

## **SUMMARY FOR THE 8<sup>TH</sup> ACSB & 9<sup>TH</sup> ACC MEETING IN HO CHI MINH CITY VIETNAM**

### **COUNTRY REPORT**

All member countries are ready to embrace the challenge-implement the ASEAN Cosmetic Directive effective from 1 Jan 2008. All necessary measures including transposition of the ACD requirements into local law have been taken to ensure smooth implementation .

### **IMPLEMENTATION OF THE ASEAN HARMONIZED COSMETIC REGULATORY SCHEME**

#### 1) Harmonized Labelling Requirements

Brunei, Indonesia and Malaysia are allowed to have country specific labelling for animal ingredients due to religious reason .

#### 2) Product Notification

Product Notification System will take effect on 1 January 2008. The validity of the notification period as well as the notification fee will be left to the discretion of the member countries taking into consideration the differences in infrastructure and resources of each country.

#### 3) Grace Period

New products placed in the market on or after 1 January 2008 will have to comply with the ACD requirements, while existing products will be allowed to be marketed with a grace period of 36 months , provided that products are still categorized as cosmetics and they do not contain any banned ingredients .

#### 4) Implementation of the ACD

Member countries need to observe 3 fundamental principles in the transposition process i.e mandatory product notification; harmonized labelling requirements and the need to have a safety assessment system in place.

It was also stressed that member countries should not make any amendments or modification to the ACD requirements without consulting the ACC (ASEAN Cosmetic Committee) All modifications and amendments to appendixes and annexes of the EU Cosmetics Directive will be considered and discussed by the ACC before the acceptance of the amendments.

#### 5) Post Marketing Surveillance (PMS)-Testing Laboratory Network

The ACRL (ASEAN Cosmetics Reference Laboratories) made a recommendation to provide technical support to regulators for PMS activities in ASEAN and assist other ASEAN laboratories in proficiency testing in the related field of testing and develop new methods to deal with future testing needs. This was supported by the ACC.

Singapore will extend assistance to member countries lacking some reference materials and propose a mechanism to provide the required technical assistance.

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6) Progress of the ASEAN Cosmetic Scientific Body (ACSB):

Tranexamic Acid: The Meeting agreed to add Tranexamic acid to Annex III, Part I of the ACD with the following restrictions:

- Field of Use: Leave On Products;
- Max authorized concentration in finished cosmetic product: 2%;

Royal Jelly: The meeting agreed to the request by Malaysia to conduct consultation on the mandatory labelling requirement on Royal Jelly and to update the ACSB on their position on this issue for discussion and subsequent consideration by the 9<sup>th</sup> ACSB meeting.

Menthol: The ACC noted that the ACSB has discussed the need to regulate the requirements for Menthol including the views of some member countries that Menthol should be deleted from Annex III but be regulated as being free for use provided that the resulting product meets the safety requirements of the ACD.

Camphor: The meeting noted that there was no scientific data to support the decision to propose regulation of camphor. In this regard, the ACSB secretariat was requested to get the necessary information from Colipa on Camphor product recall in France: to be discussed at the 9<sup>th</sup> ACSB meeting.

Fluoride in Children's Oral Care Products: The meeting agreed to the proposal from ACSB to modify the wording in Annex III, Part 1 entries 26-43 inclusive, 47 & 56 (fluorine compounds for oral hygiene products as follows :

Add to column f, conditions of use and warning which must be printed on labels):

Toothpaste containing 0.1 to 0.15% fluoride unless it is already labeled as contra-indicated for children (e.g for adult use only): "Children of 6 years and younger: use a pea sized (with graphic) amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor".

Malaysia needs to consult their Dental Association on the limit of not exceeding 300mg of total Fluoride in a single unit container and revert during the next meeting.

Sunscreen Products: Accepted the guideline: "European Commission Recommendation 2006/647/EC on the Efficacy of Sunscreen products".

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Alpha Hydroxy Acids(AHAs): NRA to consult the local Dermatologist Associations to develop a proposal for uniform regulation of products used by the general public, by professionals in salons and by dermatologists. The final recommendation will be considered at the 9<sup>th</sup> ACSB.

Hydrogen Peroxide(H<sub>2</sub>O<sub>2</sub>): To be regulated under the following categories:

- Oral Hygiene Products: 0.1%
- Tooth Whitening products for application by the consumer under the supervision of a dentist: up to 6%
- Products containing above 6% for Tooth Whitening: member countries to conduct their national consultation and submit input to ACSB for discussion by 13 March 2008.

ASEAN Inventory of Botanical Ingredients: Member countries will submit the lists of natural ingredients used in cosmetics in their markets to Indonesia by 30 April 2008. Priority will be given to those ingredients which provide functional benefits such as Whitening agents, colorants, anti-dandruff agents and preservatives.

Product Categories: The Meeting agreed with the proposals from the ACSB on the followings:

(Individual claims should be assessed to ensure that they comply with the cosmetic claim guideline)

Bust Creams: Cosmetic;

False Eyelashes: Not Cosmetic;

False Eyelash Glue: Cosmetic;

Automatic Fingernail Painting: Paints applied to fingernails are cosmetics;

Face Paints: Cosmetic;

Temporary Tattoos: Cosmetic;

Permanent Tattoos: Not Cosmetic;

Denture Cleansers: Products applied to dentures outside the mouth are not cosmetics. Dentifrices intended for use in the mouth by denture wearers are cosmetics;

Moist Wipes: The liquid component of wipes making cosmetic claims is cosmetic

Heavy Metals: The Meeting agreed on the following limits for heavy metals based on ACMTHA05 Testing Method:

Mercury: 1ppm

Lead: 20ppm

Arsenic: 5ppm

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ASEAN Handbook Outstanding Issues: 5 Ingredients were left:

<u>Henna:</u>	Reviewed and added to Annex IV (CI 75480)
<u>Azaleic Acid :</u>	Banned and added to Annex II
<u>Thiolactic Acid:</u>	Added to Annex III
<u>Bimatoprost:</u>	Added to Annex II
<u>Ethyl-4 bis hydroxypropyl aminobenzoate:</u>	moved to Annex VII (sunscreens)

Grace Period for Changes to Annexes: Proposal made by ACSB accepted i.e.

- For ACSB Proposals approved before 14 June 2007:
  - For new products: effective on 1 January 2008;
  - For existing products which do not comply fully to the ACD & its Annexes a grace period shall be subjected to NRA's decision;
- For ACSB Proposals approved between 14 June 2007 & 9 December 2007:
  - Additions to Annex II: Effective on 1 January 2008
  - All other changes: Effective no later than 1 January 2010. Member countries can choose to implement these changes earlier than this date;
- For ACSB Proposals approved after 9 December 2007:
  - Each proposal will be delivered to the ACC with a recommended grace period based upon the assessed balance of risk to consumer health and the ability of industry to comply;

Red 2G: Currently banned in food as carcinogenic but permitted for use in cosmetics in Annex IV (CI 18050), restricted for use to products not to come into contact with the mucous membranes. This means that it is not for use in oral care products and lipsticks. ACSB Secretary will monitor any concerns raised for the use of Red 2G in topical products and report back in the next ACSB Meeting;

7) ASEAN Cosmetic GMP: The meeting was informed that the Japan Cosmetic Industry Association (JCIA) has adopted the ISO 22716 Cosmetic GMP Guidelines as the required standard for its members.

Date & Venue of Next Meeting: Indonesia will host the 10<sup>th</sup> ACC Meeting to be held in June 2008 (Tentative) in Bali. Singapore is the hosting country for the 11<sup>th</sup> ACC Meeting in End Nov 2008(Tentative).