FINAL REPORT

SUMMARY REPORT

THE TWENTY SEVENTH MEETING OF THE ASEAN COSMETIC SCIENTIFIC BODY (ACSB)

Bandung, Indonesia, 14-15 November 2017

INTRODUCTION

1. The Twenty Seventh Meeting of the ASEAN Cosmetic Scientific Body (ACSB) was held on 14-15 November 2017 in Bandung, Indonesia.

2. The Meeting was chaired by Mrs. Narupa Wongpiyarattanakul from the Food and Drug Administration, Ministry of Public Health, Thailand and the alternate Chair was Engr. Ana Trinidad Rivera from the Food and Drug Administration, Philippines.

3. The Meeting was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam, representatives from the ASEAN Cosmetic Association, and the ASEAN Secretariat. The list of delegates appears as **APPENDIX 1**.

AGENDA ITEM 1: WELCOMING REMARKS

4. The Chair welcomed all delegates and observers to the meeting and expressed her appreciation to the host country for organizing the meeting.

AGENDA ITEM 2: ADOPTION OF AGENDA

5. The Meeting agreed to adopt the agenda, which appears as **APPENDIX 2**.

AGENDA ITEM 3: BUSINESS ARRANGEMENTS

AGENDA ITEM 4: Remaining Questions on Annex III

6. The Secretary presented a template detailing remaining questions on Annex III and recommendations. The template appears as **APPENDIX 3**.

7. The Meeting discussed the proposal to adopt a warning statement "wear suitable gloves" for all Annex III references for oxidative and non-oxidative hair dye ingredients.

8. The Meeting agreed that the text '*The direction for use "wear suitable gloves" must be included in label or leaflet text'* will be included as an "other limitation and requirement" in column E of Annex III. Effective 1st December 2020 only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market.

Action by: The Secretary

9. The Meeting discussed the limitations on the use of thioglycolic acid and thiolactic acid in combination (Annex III, refs 2a and A9, column D) and requested AMS and ACA to bring information to the next meeting detailing any such combinations used in products in the market.

Action by: AMS & ACA

10. The Meeting discussed the possible addition of "Contains hydroquinone" as a required warning label in Annex III, Ref 14 (Hydroquinone).

11. The Meeting noted Singapore's comments that hydroquinone was allowed for professional use only, for artificial nails, and that there was consequently no safety risk. The Meeting decided to make no change to the required text.

12. The Meeting directed the Secretary to remove the superscript referring to footnote 2 in Annex III, Ref 14, Column E.

Action by: The Secretary

13. The Meeting decided that no change was required to Annex III, Ref 65 (Benzalkonium chloride, bromide and saccharinate).

14. The Meeting noted the comments from Philippines that products containing benzalkonium chloride which functions as an antiseptic agent fall under local drug regulations and are not classified as cosmetics.

AGENDA ITEM 5: Continuing Discussions from the 26th ACSB Meeting

5.1 Matrix of Follow-up Actions

15. The Secretary presented the status of actions following from the 26th ACSB Meeting. This appears as **APPENDIX 4**.

5.2 Review of Annex changes since the 21st ACSB Meeting.

16. The Secretary gave a presentation detailing the changes to Annexes II, IV, VI and VII since the 21st ACSB Meeting and confirmed that all Annex changes were complete and up-to-date. The presentation appears as **APPENDIX 5**.

17. Indonesia commented that the most recent discussion of long chain and isoparabens had actually been in the 24th ACSB Meeting.

5.3 Triclosan

18. The Secretary presented the correspondence with EC about the use of Triclosan for non-preservative functions. This correspondence appears as **APPENDIX 6**. The Secretary also presented Singapore's response that appears as **APPENDIX 7.**

19. The Meeting requested ACSB Chair to seek further clarification from EC on the specific question whether Triclosan is permitted in Europe as an active antimicrobial agent at a level of 0.3% in a cosmetic product. Pending this clarification there will be no change in the current Annex listings for Triclosan.

Action by: ACSB Chair

AGENDA ITEM 6: New Issuance of EU Regulations

20. The Secretary presented a template covering the ingredients in EU Annex III Refs 103-205 (EU2013/344). The template is included as **APPENDIX 8**.

21. Singapore commented that the restriction of hydroperoxide is important for prevention of induction of allergy. Methods to control the formation of hydroperoxides are quite easy, but measurement is very challenging.

