



**Report of the Eighth Meeting of the
ASEAN Consultative Committee for Standards and Quality (ACCSQ)
ASEAN Cosmetic Committee (ACC)
13 – 14 June 2007, Vientiane, Lao PDR**

INTRODUCTION

1. The Eighth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held on 13 – 14 June 2007 in Vientiane, Lao PDR. The Meeting was preceded by the Regional Workshop on Product Information File (PIF) 10 – 11 June 2007 and the 7th Meeting of the ASEAN Cosmetic Scientific Body on 12 June 2007.

2. The Meeting was chaired by Mr. Vongtavanh Chiemsisourath, Director of Narcotics, Chemical and Cosmetic Control Division, Food and Drug Department, Ministry of Health, Lao PDR and Co-Chair of the ACC. The Meeting was informed that due to unforeseen circumstance, Drs. Ruslan Aspan, Apt, MM, Deputy of Traditional Medicine, Cosmetic and Complementary Product Control of Indonesia, the Chair of the ACC was not able to attend the Meeting and he wishes the Meeting every success.

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 the 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 H.E. Khamhuong HEUANGVONGSY, Vice Minister of Health, Lao PDR. In his opening remarks, he welcomed all the participants to the Meeting to Lao PDR. He highlighted the importance of cooperation among Regulatory Authorities and cosmetic industry to ensure the safety and quality of the cosmetic products to be marketed in ASEAN. He congratulated the ACC for its achievements for the last few years in preparing for the implementation of the ACD and expressed his confidence that the ACD will be well implemented in ASEAN as per the timeframe. The opening remark appears as **ANNEX 2**.

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

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



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Agenda Item 3:	UPDATE AND HIGHLIGHTS OF ASEAN MEETINGS
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7. The Meeting was briefed by the ASEAN Secretariat on the latest development of the regional economic integration as well as the main outcome of the 29th ACCSQ Meeting held on 20 – 22 March 2007 in Yangon, Myanmar. The ASEAN Secretariat's paper appears as **ANNEX 4**.

Agenda Item 4:	FOLLOW-UP FROM THE 7TH ACC MEETING
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8. The Co-Chair of ACC presented to the Meeting the main outcomes of the 7th ACC Meeting held on 7 – 8 December 2006 in Bohol, Philippines. The highlight of the 7th Meeting of the ACC appears as **ANNEX 5**.

Agenda Item 5:	IMPLEMENTATION OF THE ASEAN HARMONIZED COSMETIC REGULATORY SCHEME (AHCRS)
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Agenda Item 5.1:	Outcome of Head of Delegations Workshop held on 9 – 10 May 2007, Jakarta, Indonesia and the Meeting held on 12 June 2007
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9. The ASEAN Secretariat reported to the Meeting the outcome of Heads of Delegations Workshop held on 9 – 10 May 2007, Jakarta, Indonesia. The Summary Record of Head Delegations Workshop appears as **ANNEX 6**.

10. The meeting noted the following decisions made by the ACC Heads of Delegations:

Legislation and Regulatory Framework

- a. Member Countries that have not yet done the transposition of the ASEAN Cosmetic Directive into their national legislation should make extra efforts to ensure that their legislation is ready by 1st January 2008. A comprehensive review of various aspects of the national legislations should be conducted to avoid contradictions and gaps in the transposition;
- b. Future national legislation should be developed in a way to allow updating the ASEAN Cosmetic Directive based on the ACC decisions, especially its Annexes on ingredients;
- c. Member Countries should ensure that no modifications to the technical requirements/documents which have been adopted by the ACC are made in the transposition process. If Member Countries have any concern and wish to modify the requirements or documents, they will have to report to the ACC for discussion and agreement before modifications can be made;



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- d. Regarding the Article 4.1 of the ASEAN Cosmetic Directive, it was decided that the latest EU modifications to the Annex 2 of the EU Cosmetic Directive will be immediately accepted by Member Countries upon circulation by the Secretary of the ACSB. In case of any concern regarding any ingredient, Member Countries should raise it immediately for the ACSB to review;
 - e. Cosmetics for Hotels and Spas should not be exempted from the ACD requirements while products made for use by dermatology clinics will be further discussed.

