INTRODUCTION

1. The 20th Meeting of the ASEAN Cosmetic Committee (ACC) was held on 27-28 November 2013 in Kuala Lumpur, Malaysia. The Meeting was preceded by the following events at the same venue:
   a) ASEAN Cosmetic Public-Private Forum on 25 November 2013;
   b) 19th Meeting of the ASEAN Cosmetic Scientific Body (ACSB) on 25-26 November 2013;
   c) 3rd Meeting of the ASEAN Cosmetic Testing Laboratory Committee (ACTLC) on 26 November 2013; and
   d) Meeting of the Heads of Delegations (HoDs) of the ASEAN Member States of the ACC on 26 November 2013.

2. The Meeting was chaired by Ms. 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, Myanmar, Philippines, Singapore, Thailand, Viet Nam, representatives from the ASEAN Secretariat, the ASEAN Cosmetic Association (ACA), and ASEAN Regional Integration Support by EU (ARISE). 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 Dato’ Eisah Abdul Rahman, Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia. Dato’ Eisah commended on the achievement made by ACC on the implementation of ASEAN Cosmetic Directive (ACD). She further emphasized that with the shift from pre-market approval to post market surveillance, it is very important to focus on consumer education in order to make them understand on how to choose safe cosmetic products. With the target of AEC in 2015, focus should be made to the SMEs to support them in fulfilling ACD.
requirements, i.e. GMP, PIF and safety assessment. In this regard, the Regulatory Authorities and Cosmetic Association should work together to carry out concrete actions for the SMEs. She further wished all the delegates a successful meeting. 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 updated the Meeting on the outcome of the recent developments in the ASEAN economic integration efforts, in particular the decisions made by the higher ASEAN Bodies, and the outcome from the Special ACCSQ Leaders Meeting held on 4 – 5 July 2013 in Jakarta, Indonesia. The presentation from the ASEAN Secretariat appears as ANNEX 4.

8. The Meeting noted the outcomes of decisions of the meeting of higher ASEAN bodies, as follows:

   - The Leaders tasked the ASEAN Community Councils to initiate work on a post-2015 vision and agreed to further discuss this issue at the 23rd ASEAN Summit.
   - The High-Level Task Force on ASEAN Economic Integration (HLTF-EI) started preliminary discussion on the post-2015 vision and will be engaging regional think tanks to facilitate their discussions.
   - The Leaders tasked the Ministers to develop a roadmap that will set out initiatives to facilitate business, address investment impediments, institutionalise discussions on regulatory improvement, and incorporate policies that encourage innovation into ASEAN’s efforts.
   - To build upon the relevant initiatives stipulated in the AEC Blueprint in addressing the Leaders’ mandate.
   - Prioritised deliverables for 2013 and 2015 have been endorsed by both the ASEAN Economic Ministers (AEM) and ASEAN Economic Community (AEC) Council.
The implementation rate for AEC varies between 82.1% to 87.5%, based on the assumption that all the prioritized deliverables for 2013 and 2015 are achieved.

9. The Meeting took note on the outcome of 40th ACCSQ Meeting held on 8 – 10 April 2013 in Kuala Lumpur, Malaysia and Special ACCSQ Leaders Meeting, held on 4 – 5 July 2013 at the ASEAN Secretariat. Outcome of the Meeting includes:

AEC Deliverables

The Special ACCSQ Leaders Meeting developed definition of term and stages of achievements, in order to guide various WGs and PWGs in monitoring deliverables under their purview and ensure common understanding of commitments stipulated in the deliverables. The format includes:

i. Milestones for Harmonization Activities by WGs/PWGs;
ii. Milestones for MRA and Regulatory Regimes by WGs/PWGs.

ASEAN – China Ministerial Meeting on TBT Cooperation

- The ASEAN – China MoU on TBT Cooperation will expire on 25 October 2014, while the implementation plan of MoU is not yet fully implemented.
- The ACCSQ noted that under the ASEAN – China FTA, there is TBT Protocol that will activate the Sub-Committee on Standards, Technical Regulations and Conformity Assessment Procedures (SC - STRACAP).
- The ACCSQ viewed that it is necessary to avoid duplication of work with existing mechanism of TBT, since both fora require ACCSQ involvement.
- The ACCSQ made recommendation to SEOM:
  I. To subsume the ASEAN – China MoU on TBT under the TBT Protocol to incorporate TBT and SPS into ASEAN – China FTA;
  II. 2nd ASEAN – China Ministerial Meeting on TBT is proposed to be postponed until SC – STRACAP under ASEAN – China FTA be established.

