



The Report of the Fifth Meeting of the
ASEAN Consultative Committee for Standards and Quality (ACCSQ)
ASEAN Cosmetic Committee (ACC)
7 – 8 December 2005, Bandar Seri Begawan, Brunei Darussalam

INTRODUCTION

1. The Fifth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held on 7 – 8 December 2005 in Bandar Seri Begawan, Brunei Darussalam.
2. The Meeting was chaired by Drs. Ruslan Aspan, MM, Deputy of Traditional Medicine, Cosmetic and Complementary Product Control, National Agency of Drug and Food Control, Republic of Indonesia and co-chaired by Mr. Vongtavanh Chiemsisourath, Director of Narcotics, Chemical and Cosmetic Control Division, Food and Drug Department, Ministry of Health, Lao PDR.
3. The Meeting was attended by the representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, the ASEAN Secretariat and the ASEAN Cosmetic Association. Representatives from ASEAN Cosmetic Industry also attended the Meeting as observers. The list of delegates appears as ANNEX 1.

OPENING CEREMONY

4. The Meeting was officially opened by Awang Yusof bin Amba, Acting Permanent Secretary of Ministry of Health, Brunei Darussalam. In his opening remarks, he welcomed all delegates and observers to the 5th Meeting of the ASEAN Cosmetic Committee. He highlighted the outcome of the 10th ASEAN Summit held on 29-31 November 2004 in Vientiane, Lao PDR which include, amongst others, the signing of the Agreement on Integration of 11 Priority Sectors by the ASEAN Leaders. He emphasized the contribution of the cosmetic industry to the regional economic integration and the need to remove technical barriers to trade to facilitate the growth of cosmetic industry in the region. In this regard, he expressed his confidence that with the strong collaboration between Regulatory Authorities and Cosmetic Industry in ASEAN through the ASEAN Cosmetic Committee (ACC), the ASEAN will be able to achieve its objectives towards a single regulatory scheme by 1 January 2008. He also emphasized on the commitment of Brunei Darussalam in implementing this scheme as scheduled. The Opening Remarks of Awang Yusof bin Amba appears as ANNEX 2.

ELECTION OF ACC CO-CHAIR AND SECRETARY

5. The Meeting witnessed the handover of chairmanship from Ms. Werawan Tangkeo, Deputy Secretary General, Food and Drug Administration, Ministry of Public Health, Thailand to Drs. Ruslan Aspan, MM, Deputy of Traditional Medicine, Cosmetic and

Complementary Product Control, National Agency of Drug and Food Control, Republic of Indonesia. The Meeting further elected Mr. Vongtavanh Chiemsisourath, Director of Narcotics, Chemical and Cosmetic Control Division, Food and Drug Department, Ministry of Health, Lao PDR as Co-Chair and Ms. Shelly Taurhesia, from Indonesia as the Secretary of ASEAN Cosmetic Committee (ACC).

6. The Meeting expressed its greatest appreciation to Ms. Werawan Tangkeo for her valuable contribution on the work of ACC.

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| Agenda Item 1: ADOPTION OF THE AGENDA |
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7. The Meeting adopted the agenda as amended, which appears as **ANNEX 3**.

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| Agenda Item 2: BUSINESS ARRANGEMENT |
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8. The Meeting was held in plenary.

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| Agenda Item 3: FOLLOW-UP FROM THE 26TH ACCSQ MEETING |
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9. The ASEAN Secretariat briefed the Meeting on the outcomes of the 26th ACCSQ Meeting held on 4 – 5 August 2005, in Manila, Philippines. The ASEAN Secretariat's report and its supporting documents appear as **ANNEX 4**.

10. The Meeting noted, amongst others, the following:

- (i) ASEAN Economic Ministers (AEM) during its 37th Meeting on 28th September 2005 has endorsed the ASEAN Policy Guideline on Standards, Technical Regulations and Conformity Assessment, prepared and adopted by ACCSQ. In this regard, all WGs and PWGs under ACCSQ should use the Policy as the guidance for the implementation of activities on standards, technical regulations and conformity assessment both in regulated and non-regulated sectors as one of the measures in accelerating economic integration towards the ASEAN Economic Community (AEC). The ASEAN Policy focuses on harmonization of standards, technical regulations, conformity assessment, post marketing surveillance and transparency.
- (ii) ACCSQ has requested the ACC to work out a comprehensive and concrete programme to assist Cosmetic SMEs in ASEAN Member Countries with regard to their GMP compliance.
- (iii) ACCSQ has agreed to extend its continued support for ACC activities.

