

27TH ACSB MEETING SUMMARY REPORT

| AGENDA ITEM | TOPIC | DISCUSSION | DECISION |
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| 4 | Remaining questions on ACD Annex III | <ol style="list-style-type: none"> 1. Proposal to adopt a warning statement “wear suitable gloves” for all Annex III references for oxidative and non-oxidative hair dye ingredients 2. Proposal to revise the text for Annex III entries for thioglycolic and thiolactic acids to resolve the potential confusion about maximum permitted levels in combinations “Percentages calculated as total thioacids i.e. either singly (thiolactic acid or thioglycolic acid alone) or in combination of thiolactic acid and thioglycolic acid in a given formula, provided that the level of each individual component does not exceed the maximum concentration allowed for that component. 3. Proposal to add in warning text “Contains Hydroquinone” for Ref 14. Today Hydroquinone does not require the warning text “Contains hydroquinone”. Ref 95, for hydroquinone methylether does require this text. 4. The use of Benzalkonium salts in “other products” does not appear in Annex III, these materials are permitted for use in EU at 0.1% max for non-preservative functions under Article 14(d) (ii) of the EU regulation. | <ol style="list-style-type: none"> 1. To include Text ‘<i>The direction for use “wear suitable gloves” in label or leaflet text</i>’ as an “other limitation and requirement” in column E of Annex III. Implementation: Effective 1st December 2020 only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market. 2. ACA and Member states to collect bring information to the next meeting detailing any such combinations used in products in the market. 3. To remove the superscript referring to footnote 2 in Annex III, Ref 14, Column E. No need to add the warning. 4. No change was required to Annex III, Ref 65 (Benzalkonium chloride, bromide and saccharinate). |
| 5.3 | Triclosan | <ol style="list-style-type: none"> 1. The use of Triclosan in cosmetic products for purposes other than preserving the product | <ol style="list-style-type: none"> 1. No change in the current Annex III Listing while pending further clarification from EC |

27TH ACSB MEETING SUMMARY REPORT

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| 6 | <p>New Issuance of EU Regulations</p> | <ol style="list-style-type: none"> 1. Ingredients in EU Annex III Refs 103-205 (EU2013/344) 2. Inclusion to Annex III separate entries for N,N'-Bis(2-hydroxyethyl)-2-Nitro-p-phenylenediamine and 2,6-Dihydroxyethylaminotoluene, and several new hair dye additions 3. Restriction of Methylisothiazolinone to a maximum of 15ppm as already actioned in EU in EU2017/1224 4. Proposal to add three fragrance components, Lyral (HICC), Atranol and Chloroatranol to Annex II which has already been actioned in EU in EU2017/1410 5. Proposal to amend Annex IV listing for zinc oxide to include the condition that it must <i>“not be used in applications that may lead to exposure of the end-user’s lungs by inhalation”</i>, following a similar change to EU Annex IV in regulation EU2017/1413 | <ol style="list-style-type: none"> 1. ACA to provide an assessment of the safety profile of the ingredients for discussion in the 28th ACSB Meeting ACSB Secretary to seek clarification from EC on how EU implements the regulation of these ingredients, any labeling implications and test methods. 2. ACA to bring information to the next meeting on the usage of these ingredients by industry and that the action and Implementations would be decided at the 28th ACSB Meeting 3. ACSB Secretary to amend Annex VI to reflect Methylisothiazolinone in rinse-off products to a maximum of 15ppm. Implementation: Effective 1st June 2019 (except Indonesia which has already implemented) only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market. 4. Lyral (HICC), Atranol and Chloroatranol to be added to Annex II, ACSB Secretary to amend the Annex accordingly. Implementation: Effective 23rd August 2019 (except Indonesia) no cosmetic product with the banned |
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27TH ACSB MEETING SUMMARY REPORT

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| | | | <p>materials can be placed in the ASEAN market, and effective 23rd August 2021 (except Indonesia) non-compliant products must be completely withdrawn from the market. In Indonesia, effective 1st Jan 2020 no cosmetic product with the banned materials can be placed in the market, and non-compliant products must be completely withdrawn from the market.</p> <p>5. ACA to bring in the next meeting input about the assessment of products that would and would not be covered by the condition. ACSB Secretary to amend Annex IV in line with the proposal. Implementation: Effective 1st December 2018 only compliant products can be placed in the market, and non-compliant products must be completely withdrawn from the market</p> |
| 7.1 | Climbazole | <ul style="list-style-type: none"> Addition of Climbazole into Annex III in addition to its current entry in Annex VI | <ul style="list-style-type: none"> ACA to bring input on the safety assessment of Climbazole to the 28th ACSB Meeting for continued discussion, noting Malaysia's observation of the apparent inconsistency between the SCCP conclusion that the ingredient is safe for cosmetic use in only face and hair care products at 0.5% and the listing in Annex VI for all product forms with a maximum level of 0.5%. |

