



**REPORT OF THE SEVENTEENTH MEETING OF THE ASEAN
COSMETIC COMMITTEE (ACC)**
11-12 July 2012, Siem Reap, Cambodia

1. The 17th Meeting of the ASEAN Cosmetic Committee (ACC) was held on 11-12 July 2012 in Siem Reap, Cambodia. The meeting was preceded by the following events at the same venue:

- ASEAN Cosmetic Public-Private Forum “Regulatory Harmonisation of the Cosmetic Sector in ASEAN – Successes and Challenges” on 9 July 2012;
- Meeting of the Heads of Delegations of the ASEAN Member States of the ACC on 9 July 2012;
- 3rd Special Experts Meeting of the ASEAN Cosmetic Testing Laboratory Network (ACTLN) on 10 July 2012; and
- 16th Meeting of the ASEAN Cosmetic Scientific Body (ACSB) on 10 July 2012.

2. The Meeting was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, representatives from the ASEAN Secretariat and the ASEAN Cosmetic Association (ACA). Representatives from the cosmetic industry of ASEAN Member States were also in attendance as observers.

3. HANDOVER OF CHAIRMANSHIP AND CO CHAIRMANSHIP

The Meeting witnessed the handover of Chairmanship of the ACC from Malaysia to the Philippines and the handover of the Co-chairmanship of the ACC from the Philippines to Singapore.

4. UPDATE ON THE LATEST DEVELOPMENT ON ECONOMIC INTEGRATION AND OTHER DECISIONS IMPACTING THE COSMETIC SECTOR

The ASEAN Secretariat updated the meeting on the recent developments in Economic integration initiatives in ASEAN as well as the relevant decisions made at the ASEAN Summit, AEC Council, AEM, SEOM and the 37th ACCSQ Meeting and other developments related to the cosmetic sector.

ACC had agreed to invite representatives from the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and the State Food and Drug Administration (SFDA) of China to share information with the ACC on the regulatory requirements in China. An invitation had been extended to the SFDA to attend the 17th ACC Meeting but the SFDA had expressed apologies for not being able to attend.

Action: The ASEAN Secretariat was requested to follow-up with AQSIQ and SFDA for the attendance of their representatives at the 18th ACC Meeting.

5. FOLLOW-UP FROM THE 16th ASEAN COSMETIC COMMITTEE MEETING

The ASEAN Secretariat briefed the meeting on the matters arising from the 16th ACC Meeting held on 22-23 June 2012, in Bandar Seri Begawan, Brunei Darrusalam and the follow up actions taken on the matters arising from the meeting.

The Chair briefed the Meeting on the decisions made by the HoDs during the Special ACC HoDs Meeting held on 22-23 February 2012 in Petaling Jaya, Selangor, the ACC HoDs Meeting held on 9 July 2012 in Siem Reap, Cambodia and the ASEAN Cosmetic Public-Private Forum held on 9 July 2012 in Siem Reap, Cambodia.

o Dialogue with the European Commission on Cosmetic Regulation

As the ACC HoDs had sought clarifications from the European Commission (EC) on a number of issues related to the implementation of the cosmetic regulation, the EC representative agreed to provide more information through the ASEAN Secretariat. The contact point for the ASEAN related matters is Mr. Roman Mokry from the European Commission.

o Follow up action from the special ACC HoDs Meeting

ACC HoDs have agreed to consider mechanism to overcome common implementation gaps within a timeframe to address country specific requirements, with the support of technical experts through the technical assistance programme under the ASEAN-EU cooperation, ARISE.

ACC HoDs have also agreed to share information on local manufacturers which have complied with GMP requirements of the ACD as well as to consider sharing information on how to verify GMP of manufacturers from outside ASEAN.

Action: Malaysia has volunteered to look into the EU strategies on GMP of cosmetic products and provide feedback to the ACC HoDs.

6. PROGRESS OF THE IMPLEMENTATION OF THE ASEAN COSMETIC DIRECTIVE

The meeting discussed the progress made on the implementation of the ACD at the regional and national level. The meeting was informed that there was no update from Myanmar and Myanmar had submitted the focal point to the ASEAN Secretariat.

