



**The Report of the Fourth Meeting of the
ASEAN Consultative Committee for Standards and Quality (ACCSQ)
ASEAN Cosmetic Committee (ACC)**

2 - 3 June 2005, Kuala Lumpur Malaysia

INTRODUCTION

1. The Fourth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held on 2 – 3 June 2005 in Kuala Lumpur, Malaysia
2. The Meeting was chaired by Mrs. Werawan Tangkeo, Deputy Secretary General, Food and Drug Administration, Ministry of Public Health, Thailand, and co-chaired by Drs. Ruslan Aspan, MM, Deputy, Traditional Medicine, Cosmetic and Complementary Product Control, National Agency of Drug and Food Control, Republic of Indonesia.
3. The Meeting was attended by the representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, 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 Ms. Mariani Mohammed, Director General, Department of Standard Malaysia (DSM). In her opening remarks, she welcomed all delegates and observers to the 4th Meeting of the ASEAN Cosmetic Committee. She highlighted the outcomes of the 10th ASEAN Summit held on 29-31 November 2004 in Vientiane, Lao PDR and emphasized the role of standards and conformance in facilitating the implementation of the 10th ASEAN Summit's decisions, particularly with regard to the integration of eleven priority sectors and the realization of the ASEAN Economic Community (AEC). She congratulated the ACC for the progress made and expressed her confidence that the ACC could steer the regional integration to the highest level of achievement. She also informed the Meeting that Malaysia has launched a National Biotechnology Policy with a focus on three areas *viz*; Agriculture, Industrial and Healthcare that would benefit the Cosmetic Industry.
5. The Opening Remarks of Ms. Mariani Mohammed appears as ANNEX 2.

Agenda Item 1:	Adoption of the Agenda
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6. 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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7. The Meeting was held in plenary.

Agenda Item 3:	Follow-up from the 25th ACCSQ Meeting
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8. The ASEAN Secretariat briefed the Meeting on the outcomes of the 25th ACCSQ Meeting held on 9 -10 March 2005 in Vientiane, Lao PDR. The ASEAN Secretariat's paper appears as ANNEX 4.

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

- (i) The ASEAN Policy on Standards and Conformance is being developed by the ACCSQ, which would serve as guiding principles for the ACCSQ and its WGs/PWGs as well as industry and relevant regulatory bodies in the formulation and implementation of their activities towards the ASEAN Economic Integration.
- (ii) The ACCSQ requested all WGs and PWGs to focus on the implementation of the specified measures, at the same time to look into additional measures as necessary to ensure the integration of standards and conformance for each of the priority sectors by 2010.
- (iii) The ACCSQ endorsed the 3rd Report of the ACC Meeting and its revised Work Programme.
- (iv) Joint Action Plans on Standards and Conformance with Japan, Korea and CER are being developed and all WGs and PWGs are invited to provide the inputs.

10. A concern was raised for discussion that there are on- going bilateral FTA negotiations between some ASEAN Member Countries and other countries/ sub-regions which may also involve negotiations for the elimination of technical barriers to trade for cosmetics. If these Member Countries do not refer to the ASEAN requirements for cosmetic products during the bilateral trade negotiations, products entering the ASEAN market place might not meet the ASEAN technical requirements for cosmetic products.

11. The Meeting discussed and made the following conclusions:

- (i) Products to be marketed in ASEAN have to fully meet the requirements of the ASEAN Cosmetic Directive regardless of the country of origin of the products.



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- (ii) Suppliers/ Manufactures that would like to place their products in any ASEAN Member Countries will have to declare their compliance with the ASEAN Cosmetic Directive and notify the regulatory authority in the respective country.
- (iii) Member Countries shall use the ASEAN Cosmetic Directive as the platform for any trade negotiations for cosmetic sector with other countries/ sub-region. Regulatory Authorities in Member Countries should convey this message to their FTA Negotiation Team.

Agenda Item 4: Follow-up from the 3rd ACC Meeting

12. The Chair presented to the Meeting the main outcomes of the 3rd ACC Meeting held in Yogyakarta, Indonesia, 8 - 9 December 2004. The report of the 3rd Meeting of the ACC appears as ANNEX 5.

