INTRODUCTION

1. The 18th Meeting of the ASEAN Cosmetic Committee (ACC) was held on 21-22 November 2012 in Solo, Indonesia. The Meeting was preceded by the following events at the same venue:

   a) 17th Meeting of the ASEAN Cosmetic Scientific Body (ACSB) on 19-20 November 2012.
   b) 1st Meeting of the ASEAN Cosmetic Testing Laboratory Committee (ACTLC) on 20 November 2012; and
   c) Meeting of the Heads of Delegations (HoDs) of the ASEAN Member States of the ACC on 20 November 2012.

2. The Meeting was chaired by Mrs Nazarita T. Tacandong, Acting Director III, Food and Drug Administration, Department of Health, Philippines and co-chaired by Mrs. Marie Tham, Advisor, International Collaboration, Health Products Regulation Group, Health Sciences Authority, Singapore.

3. 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. The list of delegates appears as ANNEX 1.

OPENING CEREMONY

4. The Meeting was officially opened by the Dra. Lucky S. Slamet MSc, Head of the National Agency of Drug and Food Control of Indonesia. She welcomed all delegates to the 18th ACC Meeting and commended the ACC for the success of the integration efforts in the cosmetic sector with the implementation of the ASEAN Cosmetic Directive. The Opening Speech appears as ANNEX 2.
AGENDA ITEM 1 : ADOPTION OF AGENDA

5. The Meeting adopted the agenda which appears as ANNEX 3.

AGENDA ITEM 2 : BUSINESS ARRANGEMENT

6. The Meeting was held in plenary.

AGENDA ITEM 3 : UPDATE ON THE LATEST DEVELOPMENT ON ECONOMIC INTEGRATION AND OTHER DECISIONS IMPACTING THE COSMETIC SECTOR

7. The ASEAN Secretariat briefed the Meeting on the recent developments in the economic integration initiatives in ASEAN as well as the relevant decisions made at AEM, AFTA Council, SEOM and the 39th ACCSQ Meeting. The presentation from the ASEAN Secretariat appears as ANNEX 4.

8. The Meeting noted that the following:

   a) The SEOM had endorsed the revised ASEAN Good Regulatory Practice Guide (AGRPG) and the ACCSQ is exploring support from Japan and the US to assist with the implementation of good regulatory practice based on the AGRPG by Member States through awareness programmes.

   b) The 2nd ASEAN-China Ministerial Meeting on TBT Cooperation has been proposed to be held in September 2013 in Brunei Darussalam and the ACCSQ is considering the issues to be discussed at the Ministerial meeting.

   c) The AEM and the AFTA Council have urged the sectoral bodies to prioritise key deliverables for 2015 and the ACCSQ has finalised the key deliverables based on the activities of the bodies under its purview.

AGENDA ITEM 4 : FOLLOW-UP FROM THE 17TH ASEAN COSMETIC COMMITTEE MEETING

9. The ASEAN Secretariat briefed the Meeting on the action taken on matters arising from the 17th ACC Meeting held on 11-12 July 2012 in Siem Reap, Cambodia. The matrix of follow-up actions taken on the matters arising from the 17th ACC Meeting appears as ANNEX 5.
10. The Meeting was informed that the European Commission (EC) had provided information as requested by the ACC on the implementation of the EU cosmetics regulation such as the requirements for nano-materials ingredients, e-commerce of cosmetic products, qualification of safety assessors in-market control of cosmetics, and carcinogenic, mutagenic or toxic for reproduction (CMR) ingredients.

