178/2002</td>
<td>CMR 1A, 1B</td>
</tr>
<tr>
<td>No suitable alternative</td>
<td>CMR 1A, 1B</td>
</tr>
<tr>
<td>Specific use with known exposure</td>
<td>CMR 1A, 1B</td>
</tr>
<tr>
<td>Positive evaluation by SCCS</td>
<td>CMR 1A, 1B and CMR 2</td>
</tr>
</tbody>
</table>

### Nanomaterials (1 - 100 nm)

- Notification 6 months before placing in market
- Mandatory inclusion of word [Nano] on label
- Authorization
### Annexes dictate:

- Product type – ingredient restricted in certain range of cosmetics
- Maximum concentration
- User – ingredient can be limited/forbidden for certain users
- Area of skin – for example, forbidden on mucous membranes
- Type of use – ingredient allowed only in product for professional use

<table>
<thead>
<tr>
<th>Annex</th>
<th>Category</th>
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<tbody>
<tr>
<td>Annex II</td>
<td>Prohibited substances</td>
</tr>
<tr>
<td>Annex III</td>
<td>Restricted substances</td>
</tr>
<tr>
<td>Annex IV</td>
<td>Authorized colorants</td>
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<tr>
<td>Annex V</td>
<td>Authorized preservatives</td>
</tr>
<tr>
<td>Annex VI</td>
<td>Authorized UV filters</td>
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</tbody>
</table>
(EC) 1223/2009 INGREDIENT REQUIREMENTS EXAMPLE

Orange Lipstick with SPF15, containing Oxybenzone, Color CI 45396, and Substance A

Cosmetic product according to (CR) (EC) No 1223/2009

Oxybenzone UV protection

CI 45396 Orange Colorant

Substance A not listed in Annexes and determined to be safe

Annex VI

≤ 6%
Label - “Contains Benzophenone-3”

Annex IV

≤ 1%
For lip products
Only free acid form

No restriction

Finished product
ASEAN NATIONS – LEGISLATION

▪ Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar (Burma), Philippines, Singapore, Thailand, and Vietnam

  • Harmonization of cosmetic regulations among member states to enhance product safety and remove trade barriers
  • Borrows features from EU regulatory framework
  • Definition of cosmetics as in EU
### ACD – INGREDIENT REQUIREMENTS

<table>
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<td>II</td>
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<td>VI</td>
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<tr>
<td>VII</td>
<td>Authorized UV filters</td>
</tr>
</tbody>
</table>

- CMR/Nano substances not directly addressed as in EU
- Included nanomaterials in Annexes; must not be used when lung exposure is possible
(ACD) AND INDIVIDUAL ASEAN MEMBER STATES

- Member states implement ACD as national legislation
- National law should always be consulted – differences exist

**Examples**

| Fluoride concentration in oral products (toothpaste, mouthwash, etc.) | ACD – 0.15%  
Thailand – 0.11% |
<table>
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<tr>
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<tbody>
<tr>
<td>Benzylparaben is not allowed under ACD, but is, with limitations, in Indonesia</td>
<td></td>
</tr>
</tbody>
</table>
Orange Lipstick with SPF15, containing Oxybenzone, Color CI 45396, and Substance A

Cosmetic product according to ACD

Consult national legislation for any differences on substances (e.g. concentration)

Oxybenzone UV protection

CI 45396 Orange Colorant

No restriction

Annex VI
≤ 6%
Label - “Contains Benzophenone-3”

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≤ 1%
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Finished product
US – COSMETICS LEGISLATION

- Federal Food, Drug, and Cosmetic Act (FD&C Act) Cosmetic Regulations under Title 21 (21 USC Ch. 9)
  - General provisions
  - Ingredient requirements
  - Specific labelling requirements

- Fair Packaging and Labeling Act (FPLA)

- Microbead-Free Waters Act of 2015

- Individual States Legislations (e.g. California)
US – COSMETIC, DRUG, OR BOTH

Articles to be applied to the human body in order to cleanse, beautify, or alter appearance and components thereof; not including soap*

Products with protective function such as sunscreens, antiperspirants and components

Products with protective and cosmetic function (e.g. skin lotion with sunscreen)

Cosmetic: Cosmetic regulations
Drug (OTC): Drug regulations - OTC monographs
Cosmetic/OTC Drug: Both cosmetic and drug regulations
US – INGREDIENT REQUIREMENTS IN COSMETICS

- 21 CFR 700.11 - 700.35
  - Prohibits only 12 Ingredients
  - Restricts 4

- Microbead-Free Waters Act of 2015
  - Microbeads prohibited in rinse-off cosmetics and OTC drugs