22. ACA pointed out that many ingredients are used in fragrances and the quality is controlled by IFRA standards and compliance is already a requirement in ASEAN regulations, whereas this is not the case in EU regulations.

23. The Meeting requested ACA to provide an assessment of the safety profile of the ingredients to the 28th ACSB Meeting and that the discussion of this case should be continued at that meeting.

Action by: ACA

24. Malaysia requested the Secretary to seek clarification from EC on how EU implements the regulation of these ingredients, any labeling implications and test methods.

Action by: The Secretary

25. The Meeting discussed the possible inclusion of several new Annex III entries following EU 2017/237, including separate entries for N,N'-Bis(2-hydroxyethyl)-2-Nitro-p-phenylenediamine and 2,6-Dihydroxyethylaminotoluene, and several new hair dye additions to the Annex. The ACSB Template is included as **APPENDIX 9**.

26. The Meeting noted ACA's comment that N,N'-Bis(2-hydroxyethyl)-2-Nitro-p-phenylenediamine had very high MOS at the maximum levels proposed in the EU Regulation.

27. The Meeting requested ACA to bring information to the next meeting on the usage of these ingredients by industry and that the action and grace periods would be decided at the 28th ACSB Meeting.

Action by: ACA

28. The Meeting discussed the restriction of Methylisothiazolinone to a maximum of 15ppm as already actioned in EU in EU2017/1224. The ACSB Template is included as **APPENDIX 10**.

29. The Meeting agreed to the restriction of Methylisothiazolinone in rinse-off products to a maximum of 15ppm and directed the Secretary to amend Annex VI accordingly. Effective 1st June 2019 (except Indonesia) only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market. In Indonesia the 15ppm limit has already been applied as detailed in previous ACSB reports.

Action by: The Secretary

30. The Secretary presented a proposal to add three fragrance components, Lyral (HICC), Atranol and Chloroatranol to Annex II. This has already been actioned in EU by EU2017/1410. The ACSB Template appears as **APPENDIX 11**.

31. ACA presented on the safety of the three ingredients including data on the allergy incidences arising from the use of Lyral (HICC). The ACA presentation appears as **APPENDIX 12**.

32. Indonesia requested comments from ACA on why the period before the regulation came into effect in Europe was lengthier than usual. ACA responded that the reformulation was very complex with a requirement to ensure the brand signature was maintained. There was also an existing product pipeline of products that had been formulated but had not yet been brought to market.

33. ACA explained that atranol and chloroatranol were not typically used as individual ingredients but were present at trace levels in the fragrance ingredients oakmoss and treemoss with residue levels restricted by IFRA quality standards. Their addition to Annex II would not affect the use of oakmoss and treemoss as the presence of atranol and chloroatranol is technically unavoidable and allowed under ACD Article 4.

34. The Meeting agreed that Lyral (HICC), Atranol and Chloroatranol should be added to Annex II and directed the Secretary to amend the Annex accordingly. Effective 23rd August 2019 (except Indonesia) no cosmetic product with the banned materials can be placed in the ASEAN market, and effective 23rd August 2021 (except Indonesia) non-compliant products must be completely withdrawn from the market. In Indonesia, effective 1st Jan 2020 no cosmetic product with the banned materials can be placed in the market, and non-compliant products must be completely withdrawn from the market.

Action by: The Secretary

35. Indonesia agreed to seek input from local industry, clinicians and dermatologists about the incidence of Lyral allergy in Indonesia.

Action by: Indonesia

36. The Secretary presented a proposal that the Annex IV listing for zinc oxide should be amended to include the condition that it must "*not be used in applications that may lead to exposure of the end-user's lungs by inhalation*". This follows a similar change to EU Annex IV in regulation EU2017/1413. The ACSB Template appears as **APPENDIX 13**.

37. Thailand requested ACA to comment on what products would be covered by this new condition. ACA responded that the assessment should be by an expert safety assessor and agreed to bring input to the next meeting about products that would and would not be covered by the condition.

Action by: ACA

38. The Meeting directed the Secretary to amend Annex IV in line with the proposal. Effective 1st December 2018 only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market

Action by: The Secretary

AGENDA ITEM 7: New Proposals from AMS

7.1 Climbazole

39. The Secretary presented Indonesia's request to discuss the addition of Climbazole into Annex III in addition to its current entry in Annex VI. This appears as **APPENDIX 14**.