AGENDA ITEM 4 : FOLLOW-UP FROM THE 19th ASEAN COSMETIC COMMITTEE MEETING

10. The ASEAN Secretariat briefed the Meeting on matters arising from the 19th ACC Meeting held on 23-24 May 2013 in Vientiane, Lao PDR, and the follow-up actions
The matrix of actions taken from the 19th ACC Meeting appears as ANNEX 5.

11. The Chair of ACC presented to the Meeting issues that were discussed by ACC HoDs, at their Meeting held on 26 November 2013, which include:

   a) Progress on the Evaluation Study on AHCRS by ARISE;
   b) Challenges faced by Member States in the implementation of ACD;
   c) Stem Cell in Cosmetic Products;
   d) Venue for 21st ACC Meeting.

The presentation appears as ANNEX 6

12. On the issue related to stem cell, the Meeting noted that Philippines is not allowing the use of stem cell as product name, as stipulated in its Law. To further study this matter, the Meeting agreed to discuss technical issue related to stem cell at the ACSB Meeting.

13. The Meeting recalled on the decision made by ACC to invite representative from the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and the China Food and Drug Administration (CFDA) to share information with the ACC on the regulatory requirements in China. In this regard, the ASEAN Secretariat will follow up with AQSIQ and CFDA for the attendance of their representative at the next ACC Meeting.

14. The Meeting agreed to discuss other pending issues from the 19th ACC Meeting 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, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Viet Nam appear together as ANNEX 7.

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

16. The Meeting noted that all Member States have implemented the notification of cosmetic products as follows:
a) Brunei Darussalam
   - The notification forms for placement of cosmetic products are submitted manually.
   - As of 31 October 2013, 37,535 cosmetic products have already been notified.

b) Cambodia
   - The notification forms for placement of cosmetic products are submitted manually.
   - The notifications are processed within 5 to 10 working days and the notifications are valid for two years.
   - As of November 2013, 6102 new cosmetic products have been notified and 986 renewal of notification have been handled.

c) Indonesia
   - The notification forms for placement of cosmetic products are online.
   - The e-payment for notification has been implemented since 1 October 2013.
   - 63,034 cosmetic products have been notified until September 2013.
   - Notification information can be accessed through email, telephone, desk, and mail.

d) Lao PDR
   - The notification has been processed manually.
   - The total number of notification so far is 1346.

e) Malaysia
   - The notification forms for placement of cosmetic products are submitted online through the QUEST System.
   - Screening on prohibited and restricted ingredients is conducted automatically.
   - As of 15 November 2013, a total of 133,296 cosmetic products have been notified.

f) Myanmar
   - The total number of notifications so far is 3,000 and the validity of notifications is two years.

g) Philippines
   - The Philippines has recently shifted from manual submission to e-notification system since 15 March 2013.
   - As of now, 30,387 cosmetic products have been notified.
h) **Singapore**
- The notification forms for placement of cosmetic products are submitted online through the PRISM System.
- A new online notification system is targeted to be implemented by Q3 of 2014 named FRONTIER.
- As of 15 November 2013, about 130,000 cosmetic products have been notified.

i) **Thailand**
- The notification forms for placement of cosmetic products are submitted online and as walk-in.
- As of 1 October 2013, the total number of notified cosmetic products is 267,088, whereby 187,677 of this were coming from e-submission.

j) **Viet Nam**
- The notification forms for placement of cosmetic products are submitted manually and online. In 2014, the notification process is expected to be fully online.
- As of now 92,000 cosmetic products have been notified.

17. The Meeting noted that Brunei Darussalam, Cambodia, Lao PDR and Myanmar have yet to implement the e-notification. In this regard, the Meeting was informed that the ARISE Project will extend its support to CLMV countries in developing their on-line notification system.

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

18. The representative from the ACA briefed the Meeting on the progress of its activities related to the support for the implementation of the ACD. The presentation from ACA appears as **ANNEX 8**.

