

# **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**

**Republic of Indonesia**

**Kingdom of Cambodia**

**Republic of Philippines**

**Singapore**

**COMPOSITION  
OF THE CPWG**

**Lao People's  
Democratic Republic**

**Malaysia**

**Union of Myanmar**

**Kingdom of Thailand**

**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**



**8<sup>th</sup> CPWG & 1<sup>st</sup> 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**



**Legislative Changes**



**Public Announcement & Trade Briefing**



**Implementation of the ASEAN  
Cosmetic Directive by 1 Jan 2008**

## **8<sup>th</sup> CPWG Meeting & 1<sup>st</sup> ACC Meeting**

- **Agreed at 7<sup>th</sup> CPWG meeting in June 03 – 8<sup>th</sup> CPWG Meeting to be held back to back with 1<sup>st</sup> 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 6<sup>th</sup> and 7<sup>th</sup> 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**

# Post-Marketing Surveillance / Safety Evaluation Guidelines

## 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