

<u>NO</u>	<u>AGENDA/TOPIC</u>	<u>DISCUSSION</u>	<u>ACTION</u>
ACSB Meeting - 21 & 22 May 2013			
1	Adoption of EU Directive 2012/21/EU	<p>EU Regulation No. 1223/2009 will be implemented on 11 July 2013, which will be replacing EU Directive 76/768 where EU Directive 2012/21 is the latest amendment of EU Directive 76/768.</p> <p>Due to safety concerns, some Member States have already implemented or in the plan to implement EU Directive 2012/21 before December 2013.</p>	To discuss on the 24 new ingredients in Annex III part 1 at the 19 th ACSB meeting.
2	EU Cosmetics Regulation Annex -Cosmetic Product Safety Report (CPSR) Annex 1	Taskforce which comprises of Indonesia, Malaysia, Philippines , led by ACA will continue to review the Cosmetic Product Safety Report (CPSR), comparing with ASEAN Safety Assessment Guideline	<p>ACA will share the comparison of CPSR & ASEAN Safety Assessment Guideline in September 2013.</p> <p>1st proposal to be shared in 1st week of October 2013.</p> <p>To discuss the CPSR at the 19th ACSB meeting</p>
3	Reviewing the Implication of Eliminating Annex V (List of Substances excluded from the scope of Directive)	The meeting agreed to remove Annex V from ASEAN Cosmetic Document	ACSB Secretary to remove Annex V from the ACD and request ACC to liaise with EU contact to understand the rationale behind the inclusion of Annex V of the EU Directive

4	Working Definition for Nanomaterials & Its Safe Use in Cosmetic Products	ACA informed that there is no updated information on Nanomaterials. The meeting agreed to await International Standard Organization's (ISO) progress on nanomaterials.	ACA to follow the progress of ISO on working definition for nanomaterials and its safe use in cosmetic products
5	Feedback from National Dental Associations on the use of Hydrogen Peroxide at concentrations between 6% to 35%	Currently, there is discrepancy in the practice of the ACD implementation on the use of Hydrogen Peroxide for teeth whitening at a concentration of above 6%, which is considered as either medical devices or pharmaceuticals . Malaysia highlighted the concern on the use of tooth whitening product containing more than 35% Hydrogen Peroxide by dental practitioner, provided that all the safety requirements are fulfilled.	Member states agreed to maintain the ACD requirement- maximum concentration of Hydrogen Peroxide is up to 35% for tooth whitening. To discuss the differences in regulatory approach on the use of Hydrogen Peroxide at the 19th ACSB meeting
6	Singapore proposed to amend the maximum authorised concentration in finished tooth-whitening products for use by the consumer under the supervision of a qualified dental practitioner to : "Up to 6% H2O2 present or released" in ref #12 for better clarity	The meeting discussed and noted that member states require more data and time to review this proposal	To discuss at the 19th ACSB meeting
7	Annex II Entries Ref #21,293,323 & 419 in relation to ASEAN-Clarification	Philippines recommended retaining the cross references stated for those entries while Malaysia's feedback to review	To discuss at the 19th ACSB meeting

		the cross references of the EU documents within the ASEAN context	
8	Annex II Entry Ref #327 -Proposal to include all the CAS numbers for Trichlormethine (INN) & its salts to follow COSING	The meeting agreed to discuss further with 2 options: Option a : to remove all CAS numbers Option b : to include all CAS numbers with disclaimer	To review the options at the 19th ACSB meeting
9	Annex II Entry Ref #411 & 420 - to include the CAS number/s as in Cosmetic Directive for better clarity	Ditto	Ditto
10	Reviewing the issue of Trace Ingredients	To remove trace ingredients , including Diethylene Glycol (DEG) from Annex III Part I into Annex II, and the allowable unavoidable limit will be declared as: Diethylene glycol (except if it is present as unavoidable trace limit of 0.1% in finised product)	ACSB Secretary to update the annex accordingly
11	Annex II Entry Ref #41 -Indonesia proposed to amend the name to Apocynum cannabinum L. and to include all the CAS numbers for better clarity	To make correction on "cannabium" to "cannabinum"	ACSB Secretary to update the annex accordingly
12	Annex II Entry Ref #46 -Indonesia proposed to revise the stated list of exceptions for barium salts for better clarity	To make correction on ref#46 to : Barium salts, with the exception of barium sulphide under the condition laid down in Annex III Part I ref #23, and the barium sulphate, lakes, salts, and	ACSB Secretary to update the annex accordingly

