34th ACSB Meeting Outcome & ACA Next Step (5-6 Oct 2021)
For ACA and ACA Members use only

Link to updated Annexes: https://drive.google.com/drive/folders/1bCLnqEKMODfW83YEdmj37-4WioKyhlhB?usp=sharing

34th ACSB Meeting Agenda	34th ACSB Meeting Outcome	ACA Update
Agenda Item 4: CONTINUING DISCUSSIONS FROM the 33rd ACSB MEETING		
4.1 Matrix of Follow-up Actions		
4.2 EU INGREDIENT SAFETY ASSESSMENT AND CRITERIA	The ACSB Secretary informed the Meeting that the list of topics of discussion for this workshop has been prepared based on the previous ACSB Meeting topics requested for clarifications from EU, mainly on the process and criteria for categorizing cosmetic ingredients as banned and CMR. The list will be circulated to ACSB and request for additional topics shall be submitted to the ACSB Secretary by 31 October 2021 to be forwarded to the ASEAN Secretariat.	List of topics/questions raised by AMS: Refer attachment here: https://bit.ly/3cKGIdH *File Name: Appendix 4 - ACSB - EU Discussion on EU Regulations - Topics Time Allocation.pdf*
4.3 Amendment of Annex II (EU 2019/1966 & 2019/831)	The Secretary presented the updated consolidated list of banned substances under EU 2019/1966 and 2019/831, indicating the 222 substances that are not used for cosmetic products in the ASEAN market. The list incorporates inputs from all AMS and ACA. **The Meeting agreed to include the 222 substances in ACD Annex II. The AMS except for Vietnam agreed to the following grace period - Effective 06 October 2022 (12 months), only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.** Vietnam will seek consultation with her local industry and update in the next Meeting. For the balance ingredients (used in ASEAN) in the Consolidated List, the Meeting agreed for AMS and ACA to review and indicate the # of notified products that use such ingredients and those that have safety concerns. ACA requested the AMS to inform the industry of these substances that are for potential ban and solicit their inputs on the list. Brunei commented that among these substances, Reference # 1388 (Octamethylcyclotetrasiloxane, D4) has high usage in some Member States as reflected in the consolidated list, and the Meeting agreed to include this substance in the ACSB discussions. The Secretary informed the Meeting on Thailand's update that they will be adopting the option to move Formaldehyde from ACD Annex III (Restricted Ingredients) to Annex II (Prohibited Ingredient) as previously agreed in the 32nd ACSB Meeting. The Secretary to update the ACD Annexes II and III to incorporate the 222 substances in Annex II and to reflect Thailand's updates on Formaldehyde accordingly. The Secretary will also update the balance List of Banned Ingredients following inputs received from AMS	**ACA** to review the remaining substance and request members to share any information for review with ACSB. Refer attachment here: https://bit.ly/3cKGIdH *File Name Appendix 5 - Consolidated List of Banned Ingredients by EU_ASEAN 04Oct2021.xlsx*

4.4 Climbazole	ACA presented the updated information on the safety assessment of Climbazole using the Tier 2 - Probabilistic Exposure Assessment Approach including the efficacy study done for the combination use of both shampoo and conditioner with Climbazole. ACA shared that while the efficacy data presented include log Malassezia reduction, the efficacy of the product is assessed as a whole formula and the product presentation remains to be within the cosmetic context. The product information including efficacy and claims shall be captured as part of the Product Information File (PIF). The Meeting requested for a copy of the document on the probabilistic exposure assessment approach for reference and review. Further, Indonesia requested for human efficacy data on the combination of shampoo and conditioner with Climbazole. ACA agreed to circulate the probabilistic assessment document and expressed that further data on Climbazole are with the manufacturers. ACA also requested clarification on the principle of ACSB's assessment of ingredients which shall be safety and not efficacy. The Chair responded that while safety is primarily the main consideration for ACSB's ingredient assessment, it is also important to look at the efficacy as necessary to make a sound decision in allowing the use of substances in cosmetic products. The Meeting agreed for AMS to check the available efficacy data with their respective industry/manufacturers and share the information in the next ACSB Meeting to facilitate further review of Climbazole.	Request ACA members to share information on efficacy data particularly on use in hair conditioner.
4.5 Cosmetic Refilling and Cosmetic Forms	The Chair provided guidance that the effort of the Technical Working Groups (TWGs) on the Cosmetic Refilling and Cosmetic Forms is to develop a document intended as an Information Sharing Paper for the AMS. In this context, this should be within the scope of the ACSB.	
4.5.1 Cosmetics Refilling	The Philippines, on behalf of the Technical Working Group (TWG), presented the draft Information Paper on Cosmetic Refilling which provides the Elements, General Guidelines, Pre and Post Marketing Measures and Responsibilities of the Company associated with the refilling set-up. The Meeting agreed to further review the paper and discuss in the next ACSB Meeting.	Draft attached in the link below for review Refer attachment here: https://bit.ly/3cKGIdH *File Name: Appendix 7 - Draft Information Paper on Cosmetic Refilling Activity.pdf*
4.5.2 Cosmetics in vials and ampoules	Thailand, on behalf of the TWG, presented the draft Information Sharing Document on Cosmetic Products Packaged in Injectable-like Packaging (Vials/Ampoules). The document includes background information on the products concerned, survey method conducted and the results of survey. The Meeting agreed to further review the document for discussion in the next ACSB Meeting.	Draft attached in the link below for review Refer attachment here: https://bit.ly/3cKGIdH *File Name: Appendix 8 Info_Sharing_Document_Cosmetic_Vial_Ampoules _21 September 2021.pdf* *File Name: Appendix 8(1) - Appendix 1 Information_regarding_t…e packaged in vials and ampoules_18 April 2021.pdf* *File Name: Appendix 8(2) - Appendix 2 Summary_from_questionnaire_response_21 September 2021.pdf*