40. The Meeting noted Malaysia's observation of the apparent inconsistency between the SCCP conclusion that the ingredient is safe for cosmetic use in only face and hair care products at 0.5% and the listing in Annex VI for all product forms with a maximum level of 0.5%.

41. The Meeting requested ACA to bring input on the safety assessment of Climbazole to the 28th ACSB Meeting and that the discussion would be continued at that meeting.

Action by: ACA

7.2 Methylpyrrolidone

42. The Secretary presented Indonesia's request to evaluate the use of N-Methyl-2-Pyrrolidone (NMP). This appears as **APPENDIX 15**.

43. ACA commented on the status of NMP in EU, that while it was assessed by SCCS to be not safe at 5%, and while it has been classified as Reprotox category 1B, it is not currently included in Annex II of the EU Regulation.

44. ACA will provide a review of the safety profile of NMP and an assessment of industry use of NMP to the 28th ACSB Meeting and the discussion will be continued at that meeting. AMS will provide information on the reported usage of NMP.

Action by: ACA & AMS

7.3 Alpha, Beta and Deoxyarbutin

45. The Secretary presented Indonesia's proposal to discuss the use of alpha, beta and deoxyarbutin in cosmetics. This appears as **APPENDIX 16**.

46. ACA commented that the ingredients are not currently regulated in EU and the EU public hearing on arbutins has been delayed, probably because more data is pending.

47. The Meeting agreed to wait for the EU proposal on arbutins and requested ACA to survey the usage of these ingredients.

Action by: ACA

7.4 Formaldehyde

48. The Secretary presented Indonesia's request to review the safety of formaldehyde in cosmetic products. This appears as **APPENDIX 17**.

49. The Meeting agreed that the ACSB should monitor closely the discussion and developments in Europe on this topic.

7.5 Ethyl Tosylamide

50. The Secretary presented Indonesia's request to clarify whether Ethyl Tosylamide is prohibited in cosmetics. This appears as **APPENDIX 18**.

51. Following a discussion of the scope of the sulphonamide class in Annex II, Ref 307, and of the differences in chemical structure between sulphanilamide and ethyl tosylamide the Meeting concluded that ethyl tosylamide does not fall within the scope of Annex II, Ref 307 and therefore its use is permitted in cosmetics.

52. Indonesia requested to revisit Annex II, Ref 307 with reference to the description and interpretation of "*Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH2 groups) and their salts*". Indonesia will propose an ACSB Template that will be discussed at the 28th ACSB Meeting.

Action by: Indonesia

7.6 Potassium Alum

53. The Secretary presented Indonesia's request to review the use of Potassium Alum in Cosmetic products. This appears as **APPENDIX 19**.

54. Indonesia clarified that their concern was on the irritation of the mucous membranes caused by feminine hygiene products containing this ingredient.

55. Singapore commented that the ingredient was widely used around the world with no safety issue other than occasional irritation.

56. ACA proposed that the subject needs more review. SCCS is currently assessing alum salts from the safety perspective.

57. AMS will investigate their PMS data to assess the incidence of irritation and will bring this as input to the 28th ACSB Meeting,

Action by: AMS

7.7 1,4-Dioxane

58. The Secretary presented Indonesia's request to review 1,4-dioxane impurities in cosmetic products. This proposal appears as **APPENDIX 20**.

59. The Meeting noted the information from Singapore and ACA that ICCR has set a limit of 1,4-dioxane in finished products in two phases. Phase 1 at 25ppm and phase 2 at 10ppm with no specific timings.

60. Philippines pointed that the SCCS opinion, where 10ppm in finished products was the maximum safe limit did not agree with ICCR report.

61. The Meeting noted ACA's comment that the 17th ACSB Meeting had agreed to wait for ICCR recommendation.

62. Singapore pointed out that the limit of 10ppm in finished products was readily achievable with current, good manufacturing practice.

63. The Meeting requested that ACA continue to urge members to seek to achieve compliance with a maximum 1,4-dioxane level of 10ppm in finished products, and to present the ICCR report at the 28th ACSB Meeting.