Post Market Surveillance

- f. In considering the difficulty that industry would face in developing the PIF, it is necessary to develop a Guideline on PIF covering the following:
 - Defining the timeframe regarding “readiness” as stated in Article 8;
 - Minimum information that a company has to provide upon regulators’ request;
 - Specific timeframe to supply regulators with other information when required, taking into consideration that not all manufacturers would provide distributors in advance with all the information related to products;
- g. Development of basic criteria and principles for conducting post market surveillance based on risk assessment, to be used as a guideline by regulators;

Strengthening ACSB working process

- j. ACSB should be more proactive and more responsive to assignments given by the ACC as specified in the TOR, taking into consideration that Member Countries would have to adjust the technical regulations at their national level. Additionally, the ACSB should maximize communication by email and/or fax to make decisions without waiting for the Meeting to be held;
- k. ACSB should update all annexes of the ACD as approved by the ACC and circulate it to all Member Countries prior to each Meeting;

Consideration of concerns from industry

- l. Those Member Countries having labeling requirements that are not in line with the ASEAN Cosmetic Labeling Requirements should allow companies to put products meeting ACD Labeling Requirements prior to 1st January 2008 (ASAP), taking into consideration that companies cannot change labeling within a very short period of time;



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- m. Allowing the use of either “expiry date” or “best before” to be printed on the label and regulators should not demand stability data before products are placed on the markets.

Grace Period

- n. The ACC Heads of Delegations revisited the Article 12.2 of the ACD regarding the grace period and agreed on the following interpretation: “Member Countries may allow products, which do not conform to the requirements of the Directive and have been in the market or produced before the Directive comes into effect, to continue to be sold in their territories for 36 months after the effective date of the ACD or expiry of the registration. Products produced after the effective date must conform to the requirements of the Directive. In this context, “Products that have been in the market or produced before the Directive comes into effect”, has to be understood as *products under the same brand and name marketed locally in the respective Member Countries provided that they continue to be classified as cosmetics in accordance with the ACD.*

Additional Clarifications

11. Indonesia sought further clarification on whether cosmetic products used in beauty salon and products produced for the purpose of research should be treated as cosmetics. Based on the definition of the ACD, the Meeting confirmed that the cosmetic products used at beauty salon should be covered under the ACD while products produced for research should be exempted from the implementation of the ACD.

12. Philippines also sought clarification on the grace period for ingredients placed in the Annexes of the ACD starting from 1st January 2008. The Meeting agreed that all modifications to the ACD Annexes which have been adopted by 14 June 2007 will be applied starting on 1st January 2008. Any modifications to be made after 14 June 2007, a grace period will be approved by the ACC based on recommendations of the ACSB with consideration of the risk level for each ingredient.

13. The Meeting further clarified that if a product has the same formula, the same brand and the same name and has been marketed in the territory of a Member Country before 1st January 2008, regardless whether it is produced before or after 1st January 2008, it can continue to be placed in that market for 36 months ***as long as that particular product will continue to be classified as a cosmetic*** after 1st January 2008. Further clarifications are given in paragraph 17.



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Notification Template

14. Based on the decision of the Heads of Delegations Workshop, Singapore presented to the Meeting the modified notification template. The modified notification template appears as **ANNEX 7.**

15. The Meeting discussed and agreed that:

- (i) The notification template should be as simple as possible to avoid any confusion;
- (ii) The requirements on particulars on importers should be added;
- (iii) The requirements on particulars of storage facilities should be removed. This will remain as a country specific requirement for Singapore;
- (iv) The original wording for the self declaration should be kept;

16. The Meeting revisited and agreed to adopt the revised notification template as appears in **ANNEX 8.**

17. The Meeting further discussed the notification period for new products and existing products that are already placed in the market. In this regard, the Meeting agreed on the following decisions:

New products: New products to be placed in the market from 1st January 2008 will be notified to the Regulatory Authority in the respective Member Countries where the products will be marketed;

Existing products means products placed in the market prior to 1st January 2008. These are classified into four categories with the specific grace periods as follows:

- a) Product meets the ACD and is already registered with the authorities will only require notification upon the expiry of existing registration;
- b) Product meets the ACD and is already registered/notified with the authorities while the registration/notification does not have a validity period will require notification by 1st January 2011;
- c) Product meets ACD but is not notified/registered with the authorities will require notification no later than 1st January 2011, subject to decisions of the NRA in the respective countries as follow:
 - (i) Brunei Darussalam, Singapore, Thailand will decide timeframes and inform the ACC Members and the Industry accordingly;
 - (ii) Cambodia, Indonesia, Lao PDR, Philippines and Viet Nam will require notification by 1st January 2008.