Agenda Item 5: Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS)

Agenda Item 5.1: Implementation of the ASEAN Cosmetic GMP
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13. Malaysia reported to the meeting on the progress of Regional GMP program especially the development of the 14 training modules. Malaysia's report appears as ANNEX 6.

14. The Meeting noted the following:

- (i) Meeting to review the drafted training modules will take place in Jakarta on 14 – 16 June 2005.
- (ii) Training in EU will be conducted in September 2005.
- (iii) Meeting to finalize the training modules will take place in Malaysia on the 1st week of October 2005.

15. On behalf of ASEAN Cosmetic Industry and some Member Countries, ACA raised a concern on the impact of the application of the ASEAN Cosmetic GMP Guideline on the cosmetic SMEs in ASEAN, which comprises 75% of the 2000 cosmetic companies and a number of them would not be ready to implement the Guideline by 1 January 2008.



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In this context, the following decisions were made:

- (i) Regulatory authorities continue to disseminate information and assist cosmetic industry especially in ASEAN to put in place a system that complies with the ASEAN Cosmetic GMP Guideline.
- (ii) Cosmetic industry in ASEAN and outside ASEAN who intend to place their cosmetic products in ASEAN market should make an effort to comply with the ASEAN Cosmetic GMP Guideline and the targeted date for compliance is by 1st January 2008. However, Member Countries may, for a period of 36 months from effective date of 1 January 2008, authorize the marketing in their territory of cosmetic products placed in the market before this date that do not conform to the requirements of the ASEAN Cosmetic Directive including the ASEAN Cosmetic GMP Guideline. The next ACC Meeting will discuss the requirements for new products placed in the market after 1 January 2008.
- (iii) With regard to the Post Marketing Surveillance approach, there is no requirement for the GMP Certification from 1 January 2008. Instead, cosmetic industry will have to declare their compliance with the ASEAN Cosmetic Directive including the ASEAN Cosmetic GMP Guideline. The Regulatory Authority should put in place a Post Marketing Surveillance system to ensure compliance.
- (iv) The Regulatory Authorities in Member Countries will conduct a survey on the level of GMP compliance by cosmetic industry in ASEAN in January 2007. The result of the survey will be the basis for ACC to determine the necessary follow-up actions.

16. To facilitate the Member Countries on the implementation of the ASEAN Cosmetic GMP Guideline, the Meeting also agreed that Malaysia will work with the GMP working group under the EC-ASEAN program to develop mechanism / system including standardized operating procedures for ACC to consider by the next Meeting.

17. Malaysia also proposed to the Meeting the Creation of the GMP Inspection Body (GMPiB) of the ASEAN Cosmetic. Malaysia's proposal appears as ANNEX 7.

The Meeting reviewed and agreed for Member Countries to take consultation with their local authorities and come back to Malaysia whether they agree to proceed with the creation of GMP Inspection Body (GMB) by end of August 2005.



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Agenda Item 5.2:	ASEAN Post Marketing Surveillance/Safety Evaluation
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18. Singapore presented to the Meeting the revised Guide Manual for the Industry - Adverse Event Reporting of Cosmetic Products and revised Template for Notification for a Cosmetic Product as appeared in ANNEX 8 and ANNEX 9 respectively.

19. The Meeting considered and adopted the revised Guide Manual for the Industry and the revised Template for Notification.

20. The Meeting also discussed issues with regard to the notification procedures that include information to be provided by industry, notification period and validity of notification. The Meeting then agreed that Singapore would draft the notification procedures and circulate to Member Countries by 30 June 2005. Member Countries then submit their inputs on the Draft to Singapore by 30 August 2005. The final Draft will be considered and adopted at the next ACC Meeting.

21. Singapore also presented to the Meeting the Draft Post Marketing Surveillance Alert System for Defective or Unsafe Medicinal Products, Cosmetic Products, Traditional Medicine and Health Supplement developed under Malaysia/ Singapore technical cooperation. Singapore's paper appears as ANNEX 10.

22. The Meeting considered and agreed to adopt the Draft Post Marketing Surveillance Alert System proposed by Singapore as ASEAN Alert System for Unsafe and Defective Cosmetic Products. The Meeting requested Singapore to convert the endorsed Draft to an official ASEAN document and circulate it to Member Countries for their application.

