Current Updates of Cosmetic Regulations around Asia Pacific

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Asia Pacific Cosmetic Regulation Updates

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Australia

Cosmetic Regulation Updates
**IMPORTANT CHANGE!**

The Cosmetics Standard is no longer in force. From 1 October 2018, you must refer to the new Therapeutic Goods (Excluded Goods) Determination 2018 under the Therapeutic Goods Administration (TGA). Read more.

- The Cosmetics Standard 2007 was “sunsetted” on the 1st October 2018
- Under the Industrial Chemicals (Notification and Assessment) Act 1989 by NICNAS (National Industrial Chemicals Notification and Assessment Scheme)
- No longer in force

- Therapeutic Goods (Excluded Goods) Determination 2018
- New instrument by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989
Australia | Cosmetic Regulation updates

• Cosmetic products previously regulated under the Cosmetics Standard will now be considered as Therapeutic Goods, but continue to be excluded from the operation of the Therapeutic Goods Act
• Provided they are exported, imported or supplied in a manner consistent with the terms of their exclusion
• NICNAS will continue to regulate the manufacture and importation of cosmetics (for now!)

• Relevant content of the Cosmetic Standard is reproduced in the new determination to provide regulatory status quo
• Therapeutic Goods Administration will continue to have oversight of goods which do not meet the terms of the exclusion

• Product Safety and cosmetic labelling standards will continue to be the responsibility of the Australian Competition and Consumer Commission (ACCC)
Australia | Cosmetic Regulation updates

Key changes – categories added to Therapeutic Goods (Excluded Goods) Determination 2018

- Antiperspirants are now considered as Excluded Therapeutic Goods (if the antiperspirant properties are derived from inorganic salts of aluminium, zinc or zirconium only)

- Dental bleaches and dental whiteners

- Hair bleaches, hair dyes, hair colourants and hair perming preparations

- Topical preparations for hardening of nail
Australia | Cosmetic Regulation updates

Key changes – categories added to Therapeutic Goods (Excluded Goods) Determination 2018

Cosmetic Products with a **Secondary** Sunscreen Function (as defined by AS/NZS 2604:2012)

- Lip stick and lip balm products
- Tinted bases and foundations (liquids, pastes or powders)
- Moisturising skin care products with an SPF of **not more than 15**
- Sunbathing skin care products (oils, creams, gels, sunless tanning and after-sun care) with an SPF of **at least 4 and not more than 15**

Since **1st August 2018** the above products must meet the requirements for **Broad-Spectrum** Protection (UVA and UVB as set out in AS/NZS 2604/2012)

Secondary sunscreen products may not be advertised or presented for supply as Water Resistant

Therapeutic claims can only be related to premature ageing in connection with sun exposure
Australia | Cosmetic Regulation updates

Products with a **Primary Sunscreen** Function are Therapeutic Goods, not Cosmetics

- Regulated under the Therapeutic Goods (Permissible Ingredients) Determination 2019

Active sunscreen ingredients must be listed and their use must be in accordance with the listed conditions:
- Maximum usage concentration
- Mandatory labelling
  - Avoid prolonged exposure in the sun
  - Wear protective clothing – hats and eyewear when exposed to the sun

The mandatory label warnings were effective for all applicable products placed on the market since 1st July 2019
Australia
Changes to Introduction of Chemicals
Australia | Changes to Introduction of Chemicals

There are no lists of Prohibited, Restricted or Permitted Cosmetic Ingredients in Australia

- There may be restrictions on import or manufacture of industrial chemicals including usage conditions and secondary notification conditions

- Chemicals may be restricted or prohibited under the Poisons Standard – also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

- Industrial Chemicals are regulated by NICNAS (National Industrial Chemicals Notification and Assessment Scheme)

- All Industrial Chemicals must be listed on the Australian Inventory of Chemical Substances (AICS) before import or manufacture in Australia

- If a chemical is not listed on the inventory or the conditions of use are different from the intended use, it is a new industrial chemical in Australia
Australia | Changes to Introduction of Chemicals

But......