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- d) Products do not meet the ACD requirements and have been marketed in the territory of a Member Country before 1st January 2008, regardless if the product has been registered with the NRAs or not, will have to be notified to the NRA of that particular Member Country no later than 1st January 2011, depending on the decision of each NRAs. The grace period given for this category of products to continue to be sold in the territory of that Member Country will be also decided by the respective NRA in that Member Country, on a case by case basis, taking into consideration the risk level of the products. In this case, Member Countries concerned will have to develop country specific notification format for this category of products.

Agenda Item 5.2:	Progress in preparing for the implementation of the ASEAN Cosmetic Directive at National Level
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18. Member Countries presented to the Meeting their country report on preparation towards the implementation of ACD. Member Countries reports appear together as **ANNEX 9**.

19. The Meeting noted the challenges being faced by Member Countries and agreed that additional technical assistance should be provided to enable Member Countries to implement the ACD within timeframe, in particular in the following areas:

- a) Strengthen capability of the SMEs in meeting the ACD requirements in GMP, PIF, labeling requirement and safety assessment;
- b) Strengthening competency for Regulatory Authorities in PMS especially in evaluation of product safety and testing.

20. The Meeting noted that several Member Countries have already finalized the draft of national legislation to be in line with the ACD requirements and encouraged those countries that have done so to accelerate the process, noting that legislation is fundamental element for regulators to start with the implementation of the ACD.

Agenda Item 5.3:	Post Marketing Surveillance (PMS)
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Agenda Item 5.3.1:	Draft PIF Guideline
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21. Singapore presented to the Meeting the final draft PIF Guideline as well as recommendations for follow up action, which were finalized during the Regional Workshop on PIF held on 10 – 11 June 2007, Vientiane, Lao PDR. The presentation and final draft PIF Guideline appear together as **ANNEX 10**.



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22. The Meeting discussed and agreed to the following modifications to the draft PIF Guideline as follows:

- a) Introduction and Objective: “*this is not a legal document and as such, compliance is not mandatory requirements” should be amended as “this is not a legal document and as such, compliance to the Guideline is not mandatory requirements while PIF is mandatory requirements as stated in Article 8 of the ACD;
- b) Part II: For fragrance materials, the word “certification of compliance” should be amended as “declaration of compliance”;
- c) Insert provision on proprietary information to be read as follow: noting that due to trade secret, the product owner may not disclose some product information for any parts of the PIF to the distributor/ importer, the person or company placing the product in the market will need to make their own arrangements with the product owner to provide the relevant and necessary information directly to the Authorities upon request.

23. The Meeting agreed to adopt the revised PIF Guideline as appears as **ANNEX 11**.

Agenda Item 5.3.2: Testing Laboratory Network

24. Singapore reported to the Meeting on progress in following up 7th ACC decision: in identifying short, medium and long term action plans as well as priority activities in 2007, including possibility to look into the establishment of regional reference testing laboratory network.

25. The ASEAN Secretariat informed the Meeting that there will be a regional workshop to be held in September 2007 in Philippine and followed by national training if necessary. In this regard, the Meeting requested Singapore to coordinate with the APRIS 2 expert and members of the PMS 1 to ensure activities to be delivered to the needs of Member Countries.

Agenda Item 5.4: Progress of the ASEAN Cosmetic Scientific Body (ACSB)

26. The Chair of ACSB reported to the Meeting on the outcome of the 7th ACSB Meeting held on 12 June 2007 in Vientiane, Lao PDR. The report of the ACSB, draft ASEAN Cosmetic Claim Guideline and amended Annexes of the ACD appears together as **ANNEX 12**.