11. The Meeting noted the following progress since the last meeting:

a) Updates from the EC

i. The information on nano-materials and CMR ingredients from the EC appears together as ANNEX 6.

ii. There is no specific EU legislation for e-commerce of cosmetic products but the EU horizontal legislation for e-commerce applies. More information on this is available at the EU web site on e-commerce at the following URL: (http://ec.europa.eu/internal_market/e-commerce/directive_en.htm).

iii. Both the Cosmetics Directive 76/768/EEC and Regulation (EC) No 1223/2009 set only minimum training requirements for safety assessors. However, in the present state of the law, Member States are free to set higher standards provided they comply with the relevant provisions of Directive 2005/36/EC (on the recognition of professional qualifications) when they recognise professional qualifications acquired in other Member States.

iv. ASEAN needs to identify specific issues for discussion to justify the attendance of regulators of the EU Member States to share experience with ASEAN on the implementation of cosmetic regulations.

b) Updates on EU strategies on GMP of cosmetic products

i. In the EU, compliance to GMP is mandatory for cosmetic manufacturers but certification is not required. The choice of GMP is voluntary and the compliance is presumed if the manufacturer is in accordance with the relevant harmonised standards (CEN 22716:2007). Compliance may also be demonstrated in other ways, e.g. via industry-recognised standards and code.

ii. EU Member States do not issue certificates of compliance with GMP but the inspection is conducted by certifiers (e.g. testing houses) which are usually private entities.
iii. It is up to the competent authorities of the EU Member States to decide how the inspections will be conducted and which documentation can be accepted to demonstrate the compliance. In most cases the inspections concerning GMP are done in relation with random controls of the product information file conducted by the EU Member States competent authorities.

iv. EU Member States may ask for full GMP documentation, in addition to the statement of compliance by the manufacturer. This is similar to the imported product where the person responsible for placing an imported cosmetic product on the EU market has to keep, for control purposes, the product information file which include the compliance to the GMP must be readily accessible to the competent authorities of the EU Member State concerned and no specific documentation required for GMP verification.

12. The Chair briefed the Meeting on the decisions made by the HoDs during the ACC HoDs Meeting held on 20 November 2012 in Solo, Indonesia. The Chair’s presentation appears as ANNEX 7.

13. The Meeting noted the following decisions of the HoDs:

a) Challenges faced with the implementation of the ASEAN Cosmetic Directive (ACD)

i. The HoDs discussed the challenges faced with the implementation of the ACD and noted that Member States are still facing difficulties with the post-market surveillance of notified cosmetic products. The HoD noted the issue of traceability in post market surveillance and discussed various mechanisms such as insertion of hologram and notification number and agreed to further discuss this under agenda item 5.1.

ii. The HoDs agreed to gather information from all the Member States on the challenges faced and the information could be used to identify regional concerns with regards to the implementation of the ACD with the assistance from technical experts under EU programme.

iii. The HoDs noted that the ASEAN-6 had been requested to share with CLMV the training programmes that are available and encouraged CLMV to liaise directly with the ASEAN-6 to participate in the relevant trainings.

b) Public-Private Forum
i. The HoDs noted the recommendations from the ACA for the Public-Private Forum (PPF).

ii. The HoDs agreed to hold a half-day PPF annually during the second meeting of the year and requested the ACA to provide some recommendations on the theme/topic for the next PPF. The recommendations from the ACA will be considered by the HoDs.

iii. The HoDs also noted the interest expressed by the EU and US to support public-private engagement under their technical assistance and cooperation programmes.

c) AEC Scorecard

i. The HoDs agreed to consider additional measures that need to be monitored for effective implementation of the ACD at the regional level for inclusion in the AEC Scorecard after the analysis is carried out on the information gathered from Member States on implementation gaps.

ii. The HoDs noted that the Economic Research Institute for ASEAN and East Asia (ERIA) has been requested to improve the AEC Scorecard to include a weighted scoring method.

d) Concerns from Personal Care Products Council

i. The HoDs noted the concern raised by the Personal Care Products Council (PCPC) on the challenges faced with the implementation of the ACD.

ii. The HoDs agreed to convey to the PCPC that concerns from the industry should be channelled through the ACA and the national industry associations.

iii. The HoDs agreed to request the ASEAN Secretariat to reply to PCPC explaining the decision of the ACC that the concerns from the industry should be channelled through the ACA and the national industry associations.