Action: The meeting requested ASEAN Secretariat to follow up with Myanmar to provide update on the progress made with the implementation of the ACD.

- o Status of implementation of the notification system for placement of cosmetic products by ASEAN Member States

Member states updated the meeting on the status of the notification system for the placement of cosmetic products. The meeting agreed that all member states should migrate to an online notification system to expedite the notification process as well as to speed up the process in identifying cosmetic products that do not comply with the ACD.

- o Issues faced by the industry following the implementation of the ASEAN Cosmetic Directive

The representative of ACA provided feedback to the meeting on the issues faced by the industry following the implementation of the ACD.

Currently, only associations from 5 member states (Indonesia, Malaysia, Philippines, Singapore and Thailand) are members of ACA. Request was made to ACA to increase the membership and ACA informed the meeting of the difficulties faced in getting representation from member states that do not have national cosmetic associations. ACA sought the support of the member states to encourage the local industries to become members of ACA.

Action: ACA to promote membership with the local industries in the other 5 countries.

The representative of ACA also updated the meeting on the progress made with the initiative to establish collaboration with their counterparts in China, EU, Japan and Korea including training programmes for cosmetic companies in Japan to promote the compliance to the ACD requirements of imported products.

Request was made to ACA to provide more support for the SMEs in ASEAN.

Action: ACA expressed its difficulties in reaching out to all SMEs and sought regulatory agencies' support in that respect.

- Raising consumer awareness on the implications of the ACD and the safe use of cosmetic products

Member states updated the meeting on the policies, strategies and efforts taken at the National level to raise consumer awareness and understanding on the safe use of cosmetic products.

The Meeting also discussed the draft framework of the ASEAN Consumer Information Handbook.

Action: Member states to provide comments to the ACA by 15 September 2012 to collate and discuss during the next meeting.

- Enhancing the capability of SMEs to comply with the ACD

The Meeting discussed the feedback from the member states with regards to the capability of the SMEs' capability to meet the requirements of the ACD, the challenges faced with the preparation of the PIF and compliance to safety.

The meeting also discussed the efforts carried out by ACA to assist the SMEs in enhancing the capability of SMEs to meet the requirements of the ACD.

- Post market surveillance

The meeting discussed the issue of counterfeit products in ASEAN and regional efforts in PMS of cosmetic products as sustainable measures to stress the importance of safety, quality and claimed benefits of the cosmetic products.

The ACA sought clarification from Thailand on the new request for product image, packaging size and direction of use when notifying products. Thailand responded that the requested information will be requested only once for the notified products and will not affect the 3-day notification period.

Malaysia as the new coordinator for Post Market Alert System (PMAS) presented the annual statistical report of unsafe healthcare products in ASEAN for January-December 2011.

A total of 111 alerts involving 131 products were received in 2011 out of which 43 were for cosmetic products.

- Harmonisation of standards for the cosmetic sector

The ASEAN Secretariat updated the meeting that during the special ACC HoD meeting held on 21-22 February 2012 in Petaling Jaya, Malaysia, the

ACC HoDs considered the possibility to adopt the ISO/TC 217 standards on cosmetics as national standards.

Action: The ACC HoDs agreed to carry out a survey on the availability of corresponding national standards and its degree of equivalence with ISO/TC 217.

The Meeting was informed that Singapore has been recently accepted as a P-member of ISO/TC 217 in May 2012.

Thailand informed the meeting that the ASEAN Cosmetic Method for heavy metals will be submitted by Japan for consideration as a new proposal by ISO/TC 217.

7. REPORT OF THE 3RD SPECIAL EXPERTS' MEETING OF THE ASEAN COSMETIC TESTING LABORATORY NETWORK

The chair of the 3rd Special Experts' Meeting of the ASEAN Cosmetic Testing Laboratory Network (ACTLN) briefed the meeting on the outcome of the ACTLN Meeting held on 10 July in Siem Reap, Cambodia.