27TH ACSB MEETING SUMMARY REPORT

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| 7.2 | Methylpyrrolidone | <ul style="list-style-type: none"> To evaluate the use of N-Methyl-2-Pyrrolidone (NMP) | <ul style="list-style-type: none"> ACA will provide a review of the safety profile of NMP. ACA and AMS to report on industry use of NMP for continued discussion during the 28th ACSB Meeting |
| 7.3 | Alpha, Beta and Deoxyarbutin | <ul style="list-style-type: none"> To discuss the use of alpha, beta and deoxyarbutin in cosmetics | <ul style="list-style-type: none"> ACA to survey the usage of these ingredients while awaiting EU proposal on arbutins, noting ACA's comment that are currently not regulated in EU and the EU public hearing on arbutins has been delayed, probably because more data is pending |
| 7.4 | Formaldehyde | <ul style="list-style-type: none"> To review the safety of formaldehyde in cosmetic products | <ul style="list-style-type: none"> ACSB to monitor closely the discussion and developments in Europe |
| 7.5 | Ethyl Tosylamide | <ul style="list-style-type: none"> Clarification on whether Ethyle Tosylamide is prohibited in cosmetics. Following a discussion of the scope of the sulphonamide class in Annex II, Ref 307, and of the differences in chemical structure between sulphanilamide and ethyl tosylamide the Meeting concluded that ethyl tosylamide does not fall within the scope of Annex II, Ref 307 and therefore its use is permitted in cosmetics | <ul style="list-style-type: none"> Ethyl tosylamide does not fall within the scope of Annex II, Ref 307 and therefore its use is permitted in cosmetics Indonesia to propose a ACSB template for discussion in the 28th ACSB meeting, following their request to revisit Annex II, Ref 307 with reference to the description and interpretation of "<i>Sulphonamides and their salts</i>" |
| 7.6 | Potassium Alum | <ul style="list-style-type: none"> Concern on the irritation of the mucous membranes caused by feminine hygiene products containing Potassium Alum | <ul style="list-style-type: none"> AMS to investigate their PMS data to assess the incidence of irritation and provide input to the 28th ACSB Meeting. ACA informed that the SCCS is currently assessing alum salts from the safety perspective |

27TH ACSB MEETING SUMMARY REPORT

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| 7.7 | 1, 4-Dioxane | <ul style="list-style-type: none"> To review 1, 4-Dioxane impurities in cosmetics, noted ICCR has set a limit of 1, 4-dioxane in finished products in two phases. Phase 1 at 25ppm and phase 2 at 10ppm with no specific timings | <ul style="list-style-type: none"> ACA to continue to urge members to seek to achieve compliance with a maximum 1,4-dioxane level of 10ppm in finished products, and to present the ICCR report at the 28th ACSB Meeting |
| 8 | Joint Opinion Statements (JOS) | <ul style="list-style-type: none"> Reviewing the progress made on the JOS and the Talc draft JOS. ACA provided the scientific references | <ul style="list-style-type: none"> To release of the final version of the Talc JOS, including references ACSB Secretary to make final check to ensure correct format of the references and liaise with the ASEAN Secretariat for the publication of the final Talc JOS on the ASEAN website Philippines proposed 3 additional topics requiring JOS: heavy metals, hydroquinone and tretinoin |
| 9 | Process for New Materials | <ol style="list-style-type: none"> ACA presented the proposal for a process for introduction of new ingredients into Annexes IV, VI and VII and explained that under the ACSB Terms of Reference, Article 3.2, it is within the purview of the ACSB to establish an ACSB Expert Panel if required to advise on the safety of new ingredients | <ol style="list-style-type: none"> ACA to revise the proposal taking into account the comments from the ACSB, to circulate the revised process for ACSB consideration, and that the topic would be discussed further at the 28th ACSB Meeting |

27TH ACSB MEETING SUMMARY REPORT

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| 10 | AOM | <ol style="list-style-type: none">1. ACA requested to submit a revised version of their proposal on Lyral (HICC) taking account of the earlier discussion by the ACSB2. ACA presented a draft proposal for a process for JOS | <ol style="list-style-type: none">1. ACA made corrections and aligned the text with the EU Regulation2. ACA to prepare a revised process, taking into account of the comments of the Meeting for continued discussion at the 28th ACSB Meeting |
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