- Non-regulatory guidance on ingredients
US – OTC DRUG MONOGRAPHS

- FDA Monographs for many OTC drugs:
  - Anticaries - 21 CFR Part 355
  - Antiperspirants - 21 CFR Part 350
  - Lip protectant - 21 CFR Part 347
  - Sunscreens - 21 CFR Part 352

- Monographs dictate:
  - Permitted active ingredients
  - Permitted concentrations and combinations
  - Label requirements (warnings, claims, directions for use)
  - Testing procedures
US – FD&C ACT COLOR ADDITIVES

- Permitted color additives:
  - 21 CFR Part 73: FDA exempt from batch certification
  - 21 CFR Part 74: FDA subject to batch certification (e.g. FD&C Yellow 5 (do not reference as CI 19140))

- CFR addresses:
  - Maximum concentrations
  - Conditions of use
  - Specifications on purity of the color
US STATE LEGISLATIONS – CALIFORNIA

- California Safe Cosmetics Act of 2005
  - Cosmetic products with harmful ingredients must be disclosed to California Department of Public Health

- California – Proposition 65
  - Warning must be provided on products substances known to cause cancer, birth defects or other reproductive harm

- California Consumer Product Regulations
  - Sets VOC limits in consumer goods (e.g. hairspray, antiperspirant)
US – INGREDIENT REQUIREMENTS EXAMPLE

Orange Lipstick with SPF15, containing Oxybenzone, Color CI 45396, and Substance A

Cosmetic/OTC drug according to FDA

Oxybenzone UV protection

CI 45396 Orange Colorant

Substance A determined to be safe

Monograph 21 CFR §352

≤ 6%

NOT ALLOWED (Not listed in CFRs 73 nor 74 for permitted colors)

No restriction

Reformulate?
AUSTRALIA - COSMETICS LEGISLATION

- Industrial Chemicals (Notification and Assessment) Act (ICNA Act)

- Australia Competition and Consumer Commission
  - Trade Practices (Consumer Products Information Standards) (Cosmetics) Regulations - Labelling

- Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Poison Standard
  - Classification of medicines and chemicals, prohibitions, restrictions
AUSTRALIA – WHAT IS A COSMETIC?

Substance or preparation in contact with external parts of body, teeth, oral cavity to alter odor, alter appearance, cleanse, keep in good condition, perfume or protect

Cosmetic

Products that prevent, treat diseases, or affect structure or functions of the human body e.g. Primary sunscreens

Therapeutic good (TG)

NICNAS: National Industrial Chemicals Notification and Assessment Scheme
TGA: Therapeutic Goods Agency

NICNAS

TGA
AUSTRALIA – COSMETIC INGREDIENTS

- Industrial Chemicals (Notification and Assessment) Act (ICNA Act)
  - Ingredients should be listed in Australian Inventory of Chemical Substances (AICS) otherwise considered **NEW**
  - AICS – includes conditions of use for some chemicals
  - Naturally-occurring chemicals treated as listed in AICS
  - **NO** separate lists of approved, restricted, or banned chemicals

Substance status can be searched in the **Poison Standard** (SUMSP) under TGA. If listed in **Standard**, then should only be in Schedules 5 or 6
AUSTRALIA – THERAPEUTIC GOODS/EXCLUSIONS


- Under specified conditions of the TGA Act some low risk products are considered excluded:
  - Antiperspirants with only inorganic salts
  - Hair bleaches, hair dyes, hair colorants
  - Certain cosmetics with sunscreen ingredients (i.e. secondary sunscreen products)
AUSTRALIA – INGREDIENT REQUIREMENTS EXAMPLE

Orange Lipstick with SPF15, containing Oxybenzone, Color CI 45396, and Substance A

Excluded Therapeutic Good

Oxybenzone UV protection

CI 45396 Orange Colorant

Substance A Not listed in Poison Standard

ARGS ≤ 10%

Not listed in AICS NEW Substance

No restriction

Finished product
GOING BEYOND – RETAILER REQUIREMENTS
Major retailers of personal care products are setting company chemicals policies

- Address consumer concerns
- Provide more sustainable products
- Reduce environmental impact
- May restrict/prohibit ingredients of concern in their products
RETAILERS INGREDIENT RESTRICTIONS – EXAMPLES

Amazon
Restricts substances in private owned brand personal care products (US)

Walgreens Boots Alliance
Restricts substances in private owned brand personal care products

H&M
Restricts/prohibits substances in private owned brand personal care products

Whole Foods
Prohibits substances in privately owned brand premium personal care products
SUMMARY

- Significant differences exist on how cosmetic products are defined and regulations can span from regional, country and even to state level

- Ingredient compliance is a major step forwards but searching their regulatory status can be cumbersome

- Additional non-regulatory requirements regarding ingredients may also impact a supply chain

- Companies need to have systems in place to monitor regulatory and non-regulatory changes impacting their business on an on-going basis
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