Agenda Item 5:3	Report Progress of the ASEAN Cosmetic Scientific Body (ACSB)
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23. The Chair of the ACSB briefed the Meeting on the outcomes of the 3rd ACSB Meeting held on 1 June 2005. The Report of the 3rd ACSB Meeting appears as ANNEX 11.

24. The Meeting noted the following:



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- (i) The training course at the Vrije Universiteit of Brussels (VUB) on 4-9 April 2005 was conducted successfully.
 - (ii) The ACSB will discuss the possibility of running a short summary course on issues and approaches in ASEAN later this year using local and EU industry experts.

25. The Meeting endorsed the following recommendations of the ACSB:

- (i) Only members of the ACSB will be allowed to participate in the discussion of the ACSB Meeting. ACC representatives will be invited to attend the Meeting as observers.
- (ii) ACSB will 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.
- (iii) In case there is any urgent issue regarding the safety of cosmetic products, the ACSB should immediately conduct consultations amongst its Members, provide scientific opinion and circulate it to each National Regulatory Authority in ASEAN for their follow-up action.
The ACSB will prepare a proposal of mechanism for consideration in the next ACC Meeting.

26. The Meeting also agreed that the ACSB Members should make use of the ACA website for posting their scientific opinions and discussing scientific issues. The discussion on scientific issues on the website should be restricted to ACSB Members only.

Agenda Item 5.4:	Progress of the implementation of the AHCRS by Member Countries
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27. Member Countries except Myanmar reported to the Meeting on the status of the implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme. Countries' reports appear altogether as ANNEX 12.

Agenda Item 5.5:	Information Booklet on the AHCRS
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28. The ACA presented to the Meeting the draft General Information Booklet on the AHCRS and ACA website as appeared in ANNEX 13.

29. The Meeting considered and suggested the following improvements to the booklet:



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- (i) The booklet should be concise and contains enough information for industry to understand the overall requirements. Detail guidelines, terminology, and definition should not be included in the booklet as they are available in the ASEAN Cosmetic Directive.
- (ii) The standardized operating procedures concerning implementation of GMP, PMS and notification procedures should be included in the booklet.

30. The Meeting requested ACA to coordinate with Malaysia and Singapore on the GMP and PMS matters, revise the booklet and circulate the final draft to Member Countries for comments by the first week of October 2005. The adoption of final draft will be considered at the next ACC Meeting in December 2005.

31. The ASEAN Officer also requested the Head of Delegate of each Member Countries to submit Country contact person with contact address including e-mail to ACC Secretariat (Ms Ananya, Thai FDA) by end June 2005 for inclusion in the booklet.

32. With regard to ACA website, it was agreed that a webpage confining to ACSB members will be developed with password access to ensure security and confidentiality of the information.

33. Besides update of the above, ACA also expressed concern on the capacity of SMEs to comply with the ASEAN Cosmetic Directive. The Meeting discussed and then agreed with the suggestion of the ASEAN Secretariat on arranging a consultative meeting between the authorities and the SMEs to determine their difficulties and assess their capabilities in complying with the ASEAN Cosmetic Directive. This information will be used to evaluate if the ASEAN SMEs will be ready by 2008.

Agenda Item 6:	Technical Assistance to support the implementation of AHCRS
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Agenda Item 6.1:	Need Assessment for Additional Assistance
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34. The ASEAN Secretariat presented to the Meeting the proposed Assistance by Member Countries for Cosmetics in 2006 as appeared in ANNEX 14.

35. The Meeting noted the following:



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- (i) It is unlikely that the current EC-ASEAN program will be extended beyond 2005. There is an effort to explore the possibility of initiating phase 2 program, however it is unlikely to be available in year 2006.
 - (ii) There is no progress re the Australian Funding Support.
 - (iii) There is a possibility of German Assistance at the National level through funding support of experts.
 - (iv) There will be no support for transposition of the ASEAN Cosmetic Directive into National Law for Brunei Darussalam and Viet Nam as the assistances are already existed under the EC – ASEAN program for Brunei Darussalam,

and under the ASEAN Program for Regional Integration Support (APRIS) by EU for Viet Nam.

36. Member Countries namely Brunei Darussalam, Cambodia, Malaysia and Singapore are requested to immediately submit their needs for assistance to ASEAN Secretariat.