1. ASEAN Cosmetic Association (ACA) also indicated its strong support to assist the ACC in carrying out its activities.

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| Agenda Item 4: FOLLOW-UP FROM THE 4TH ACC MEETING |
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12. The Secretary of ACC presented to the Meeting the main outcomes of the 4th ACC Meeting held on 2 – 3 June 2005 in Kuala Lumpur, Malaysia. The report of the 4th Meeting of the ACC appears as **ANNEX 5**.

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| Agenda Item 5: | IMPLEMENTATION OF THE ASEAN HARMONIZED COSMETIC REGULATORY SCHEME (AHCRS) |
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| Agenda Item 5.1: | Implementation of the ASEAN Cosmetic GMP |
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13. Malaysia reported to the Meeting on the outcomes of the Finalization of Cosmetic GMP Draft Training Modules and on-site Audit Report held on 14 – 19 November 2005 in Kuala Lumpur, as well as the Regional Seminar on GMP held on 30 November – 2 December 2005. Malaysia's report appears as **ANNEX 6**, **ANNEX 7** and **ANNEX 8** respectively.

14. The Meeting commended the excellent and entire efforts of Malaysia as the Lead Country and all members of the ASEAN GMP Groups. Within a short period of time they successfully completed the ASEAN GMP Training Modules.

15. With consideration to the training modules, Singapore highlighted that there are still some issues for training module 14 to be further discussed amongst the ASEAN Regulatory Authorities before it can be released to the public such as terminologies and frequency of audits. In this regard, the Meeting agreed to endorse training modules 1-13 for immediate use by the Regulatory Authorities and Industry in ASEAN, subject to confirmation by Myanmar and Viet Nam who were unable to attend the Meeting. It was also agreed that upon the confirmation of the said countries, these 13 modules will be posted immediately on the websites of ACA and of the ASEAN Secretariat. On the training module 14, the Meeting requested Malaysia to coordinate with Member Countries to settle all pending issues as soon as possible and submit the final results to the ACC for its consideration and adoption.

Action Line:

***The ACC Secretary follows up with Myanmar and Viet Nam
Malaysia***

The ACA Secretary (website of ACA)

The ASEAN Secretariat (website of ASEAN Secretariat)

16. The Meeting also agreed on the proposed follow-up actions made by the ASEAN GMP Experts Group i.e.:

- (i) The Regulatory Authority in each country will conduct Echo Seminar on GMP at its national level by **June 2006**. Feedback from the trainings will be collected and submitted to Malaysia by **July 2006**. It was also agreed that in addition to the feedback from the training, the Regulatory Authorities would also need to conduct consultations with industry especially SMEs so that wider feedback can be received.

- (ii) Upon the submission of feedback by Member Countries, a Regional Workshop will be held tentatively in August 2006 for the ASEAN GMP Taskforce to discuss the feedback.
- (iii) The Workshop will then be followed by a visit to five countries with large number of manufacturers namely, Indonesia, Malaysia, Philippines, Thailand and Viet Nam in order to gain further information with respect to national legislation and industry compliance. The team for these visits will consists of ASEAN Senior Experts supported by the expert from the International Trade Centre. The Team will come up with a comprehensive report on the status of the GMP compliance in each country visited and propose follow-up actions for each country.
- (iv) A follow-up Regional Workshop will be held in November 2006. The objective of the workshop is for the GMP Taskforce to discuss the findings and proposed follow-up actions made by the expert team during the country visits. The GMP Taskforce will then submit the final recommendation for consideration by the ACC at its 7th Meeting in December 2006.

Action Line:

1. *ASEAN Member Countries*
2. *Malaysia*
3. *The ASEAN Secretariat*

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| . Agenda Item 5.2: | ASEAN Post Marketing Surveillance/Safety Evaluation |
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| Agenda Item 5.2.1: | PMS 2, 3 and Alert System in ASEAN |
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17. Singapore presented to the Meeting the revised Draft Notification Template and Guidance on Notification Procedures as well as the final draft Post Marketing Alert System for ASEAN, which appear as ANNEX 9, ANNEX 10 and ANNEX 11 respectively.