NICNAS will be replaced on the 1st July 2020

• The new scheme is The Australian Industrial Chemicals Introduction Scheme (AICIS)

• The new Industrial Chemicals Act 2019 creates the new regulatory framework for the importation and manufacture of Industrial Chemical in Australia

• The changes are intended to align the Regulatory Effort with the likely risk of introducing a chemical

• There will be 6 categories of Introduction with different regulatory requirements proportional to the level of risk
Australia | Changes to Introduction of Chemicals

**Lower Risk** Chemical Introductions

- Streamlined introduction and reduced regulatory burden
- Incentives for greener, safer new chemicals and replacement of existing hazardous chemicals
- Reduced costs to businesses and consumers using lower risk chemicals
- Exemptions and Reported Introductions – reduce time to market and no fees for notification
Australia | Changes to Introduction of Chemicals

**Higher Risk** Chemical Introductions

- Improved Protections for Public, Workers and Environment
- Imposing Conditions of Introduction for High Risk Chemicals
- Refusal of Introduction or Halt of Introduction if risks to Human Health or Environment are not able to be managed – Not possible currently under NICNAS

Use of International Assessment Information to streamline introduction of new Chemicals to Australia which have been assessed by Trusted International Bodies

Improved monitoring and compliance and flexible evaluation processes
Australia | Changes to Introduction of Chemicals

Categorisation of Industrial Chemicals under AICIS

- **Listed** introductions (the chemical is listed on the Inventory and introduction is within the terms of the listing (if any))

- **Exempted** introductions (very low risk)

- **Reported** introductions (low risk)

- **Assessed** introductions (medium to high risk)

- **Commercial evaluation** introductions

- **Exceptional circumstances** introductions (Ministerial authorisation to allow urgent introduction to protect public health or the environment).
## Categorisation of Industrial Chemicals under AICIS

<table>
<thead>
<tr>
<th>Indicative Health Risk</th>
<th>Very Low</th>
<th>Low</th>
<th>Medium to High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Exempted</td>
<td>Reported</td>
<td>Assessed</td>
</tr>
<tr>
<td>Pathway to inventory inclusion</td>
<td>No – Chemicals not included on the inventory</td>
<td>No – Chemicals not included on the inventory</td>
<td>Yes – Chemicals will be included on the inventory</td>
</tr>
<tr>
<td>Level of interaction with AICIS</td>
<td>No pre-introduction interaction</td>
<td>Must be reported prior to introduction</td>
<td>Must be assessed by AICIS prior to introduction</td>
</tr>
<tr>
<td>Record keeping and/or information requirements</td>
<td>Record keeping requirements</td>
<td>Record keeping and specified information submitted by report to AICIS</td>
<td>Specified information must be submitted to AICIS</td>
</tr>
<tr>
<td>Details published</td>
<td>Identifying information on introduced chemicals not published</td>
<td>Limited information on specified chemical introductions published (e.g. introductions via the international pathway)</td>
<td>Assessment statement published and linked to later inventory listing</td>
</tr>
<tr>
<td>Continuing obligations</td>
<td>Annual declaration if chemicals have been introduced in this category</td>
<td>Annual declaration that the introduction still meets the criteria for this category</td>
<td>Post-assessment information obligations</td>
</tr>
<tr>
<td>Monitoring by AICIS</td>
<td>Post-introduction monitoring</td>
<td>Post-introduction monitoring</td>
<td>Post-introduction monitoring</td>
</tr>
</tbody>
</table>
Australia | Changes to Introduction of Chemicals

Polymers of Low Concern (PLC)

- Now Exempt from Notification if it meets the criteria as PLC

- Do not require a permit or certificate to import or manufacture, but reporting requirements still apply

To be eligible as PLC a polymer must have:

- A number average molecular weight higher than 1,000 and meet the requirements on low molecular weight species and Reactive functional groups (RFG)

Or

- A polyester manufactured solely from allowable reactant monomers

Removal of SDS and labelling requirements for Exempt Cosmetics
Australia | Changes to Introduction of Chemicals

