



**The 22<sup>nd</sup> WSMIA CONFERENCE**  
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**PHUKET**

**ASEAN **Cosmetics** Regulatory Harmonization**  
**Update**



**Sumalee Pornkitprasarn**  
**Thai FDA**



# **OUTLINES**

- 1. Introduction**
- 2. ASEAN Harmonized Cosmetic Regulatory Scheme (AHCERS)**
- 3. ASEAN Cosmetic Directive (ACD)**
- 4. AHCERS Implementation**
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# 1. INTRODUCTION

- **rapidly growing** of ASEAN Cosmetic industry
  - increasing levels of trade
  - increasing no. of ASEAN countries in investment of manufacturing capacity
- **2001-2012:** ASEAN cosmetics exports increased
  - a share of World cosmetics export **from 4 - 9%**
  - total Intra-ASEAN export increased **by 31%**

## 2. ASEAN Harmonized Cosmetic Regulatory Scheme (AHCERS)

- **signed** by 10 countries: **2<sup>th</sup> Sep. 2003**
- **agreed full implement:** 1<sup>st</sup> Jan. 2008  
(36 months transition)
- **Objectives:**
  - To **enhance cooperation** to ensure ASEAN marketed cosmetics with safety, quality, claimed
  - To **eliminate restrictions** to cosmetics trade by
    - ➡ **harmonization** of **technical** requirements
    - ➡ **MRA** on **Product Registration Approvals**
    - ➡ **adoption** of ASEAN Cosmetic Directive (**ACD**)

## 2. ASEAN Harmonized Cosmetic Regulatory Scheme (AHCERS)

### AHCERS' MRA COVERAGE

- **Schedule A** (Product Registration Approval for Cosmetics):
  - no longer applicable
- **Schedule B** (ASEAN Cosmetic Directive: ACD):
  - All 10 countries agreed & signed to adopt ACD on 2<sup>nd</sup> September 2003

### 3. ASEAN Cosmetic Directive (ACD)

#### Article 1: General Provisions

- 10 states ensure **marketed cosmetics conform to ACD**
- **notify cosmetics before marketing** to regulatory authority
- **keep** product's technical & safety info. File **(PIF)** readily to access by reg. authority

#### Article 2: Cosmetics Definition

- any subs./ prep. intended to
- **contact ext. human body** (epidermis, hair system, nails, lips, ext. genital organs), **oral cavity, teeth, mucous mem.**
  - **exclusive/ main to**
    - \* **clean, perfume, change appearance**
    - \* **correct body odors**
    - \* **protect/ keep in good condition**

# 3. ASEAN Cosmetic Directive (ACD)

## Article 3: Safety requirements

marketed cosmetics **not cause damage to health if normal use** as

- Product presentation
- Labeling
- Use instructions & disposal, warning statements
- any other indication/ info. provided by manufacturer/ his authorized agent/ any other person responsible for market

## Article 4: Ingredient Listing

**Adopt** Cosmetic Ingredient Listings of **EU Cosmetic Directive 76/768/EEC**

include latest amendment:

- **Prohibited** List of **ingredients**
- **Restricted** List of **ingredients**
- **Coloring** Agents
- **Preservatives**
- **UV Filters**

### 3.ASEAN Cosmetic Directive (ACD)

#### Article 5: ASEAN Handbook of Cosmetic Ingredients

- 5.1 **allow non ACD list substances**, if authorization (limited to max. 3 yrs. & official check on cosmetics & defined distinctive indication)
- 5.2 **forward to ASEAN Secretariat & members** (2 months from effect date for authorized substances)
- 5.3 **Before 3 yrs. in 5.1, submit to ACC (list of permitted substances & support documents)**
- 5.4 **ACC decision** (latest scientific & technical knowledge) **to revoke/accept** permitted substance list  
(Annex VII-the ASEAN Handbook of Cosmetic Ingredients)



### 3. ASEAN Cosmetic Directive (ACD)

#### Article 6: Labeling

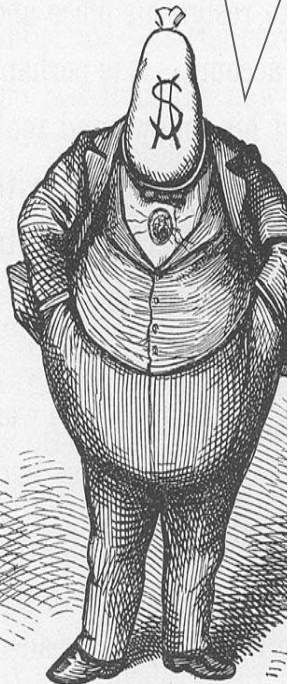
##### 6.1 ensure cosmetics labeling

- in full compliance with ASEAN Labeling,
- legible & visible lettering
- no misleading implication to consumers by
  - \* the advertising, text names, trademarks
  - \* pictures & figurative/ other signs

6.2 **label:** special precautions & warning statements & special precaution info. be printed

# 4. AHCRS IMPLEMENTATION: CHALLENGE TODAY !!!

I can't make changes

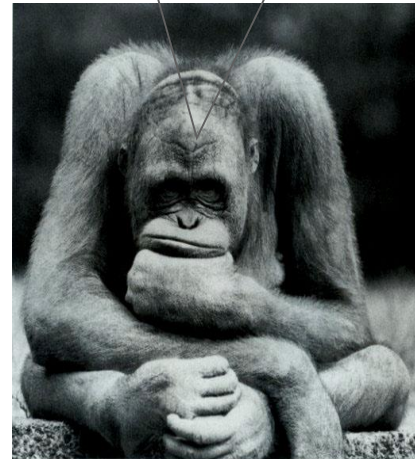


THE "BRAINS"

I will do with a  
bit delay



Where should I go  
**HELP ME!!!**



唉，该怎么办，到底该怎么办呢？  
Oh what to do, what to doooo?

**I am done**



## **4. AHCRS Implementation**

- **All members: full implementing ACD**
- **Notification system : manual (5), online (5)**
- **National Cosmetic Association (6) , No (4)**
- **Different level of PMS**
- **Sizeable local manufacturer (5)**

## 5. Challenges faced by industries

- **Implementing GMP** particularly for **SMEs**
- **Broadening representation of industries** (esp. **SMEs**) at the ACC to all ASEAN countries
- **Developing products based on indigenous ingredients**
- **Ensuring**
  - Maintaining self-regulation of product safety
  - No non-conforming products enter to market

# Summary

- No pre-market registration&approval but Notification
- Company placing products into market must responsible for safety assessment
- Great reliance on Industry's self-regulation
- Compliance with all aspects:
  - Ingredients as described in Annexes II to VII
  - Labeling & Claims guidelines
  - ASEAN Cosmetic GMP
  - Product Information File (PIF)
- Strengthening Post-Market Surveillance

# Acknowledgement

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\*Miss Neeranard Jinachai

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## THANK YOU!



ONE VISION, ONE IDENTITY, ONE COMMUNITY