(i) Draft Notification Template and Guidance on Notification Procedures

18. Malaysia highlighted that parallel imports are not allowed into the country. In order to curb parallel import, Malaysia proposed for submission of the Letter of Authorization from product owners to the person responsible for placing product in the market as one of the requirements for notification. As there are many countries that are not in the agreement with the submission of the Letter of Authorization, the Meeting agreed that the Letter of Authorization continued to be a requirement by the Regulatory Authority in Malaysia.

19. Some member countries also requested the Meeting to consider the inclusion of the Ingredient List and the definitions of manufacturers and assemblers in the Notification Template. Since, no agreement has been reached, the Meeting discussed and agreed on the following course of actions:

- (i) Singapore will draft the definition by **31 December 2005** and circulate to member countries for their comments.
- (ii) Member Countries will further review the Draft Notification Template including the issue on Ingredient list as well as the draft definitions of

- manufacturers and assemblers and submit their comments to Singapore no later than **31 January 2006**.
- (iii) Singapore will revise the Template based on the inputs submitted by Member Countries and will circulate revised Template for further consideration by Member Countries by **28 February 2006**.
 - (iv) A Regional Workshop will be organized in **March 2006** to finalize the Template and the Guidance on Notification.
 - (v) Final Template and Guidance will be submitted for consideration and endorsement by the ACC at its next Meeting in **June 2006**.

Action line:

- 1. Member Countries**
- 2. Singapore**
- 3. ASEAN Secretariat**

(ii) Post Marketing Alert System

20. The Meeting considered the Draft Post Marketing Alert System prepared by Singapore and agreed in principle to the formalization of a single Alert System for all Healthcare Products in ASEAN, which includes Pharmaceuticals, Cosmetics, Traditional Medicines and Health Supplements. Singapore clarified that the terminologies in the glossary are country specific. The Glossary should be attached together with the Alert when circulating to Member Countries. The Meeting agreed on the following:

- (i) The procedure for Alert should be the same for all Healthcare products. However, the terminologies for cosmetics need to be further revised to make it more relevant for the cosmetic sector.
- (ii) Singapore will revise the Draft and circulate it for consideration by Member Countries by **31 December 2005**.
- (iii) Member Countries will submit their confirmation of agreement or further inputs to Singapore by **15 January 2006**.
- (iv) Singapore will finalize the draft base on the submission of inputs from Member Countries and circulate for consideration and endorsement by the ACC by **31 January 2006**.
- (v) In the meantime, Member Countries will submit the contact points and their address for the Alert System to the ASEAN Secretariat with copy to Singapore by **31 December 2005**.

Action Line:

- 1. Singapore**
- 2. Member Countries**

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| Agenda Item 5.2.2: | PMS 1 including adoption of harmonized testing methods |
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21. The Meeting considered the 8 harmonized testing methods that were developed by the ASEAN Expert Group with the support of the EU Expert and agreed to adopt these testing methods for the implementation in ASEAN. The Meeting also agreed that such

testing documents will be posted on the websites of the ACA and ASEAN Secretariat for their use by the relevant stakeholders. The harmonized testing methods appear as **ANNEX 12**.

22. The Meeting expressed its appreciation to the ASEAN Expert Group for their great efforts and contribution towards the facilitation of the AHCRS implementation.

Action Line:
ASEAN and ACA Secretariat

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| Agenda Item 5.3: Progress of the ASEAN Cosmetic Scientific Body (ACSB) |
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23. The Chair of the ACSB briefed the Meeting on the outcome of the 4th ACSB Meeting held on 6 December 2005. The Report and Presentation of the 4th ACSB Meeting appears as **ANNEX 13**.

24. The Meeting endorsed the appointment of Mr. Tonny Pranatadjaja, Vice President of the ASEAN Cosmetic Association (ACA) and Ms. Anis Talib, Principal Assistant Director, Head of Cosmetic Unit, Centre for Product Registration, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia as Chair and Co-Chair of the ACSB respectively. The Meeting also agreed that Dr. Simon Young continues to be the Secretary of the ACSB.

