



**The Report of the Nineteenth Meeting of the
The ASEAN Cosmetic Scientific Body (ACSB)**
25-26 November 2013,
Kuala Lumpur, Malaysia

INTRODUCTION

1. The Nineteenth Meeting of the ASEAN Cosmetic Scientific Body (ACSB) was held on 25-26 November 2013 in Kuala Lumpur, Malaysia.
 2. The Meeting was chaired by Mr. Hary Wahyu T from the National Agency of Drug and Food Control, Republic of Indonesia; and The Alternate Chair was Mrs. Narupa Wongpiyaratthanakul, from Food and Drug Administration, Thailand.
 3. The Meeting was attended by the representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Viet Nam, the ASEAN Secretariat 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 introduced the meeting and the agenda was adopted, as appears in [Appendix 2](#).

2. Discussion on adoption of 24 new entries of Hair Dyes which included on Annex III part 1 EU Directive 2012/21/EU (follow up action on the adoption)

The Meeting recalled the decision of the 17th ACSB Meeting in Solo November 2012 that agreed to adopt 24 new entries of Hair Dyes from EU Directive 2012/21/EU into Annex III part 1 of ACD, in the meanwhile Indonesia at 19th ACSB Meeting still needs time to review the restriction requirements of the 24 new entries of hair dyes above.

Actions – Indonesia will complete the review on 24 new entries of Hair Dyes and will provide information if there is any major issue

3. Discussion on EU Cosmetics Regulation Annex (Cosmetic Product Safety Report [Annex 1])

ACA presented the comparison of CPSR and ASEAN Safety Assessment Guideline which appears in [Appendix 3](#).

Member States agreed with Task Force recommendation to maintain ASEAN Safety Guideline and PIF.

The Meeting noted Malaysia concern on industries non-compliance toward PIF requirements including the Safety Assessment Report. Responding to Malaysia, ACA offers to develop a simpler format of Safety Assessment Report.

Action - ACA will develop a simple format of outlining the basic information needed for the Safety Assessment Report as per the ASEAN Safety Assessment Guideline to be reported at the next meeting

4. Discussion to consider the documentation for differing regulatory approaches on the use of AHA at concentrations above 30%

The Meeting agreed to maintain the status quo (>20%), subject to Member States implementation with reference to Article 11 as applicable in the respective Member States.

The Meeting noted concern from Malaysia on the safety of using higher level of AHA.

5. Discussion on feedback from National dental Association on the use of Hydrogen peroxide at concentration of 6% - 35%.

6. 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 noted that Agenda 5 and 6 are having the same content and agreed to combine these two Agenda for the discussion.

The Meeting agreed to maintain the status quo of limitation of Hydrogen peroxide (6-35%), subject to Member States implementation with reference to Article 11 as applicable in respective Member States.

The Meeting noted Singapore's proposal on correction of overlap of concentration was not discussed and agreed to discuss at the next meeting. Singapore's proposal appears in [Appendix 4](#).

The Meeting noted that some Member States did not receive proposal from Thailand which include proposal for labeling requirement and the Meeting agreed to discuss it at the next meeting. The proposal from Thailand appears in [Appendix 5](#).

Action – Member States agreed to discuss Singapore's proposal on correction of overlap of concentration and proposal from Thailand on labelling requirement at the next Meeting

7. Revisit of Annexes review

A. Annex II

i) Clarification on the entries ref# 21, 293, 323 and 419 in relation to ASEAN – Philippines

The Meeting noted and agreed with proposal from Singapore to maintain as the original text, while waiting for ACA proposal to develop the ASEAN references List relating to Non-Cosmetic regulation

Action - The Meeting will discuss the List at the next ACSB meeting

ii) Proposal to include all the CAS numbers for Trichlormethine (INN) and its salts (ref#327) to follow COSING

The Meeting agreed to choose option (b) to include CAS numbers with disclaimer as

“not limited to the specified CAS numbers”

Action – Secretary to update the Annex accordingly

iii) Proposal to include the CAS number/s for ref# 411 and 420 as in Cosmetic Directive for better clarity

The Meeting agreed to maintain as they are currently stated on ACD

B) Annex III

i) Presentation on safety data concerning sensitization and corrosiveness for Thioglycolic acid ester (ref#2b) but not for Thioglycolic acid and its salts (ref#2a)

The Meeting noted ACA presentation as appear in Appendix 6 that Thioglycolic acid is corrosive substance and therefore does not allow to be studied for skin sensitization.

Further there have been no reported skin sensitization cases on Thioglycolic acid.