37. The Meeting endorsed the Proposed Assistance by Member Countries for Cosmetics in 2006 for proceeding to further discussion with Germany.

Agenda Item 6.2:	EC-ASEAN Regional Economic Cooperation Programme on Standards, Quality and Conformity Assessment.
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38. Ms Jessica Plana, the ASEAN Officer, presented to the Meeting the progress of the EC-ASEAN sub-program on Cosmetic and its action plans for the year 2005 as appears in **ANNEX 15**.

39. The Meeting noted the following:

GMP

- (i) Joint Blank Audit is now scheduled for January - February 2006. However due to the expiration of the EC-ASEAN program at the end of 2005, there is a possibility that the activities will have to be moved forward to December 2005.
- (ii) The preferred number of participants for on-the-job training in the six ASEAN Countries (Indonesia, Malaysia, Philippines, Singapore, Thailand and Viet Nam) is 20. However, the number may vary depending on the size of the Cosmetic industry in the respective countries.



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PMS 1

- (i) The eight harmonized test methods (six chemical and two microbiological tests) and audio-visual aid will be finalized during the first week of December 2005 and submitted for ACC endorsement in the next ACC Meeting in December 2005 by Singapore.
- (ii) The detailed test methods are available on the EC-ASEAN website.

PMS 2 & 3

- (i) Regional training will take place in Thailand on 7 – 9 June 2005. The training will cover risk assessment, case studies and change management.

ACSB

- (i) ACSB will develop a manual which will be submitted to the EC-ASEAN sub-program.

HORIZONTAL ASSISTANCE

- (i) The EC-ASEAN program will provide assistance for the transposition of the ASEAN Cosmetic Directive into National Laws to the following countries - Brunei Darussalam, Indonesia, Malaysia, Philippines, Singapore and Thailand.
- (ii) The six Member Countries to submit nominations of their legal experts to ASEAN Officer by 15 June 2005.

40. Assistance to Lao PDR and Viet Nam

To move forward the program, the ASEAN Secretariat requested that Laos PDR and Viet Nam identify local legal experts and translate their current local laws into English, and submit to ASEAN Secretariat by end of July 2005.

41. Assistance to Cambodia

It was advised that Cambodia should follow up with its ACCSQ representative regarding the progress of the EC-ASEAN bilateral program to support its transposition of the ASEAN Cosmetic Directive into National Law.

Agenda Item 7: Revise work program of the ACC

42. The Meeting adopted the Action/Work Programme as revised, which appears as **ANNEX 16**.



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Agenda Item 8:	Other Matters
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43. Myanmar's Country report was presented in absence of its delegation. However the report only cover the present status. The report appears as ANNEX 17.

The Meeting requested Thailand as the Chair of ACC and ASEAN Secretariat to follow up with Myanmar on their indication and preparation to participate in the AHCRS.

Agenda Item 9:	Date and Venue of the Next Meeting
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44. The fifth ACC Meeting will be held in Brunei Darussalam tentatively on 6 – 8 December 2005.

45. The Meeting requested Cambodia to host the sixth ACC meeting in June 2006. Cambodia will confirm in the next ACC Meeting in December 2005.

Agenda Item 10:	Adoption of the Minutes of the Meeting
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46. The Meeting considered and adopted the Report of the Fourth Meeting of the ACC held on 2 – 3 June 2005 in Kuala Lumpur, Malaysia.

47. The Meeting agreed to forward the Report to Member Countries, which were not in attendance to this Meeting for their consideration and confirmation.

48. The Meeting nominated Indonesia and Lao PDR to be the next Chair and Co-chair of ACC respectively. Indonesia and Lao PDR had graciously accepted the nomination.

49. The Meeting expressed its sincere appreciation to Ms Werawan Tangkeo for her Chairmanship in leading the ACC towards the ASEAN Harmonization with significant progress in the last two years.

ACKNOWLEDGMENT:

50. The delegates of Brunei Darussalam, Cambodia, Lao PDR, Indonesia, Malaysia, the Philippines, Singapore, Thailand, Viet Nam, the ASEAN Secretariat, and the ACA expressed their appreciation to the Department of Standard Malaysia and CTFA Malaysia for the warm hospitality extended and the arrangements made for the Meeting.



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