

SUMMARY REPORT OF THE 25TH ACSB MEETING

The 25th Meeting of the ASEAN Cosmetic Scientific Body (ACSB) was held on 15-16 November 2016 in Brunei Darussalam. The Meeting was chaired by Thailand and Philippines, being the alternate Chair.

Consolidation of Annex III

- The Meeting agreed that all AMS should review the draft Annex III and notify any errors, or required changes, to the Secretary within 2 months. The Secretary would at that time issue a final draft version of Annex III to AMS for their final approval within 1 further month.
- Singapore presented their request to discuss whether Triclosan should be allowed other than as a preservative in cosmetic products, noting that Triclosan does not appear in Annex III of the EU Cosmetic Regulation.
 - ACSB Secretary to clarify with the EC the regulatory approval in Europe for Triclosan as a preservative and for any other functions. The Secretary will also issue an ACSB template to cover the review of Triclosan with the request that AMS respond with their reviews within 2 months, and that ACA present on the safety data for Triclosan at the 26th ACSB meeting.

The 9 Hair Dyes (EU 1190/2015)

- ACA presented their assessment of the safety data for the 9 Hair Dyes listed in EU 1190/2015 and an overview of the general principle of hazard characterization/safety assessment for hair dyes. The Meeting discussed the evaluation of *in vitro* and *in vivo* data about genotoxic potential of ingredients, noting that positive indications from *in vitro* tests do not confirm genotoxicity *in vivo* unless there is confirmatory positive indication in one, or a battery, of appropriate *in vivo* tests.
- Indonesia informed the Meeting that ACA's presentation on the safety assessment can be used as one of the references among others to review cosmetic ingredients. Indonesia also informed the Meeting that Indonesia is still continuing reviewing the new hair dyes (including the 7 hair dyes).

ASEAN Guidelines on Limits of Contaminants

- Malaysia confirmed their agreement to the proposed format of ASEAN Guidelines on Limits of Contaminants in Cosmetics. The Meeting directed the ACSB Secretary to include into the document texts agreed in the 7th and 8th ACSB meetings.

Definition of Nanomaterials

The Task Force presented their proposal for the ASEAN definition of nanomaterials:

- That ASEAN defer the decision to adopt a definition for nanomaterials, till EU revises their nanomaterial definition.
- That AMS regulators and industry consider the EU regulatory definition and the EU Commission recommendation definition as guidance should new nanomaterials be proposed to be added for use in cosmetics.

The Meeting agreed to adopt the Task Force recommendation and asked the ACSB Secretary to circulate the EU Regulatory definition and the EC Recommendation definition to AMS.

New Issuance of EU Regulations in 2016

DEGEE

- The ACSB Secretary presented the template for DEGEE (EU 314/2016). All Member States except Philippines agreed to the inclusion of an equivalent entry for DEGEE in ACD Annex III without warning labeling.
- Philippines proposed a required warning label be included in the entry “should not be applied to broken skin or on persons with renal disorders” based upon literature hazards for DEGEE. Indonesia asked for clarity from Philippines about the proposed warning label. The Meeting requested Philippines to forward the reference to the Secretary for further circulation to AMS.
- ACA was asked to review the safety data for DEGEE and present to the 26th ACSB Meeting.
- The Meeting agreed that any decision on the inclusion of an entry for DEGEE in ACD Annex III would be deferred until the 26th ACSB Meeting.

Potassium Hydroxide

- The Secretary presented the proposal to make a sub-section in ACD Annex III covering the usage of potassium hydroxide as a callus softener following from EU regulation 622/2016.
- The Meeting agreed that the use of potassium hydroxide at a maximum level of 1.5% should be considered cosmetic usage.
- The Meeting discussed and agreed that the warning labels required should follow those in the EU regulation (EU 622/2016) 32. The Meeting agreed to add a sub-section for potassium hydroxide as a callus softener into Annex III with a grace period of a minimum of 12 months.