14. The Meeting agreed to discuss the pending issues from the 17th ACC Meeting and the decisions of the ACC HoDs under the corresponding agenda items.
AGENDA ITEM 5 : PROGRESS OF THE IMPLEMENTATION OF THE ASEAN COSMETIC DIRECTIVE

15. The Meeting discussed the progress made on the implementation of the ACD at the regional and national levels and agreed to discuss the specific aspects under the corresponding agenda items. The reports on the overall status of implementation of the ACD from Brunei Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Thailand and Viet Nam appear together as ANNEX 8.

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

16. The Meeting noted the status of implementation of the appropriate measures to support the notification for placement of cosmetic products, including the efforts taken for the publication of notified products on their respective websites.

17. The Meeting recalled the discussions at the ACC HoD meeting with regards to traceability in post market surveillance and agreed to request ACA to work together with the ACC to recommend possible solutions to overcome the challenges faced.

5.2 Issues faced by the industry following the implementation of the ACD

18. The representative from the ACA briefed the Meeting on the challenges faced with the implementation of the ACD. The presentation from ACA appears as ANNEX 9.

19. The ACA informed the Meeting that efforts are still being undertaken to encourage the local industries of ASEAN Member States to become members of ACA.

20. Thailand informed the Meeting that with effect from 16 October 2012, there is no limit on the number of notifications received by the authorities daily.

21. The Meeting reiterated that ACA should seek clarification from the Member States on the concerns of the industry on the country-specific requirements and only unresolved issues should be raised to the ACC.

22. The Meeting also urged ACA to establish cooperation with PCPC to ensure that all issues related to the concerns of the industry with regards to country-specific requirements and other related challenges faced are channelled to the ACC through ACA.

23. Indonesia expressed reservations on the letter sent by the PCPC.
5.3 Raising consumer awareness on the implications of the ACD and the safe use of cosmetic products

24. The Meeting noted the updates from Member States on the policies, strategies and efforts taken at the national level to raise consumer awareness and understanding on the safe use of cosmetic products.

25. The ACA updated the Meeting that the draft ASEAN Consumer Information Handbook has been revised by ACA taking into consideration the feedback received from Member States. The revised draft ASEAN Consumer Information Handbook appears as ANNEX 10.

26. The Meeting requested the Member States to review the revised draft ASEAN Consumer Information Handbook and provide their comments on the draft to the ACA by 31 December 2012.

27. The ASEAN Secretariat informed the Meeting that the Indonesian representative from the ASEAN Coordinating Committee on Consumer Protection (ACCCP) had agreed to attend the ACC meeting to share information on the scope and progress of its activities related to consumer protection. However, due to unavoidable circumstances, the representative was unable to attend the meeting. The Meeting agreed to follow-up with the attendance of the representative of the ACCCP at the next meeting.

5.4 Enhancing the capability of SMEs to comply with the ACD

28. The Meeting noted the feedback from the Member States with regards to the capability of the Small and Medium Enterprises’ (SMEs) to meet the requirements of the ACD, the challenges faced with the preparation of the PIF and compliance to safety.

5.5 Post market surveillance

29. The Meeting noted the national efforts taken by their respective enforcement authorities on the post market surveillance of cosmetic products for the effective implementation of the ACD and the key problems encountered. The Meeting noted the difficulties faced by the Member States in the post market surveillance of cosmetic products in identifying products that have been notified.

30. Malaysia presented the statistical information on the notification of unsafe healthcare products in ASEAN through the ASEAN Post-market Alert System (PMAS) for January-September 2012. Malaysia’s presentation appears as ANNEX 11.

31. The Meeting noted the following recommendations to improve the PMAS and urged the Member States to provide the necessary support to Malaysia:
a) prompt update of any change in contacts;
b) provide product images where possible;
c) request/expect an acknowledgement from Lead Country to confirm e-mail receipt;
d) use latest PMAS Form(s) previously circulated; and
e) provide complete details of the product where possible.

32. The Meeting agreed that the PMAS continues to be an important communication tool to alert ASEAN members on unsafe healthcare products. The Meeting also agreed that more active participation from Member States through increased reporting on alerts is required.