The Meeting agreed to maintain the direction for use “may cause sensitization in the event of skin contact” is only applied for Thioglycolic acid esters.

ii) Malaysia proposal on Fluoride in Mouthwash for children under 6 years old and labeling requirement

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.

The Meeting also noted Malaysia concern about labelling of alcohol content in mouthwash as stated in ISO 16408:2004 document, and this appears also in Malaysia’s proposal as in Appendix 7. In this regard, Malaysia highlighted the general warning on use of alcohol in mouthwash for children below 6 years. Malaysia requested for insertion such warning on the label mouthwash containing alcohol.

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 ACSB make decision at the next Meeting.

The proposed grace period for implementation is one year.

Action – The Meeting will discuss the above matters at the next meeting

8. Annex VI (new proposal)

Proposal from Singapore to amend current maximum authorized concentration for 4-hydroxybenzoic acid and its ester under Annex VI part 1 ref #12 for better clarity

The Meeting agreed with proposal from Singapore as appeared in Appendix 8 to clarify the limitation and requirement for 4-hydroxybenzoic acid and its ester as follows:

“Each of the ester in the mixture can not exceed 0.4% (acid)”

The Meeting also agreed to put additional information: "Each of the ester in the mixture can not exceed 0.4% (acid)" under column d of Annex VI part 1 ref #12

Action – Secretary to update the Annex accordingly

9. Malaysia's Proposal to review ASEAN Sunscreen Labeling Guideline

The Meeting discussed the 3 proposals from Malaysia:

- reminding to revise the SPF classification on the Guideline as it has been agreed at the 16th ACSB Meeting
- Warning statement for sunscreen as follows :
 - a) *Mandatory* :
 - *Do not stay too long in the sun, even while using a sunscreen product (as defined in Annex VII)*
 - b) *Strongly recommended warning*:
 - Re-apply frequently to maintain protection, especially after sweating, swimming or toweling;
 - The use of sunscreens is one way to reduce the dangers from sun exposure;
 - Instruction for use to ensure that sufficient quantity is applied, e.g. pictogram, illustration, etc;
 - Over-exposure to the sun is a serious health threat;
 - c) *Prohibited claim ("Waterproof," "sweatproof" or "sunblock")*

The Meeting agreed to add "(for primary sunscreen products)" to the warning of Do not stay too long in the sun, even while using a sunscreen product as stated under Annex VII (List of UV Filters which cosmetic products may contain).

The Meeting noted that due to time constraint the 2 proposals from Malaysia (b and c) are pending for discussion, and will be discussed at the next Meeting. The proposal from Malaysia appears in Appendix 9.

Action – Secretary to update accordingly, and Member States will discuss the 2 proposals from Malaysia which were postponed to be discussed at the next Meeting

10. The meeting noted due to time constraint, the below Agenda items will be discussed at the next Meeting :

- **Presentation and discussion of the revised draft of Pilot risk assessment of botanical ingredients**
 - a) Proposal from Thailand (as in Appendix 10)
 - b) New scheme from Indonesia (as in Appendix 11)
- **Proposal to make comparison on ACD, EU Directive and EU Regulation**
 - a) Philippines to present comparison of ACD vs EU Directive vs EU Regulation
 - b) Vietnam to present comparison of Annex IV
 - c) Thailand to present comparison of Annex VI
 - d) Singapore to present comparison of Annex VII

The above comparison as appear in Appendix 12 a – d

- **Confirmation on the rationale of previously recorded decisions on Borderline Products in instances that had not been reflected in the final report.**
- **Proposal from Malaysia to review and comment on the use of (new proposal) :**
 - i. nonoxynols in cosmetic product
 - ii. *Papaver rhoes* in cosmetic product
 - iii. *Pueraria mirifica* which contains phytoestrogens that had been used in cosmetic products particularly for product meant to be applied on breast

The proposal from Malaysia and the supporting documents appear in Appendix 13 a - c

- **AOB**
 - a) Proposal from Thailand to re-print the ASEAN Cosmetic Document
 - b) The venue of 20th ACSB Meeting will follow the decision of ACC Meeting

11. The Meeting considered and adopted the Report of the 19th Meeting of the ASEAN Cosmetic Scientific Body held on 25-26 November 2013 in Kuala Lumpur

12. Meeting Close

The Chair then summarized the meeting and thanked Member States, ACA, and observers on their valuable inputs, comments and attention. All present expressed their gratitude and appreciation to the ASEAN Secretariat and Malaysia as the host country for the excellent arrangements and warm hospitality during the Meeting.

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