

## **Report on the 25<sup>th</sup> ACSB Meeting, Brunei Darussalam, November 15-16, 2016**

The 25<sup>th</sup> Meeting of the ASEAN Cosmetic Scientific Body (ACSB) was held on 15-16 November 2016 in Brunei Darussalam. The Meeting was attended by 9 Member States (except Myanmar) and the ASEAN Cosmetic Association (ACA).

The following is a summary of the Meeting Discussions/Agreements.

### **1. Annex III**

Draft of Annex III Restructure has been circulated to AMS for review and for finalization of the ACSB Secretary.

TRICLOSAN (TCS) has been discussed whether this ingredient is allowed for use other than preservative in EU as this does not appear in EU Annex III. Note - TCS is currently in ACD Annex III. ACSB Secretary will clarify the status of TCS in EU and ACA was requested to present safety data on TCS in the next Meeting.

### **2. ASEAN Guidelines on Limits of Contaminants**

The draft Guidelines has been agreed with Malaysia confirming her agreement on the format. Further, the ACSB Secretary will include into the document texts agreed in the 7<sup>th</sup> and 8<sup>th</sup> ACSB meetings related to the limits of contaminants.

### **3. 9 Hair Dyes (EU Regulations 1190/2015)**

ACA presented an overview of the general principle of hazard characterization/safety assessment for hair dyes. Indonesia continues her review on hair dyes referencing to the ACA data, among others.

### **4. Nanomaterials**

The Meeting agreed to the following-

- Definition for nanomaterials has been deferred until EU finalizes.
- EU regulatory definition and the EU Commission recommended definition will be referred as guidance should new nanomaterials be proposed to be added for use in cosmetics.

### **5. New Issuance of EU Regulations (impacting Annexes/Ingredients)**

#### **i. EU Regulations 314/2016 – DEGEE (Diethyleneglycol monoethyl ether, Ethoxydiglycol)**

- The Meeting agreed to be include this entry in ACD Annex III. In addition, 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 to be circulated to AMS.
- ACA to review the safety data of DEGEE related to the proposed warning.
- Decision for this entry is deferred until to the next Meeting.

#### **ii. EU Regulation 2016/622 – Potassium Hydroxide**

The Meeting agreed to -

- the use of potassium hydroxide at a maximum level of 1.5% should be considered cosmetic
- add a sub-section for potassium hydroxide as a callus softener into ACD Annex III with a grace period of a minimum of 12 months

### iii. EU Regulations 621/2016 – Zinc Oxide

The Meeting agreed to the following –

- Include a restriction to the current entry for Zinc Oxide in ACD Annex V (A29) “Not to be used in applications that may lead to exposure of the end-user’s lungs by inhalation.” This restriction applies to Zinc Oxide (nano).
- Add 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.
- Grace period for the above is 12 months minimum.

ACA presented that the specified coating ingredients in the EU regulations may be limiting to the industry and could be a technical barrier. ACA to prepare a further proposal on coatings of both Zinc Oxide (nano) and Titanium Dioxide (nano) for presentation at the 26<sup>th</sup> ACSB Meeting.

### iv. EU Regulations 1120/2016 – Carbon Black

The Meeting agreed to the following –

- Add a detailed specification per EU 1120/2016 into the current entry in ACD Annex IV defining the required purity of Carbon Black.
- Add 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.
- Grace period for the above is 12 months minimum.

### v. EU Regulations 1143/2016 – Titanium Dioxide

The Meeting agreed to the following-

- Add a new entry into Annex V for Titanium Dioxide (nano) with the definition/criteria as nano and restricts the usage to applications that avoid end-user’s lung exposure by inhalation.
- Grace period for the above is 12 months minimum.

Indonesia informed that she has started to implement a mechanism on the review of cosmetic products with nano ingredients.

### vi. EU Regulation 1121/2016 - Ethyl Lauroyl Arginate

The Meeting agreed to the following-

- Add entry to Annex VI to expand the use to mouthwash products up to 1.5% with corresponding label not to be used for children under 10 years of age. (Entry for other uses - lip products, oral products (other than mouthwashes) and spray products - remains the same.)

- No grace period required.

**vii. EU Regulation 1198/2016 - Methylisothiazolinone (MIT)**

The Meeting agreed to the following-

- 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.
- ACA to prepare a review of the safety of MIT in rinse-off products for presentation to the next Meeting.

**6. Ketoconazole**

The Meeting agreed to include Ketoconazole in Annex II with no grace period.

**7. Joint Opinion Statements**

The Meeting agreed to the following-

- For recurrent issues, ACA would provide an initial draft of the Joint Opinion Statement 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.
- For urgent issues, ACA would provide their own statement and information directly to AMS.
- AMS to propose a list of recurrent issues needing Joint Opinion Statements and provide this list to the Secretary.

**8. 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.

**9. Grace period**

The ACC Meeting requested ACSB to look into the matters related to grace period.

The next (26<sup>th</sup>) ACSB Meeting will be held in May/June 2017, pending confirmation, in Cambodia.