The Meeting endorsed the TOR of the ASEAN Cosmetic Testing Laboratory Committee (ACTLC), discussed the issues recommendations with regards in particular to updates of existing ASEAN Cosmetic Methods (ACMs), identification and validation of new ACMs, Reference Materials and Proficiency Testing.

8. REPORT OF THE 16TH ASEAN COSMETIC SCIENTIFIC BODY MEETING

Singapore, on behalf of the chair of the ACSB reported to the meeting the outcome of the 16th ACSB Meeting held on 10 July 2012 in Siem Reap, Cambodia.

- **EU Cosmetics Regulation Update**

- a. Communication of serious undesirable effects
- b. Adaptation of the regulation annexes
- c. Nanomaterials
- d. Annex III Part 2 ingredients provisional deadline
- e. Adaptation of Directive 2011/84/EU concerning Annex III Part 1 Ref #12

- **Discussion on adoption of EU Cosmetics Regulation Annexes (Cosmetic Product Safety (Annex 1) etc**

Action: Member states to review the content and format and provide inputs to the secretary by 31 Oct 2012

- **Discussion on safety of nanoparticle ingredients, including labeling requirements**

Action: ACA is tasked to propose and present a working definition for nanomaterials and its safe use in cosmetic products at the 17th ACSB Meeting

- **Discussion on the extension of the deadline for Annex III Part 2 ingredients**

The meeting agreed to the extension of the deadline for Annex III Part 2 ingredients, HC Red No 10 + HC Red No 11 and its salts (Ref 50) and Hydroxyethyl-2-nitro-p-toluidine and its salts (Ref 10), to 30 Jun 2013, pending evaluation by the SCCS.

- **Discussion on adoption of Directive 2011/84/EU, Annex III Part 1, Ref #12**

Action: Member states to consult with the national dental association(s) on the use of hydrogen peroxide at concentration 6-35% for discussion at the 17th ACSB Meeting.

- **Discussion on new proposals**

- a. Proposal to establish maximum trace limits for chromate ion CI 77288 & CI 77289

The Meeting noted and agreed that member states may use the US FDA's limits of 0.075% of chromate ion in 2% sodium hydroxide for CI 77288 and 0.1% chromate ion in 2% sodium hydroxide for CI 77289, pending quantification of the trace limits in the EU, as a guideline for Post Market Surveillance activities.

- b. Proposal to establish maximum trace limits for cyanide ion in CI 77510

The Meeting noted and agreed that member states may use the US FDA's limits of <10ppm for cyanide ion in CI 77510, pending quantification of the trace limits in the EU as a guideline for Post Marketing Surveillance activities.

- c. Proposal of the justification of deletion of Ultramarine Green (CI 77013) from Annex IV

Indonesia requested for clarification on the deletion of Ultramarine Green (CI 77013) from Annex IV. The meeting discussed and agreed to re-instate CI 77013 in Annex IV.

- d. Proposal to add "CI" to every entry in Annex IV

As the heading of the column in Annex IV states "Color Index Number" or "Denomination" and as several member states have adopted the ACD Annexes in their current legislation, it was agreed by members not to add "CI" to the current entries of Annex IV.

The Meeting further noted that for labeling of Color Index Numbers, the number should be preceded by the abbreviation, CI.

- e. Proposal to change "aluminium, zinc, magnesium and calcium stearates" to "aluminum stearate, zinc stearate, calcium stearate, magnesium stearate" in Annex IV

As several member states have adopted the ACD Annexes in their current legislation, Malaysia informed and the meeting noted of their withdrawal of the proposal to change aluminium, zinc, magnesium and calcium stearates to aluminum stearate, zinc stearate, magnesium stearate in Annex IV