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27. The Meeting discussed recommendations of the ACSB and agreed on the following:
- a) **Claim Guideline:** Adopt revised ASEAN Claim Guideline which appears as **ANNEX 13**;
 - b) **Entry of new product categories into Annex 1 of the ACD:** based on decision tree stated in the adopted Claim Guideline, the following categories should be classified as cosmetics. Hence, they should be incorporated into Annex 1 of the ACD:
 - Mouthwash;
 - Anti-caries toothpaste;
 - Anti-dandruff;
 - Skin wash;
 - Anti-bacterial;
 - Sunscreen;
 - Skin whitening;
 - Anti-acne;
 - Anti-hair loss;
 - Bust contouring cream; and
 - Breath fresheners- liquid or spray

The Meeting clarified that the word “anti” only refers to product categories and does not refer to product claim. Noting the concern of Thailand that translation of the word “anti” into its local language would create confusion for consumer. Hence, the Meeting agreed to Thailand proposal that industry will not be allowed to translate the word “anti” into Thai language and to put on label for two products (anti-acne and anti-hair loss).

- c) **For anti- cellulite products, all countries except Thailand agreed to treat these products as cosmetics.** Thailand gave explanation that its current legislation does not consider anti-cellulite products as cosmetics. Hence, Thailand would need to consult with its national cosmetic committee and submit its confirmation to the ACC by **31 July 2007**;
- d) **Chemical Peels Products in the Annex 1 of the ACD should be understood that chemical peel face masks are skin treatments consisting of high concentrations of chemicals such as alpha-hydroxy acids, chloracetic acid or resorcinol. They are used by dermatologists under clinical conditions to remove spots, acnes or other blemishes;**
- e) **ASEAN Microbiology Limits:** agreed to adopt the ASEAN Microbiology Limits which appears as **ANNEX 14**;



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- f) **Update of Annex II (Banned list) in line with the latest EU changes:** agree to add an extra 107 ingredients to the ASEAN banned list. For the grace period of the implementation of any banned ingredient and for changes to other annexes of the ACD, it will be decided by the ACC Head of Delegations as soon as possible. The updated version appears as **ANNEX 15**.
- g) **Review of proposals for adoption of new entries to the EU Annexes:** Agree not to adopt entries 67-92 inclusive into Annex 3, part 1 of the ACD;
- h) **Labeling of colourants using US nomenclature:** the Meeting agreed that the use of either EU INCI names or US INCI names should be acceptable by regulatory authorities;
- i) **Diethylene glycol:** The Meeting noted the initial review on toxicology of the DEG and advised Member Countries to be cautious with products containing this ingredient while waiting for the ACSB to submit the final report on toxicology of the DEG by **30 June 2007**.
- j) **Eye-lash perming products:** Agree to put this category of products in the forbidden product list. A new forbidden product list to be put up by the ACSB.

Agenda Item 5.5: ASEAN Cosmetic GMP

28. The ASEAN Secretariat informed the Meeting of the additional technical assistance for GMP which includes a regional workshop and national training activities if necessary. In this regard, the Meeting agreed that Malaysia will coordinate with Member Countries and submit inputs to the ASEAN Secretariat by end of July 2007 and the regional workshop on GMP for soap industry will be held before September 2007.

29. Malaysia informed the Meeting that some countries outside ASEAN would propose the ACC to consider the equivalency between the ASEAN GMP Guideline and the GMP Guidelines in these countries. In this regard, the Meeting requested Malaysia to coordinate with the GMP Taskforce Members by all means of communications to review the proposals and submit the recommendations for consideration and approval by the ACC.

Agenda Item 8: Other Matters

30. The Meeting requested the ACSB Secretary to coordinate with ACSB Members and ACC Members to review and update entire ACD document and to be submitted for



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consideration and adoption at the forthcoming ACC Heads Delegations Meeting to be held in September 2007 in Malaysia.

Agenda Item 9: Date and Venue of the Next Meeting

31. The Meeting agreed that the 9th ACC Meeting will be held in December 2007 in Viet Nam; the 10th ACC Meeting will be held in June 2008 in Indonesia and the 11th ACC Meeting will be held in November/December 2008 in Singapore (to be confirmed). The date and venue will be communicated in due course.

Agenda Item 10: Adoption of the Minutes of the Meeting

32. The Meeting considered and adopted the Report of the Eighth Meeting of the ACC held on 13 – 14 June 2007 in Vientiane, Lao PDR.

ACKNOWLEDGMENT:

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

34. The ACC and ACSB communicated and expressed its utmost appreciation to Mme. Le Chau Giang as Senior Officer of ASEAN Secretariat for all of her outstanding work and contribution to the success of the ASEAN Harmonization Cosmetic Regulatory Scheme.