5.6 Harmonisation of standards for the cosmetic sector

33. The ASEAN Secretariat briefed the Meeting on the feedback received from Member States on the availability of corresponding national standards and its degree of equivalence with the identified cosmetic standards of ISO/TC 217.

34. The Meeting noted that all Member States had provided information on the availability of corresponding national standards and its degree of equivalence with the identified cosmetic standards of ISO/TC 217. Member States that do not have corresponding national standards have indicated acceptance of the ISO standards. The matrix of the feedback received from Member States appears as ANNEX 12.

35. Thailand updated the Meeting on the progress made by ISO/TC 217 on the activities related to the development of ISO standards for the cosmetic sector. Thailand’s presentation appears as ANNEX 13.

36. The Chair of the ACTLC informed the Meeting that some of the current ISO standards related to microbiology requirements may be of relevance to the ACTLC.

37. Noting the copyright issues of the standards developed by ISO/TC 217, the Meeting requested P-members of the ISO/TC 217 to update Member States on the progress made with the standards under development in ISO/TC 217.

38. Indonesia presented the comparison on the labelling requirements of the ACD and the requirements in ISO 22715, and the gap analysis on the ISO requirements for GMP and the ACD requirements for GMP, which appear together as ANNEX 14.

39. The Meeting requested Indonesia to carry out further analysis on the GMP requirements and make recommendations to the ACC on the harmonisation of the identified ISO standard.
AGENDA ITEM 6: REPORT OF THE 1ST MEETING OF THE ASEAN COSMETIC TESTING LABORATORY COMMITTEE

40. The Chair of the ACTLC briefed the Meeting on the outcome of the 1st Meeting of the ACTLC held on 20 November 2012 in Solo, Indonesia. The Chair’s presentation appears as ANNEX 15.

41. The Meeting noted the following progress made by the ACTLC:

   a) Eight ASEAN Cosmetic Methods (ACM) are being revised taking into consideration the editorial and technical comments received from the Member States.

   b) A coding system for the ACM has been recommended as “ACM XXX”, where “XXX” will be running numbers beginning from “001”. The information related to the origination of the cosmetic methods will be captured in the ACMs.

   c) The technical assistance for cosmetic testing based on the feedback received from the Member States will be submitted to the ASEAN Secretariat to follow up with submission to the Dialogue Partner/Donor Agency for consideration under their technical assistance programme.

   d) To hold ACTLC Meeting after ACSB Meeting to enable the participation of the ACTLC members at the ACSB Meetings noting that some of the discussions and decisions made by the ACSB may facilitate the ACTLC discussions.

42. The Meeting endorsed the Report of the 1st ACTLC Meeting, held on 20 November 2012 in Solo, Indonesia, which appears as ANNEX 16.

AGENDA ITEM 7: REPORT OF THE 17TH ASEAN COSMETIC SCIENTIFIC BODY MEETING

43. Singapore, on behalf of the Chair of the ASCB, briefed the Meeting on the outcome of the 17th ACSB Meeting which was held on 19-20 November 2012 in Solo, Indonesia. The report of the 17th ACSB Meeting appears as ANNEX 17.

44. The Meeting noted the progress made by the ACSB to support the effective implementation of the ACD.

45. The Meeting endorsed the nomination of Indonesia as the Chair of the ACSB and Thailand as the Alternate Chair of the ACSB. In consideration of the need for easier logistics support the Meeting agreed to the request from Indonesia to appoint the
Secretary of ACSB based in Indonesia, and requested ACA to assist with the nomination of the Secretary of ACSB.

46. The Meeting endorsed the Report of the 17th ACSB Meeting which was held on 19-20 November 2012 in Solo, Indonesia.

AGENDA ITEM 8: TECHNICAL ASSISTANCE AND CAPACITY BUILDING PROGRAMME FOR THE COSMETIC SECTOR

8.1 Cooperation with EU

47. The Team Leader of the ASEAN Regional Integration Support by EU (ARISE) updated the Meeting on the progress made with the technical assistance and capacity building under the ARISE and the specific details on the technical assistance for the cosmetic sector to support the effective implementation of the ACD. The presentation from the Team Leader appears as ANNEX 18.