19. The Meeting noted the information from ACA, which includes among others, the following:

- Almost all countries have transposed ACD into local law;
- Notification has been in place in all countries;
- Post market surveillance including alert system have been established in all markets;
- Industry in ASEAN and outside ASEAN has well accepted the concept of taking full responsibility for putting products in the markets (although more work needs to be done to get to 100%);
- Capacity building programmes have been conducted by the local associations in cooperation with the government agencies/ FDA. Training programme
cover several areas: INCI ingredient listing, clarifying claims, GMP knowledge & understanding, Safety Assessment;

- Focus of ACA by 2015:
  a. To increase probability of business success and sustainability;
  b. To ensure consumer safety and quality management;
  c. To strengthen and enhance business excellence of ACA members;
  d. To increase competitiveness and sustainability in each ASEAN country.

20. The Meeting commended ACA on its effort to support the implementation of ACD for cosmetic industry. In this regard, the Meeting requested ACA together with the regulatory authorities to analyse the impact of the trainings given for industry, especially for SMEs.

21. The Meeting requested ACA to undertake necessary effort in ensuring representation of all ASEAN countries in the organization, noting the current membership of ACA only consist of members from Indonesia, Malaysia, Philippines, Singapore and Thailand. The Meeting requested further update from ACA at the next ACC Meeting.

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

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

23. The ASEAN Secretariat updated the Meeting on finalization of ASEAN Consumer Information Handbook in coordination with ACA. The final version of the Handbook has been circulated to Member States through email communication. The Handbook has been uploaded on the ASEAN Secretariat website. The ASEAN Consumer Information Handbook appears as ANNEX 9.

24. The ASEAN Secretariat also informed the Meeting that a hardcopy version of the Handbook will be published by the ASEAN Secretariat. The Handbook will be distributed to Member States at the next ACC Meeting.

25. The Meeting commended Thailand for its prompt action in translating the ASEAN Consumer Information Handbook into Thai language. In this regard, the Meeting encouraged other Member States to translate into their own national language.

5.4 Enhancing the capability of SMEs to comply with the ACD
26. The Meeting noted the updates from the Member States with regards to enhancing the capability of the Small and Medium Enterprises (SMEs) to meet the requirements of the ACD.

27. The Meeting raised concern on the challenges faced by SMEs in ASEAN Member States, in particular with the preparation of the PIF and compliance to the documentation required. In this regard, the Meeting requested ACA together with the respective regulatory authorities to develop and implement concrete actions for SMEs in complying with ACD.

28. The Meeting also requested the ASEAN Secretariat to ensure that the Communication Plan on AEC 2015 includes actions to outreach business operators within and outside ASEAN to comply with ASEAN harmonized regulations.

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.


31. The Meeting noted that from January to October 2013, there are 656 products raised for alerts, whereby 578 of these products are under the cosmetic category.

32. The Meeting noted that alerts on cosmetic products were submitted by Brunei Darussalam (19), Indonesia (37), Malaysia (392), Philippines (6), Singapore (102) and Thailand (22).

33. Malaysia conveyed her recommendations to Member States for the improvement on the ASEAN PMAS to provide product images in submission of alert, whenever possible, noting that images could help in recognizing a product as it may be presented with different name in different countries.

34. The Meeting noted that there has been a significant increase in number of alerts exchanged between members of PMAS. In this regard, the Meeting encouraged Member States to continue its active participation in exchanging information especially with regards to quality and safety of health products in ASEAN region.
AGENDA ITEM 6: REPORT OF THE 3rd MEETING OF THE ASEAN COSMETIC TESTING LABORATORIES COMMITTEE

35. The Chair of the ASEAN Cosmetic Testing Laboratories Committee (ACTLC) briefed the Meeting on the outcome of the 3rd Meeting of the ACTLC held on 26 November 2013 in Kuala Lumpur, Malaysia.

