



**The Report of the Twentieth Meeting of the
The ASEAN Cosmetic Scientific Body (ACSB)**
3-4 June 2014,
Bangkok, Thailand

INTRODUCTION

1. The Twentieth Meeting of the ASEAN Cosmetic Scientific Body (ACSB) was held on 3-4 June 2014 in Bangkok, Thailand.
 2. The Meeting was chaired by Mr. Hary Wahyu T (Director of Standardization of Traditional Medicine, Cosmetic and Health Supplement) from the National Agency of Drug and Food Control, Republic of Indonesia; and alternate Chair Mrs. Narupa Wongpiyaratnanakul (Head of Cosmetic Standard Establishment) from Food and Drug Administration, Thailand.
 3. The Meeting was attended by the representatives from Indonesia, Lao PDR, Myanmar, Philippines, Singapore, Thailand, the ASEAN Secretariat representatives and the ASEAN Cosmetic Association. The list of delegates appears as Appendix 1.
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1. Welcome, introduction of chair, alternate chair, and ACSB Members & adoption of the agenda

The Chair extended his warm welcome to all delegates and expressed his gratitude to Thai FDA, ACA and TCMA in arranging and hosting the ACSB Meeting. The agenda was adopted, as appears in Appendix 2.

2. Discussion on Indonesia's review of the 24 new entries of Hair Dyes which were included in the Annex III Part 1 EU Directive 2012/21/EU

Indonesia presented on the major issues of 24 hair dyes :

- 2 (two) ingredients with different limitation on concentration based on availability of post market data in Indonesia (259, 265)
- 1 (one) ingredient with different limitation on concentration based on availability of post market data in Indonesia; with additional warning (256) (eye irritation in animal study)
- 1 (one) ingredient with additional warning (eye irritation in animal study) (253)
- 7 (seven) ingredients need additional safety data; no post market safety data available yet (255, 257, 258, 260, 262, 263, 270)
- 1 (one) ingredient is shown as a weak mutagenic agent (hazard) (266)

ACA presented on the Risk Assessment for hair dye molecules: Skin sensitization hazard identification vs consumer exposure conditions, and one of ACA's conclusion is that ACSB should wait for the SCCS final risk assessment and EU Commission decision.

The meeting noted that nine (9) Member States have accepted the 24 hair Dyes, while Indonesia accepted 12 Hair Dyes without any changes. Furthermore Indonesia explained based on SCCS Memorandum, and Indonesia experience from Post Market Surveillance that she is still having safety concern on the other 12 hair dyes, whereby one of them showed as a weak mutagenic.

The Meeting noted that Indonesia would require additional data to support a higher level than the accepted/ permissible level in Indonesia for the 12 ingredients.

Indonesia's presentation appears as [Appendix 3](#), and ACA's presentation appears as [Appendix 4](#)

3. Malaysia's proposal to review the use of Methylisothiazolinone (MIT) in leave-on cosmetic products

The Meeting noted the request to discontinue the use of Methylisothiazolinone (MIT) in skin leave-on cosmetic products and wipes. Malaysia's proposal appears as [Appendix 5](#)

The Meeting also noted ACA's explanation that there is no product recall but the industry in Europe voluntarily has already started doing the reformulation. In the meanwhile, Singapore explained changes of formulation needs a longer time considering that changing a preservative requires further stability testing.

Pending input from Cambodia, Malaysia, Singapore and Vietnam.

Actions – ACSB encourage industries to reformulate skin care leave-on and wipes product containing MIT and monitor further information from EU Commission.

4. Discussion on ASEAN Sunscreen Labeling Guideline as proposed by Malaysia, additional warning (as strongly recommended) and prohibited claim for Sunscreen – Member States

The Meeting noted that Member States agreed with the strongly recommended warning, but in different wording as proposed by Malaysia.

Regarding the prohibited claims proposed by Malaysia, Thailand informed that *waterproof*, *sweatproof* are not used while *sunblock* and *water resistance* claim are allowed. In the meantime, Indonesia accepts those claims as long as they are supported by data

The Meeting proposed that ACA develop a proper terminology particularly on waterproof, sweatproof and sunblock.

The proposal from Malaysia appears in [Appendix 6](#)

Pending input from Brunei Darussalam, Cambodia, Malaysia and Viet Nam

Action – ACA will present a proper terminology particularly on waterproof, sweatproof and sunblock at the next meeting.

5. Presentation and discussion of the revised draft of the Botanical Safety Assessment Guideline

ACA presented the revised draft of Botanical Safety Assessment Guideline which was developed by the Task Force, this draft appears as [Appendix 7](#).