- f. Proposal to move CI 75480 from Annex IV to Annex III
Philippines informed and the meeting noted of their withdrawal of the proposal to move CI 75480 from Annex IV to Annex III.
- g. Proposal to change “reference entry” to “reference number” in the footnote of Annex VI
As several member states have adopted the ACD Annexes in their current legislation, the Meeting agreed that Member states could choose to use either “reference entry” or “reference number”.
- h. Proposal to include preamble 5 of Annex VI of in column e, “conditions of use and warning which must be printed on the label” of Annex VI, Ref #5
Philippines informed and the meeting noted of their withdrawal of the proposal to include preamble 5 of Annex VI of in column e, “conditions of use and warning which must be printed on the label” of Annex VI, Ref #5
- i. Clarification on the maximum authorized concentration of zinc pyrithione allowed under Annex III, Ref#101 and Annex VI, Ref #8
Thailand sought clarification on the maximum authorized concentration of zinc pyrithione allowed under Annex III Ref #101 and Annex VI, Ref#8. Singapore clarified and the meeting noted that as a preservative, zinc pyrithione can only be used in rinse-off products, excluding oral care products. In Annex III of the ACD, zinc pyrithione is allowed for purposes other than protecting the product in leave-on hair products up to 0.1% and in rinse-off hair products up to 2.0%.
- j. Proposal to change “oral care” to “oral hygiene” and “preparation(s)” to “mixture(s)”
Secretary shared that oral care and oral hygiene appears separately in various annexes. The Meeting agreed to retain the terms oral care or oral hygiene in the various annexes.
The meeting agreed to retain the term preparation(s) instead of the term mixture(s) adopted in the EU Cosmetic Regulations.
- k. Proposal on the adoption of the preamble of Annex VII on the labeling requirements for sunscreen products made at the 10th ACSB Meeting :
Strongly recommended to print on label of sunscreen products : “Do not stay too long in the sun, even while using a sunscreen product”
Indonesia, Malaysia and Philippines proposed the mandatory labeling on sunscreen products as follows:
“Do not stay too long in the sun, even while using a sunscreen product”
The Chair highlighted that meeting needs to take into consideration the different sun exposure in ASEAN and industry will need time for compliance.
Action: The Meeting agreed to defer the decision to the 17th ACSB Meeting pending further review.

- l. Proposal to put on record the deletion of 4-isopropyl-dibenzoyl-methane and benzyl salicylate from Annex VII

The meeting agreed to put on record the deletion of 4-isopropyl-dibenzoyl-methane and benzyl salicylate from Annex VII.

Action: Secretary to update the decision tracking form to put on record this decision.

- m. Proposal to use "sulphate", "sulfites" and "bisulfites" to be aligned with the EU Cosmetic Directive

As several member states have adopted the ACD Annexes in their current legislation, Malaysia informed and the meeting noted of their withdrawal of the proposal to use "sulphate", "sulfites" and "bisulfites" to be aligned with the EU Cosmetic Directive

- **Discussion on preamble 2 of Annex VI**

The meeting noted that the preamble does not cover the 7 ingredients in Annex VI, Ref #18, 25, 32, 35, 42, 44 and 47. In this regard, the meeting agreed to maintain the original preamble 2 of the Annex VI as follows:

The substances marked with the symbol (+) may also be added to cosmetic products in concentration other than those laid down in this Annex for other purposes apparent from the presentation of the products, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos.

- **Discussion and recommendation on the document on the pilot risk assessment of botanical ingredients**

Action: Member states to provide any further comments to ACA by 31 August 2012. ACA to incorporate comments in the document and tabulate the comments for circulation to member states by 30 September 2012.

- **Discussion on feedback of Azelaic Acid**

Singapore proposed and the meeting agreed to maintain Azelaic Acid in Annex II of the ACD until further review of the safety is required.

Malaysia requested for the safety profile of Azelaic Acid derivatives, such as potassium azeloyl diglycinate

Action: ACA agreed to review and present the safety profile of potassium azeloyl diglycinate at the 17th ACSB Meeting

- **Discussion on feedback on template for the decision history on borderline products and its accessibility in the ACD**

The Meeting agreed to capture the rationale of the decision as stated in the past meeting reports.

Action: Secretary to update the template to capture the rationale of the decision as stated in the past meeting reports by 30 September 2012.