		pigments prepared from colouring agents listed in Annex IV	
13	Annex III Entry Ref #22 - Malaysia requested to remove footnote (3) for Resorcinol	The meeting agreed to remove footnote (3) as proposed by Malaysia	ACSB Secretary to update the annex accordingly
14	Annex III Entry Ref #98, 99, 100, 101 & 207 - Malaysia requested to reduce the number of footnotes by transferring the information to column "E"	The meeting agreed to Malaysia's proposal	ACSB Secretary to update the annex accordingly
15	Annex III Entry Ref #1a (Boric Acid, Borates & Tetraborates) & Ref #1b(Tetraborates)- Indonesia requested to clarify the field of application and the corresponding maximum authorized concentrations	The meeting agreed to add "see also 1b" for Boric Acid, Borates and Tetraborates (ref #1a), and "see also 1a" for Tetraborates (ref #1b) as proposed by Indonesia	ACSB Secretary to update the annex accordingly
16	Annex III Entry Ref #2b Thioglycolic acid ester but not for Thioglycolic acid & its salts ref #2a-Indonesia's request to clarify the rationale for the requirement to label 'may cause sensitization in the event of skin contact'	ACA explained that Thioglycolic esters cause sensitization, while Thioglycolic acid is corrosive substance (eg. as per CIR data). The Meeting discussed about severity of corrosiveness compare to sensitization, and noted that it still requires more data for further review.	ACA to provide and present safety data concerning sensitization and corrosiveness for both substances at the 19 th ACSB Meeting and will discuss based on ACA's presentation

17	Annex III Entry Ref #14 (Hydroquinone) & Ref #95 (Hydroquinone methylether)-Review the safety data in order to consider adopting Indonesia's proposal to have the same cautionary statement, 'Contains hydroquinone, do not use on children under the age of 12 years"	The Meeting noted Indonesia's clarification that the statement "do not use on children under the age of 12 years" never appeared on the original ACD, but it appeared on the ref #95 of ACD since 2007 without any discussion. The Meeting agreed to delete this statement.	ACSB Secretary to update the annex accordingly
18	Myanmar's clarification on the maximum permissible limit for Fluoride in Mouthwash for children under 6 years-old and labeling requirements for mouthwash containing fluoride	Thailand commented that based on BS EN ISO 16408:2004, Fluoride in Mouthwash is not to be used by children under 6 years-old.	ACSB Secretary to send this feedback to Myanmar and Malaysia will give feedback at the 19 th ACSB meeting
19	Annex IV Field of application column 4 - Indonesia's request to clarify the interpretation of the contact time for the term 'briefly'	Philippines informed that briefly refers to rinse-off or wash-off as stated in EU Regulation 1223/2009 Annex IV. ACA's comment that briefly specify more to the contact time as it is applied as rinse-off or wash-off.	The Meeting agreed to maintain current terminology on briefly.

20	ACA proposed to include the statement that the labeling requirement 'Do not stay too long in the sun, even while using a sunscreen product' only applies to primary sunscreen products and to discuss on the grace period for the industry to comply to this requirement'	Some Member States have already implemented the mandatory statement "Do not stay too long in the sun, even while using a sunscreen product" which applies as primary sunscreen products as explained in ASEAN Sunscreen Labeling Guideline, while some Member States are still planning to have it implemented. Malaysia made 2 proposals to revise ASEAN Sunscreen Labeling Guideline and also reminded to revise the SPF classification on the guideline as agreed in the 16th ACSB meeting	To review and discuss Malaysia's proposals at the 19th ACSB meeting
21	Discussion to adopt the document on the pilot risk assessment of botanical ingredients	Indonesia proposed to redraft the Guideline considering possibility of traditionally and non-traditionally used botanical for cosmetic. ACA's proposed to establish the Task Force for redrafting the Guideline, and the Task Force consists of Indonesia as the lead, Philippines, Thailand and ACA agreed to meet the next day to discuss	The Taskforce will circulate the first draft to Member States on 1 st week of September 2013, and to be discussed at the 19 th ACSB Meeting.
22	To review the rationale of previously recorded decisions on Borderline Products in instances that have not been reflected in the final report	To postpone the discussion on Borderline Products due to time limitation.	To discuss at the 19th ACSB meeting

23	Clarification on decision on the product classification for denture adhesive and nail glue	Member States have already agreed on the classification of : -nail glue as cosmetic, -denture adhesive as non-cosmetic where most of Member States classified it under medical device.	ACSB Secretary to update decision history on the Borderline product accordingly
24	To consider the documentation for differing regulatory approaches on the use of AHA at concentrations above 30%	To postpone the discussion due to time limitation.	To discuss at the 19th ACSB meeting
25	Philippines proposed to make comparison on ACD, EU Directive and EU Regulation, for further review	Some Member States agreed to become volunteers to prepare the comparison matrix	To discuss at the 19th ACSB meeting