Thailand expressed concern that the decision chart on botanical ingredients did not include consideration for traditional medicines. Thailand proposed to conduct further consultation with her experts and will come back with the revised draft to the Task Force.

Indonesia, Philippines and ACA explained that the understanding of "traditional" is subject to regulatory authority in Member States. Since we should start with the safe botanical ingredients for cosmetic, Traditional Medicines are still having big opportunity to be used as cosmetic from

Botanical ingredient as long as the risk has been addressed. Parameters in the Table include mandatory (e.g source of botanical raw material) and non-mandatory (e.g chemical characterization) parameters.

The Meeting noted that Indonesia, Lao PDR, Myanmar, Philippines, Singapore and ACA accepted the Botanical Safety Assessment Guideline.

Pending input from Brunei Darussalam, Cambodia, Malaysia, Thailand and Viet Nam

Action – Thailand will present the result of internal consultation at the next meeting

6. Comparison on ACD, EU Directive and EU Regulation

The Meeting agreed to postpone the discussion on Agenda 6(a), (b) and (d) to the next Meeting.

Thailand presented the comparison on Annex VI – List of Preservative which Cosmetic Product may contain as appears in Appendix 8

The Meeting noted the differences indicated by Thailand (e.g on the Preamble and entries ref # 12, 19, 42 and 56) and agreed to postpone the discussion until the next Meeting.

Action – The Meeting agreed to further discuss the comparison at the next Meeting

7. Confirmation on the rationale of previously recorded decisions on Borderline Products in instances that had not been reflected in the final report

The Meeting noted and agreed not to discuss the rationale since we have already decided on the Borderline products as appear in Appendix 9, unless there is major issue.

Pending input from Brunei Darussalam, Cambodia, Malaysia and Viet Nam

8. Proposal from Malaysia to review and comment on the use of nonoxynols, *Papaver rhoeas*, and *Pueraria mirifica* in cosmetic products.

Member States shared information regarding the status of these ingredients in their respective Member States

- Indonesia, Lao PDR, and Myanmar informed that they allow the use of nonoxynols, *Papaver rhoeas*, and *Pueraria mirifica*
- Philippines and Thailand allow the use of nonoxynols, *Pueraria mirifica*, and prohibit the use of *Papaver rhoeas*

Noting the absence of Malaysia, the Meeting agreed to postpone further discussion of Malaysia's proposal on the use of nonoxynols and *Papaver rhoeas* in cosmetic products to the next ACSB Meeting.

Thailand expert presented the safety profile of *Pueraria mirifica* in cosmetic preparation, which appears as Appendix 10. The Meeting noted Thailand's consideration on the safe use of *Pueraria mirifica* under the following condition:

- *The quantity of the crude extract used per day should not exceed the amount that is extracted from 100 mg of dried rhizome*

Action – Malaysia’s proposal will be discussed at the next Meeting

9. Proposal from Thailand to re-print the ASEAN Cosmetic Directive

Thailand informed the Meeting to postpone her proposal on re-printing the ASEAN Cosmetic Directive until the revision of the current annexes in ACD has been concluded.

10. ACA presentation on a simple format of the Safety Assessment Report

ACA presented its proposal of a simple format of Safety Assessment Report. The ACA’s proposal appears as Appendix 11.

The Meeting agreed to the ACA proposal.

Action – Waiting for input from Brunei Darussalam, Cambodia, Malaysia and Viet Nam

11. Proposal to revise the ‘field of application and/or use’ and its corresponding ‘maximum authorized concentration in finished products’ for hydrogen peroxide (Annex III, Part 1, ref #12) in tooth-whitening products

The Meeting discussed the limitation of Hydrogen peroxide used in tooth-whitening products. In this regard, the Meeting agreed to have three categories of the concentration of Hydrogen peroxide as follows:

- a) $\leq 0.1\%$
- b) > 0.1 to $\leq 6\%$
- c) > 6 or > 6 to 35%

In view of the above, the Meeting noted that there are differences in regulation within ASEAN Member States for (a) and (c). Thailand does not allow the use of Hydrogen peroxide $< 0.1\%$ (for Tooth Bleaching) and $> 6\%$ is classified as Medical Device. Meanwhile Indonesia allows the concentration of up to 35% as Cosmetic.

The Meeting noted the proposal from Thailand and Indonesia to add the warning “Not to be used under the age of 18”.

The Meeting also noted the proposal from Thailand to put the percentage of Hydrogen peroxide on the label.

Member States require time to do internal consultation particularly with their Dental Association.

The proposals from Thailand and Singapore appear as Appendix 12 and Appendix 13.