36. The Meeting noted that the progress made and issues discussed, which include among others, the following:

   a) Eight ASEAN Cosmetic Methods (ACMs) have been finalized taking into consideration the comments received from the Member States.

   b) A list of priority of technical assistance for ACTLC was discussed and further submitted to the ASEAN Secretariat for its discussion and coordination with the ARISE and PTB Germany.

   c) Work plan on the establishment of ASEAN Cosmetic Reference Material Database.

   d) Drafting the ASEAN Guideline for Analytical Method Validation by Inter-Laboratory Comparison.

   e) Drafting the criteria of new ACMs.

   f) Appointment of Lead and participating countries for the proposed new ACMs are as follows:

<table>
<thead>
<tr>
<th>No</th>
<th>Testing for</th>
<th>Lead Country</th>
<th>Participating Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Determination of DEG by GC-MS</td>
<td>Philippines</td>
<td>Brunei Darussalam, Indonesia, Malaysia, Singapore, Thailand.</td>
</tr>
<tr>
<td>2</td>
<td>Screening and determination of hair dyes by HPLC-PDA</td>
<td>Singapore</td>
<td>Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam</td>
</tr>
<tr>
<td>3</td>
<td>- Determination of AHA (Glycolic and lactic acid)</td>
<td>Thailand</td>
<td>Brunei Darussalam Cambodia, Indonesia, Malaysia Singapore, Vietnam</td>
</tr>
<tr>
<td></td>
<td>- Determination of BHA (salicylic acid)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
37. HoD of Lao PDR expressed her regret for being unable to attend the 3rd ACTLC Meeting. Nevertheless she indicated her interest to participate in new ACMs and requested the Chair of ACTLC to include Lao PDR as one of the participating countries.

38. The Meeting discussed and endorsed the 8 (eight) ACMs and requested the ASEAN Secretariat to publish them on the ASEAN website. The Meeting also endorsed the Report of the 3rd Meeting of the ACTLC and its Annexes which appear as ANNEX 11.

AGENDA ITEM 7: REPORT OF THE 19TH ASEAN COSMETIC SCIENTIFIC BODY MEETING

39. The Chair of the ASEAN Cosmetic Scientific Body (ACSB) briefed the Meeting on the outcome of the 19th ACSB Meeting held on 25-26 November 2013 in Kuala Lumpur, Malaysia.

40. The Meeting noted the following inputs from Member States on the final report of the 19th ACSB Meeting:

On Agenda 2

- To clarify the first paragraph as follows:

  The Meeting noted that all Member States, except Indonesia, have adopted the 24 new entries of Hair Dyes from EU Directive 2012/21/EU into Annex III part 1 of ACD. The Meeting further agreed to allow Indonesia to continue its safety assessment review, while other Member States start to implement it by 1 December 2013.

On agenda 7, Annex III, part ii

- To clarify the first paragraph as follows:

  The Meeting noted the feedback from some Member States that currently the warning “not to be used for children under 6 years-old” is already printed on mouthwashes available in the market. Some Member States agreed to require such warning to be put on the label. In the meanwhile, Philippines informed the meeting that they still need to have internal consultation, since this is voluntary, not mandatory.

- To clarify the third paragraph as follows:

  The Meeting noted that ACA voluntarily offered to provide safety assessment for mouthwash containing alcohol as well as fluoride for
children below 6 years-old to enable assist ACSB to make its decision at the next Meeting.

41. The Meeting expressed its concern on the adoption process of ACSB Report. In this regard, ACSB Members are requested to review the draft ACSB Report comprehensively prior to adoption.

42. The Meeting endorsed the Report of the 19th ACSB Meeting and its Annexes which appears as ANNEX 12.

43. The Meeting further requested the ACSB Secretary to submit the updated Annexes of ACD to the ASEAN Secretariat to be uploaded at the ASEAN website.

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

8.1 Cooperation with EU

44. The representative of EU ARISE presented to the Meeting its activities to assist the ASEAN Cosmetic Committee on the effective implementation of the ACD. The presentation appears as ANNEX 13.

45. The Meeting noted the following activities proposed in the ARISE work plan:

- Evaluation Study on the implementation of the ASEAN Harmonised Cosmetics Regulatory Scheme (AHCRS);
- Strengthening the understanding of the harmonised requirements of the ACD;
- Workshop on Post Market Surveillance for Cosmetics;
- Support ACTLC in the development of a network of cosmetics test laboratories and provide training on cosmetics testing;
- Provide Training on GMP and PIF;
- Assist in the development of on-line notification system for CLMV.