48. The Meeting noted the remarks from Mr Andreas Roettger, Head of Economic and Regional Cooperation, EU Delegation to Indonesia, Brunei Darussalam and ASEAN, read by the Team Leader, which appears as ANNEX 19.

49. The Meeting noted the scope of the ARISE which includes support for the cosmetic sector. The Meeting was informed that during the inception period which will lead to the development of the Overall Work Plan and Annual Work Plans for the implementation of the technical assistance for the identified sectors, namely agro-based products, automotive, cosmetics, electrical and electronic equipment.

50. The Meeting noted that the ACCSQ had requested the ACCSQ WG 2 (Accreditation and Conformity Assessment) to cease all work related to the development of the ASEAN Conformity Mark until the Feasibility Study for the ASEAN Conformity Mark which will be conducted by PTB (Germany) is completed.

8.2 Cooperation with China

51. The ASEAN Secretariat briefed the Meeting on the status of the Terms of Reference (ToR) of the ASEAN-China Cooperation in the Cosmetic Sector to support the implementation of the ASEAN-China TBT MoU.

52. The Meeting noted the ACC HoDs had discussed and finalised the draft ToR taking into consideration the comments received from Member States. The Meeting agreed to re-circulate the final draft ToR to the Member States and requested the Member States to submit their comments on the final draft ToR, if any, to the ASEAN
Secretariat by 10 December 2012. Singapore informed the Meeting that the comments from Singapore are not completely incorporated and the comments on the draft ToR will be re-sent to the ASEAN Secretariat. The Meeting also noted that Thailand had submitted comments on the draft ToR which appears as ANNEX 20.

53. The Meeting noted that the ASEAN Secretariat has extended an invitation to the representatives from the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and/or the State Food and Drug Administration (SFDA) to attend the 18th ACC Meeting and there has been no response.

54. The Meeting agreed to identify a list of substantial issues to be discussed with AQSIQ/SFDA and noted the following areas of cooperation in the ASEAN-China TBT MoU:

   a) establishment of an efficient system of information exchange and communication for which the Parties will decide on the priority sectors for cooperation;

   b) conducting exchange visits of relevant management, enforcement and technical personnel of the Parties so as to exchange experience and consult and resolve relevant problems;

   c) conducting training courses, seminars and other similar activities based on the needs and capabilities of the Parties, and in consideration of narrowing the development gap within ASEAN;

   d) conducting collaborative research in areas of mutual interest within the scope of the Memorandum of Understanding; and

   e) other areas as agreed by Parties.

55. In this regard, the Meeting agreed to develop an agenda for the discussion with the representatives from AQSIQ/SFDA based on the agreed mechanisms for cooperation given above taking into consideration the concerns raised by ACA on the challenges faced by the ASEAN cosmetics industry with China. The ASEAN Secretariat was requested to draft the proposed agenda for consideration by the ACC.

56. The Meeting noted the recommendation from Indonesia for a meeting with the representatives from SFDA, facilitated by the ASEAN Secretariat, to discuss issues related to the placement of cosmetics products in China. Noting that the representatives from SFDA have been invited to attend the 19th ACC Meeting, it was agreed to include this matter in the agenda for discussion with the SFDA. The Meeting also agreed to request Indonesia to gather information from the Member States on the challenges faced by the ASEAN cosmetics industry on placement of cosmetics products in China in preparation for the discussion with SFDA.
8.3 Support for CLMV under the Initiative for ASEAN Integration

57. The ASEAN Secretariat updated the Meeting that the Initiative on ASEAN Integration and Narrowing the Development Gap (IAI & NDG) Division of the ASEAN Secretariat has agreed to follow-up on the proposed support for CLMV under the IAI Work Plan. The ASEAN Secretariat’s Information Paper appears as ANNEX 21.