Cosmetic – Example of necessary information

• What is the Chemical Identity?
• Is the Chemical listed on the inventory?
• What is the End Use?
• What is the initial Introduction volume?
• Is Hazard Information available for the Chemical?
• Is the Chemical in a nanoscale form?
• Is there a specified class of Introduction?
• What is the concentration of the chemical when introduced into Australia?
• What is the concentration of the chemical in end use products?
• Available information on degradation products in the environment?
• Is it a high molecular weight polymer?
• Has it been assessed by internationally trusted bodies for human health or environment?
Australia
Animal Testing Ban
Australia | Animal Test Ban for Cosmetics

Restriction on the use of animal test data for supporting the introduction of cosmetic ingredients

- Animal test data generated after 1st July 2020 will be banned for supporting the categorisation or assessment of chemicals used solely in cosmetics

- No data generated from an animal test after the ban date will be permitted for any application of new industrial chemical introduction for cosmetic use
China
Cosmetic Regulation Updates
China | Cosmetic Regulation Current Situation

Safety and Technical Standards for Cosmetics 2015

Four Categories of Cosmetic for registration purposes
• Each have different requirements

• Domestic Non-Special Use
• Imported Non-Special Use
• Domestic Special Use
• Imported Special Use

Non-Special Use cosmetics include:
• Skin care, hair care, nail care, perfume, make up

Special Use cosmetics include:
• Whitening, Hair growth, Perming, Depilating, Breast shaping, Slimming, Hair dye, Deodorants, Freckle-removing, Sunscreens
China | Cosmetic Regulation Current Situation

Domestic Non-Special Use
• Pre-market online notification
• Animal testing can be waived

Imported Non-Special Use
• Pre-market Filing and Filing Certificate
• Mandatory Animal Testing Requirements

Domestic and Imported Special Use
• Pre-market Administrative Licensing
• Mandatory Animal Testing Requirements
China | Upcoming Regulatory Changes

Cosmetics Supervision and Administration Regulation 2018 (draft) – CSAR
• Expected to be published before the end of 2019

Administration Measures for Non-special Cosmetic Notification (draft)

Introduces some key new concepts particularly for Imported Non-Special Use Cosmetics in China
• Product Notification
• Domestic Responsible Person
• Product Safety Risk Assessment
  Animal testing may be exempted
• Post-market Supervision and Inspection
China | Upcoming Regulatory Changes

Product Notification
- Domestic non-special cosmetics should be notified to the Provincial Medical Products Administration
- Imported non-special cosmetics should be notified to the National Medical Products Administration by a Domestic Responsible Person (DRP)

Domestic Responsible Person (DRP)
- Must be a Chinese legal entity
- Obligations are similar to those of an EU RP
  Notification, Adverse Event Monitoring, Implementing Product Recalls, etc.
China | Upcoming Regulatory Changes

Product Safety Risk Assessment
• If product safety can be fully ensured by product safety assessment, laboratory animal toxicological testing can be exempted

Guidance on Product Safety Risk Assessment
• Follow relevant requirements on Substance Risk Evaluation Guidance and Product Safety Assessment Guidelines
• Must be in Chinese
• Safety Assessor must have a minimum of 2 years experience in Cosmetic Safety

• Reference to chemicals permitted in Safety and Technical Standards 2015 and Inventory of Existing Chemicals in China (IECIC)
• Supporting information from Trusted International Bodies can be used, e.g. SCCS, CIR, WHO
China | Upcoming Regulatory Changes

Animal Testing can be exempted unless:

- The product is intended and claimed for use by Children or Infants
- The product uses new ingredients which have been approved or notified, but are not yet listed in the IECIC
- The notifier, domestic responsible person or manufacturer is classified as a priority entity to be inspected
- The notifier, domestic responsible person or manufacturer has received official investigation or punishment related to safety quality in the past 3 years
China | Upcoming Regulatory Changes

Post Market Supervision and Inspection

• The Medical Product Administrations will conduct sampling checks regarding the authenticity of notified materials
• On-site inspections and compliance of quality management systems
• In case of incompliance, will inform a specified period to make corrections, in particular:
  - Incomplete or missing mandatory test items
  - Raw material quality specification not as required
  - Product Safety Assessment deemed not sufficient to determine product safety
  - Non-compliance with cosmetic safety standard requirements
  - Other circumstances deemed insufficient to determine product safety