25. The Meeting expressed its appreciation to Mr. Chong Chee Kiong, Acting Chief Scientific Officer, Drug Quality Control Section, Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam for his valuable contribution to the ACSB activities during his chairmanship.

26. The Meeting also endorsed the following recommendations of the ACSB:

- (i) Remove 76 ingredients from ASEAN Handbook of Cosmetic Ingredients;
- (ii) 20 ingredients still remain in the ASEAN Handbook of Cosmetic Ingredient in which:
 - ACSB will further review another 19 ingredients
 - On CFC issue, the Meeting was of the view that the CFC can be included in the banned ingredient list since most of Member Countries already banned all products containing the CFC. However, prior to this decision, the Secretary of the ACSB is requested to check with Member Countries to get their confirmation on this matter.

27. The Meeting requested the ACSB to review the usage of Hydrogen Peroxide- tooth whiteners with regard to product classification and control and submit the recommendation to the ACC for its consideration at its next Meeting. The Meeting further requested the ACSB to look into the current actions taken by the US and EU FDAs over anti-bacterial products in relation with Avian Flu and submit its observations and recommendations to the ACC as early as possible for its consideration and follow-up actions.

Action Line

1. ACSB Secretary
2. ACSB Chair, Co-Chair and Members

Agenda Item 5.4: Progress of the implementation of the AHCRS by Member Countries

28. Member countries except Myanmar and Viet Nam reported to the meeting on the status of the implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme. Country Reports appears as **ANNEX 14**. The Meeting requested the ASEAN Secretariat to follow-up with these countries on the status of their implementation.

29. The Meeting urged Member Countries to accelerate the preparation process especially in terms of transposition of the Agreement into national legislation and preparation for industry to comply with the ASEAN Cosmetic GMP Guideline in order to ensure that there will be no delay in implementing the Agreement by 1 January 2008.

30. Philippines and Malaysia indicated their interest in participating in the Schedule A of the AHCRS. The Meeting encouraged these countries to proceed with necessary arrangement so that the bilateral agreement can be reached as soon as possible. The Meeting also requested the ASEAN Secretariat to provide any necessary assistance in this matter.

Agenda Item 5.5: Information Booklet on the AHCRS

31. The ACA presented to the Meeting the revised Draft Information Booklet on ASEAN Harmonized Cosmetic Regulatory Scheme, which appears as **ANNEX 15**.

32. The Meeting expressed its appreciation to the ACA for its continued commitment and contribution to the ACC activities and agreed in principle the revised Draft Information Booklet. The Meeting, however, was of the view that Member Countries need to be given more time to consider the revised Draft. In this regard, the Meeting agreed on the following:

- (i) Member Countries will submit their inputs to the ACA (attention to Ms. Jessica Plana at jessica_plana@yahoo.com.sg) by **15 January 2006**. Member Countries who have not submitted their contact persons for their national cosmetic association are requested to do so by that deadline.
- (ii) The ACA will further improve the Draft Information Booklet and circulate for official endorsement by the ACC by **31 January 2006**.
- (iii) The Final Information Booklet will be posted on the websites of the ACA and the ASEAN Secretariat by **3 February 2006**.
- (iv) Member Countries are encouraged to translate the Information Booklet into their national language for the purpose of better understanding for local industry.

Action Line:

1. ACA
2. Member Countries

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| Agenda Item 6: | TECHNICAL ASSISTANCE TO SUPPORT THE IMPLEMENTATION OF THE AHCRS |
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| Agenda Item 6.1: | Assistance by ACCSQ Dialogue Partners for 2006 |
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33. ASEAN Secretariat briefed the Meeting on the assistance by ACCSQ Dialogue Partners for Cosmetic Sector in the year 2006. The ASEAN Secretariat's paper appears as **ANNEX 16.**

34. The Meeting requested all Member Countries to submit to the ASEAN Secretariat their inputs for further training in PMS by **15 January 2006.** The Meeting also encouraged Member Countries to closely coordinate with the ASEAN Secretariat to organize the activities successfully.