58. The Meeting also noted that the EU, Germany (PTB) and the US have also indicated interest to support CLMV under their respective technical assistance and cooperation programmes. The Meeting further noted the recommendation from the ASEAN Secretariat to organise a meeting with CLMV to discuss the work plan to support CLMV for the cosmetic sector under the IAI Work Plan. In this regard, the Meeting requested the ASEAN Secretariat to follow-up with CLMV to assist with the development of the work plan.

59. The ASEAN Secretariat also informed the Meeting as Brunei Darussalam, Indonesia, Malaysia, Philippines and Singapore have submitted information on the available training programmes for the cosmetic sector. The matrix of available training programmes appears as ANNEX 22.

60. The Meeting noted the decision of the HoDs with regards to the support from ASEAN-6 for CLMV to narrow the development gap and encouraged CLMV to liaise directly with the respective Member States of ASEAN-6 to participate in the relevant trainings.

61. The ACA informed the Meeting that it will be able to provide trainings to the CLMV at no cost. In this regard, the Meeting agreed to include the support from ACA in the proposed work plan.

AGENDA ITEM 9: COUNTERFEIT COSMETICS PRODUCTS

62. The Meeting discussed the prevalence of counterfeit cosmetic products in Member States and the mechanisms adopted at the national level to combat the counterfeit cosmetic products. Noting that the ASEAN Working Group on Pharmaceutical Development (AWGPD) is also addressing this issue, the Meeting agreed to delete this item from the ACC discussions to avoid duplication of activities.

63. The Meeting also requested ACA to include information on counterfeit cosmetic products in the ASEAN Consumer Information Handbook.
AGENDA ITEM 10: AEC SCORECARD

64. The Meeting noted the decision made by the HoDs that additional measures that need to be monitored for effective implementation of the ACD at the regional level for inclusion in the AEC Scorecard will be considered after the analysis is carried out on the information gathered from Member States on the ACD implementation gaps.

65. The Meeting also noted that the Economic Research Institute of ASEAN and East Asia (ERIA) is assisting ASEAN to improve the AEC Scorecard to include a weighted scoring method.

66. The Meeting noted that the Member States were requested to provide the updated information on the status of implementation of the existing measures in the AEC Scorecard for the cosmetics sector to the ASEAN Secretariat by 30 November 2012. The ASEAN Secretariat was requested to update the AEC Scorecard based on the information received from the Member States.

AGENDA ITEM 11: POOL OF COSMETIC SAFETY EXPERTS

67. Malaysia updated the Meeting on the progress of the National Cosmetic Safety Expert Committee (CoSEC).

68. The Meeting noted the constitution of the CoSEC which comprises the following experts:
   a) 5 Senior Pharmacists from the Ministry of Health;
   b) 2 representatives from research centres;
   c) 2 representatives from the academia;
   d) 1 dermatologist;
   e) 2 representatives from the Cosmetic, Toiletry and Fragrance Association of Malaysia (CTFAM); and
   f) 1 representative from the Federation of Malaysian Manufacturers – Malaysia Cosmetics and Toiletries Industry Group (FMM-MCTIG).

69. Malaysia agreed to continue to share more information on the progress made by the CoSec at the future meetings.

AGENDA ITEM 12: OTHER MATTERS

70. There were no other matters raised for discussion.
AGENDA ITEM 13: DATE AND VENUE OF THE 19th ASEAN COSMETIC COMMITTEE MEETING

71. The Meeting expressed appreciation to Lao PDR for the offer to host the 19th ACC Meeting on 21-24 May 2013.

72. The Meeting also expressed appreciation to Malaysia for the offer to host the 20th ACC Meeting on 25-28 November 2013.

73. The List of Meetings of the ACC appears as ANNEX 23.

AGENDA ITEM 14: ADOPTION OF THE REPORT

74. The Meeting considered and adopted the Report of the 18th ASEAN Cosmetic Committee Meeting held on 21-22 November 2012 in Solo, Indonesia.

ACKNOWLEDGEMENT

The delegates from Brunei Darussalam, Cambodia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, the representatives from the ASEAN Secretariat and the ASEAN Cosmetic Association expressed their appreciation to the National Agency of Drug and Food Control, Indonesia, 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.