Action by: ACA

AGENDA ITEM 8: Joint Opinion Statements

64. The Secretary reviewed for the meeting the progress made on the topic of Joint Opinion Statements (JOS) since this topic was initiated, and showed the draft JOS for talc that appears as **APPENDIX 21.**

65. ACA provided scientific references for the Talc JOS.

66. The Meeting approved the release of the final version of the Talc JOS, including references that appears as **APPENDIX 22.**

67. The Meeting directed the Secretary to make final check to ensure correct format of the references and liaise with the ASEAN Secretariat for the publication of the final Talc JOS on the ASEAN website.

Action by: The Secretary

68. Philippines proposed three additional topics requiring JOS: heavy metals, hydroquinone and tretinoin.

AGENDA ITEM 9: Process for New Materials

69. ACA presented their proposal for a process for introduction of new ingredients into Annexes IV, VI and VII that appears as **APPENDIX 23.**

70. ACA explained that under the ACSB Terms of Reference, Article 3.2, *"The ACSB may invite, upon approval by the members of the ACSB, any expert in cosmetic sector, as a resource person to provide input and facilitate technical discussions",* and therefore it is within the purview of the ACSB to establish an ACSB Expert Panel if required to advise on the safety of new ingredients.

71. Thailand requested that ACA establish base criteria for new ingredients e.g. in a standard template. ACA responded that there are many processes for safety assessment and the criteria depend upon the ingredient, and ACA would not recommend setting a standard set of criteria.

72. Philippines asked whether the process was intended to cover new ingredients that were not listed in Europe or elsewhere. ACA responded that the process was intended for new ingredients and that the intent was the promotion of innovation within ASEAN.

73. Singapore commented that much data is proprietary and it will be important to define how confidential data is handled appropriately within this process.

74. Vietnam commented that it might be necessary also to consider efficacy data for some ingredients and ACA agreed to include efficacy as part of the next steps.

75. The Meeting agreed that proposal for new ingredients should be restricted to ACSB Members thus in the flow chart on page 3 of **APPENDIX 23** the arrows numbered 3 and 6 should be deleted.

76. The Meeting directed ACA to revise the proposal taking into account the comments from the ACSB, to circulate the revised process for ACSB consideration, and that the topic would be discussed further at the 28th ACSB Meeting.

Action by: ACA

AGENDA ITEM 10: OTHER MATTERS

77. ACA requested to submit a revised version of their proposal on Lyral (HICC) taking account of the earlier discussion by the ACSB, making corrections and aligning the text with the EU Regulation. The revised version appears as **APPENDIX 24,** specifically on page 9.

78. With the permission of the ACSB Chair, ACA presented their proposal for a draft process for JOS. The ACA proposal appears as **APPENDIX 25.**

79. Thailand proposed that for existing statements a date should be set for automatic review and revision.

80. Singapore proposed that ACSB delegates should be able to raise topics, that ACA could also be appointed to lead Task Forces, and that position statements should also include scientific references.

81. Vietnam proposed that in urgent cases timings should be set.

82. Philippines proposed that in urgent cases the proposing AMS could submit a draft text for review. Philippines also requested that ACA prepares a process flow diagram, and clarify how to select a Task Force.

83. The ASEAN Secretariat suggested to make use of existing working groups as far as possible before adding new Task Forces.

84. The Meeting directed ACA to prepare a revised process considering the comments of the Meeting and the discussion will be continued at the 28th ACSB Meeting.

Action by: ACA

AGENDA ITEM 11: DATE AND VENUE OF NEXT MEETING

85. The 28th ACSB Meeting will be held in Vientiane, Lao PDR, on 8-9 May, 2018.

AGENDA ITEM 12: ADOPTION OF THE REPORT

86. The Meeting agreed to adopt the Final Report of the 27th ACSB and to seek ACC Meeting endorsement

87. Meeting Close

The Chair and Alternate Chair of ACSB thanked all Member States, delegates, ACA representatives and ASEAN Secretariat for their cooperation, support and valuable inputs during the meeting.

Acknowledgement

The delegates from Brunei Darussalam, Cambodia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam, representatives from the ASEAN Secretariat and representatives from the ASEAN Cosmetic Association expressed their appreciation to the National Agency of Drug and Food Control, the Republic of Indonesia for the warm hospitality extended to all delegates and for the excellent arrangements made for the meeting.

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

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