- **Discussion on feedback on AHA concentration for use in cosmetics**
Action: Member states were requested to have consultation with the national medical association(s) on the use of AHA at concentrations above 30% and provide feedback to secretary for collation by 31 October 2012.
- **Safety assessment of ingredients**
 - a. Safety assessment on products using 2 preservatives methylisothiazolinone and Kathon CG
Action: ACA to present on the safety assessment of methylisothiazolinone and Kathon CG when used in combination at the 17th ACSB Meeting.
 - b. Menadione and other derivatives of Vitamin K1
Singapore clarified that there is no restriction to the use of menadione, a naphthoquinone, which is currently used as a masking agent in cosmetics. Indonesia may seek further clarifications at the next ACSB Meeting, if required.
- **Discussion on the establishment of criteria for clinical safety testing and ethics approval**
ACA made a presentation on the criteria for clinical safety testing and ethics approval.
The Meeting agreed to consider this presentation as an information document.
Member states may clarify with ACA on the information provided, if necessary.
- **Proposal to change SPF classification under the ASEAN Sunscreen Labeling Guidelines**
The meeting agreed to maintain the current SPF classification under the ASEAN Sunscreen Labeling Guidelines with amendments (as highlighted below):

Level	SPF Level
Low	≥6 - <15
Medium	≥15 - <30
High	≥30 - <50
Very High	≥50

- **AOB**
Philippines proposed a template for future agenda items to facilitate preparations prior to the meeting.
Action: Member states to review the template and provide feedback to secretary by 31 August 2012.

The meeting noted that some member states have yet to receive the updated annexes of the ACD.

Action: Secretary was requested to circulate the updated annexes of the ACD following this meeting.

9. POOL OF COSMETICS SAFETY EXPERTS

As requested, Malaysia will provide a list of experts that have been appointed under its National Cosmetic Safety Expert Committee in the next meeting.

Malaysia updated the meeting that a local ingredient used as a colorant is being reviewed and agreed to share the information when it is available.

10. TECHNICAL ASSISTANCE AND CAPACITY BUILDING PROGRAMME FOR THE COSMETIC SECTOR

The ASEAN Secretariat updated the meeting on the progress made with the technical assistance and capacity building under the ASEAN Regional Integration Support by EU (ARISE) to support the effective implementation of the ACD.

11. COUNTERFEIT COSMETICS

Decision was made at the 16th ACC Meeting to include an agenda in the future meetings to discuss the prevalence of counterfeit cosmetics in ASEAN.

Action: Member states to share information on the prevalence of counterfeit cosmetics and the appropriate mechanism adopted to combat counterfeit cosmetics during the next meeting.

12. AEC SCORECARD

Decision was made by the ACC to discuss additional measures that need to be monitored for effective implementation of the ACD at the regional level for inclusion in the AEC Scorecard by the ACC HoDs.

Action: This will be discussed during the next ACC meeting.

13. DATE AND VENUE OF THE 18TH ASEAN COSMETIC COMMITTEE MEETING

Indonesia has kindly offered to host the 18th ACC Meeting which will be held on 19-22 November 2012 in Solo, Indonesia.

Request was made by the chair of the ACSB for a two-day session to be allocated for the 17th ACSB Meeting which will be held back to back with the 18th ACC Meeting, to enable sufficient time for scientific discussion and for adoption of the report.

Action: Indonesia to take this request into consideration when scheduling the 18th ACC Meeting and its related events.

The meeting also considered the schedule of the future ACC Meetings:

18 th ACC	Indonesia	2 nd Half of 2012
19 th ACC	Lao PDR	1 st Half of 2013
20 th ACC	Malaysia	2 nd Half of 2013
21 st ACC	Myanmar	1 st Half of 2014
22 nd ACC	Philippines	2 nd Half of 2014
23 rd ACC	Singapore	1 st Half of 2015
24 th ACC	Thailand	2 nd Half of 2015
25 th ACC	Vietnam	1 st Half of 2016

The delegates from Brunei Darussalam, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, the representatives from the ASEAN Secretariat and ACA expressed their appreciation to the Department of Drug and Food of Ministry of Health of Cambodia for the warm hospitality extended and the excellent arrangements made for the Meeting. The delegates also expressed their appreciation to the ASEAN Secretariat for the assistance provided to the Meeting.

**The Meeting was held in the traditional spirit of
ASEAN cordiality and solidarity.**