ASEAN HARMONIZED COSMETIC REGULATORY SCHEME

21 October 2003

Centre for Pharmaceutical Administration
Health Sciences Authority
Milestones

1992  
Formation of ACCSQ

July 1998  
Cosmetic Product Working Group (CPWG) started discussions on common technical requirements after comparative study

June 2002  
Finalization of draft document on harmonized cosmetic regulatory scheme

2 Sep 2003  
Signing of Cosmetic Agreement

1 Jan 2008  
Full Implementation of the ASEAN Cosmetic Directive
10 ASEAN Member States

Brunei Darussalam
Kingdom of Cambodia
Singapore
Malaysia
Kingdom of Thailand

Republic of Indonesia
Republic of Philippines
Lao People’s Democratic Republic
Union of Myanmar
Socialist Republic of Vietnam
Technical Documents

- Definition of Cosmetic Product
- Common Labeling Requirements
- Common Claims Guidelines
- ASEAN Common Ingredient Lists
- ASEAN Cosmetic Product Registration Requirements
- ASEAN Cosmetic Good Manufacturing Practice (GMP) Guidelines
Definition of Cosmetic Product

Current Definition:

“Cosmetic products are products intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and includes a deodorant or any depilatory substance but does not include a soap”
Definition of Cosmetic Product

ASEAN Cosmetic Directive:

“A cosmetic product shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition”
Agreement on ASEAN Harmonized Cosmetic Regulatory Scheme

• ASEAN Mutual Recognition of Product Registration Approvals for Cosmetics (Schedule A)

• The ASEAN Cosmetic Directive (Schedule B)
MRA on Product Registration Approvals

• Interim phase, voluntary
• No advantage to Singapore as TATs to registration shortest but range of products small
ASEAN Cosmetic Directive

Adopts European Cosmetic Directive and amendments (Current)
ASEAN Cosmetic Directive

**Annex I:** Illustrative list by category of cosmetic products

**Annex II:** List of prohibited substances

**Annex III:** List of restricted substances

**Annex IV:** List of permitted colouring agents

**Annex V:** List of substances excluded

**Annex VI:** List of permitted preservatives

**Annex VII:** List of permitted UV filters

**Annex VIII:** ASEAN Handbook of Cosmetic Ingredients
ASEAN Cosmetic Handbook of Cosmetic Ingredients

- Contains a list of substances not found in the annexes to the Directive

- Member States allowed 3 years after implementation to authorize cosmetic products with ingredients in the ASEAN Cosmetic Handbook to be sold within their countries

- ACC will decide on inclusion of substances
The Road Map

Signing of Agreement by ASEAN Ministers at AEM on 2 Sep 03

8th CPWG & 1st ACC Meetings
proposed 18-19 Dec 03

Formation of ASEAN Cosmetic Scientific Body

Completion of project on Post-Marketing Surveillance & Safety Evaluation
The Road Map

On-going Trade Dialogue

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Legislative Changes

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Public Announcement & Trade Briefing

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Implementation of the ASEAN Cosmetic Directive by 1 Jan 2008
8th CPWG Meeting & 1st ACC Meeting

• Agreed at 7th CPWG meeting in June 03 – 8th CPWG Meeting to be held back to back with 1st ASEAN Cosmetic Committee (ACC) Meeting

• ACC to coordinate, review and monitor the implementation of the Cosmetic Agreement including the formation of the ASEAN Cosmetic Scientific Body (ACSB)
ASEAN Cosmetic Committee (ACC)

- Comprises of the Chair and Co-Chair and one representative from each Member Country’s Regulatory Authority
- Representative from the ASEAN Secretariat
- Representative from the ASEAN Cosmetic Industry (such as ACA)
- To co-ordinate, review and monitor the implementation of the Directive
- To establish the ASEAN Cosmetic Scientific Body (ACSB)
Projects to strengthen infrastructure

• **Singapore** – Establish Post-Marketing Surveillance/Safety Evaluation Work Programme

• **Thailand** – Establish the ASEAN Cosmetic Scientific Body (ACSB)

• **Malaysia** – Develop the ASEAN Cosmetic GMP Guidelines
Post-Marketing Surveillance / Safety Evaluation Project

• Draft of the Post-Marketing Surveillance / Safety Evaluation Guidelines has been adopted at 6th and 7th meetings

• Survey on the status of post-marketing surveillance system has been completed and results are being analysed

• Budget will be presented to the ACC for approval

• Workshop planned in 2004 depending on budget available
Outline:

- Manufacturer’s Responsibility
- Person Placing Product in Market (Distributor / Importer)’s Responsibility
- Regulatory Authority’s Responsibility
- Guidelines on Post-marketing Quality Compliance Programme
  (will be expanded after the survey result is collated and analysed)
- Guidelines on Cosmetic Product Adverse Reporting System (Electronic)
  (will be expanded after the survey result is collated and analysed)
- Guidelines on Management of Non-Compliant Cosmetic Products
  (will be expanded after the survey result is collated and analysed)
- Guidelines on Management of Adverse Information on Cosmetic Products
  (will be expanded after the survey result is collated and analysed)
ASEAN Cosmetic Scientific Body (ACSB)

Comprises

• Cosmetic Scientific Steering Committee
• Cosmetic Scientific Expert Group

To review technical issues and provide scientific advice to ACC
Trade Implications

- Ease of doing business in the ASEAN countries (harmonisation of regulatory requirements)
- Greater reliance on market forces and industry self-regulation to ensure products meet the standards set out in the Directive
- Faster product-to-market timeline (24 hours notification period)
- Facilitate export to EU countries (standards raised to be similar to EU Cosmetic Directives)
Thank You