Pending input from Brunei Darussalam, Cambodia, Malaysia and Viet Nam

Actions – The result of the above internal consultation will be discussed at the Next Meeting

12. Presentation on development of ASEAN references on non-cosmetic regulation list for the entries ref# 21, 293, 323 and 419

ACA presented the EU references on Non-cosmetic regulation for entries ref# 21, 293, 323 and 419 which appear as Appendix 14 and proposed the following options for the Meeting consideration :

- i. To delete these entries, as these ingredients are not considered as cosmetic ingredients
- ii. To refer to the Non-Cosmetic ingredient regulations of each Member States
- iii. To extract relevant information from the EU references and put them as attachment/reference in the ACD

Following ACA options, there are different opinion among Member States. In the view of that, the Meeting noted that Singapore volunteered to develop option (iii) asisted by ACA.

Action – Singapore and ACA will extract the relevant information/s (option iii) and discuss them at the next Meeting

13. Malaysia’s proposal to review Mouthwash labeling requirements for children under 6 years old and Mouthwash containing alcohol

Considering the absence of Malaysia, the Meeting agreed to postpone the discussion on Malaysia’s proposal on the review of Mouthwash labeling requirements for children under 6 years and Mouthwash containing alcohol (including ACA presentation regarding Safety Aessment for Mouthwash containing alcohol as well as Fluoride for chidren under 6 years old) to the next ACSB Meeting.

The proposals from Malaysia and ACA presentation appear as [Appendix 15](#) and [Appendix 16](#)

14. Proposal from Indonesia about Trace Limit of Cadmium

The Meeting noted Indonesia’s proposal to set the trace limit of Cadmium, appears as [Appendix 17](#).

Indonesia presented scientific article published in Journal of Regulatory Toxicology and Pharmacology 68 (2014) 447-467 “Toxic metals contained in Cosmetics : Status report”

Indonesia informed based on her Post Marketing Surveillance data, that they detected trace levels of Cadmium. Since Cadmium is listed on Annex II, Indonesia proposed to set the trace limit of Cadmium.

Indonesia informed that the limitation in Germany and Canada are 5 ppm (except tooth paste at ≤ 0.5 ppm) and 3 ppm respectively.

Thailand and Lao-PDR proposed the limit of maximum level of Cadmium at 3 ppm, and Myanmar at 1 ppm.

The Meeting noted Member States need to have internal consultation prior to come up with a decision and noted ACA offer to present on this matter.

Action - ACA will present on Cadmium as trace limit, and will share it by end of October 2014. The Meeting will discuss this at the next Meeting

15. Update information following the new issuance of EU Regulations – Secretary

The Secretary presented 5 (five) amendmments to the Annexes of the EU Regulation. The five ammendments refer to Annex II and/or Annex III and/or Annex V and/or Annex VI. The latest ammendment No. 358/2014 of Annex II is yet to be included in the Annex II of the ACD.

The Meeting noted that it is important for Member States to take into consideration the latest update of the EU Regulation Annexes.

The Meeting noted and agreed to ban the (5) five parabens and to include those parabens in the Annex II of ACD as entries Ref # 1374 – 1378. The grace period for the existing product containing those parabens will be one year or 30 July 2015. Indonesia explained that she is considering a grace period shorter than July 2015 and will inform Member States.

The Meeting noted that Philippines proposed to extend the grace period of cosmetic products which shall be placed on the market until 31st December 2014 and which shall be made available on the market until 30th July 2015.

The presentation on Ingredient Update on Annex II and Other Annexes appear as Appendix 18 and Appendix 19

Pending input from Brunei Darussalam, Cambodia, Malaysia and Viet Nam.

Action - Secretary to update the Annex II of ACD on the 5 (five) parabens.

16. AOB

Philippines requested the Task Force members of Botanical Safety Assessment Guideline to communicate intensively on the finalisation of the Guideline and inform The Philippines as the host country on the possibility of another Task Force meeting prior to the next ACC meeting, as soon as possible.

Philippines informed the Meeting that the next 21st ACSB Meeting will be held back to back with ACC and its related Meetings in Manila, Philippines on 25 – 28 November 2014.

17. Meeting Close

The Chair of ACSB thanked to all Member States delegates and ACA on their valuable inputs, comments and attention during the meeting.

Acknowledgement

The delegates from Indonesia, Lao PDR, Myanmar, Philippines, Singapore and ASEAN Secretariat representatives expressed their appreciation to the Food and Drug Administration, Ministry of Public Health, Thailand which is supported by ASEAN Cosmetic Association (ACA) and Thai Cosmetic Manufacturer Association (TCMA) for the excellent arrangements made for the meeting and for the warm hospitality extended to the members.

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