46. In the effort to develop on-line notification system for CLMV, ARISE will arrange and facilitate representatives from CLMV to undertake a study visit to Malaysia and the Philippines to familiarize with the on-line notification process. Brunei Darussalam will also be invited to participate in this activity. ARISE will further explore to provide support for the development of an on-line notification system which will include: 1) processes for acknowledging and processing notification, and 2) automatic screening and risk classification.

47. The Meeting further noted that the Evaluation Study on AHCRS is currently ongoing by selected ARISE Experts. The main outcomes of the study will include Lessons Learnt and Future Priorities for possible technical assistance from ARISE. Upon
completion of the Study, ARISE will arrange a Workshop for ACC HoDs to discuss the outcomes and recommendations.

8.2 Supports for CLMV under the Initiative for ASEAN Integration

48. The Meeting noted information on Training Programs for Cosmetic Sector which is available in Indonesia, Malaysia, Philippines, Singapore, and Thailand, which may be attended by CLMV countries. The compilation of Training Programmes appears as ANNEX 14.

49. The Meeting further requested Indonesia, Malaysia, Philippines, Singapore and Thailand to give more detail on the Trainings through ASEAN Secretariat for subsequent circulation to CLMV countries.

AGENDA ITEM 9: AEC SCORECARD

50. The Meeting noted the status of implementation of measures for the cosmetic sector in the AEC Scorecard which appears as ANNEX 15, and requested the ASEAN Secretariat to update the remarks column as applicable.

AGENDA ITEM 10: OTHER MATTERS

10.1 Attendance at ACTLC Meeting

51. Lao PDR expressed her concern on her inability to attend to ACTLC meeting due to budgetary constraint. In this regard, Lao PDR requested consideration from the host country of ACC Meeting to consider waiving registration fee for 1 (one) delegate from national laboratory of each Member State to attend the ACTLC Meeting. Lao PDR also requested to have a separate invitation for ACTLC meeting.

10.2 20th ACSB Meeting

52. Representative from ACA expressed its concern on number of pending issues at the ACSB Meeting that need to be immediately discussed by the ACSB members. Noting that the next ACC Meeting will only be held on 2nd half of 2014, ACA offered its support to provide logistic arrangements of the meeting, while Member States would cover travel and accommodation cost.

53. The Meeting discussed the proposal from ACA, and further agreed to have the 20th ACSB Meeting in Bangkok, Thailand. Date and venue will be informed by the ASEAN Secretariat in due course.
10.3 Industry concern on country specific requirement

54. Representative from ACA shared to the Meeting their concern on country specifics requirements, and requested ACC to continue discussing this matter to ensure the smooth implementation and harmonisation of the ACD.

55. ACA further requested Indonesia for her kind consideration regarding the implementation of notification number to be put on the label and ACA expressed its willingness to tackle issues on counterfeit.

10.4 Handover of Chairmanship

56. The Meeting witnessed the handover of Chairmanship of the ACC from Philippines to Singapore and the handover of the Co-chairmanship of the ACC from Singapore to Thailand, effective from the 21st ACC Meeting.

57. The Meeting expressed its highest appreciation to Ms. Nazarita T. Tacandong, Acting Director III, Food and Drug Administration, Department of Health, Philippines for the excellent chairmanship during her tenure.

AGENDA ITEM 11: DATE AND VENUE OF THE 21st ASEAN COSMETIC COMMITTEE MEETING

58. Myanmar informed the Meeting on her inability to host the 21st ACC Meeting, due to budgetary constraint.

59. In this regard, the Meeting agreed that the 21st ACC Meeting will be held in Philippines tentatively in the second week of November 2014. Exact date and venue will be informed in due course.

AGENDA ITEM 12: ADOPTION OF THE REPORT

60. The Meeting considered and adopted the Report of the 20th ASEAN Cosmetic Committee Meeting held on 27-28 November 2013 in Kuala Lumpur, Malaysia.

ACKNOWLEDGEMENT

The delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Myanmar, Philippines, Singapore, Thailand, Viet Nam and the ASEAN Secretariat expressed their appreciation to the National Pharmaceutical Control Bureau, Ministry of Health Malaysia, for the warm hospitality extended and the excellent arrangements
made for the Meeting. The Meeting also expressed their appreciation to the ASEAN Secretariat for the assistance provided to the Meeting.

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