Action Line:

Member Countries and ASEAN Secretariat

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| Agenda Item 6.2: | Summary of the EC-ASEAN Regional Economic Cooperation Programme on Standards, Quality and Conformity Assessment. |
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35. The ASEAN Officer on behalf of the Team Leader of the Programme, presented to the Meeting on the outcomes of the cosmetic sub programme (2003-2005) under the EC-ASEAN Programme on Standards, Quality and Conformity Assessment. The ASEAN Officer's presentation appears as **ANNEX 17.**

36. The EU Experts were also invited to present to the Meeting the outcome of activities on PMS 1,2 and 3 and their recommendations to facilitate the implementation of the Agreement, subject to consideration and further discussion by the ACC Members. The EU Experts' presentations appear as **ANNEX 18.**

37. The Meeting expressed the appreciation to the Team Leader of the Programme, the ASEAN Officer and the EU and ASEAN Experts for their excellent assistance and efforts provided to the ACC and its stakeholders for the last two years. This has made a great contribution to the implementation of the AHCRS.

38. The Meeting noted the achievement under the Programme, as follows:

- (i) More than 600 ASEAN delegates have been trained in ASEAN and in EU for the Cosmetic Sector;
- (ii) Harmonized Testing Methods, including video CD have been developed;
- (iii) 14 Training Modules on GMP as well as basic and in-depth training modules on PMS 2 and 3 have been developed including video CD.

39. The Meeting also agreed that the Chair of the ACC to send a letter of appreciation to people who have contributed to the success of the Programme.

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| Agenda Item 7: | Revise work program of the ACC |
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40. The Meeting adopted the revised Action/Work Programme, which appears as ANNEX 19.

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| Agenda Item 8: | Other Matters |
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(i) Borderline products between pharmaceuticals and cosmetics

41. The ASEAN Secretariat highlighted to the Meeting the issue on the borderline products i.e products that can fall under the classification of pharmaceuticals or cosmetics. Currently, there are differences in the technical requirements on these products across ASEAN. It is suggested that the Regulatory Authorities in ASEAN come into agreement with regard to technical requirements of these products to ensure the smooth implementation of the AHCRS. In this regard, the Meeting agreed that the matter needs to be further deliberated amongst ASEAN Member Countries at the coming Good Regulatory Practice Workshop.

(ii) Issue on recent banned ingredient in EU

42. Malaysia and Singapore expressed concern over the addition to Annex II of the EU Directive of 710 ingredients since 2004. Since these 710 newly prohibited ingredients have not been adopted in ASEAN, it provides an opportunity for cosmetic companies in EU to ship these products in ASEAN markets. Member Countries, therefore, are urged to take immediate actions to stop these products by including these ingredients to the ASEAN prohibited ingredient list. The Meeting discussed and was of the view that the implementation of the ASEAN Cosmetic Directive will only come into effect starting from 1st January 2008 so any decision to ban these ingredients prior to that date in ASEAN will not be mandatory for Member Countries. However, Member Countries may opt to have some control over the products containing these ingredients if they find it necessary to protect consumer.

43. In the meantime, the Meeting requested the ACSB to look into these banned ingredients in EU and submit its recommendations to the ACC for its consideration at the next meeting.

Action Line:

- 1. Member Countries*
- 2. ACSB*

(iii) Requirements for Soaps

44. Malaysia proposed for exclusion of soap from ASEAN Cosmetic Directive (ACD) and recommended for listing of soap instead of notification. Malaysia further proposed for exemption of soap manufacturers from the requirements of GMP. The Meeting agreed that since soap falls into the definition of cosmetics, soap will be subjected to the requirements of the ACD including notification and GMP compliance.

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| Agenda Item 9: | Date and Venue of the Next Meeting |
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45. The Meeting agreed that the 6th ACC Meeting will be held tentatively in June 2006 in Siem Reap, Cambodia and the 7th ACC Meeting will be held in Philippines late 2006, subject to confirmation by the Philippines.

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| Agenda Item 10: Adoption of the Minutes of the Meeting |
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46. The Meeting considered and adopted the Report of the Fifth Meeting of the ACC held on 7 – 8 December 2005 in Bandar Seri Begawan, Brunei Darussalam.

ACKNOWLEDGMENT:

47. The delegates of Cambodia, Indonesia, Lao PDR, Malaysia, the Philippines, Singapore, Thailand, the ASEAN Secretariat, and the ACA expressed their appreciation to the Ministry of Health, Brunei Darussalam for the warm hospitality extended and the arrangements made for the Meeting.