Annex VII Zinc Oxide

- The Secretary presented a proposal following EU Regulation 621/2016, to modify the Annex VII entry for Zinc Oxide as follows:
 - To introduce a restriction to the current entry for Zinc Oxide that it is “Not to be used in applications that may lead to exposure of the end-user’s lungs by inhalation.” This
 - restriction would apply also to the Zinc Oxide (nano) detailed below.
 - To introduce a new entry for Zinc Oxide (nano) that allows use of nanomaterial Zinc Oxide only if its specification meets detailed criteria as laid out in EU 621/2016.
- ACA proposed a modification to the definition of the permitted coatings of Zinc Oxide (nano) detailed in EU 621/2016. The Meeting requested ACA to prepare a further proposal on coatings of both Zinc Oxide (nano) and Titanium Dioxide (nano) for presentation at the 26th ACSB Meeting, and also requested that this work be initiated by ACSB Template.
- The Meeting agreed to the modification of the current entry for Zinc Oxide and to the inclusion of an entry for Zinc Oxide (nano) following the material specification detailed in EU 621/2016 with grace period of a minimum of 12 months.

Annex IV Carbon Black

- The Secretary presented a proposal following EU 1120/2016 to modify the Annex IV entry for Carbon Black as follows:
 - To introduce a detailed specification into the current entry defining the required purity of Carbon Black.
 - To introduce a new entry for Carbon Black (nano) into Annex IV with the same purity specification, a particle size specification and a restriction to application that avoids end-user’s lung exposure by inhalation.
- The Meeting agreed to the modified current entry into Annex IV for Carbon Black and to the new entry for Carbon Black (nano) with grace period of a minimum of 12 months.

Annex VII Titanium Dioxide (nano)

- The Secretary presented a proposal following EU 1143/2016 to introduce a new entry into Annex VII for Titanium Dioxide (nano).
- The proposal provides a detailed specification of materials that can be considered to meet the definition of Titanium Dioxide (nano), and also restricts usage to applications that avoid end-user’s lung exposure by inhalation.

- The Meeting agreed to the new entry into Annex VII for Titanium Dioxide (nano) with grace period of a minimum of 12 months.
- Indonesia informed the Meeting that she has implemented the mechanism of reviewing cosmetics containing nano ingredients.

Annex VI Ethyl lauroyl arginate

- The Secretary presented the proposal to modify the entry for ethyl lauroyl arginate in Annex VI to allow usage in mouthwash preparations at a maximum level of 0.15% (EU 1121/2016).
- The Meeting agreed to adopt the proposal to permit usage of ethyl lauroyl arginate for mouthwash as a preservative under Annex VI at a maximum level of 0.15% with the restriction and warning label “Not to be used for children under 10 years of age”. No grace period is required.

Annex VI Methyl isothiazolinone (MI or MIT)

- The Secretary presented the proposal to restrict methyl isothiazolinone (MI or MIT) in Annex VI to rinse-off products only with a maximum usage level of 100ppm (0.01%) following EU regulation 1198/2016.
- The Meeting agreed to the restriction of MIT in Annex VI for use in rinse-off products only i.e. the use of MIT in leave-on products is prohibited.
- The Meeting requested ACA to prepare a review of the safety of MIT in rinse-off products for presentation to the 26th ACSB Meeting.
- All AMS, except Indonesia, agreed to the restriction of MIT in Annex VI to rinse-off products only with a maximum level of 100ppm (0.01%) with a grace period of a minimum of 12 months. For Indonesia the use of MIT will be restricted to rinse-off products only with a maximum usage level of 15ppm (0.0015%) with a grace period of 18 months.

Ketoconazole

- The Meeting agreed to the proposal to include ketoconazole in Annex II with no grace period.

Joint Opinion Statements

- The Meeting agreed that for recurrent issues ACA would provide an initial draft of the Joint Opinion Statement and provide it to the Secretary who will coordinate inputs by AMS. Once approved by ACSB, and endorsed by ACC, the statement will be posted on the ASEAN website.
- The Meeting agreed that for urgent issues ACA would provide their own statement and information directly to AMS.

55. The Meeting requested AMS to propose a list of recurrent issues needing Joint Opinion Statements and provide this list to the Secretary.

Publication of ACD

- The Meeting agreed that once AMS had reviewed and approved the consolidated Annex III, the ACD with updated Annexes and supporting documents would be published in print format.

The next meeting will be held in May 2017 in Siem Reap, Cambodia.