Appropriate enforcement action as necessary:
• Recall of Products, or Cessation of Production or Importation
• Cancelling of Notifications
• Restriction of Domestic Responsible Person
Taiwan
Cosmetic Regulation Updates
Taiwan | New Cosmetic Regulation

Previous regulation Statute for Control of Cosmetic Hygiene has been replaced

Cosmetic Hygiene and Safety Act entered into force on 1st July 2019

2 Categories
• General Cosmetics
• ‘Medicated Cosmetics’ are now termed as ‘Specific Purpose Cosmetics’

Introduces new requirements for Notification and a Product Information File (PIF)

Online Notification System available for use since 1st July 2019 for general cosmetics
Notification will become Mandatory from 1st July 2021

Specific Purpose Cosmetics still currently require pre-market registration, but will be subject only to notification and PIF requirements from 1st July 2024
Taiwan | New Cosmetic Regulation

Cosmetic Definition now includes the teeth and the oral cavity within its scope

- Toothpastes and Mouthwash for non-medicinal use are now regulated as cosmetics

Good Manufacturing Practice (GMP) is now Mandatory in line with the new GMP Regulations

Cosmetic Manufacturing sites should have experienced personnel with relevant qualifications - Licensed Pharmacist or with professional skills in the field of cosmetics

New Labelling requirements (from 1\textsuperscript{st} July 2021)

- Name, Address and \textbf{Telephone Number} of Manufacturer or Importer, and \textbf{Country of Origin}
- Ingredient labelling in English will be accepted

Advertisements for cosmetic products no longer require pre-approval, however maximum penalties for unlawful advertisements has been increased
ASEAN
Cosmetic Regulation Updates
The Annexes of the ASEAN Cosmetic Directive are continuously updated
Most recent update in July 2019

Prohibited
2-Chloro-p-phenylaminediamine (including sulphate and dihydrochloride salts) in hair dyes
• New products implementation date 18th June 2020
• All products which do not comply must be withdrawn by 18th December 2020

Silver Nitrate in eyebrow and eyelash dye products
• Effective immediately
ASEAN | Cosmetic Regulation Updates

**Restricted**

**Climbazole**

- When not used as a preservative, can only be used in rinse-off anti-dandruff shampoo at a maximum of 2%
- When used as a preservative
  - 0.5% in a rinse off shampoo
  - 0.2% in face cream, hair lotion and foot care products
- New products implementation date 18th June 2020
- All products which do not comply must be withdrawn by 18th June 2021

**Tagetes Minuta and Tagetes Patula Flower Extracts and Oils**

- 0.01% in Leave-on products
- 0.1% in Rinse-off products
- Effective 19th December 2020
ASEAN | Cosmetic Regulation Updates

Permitted UV Filter

Phenylene bis diphenyltriazine

- Permitted for use as a UV Filter in Sunscreens and other cosmetic products
- Maximum Concentration 5%
- Not permitted in applications that could lead to inhalation exposure
- Effective immediately
Summary

Australia
• Cosmetic Products now regulated as Excluded Therapeutic Goods
• Cosmetic Ingredients must be listed as Industrial Chemicals under the AICIS after 1st July 2020
• Animal Test Data generated after 1st July 2020 will be banned

China
• Imported Non Special Use Cosmetics will be subject to simplified requirements, and Product Notification to replace lengthy and costly Authorisation Processes
• Domestic Responsible Person system
• Acceptance of Product Safety Risk Assessment to ensure cosmetic safety
• Exemption of Animal Testing in most cases, except:
  - Products for Children and Infants
  - Products with New Ingredients not listed on the IECIC
• Post Market Supervision by the Medical Products Authority
Summary

Taiwan
- Cosmetic Hygiene and Safety Act effective from July 2019
- Online Notification and PIF applicable for general cosmetics
- Will become mandatory from 1st July 2021
- Updated definition, GMP and labelling requirements
- Removes pre-approval of cosmetic advertising but increases maximum penalties

ASEAN
- Annexes to the ASEAN Cosmetic Directive are continuously updated
- Most recent additions in July 2019
- Be aware of updates and implementation dates
Questions?