4.5.3 Customized cosmetic products and products in tablet forms	ACA, on behalf of the TWG, presented the draft Information Paper on Personalized Cosmetics and as aligned to the existing provisions of the ASEAN Cosmetic Directive. The paper is specific on cosmetic products that are personalized at the point of sale before purchase in the context of formulation. It includes approaches on safety/quality requirements, product notification, labeling, preparation and post marketing surveillance. The Meeting agreed to further review the document and discuss in the next ACSB Meeting.	Draft attached in the link below for review Refer attachment here: https://bit.ly/3cKGIdH *File Name: Appendix 9 - Information paper on Personalized Cosmetic Products in ASEAN_TWG_FINALDRAFT.pdf*
4.6 Classification of Alcohol-based Solutions	ACA presented the review on the cosmetic safety of current Methanol usage (as alcohol denaturant) in ACD Annex III Ref #52, based on the CIR safety report on Methanol. It concludes that Methanol can be safely used to denature ethyl alcohol used in cosmetic products due to its moderating effect on ethyl alcohol. Brunei sought clarification whether the same conclusion applies to the use of alcohol for hand sanitizers. ACA clarified that the safety data presented is specific to the presence of 5% methanol as a denaturant for ethyl alcohol and isopropyl alcohol. The Meeting agreed to retain the entry of Methanol as denaturant for ethanol and isopropyl alcohol up to 5% in ACD Annex III.	No further action
4.7 Nano Ingredients	ACA presented the available information on nano ingredients mainly on the definition from EU and ISO. As nano ingredients have been adopted by ACSB and reflected into the ACD Annexes based on previous reviews, the proposal from ACA is to refer to the same definition as in EU Cosmetic Regulation, noting that there may be an update from EU Commission by end 2021. The AMS except for Indonesia, Singapore and Thailand agreed to ACA proposal to adopt the EU definition for nano ingredient. Indonesia informed the Meeting that she will retain the current local definition pending the EU update. Singapore and Thailand will seek internal consultation and update in the next ACSB Meeting. The Meeting further requested the Nanomaterial Task Force (ACA, Indonesia and Thailand) to look into the safety (in general) of nanomaterials and nano labeling and report in the next ACSB Meeting.	Request information that could support ACA presentation on safety of nano ingredient in cosmetic products.
AGENDA ITEM 5: CONTINUING DISCUSSIONS FROM the 31st ACSB MEETING		
5.1 UV Filters Safety Assessment	Referring to the request from the last Meeting to review the basis of the EU Notification at WTO regarding the levels of Menthyl Anthranilate, ACA presented a clarification that the Notification is on Methyl-N-methylanthranilate (M-N-MA) (fragrance) and not Menthyl Anthranilate (sunscreen active ingredient). Further, ACA shared that the Menthyl Anthranilate (sunscreen active ingredient) is approved for use in US, Canada and Australia and is undergoing review by the US FDA. Singapore informed the Meeting that the US FDA is currently doing a review on sunscreen active ingredients, and requested ACA to share data on Menthyl Anthranilate as well as update on the US FDA review to ACSB.	
5.2 Amendment of Annexes II, III and V (EU 2020/1682 and EU 2020/1683).	The Secretary informed the Meeting the feedback from Singapore on her review of the EU Regulations (EU 2021/1682 and EU 2021/1683) and agreed to adopt the 3 substances namely 1,2,4-Trihydroxybenzene,4-Amino-3-hydroxytoluene and 2-(4-Amino-2-nitropheny-amino-benzoic acid) into ACD Annex II (Prohibited) and the 2	

	substances namely 2-hydroxyethyl methacrylate and Di-HEMA Trimethylhexyl Dicarbamate into ACD Annex III (Restricted), with the same grace period as agreed in the 33rd ACSB Meeting. The Secretary will revise the ACD Annexes II and III accordingly. The AMS updated the Meeting on the review of the safety data on substances Reference #s 315-320 under Annex III of EU 2020/1683. Following this, the AMS, except Indonesia, agreed to adopt these substances into ACD Annex III with a grace period of 18 months - Effective 06 April 2023, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. Indonesia will do further review and advise accordingly. The Secretary will update the Annex III to incorporate these substances. ACA confirmed that Acid Orange 7 (Ref#318) can be used as hair dye and need to fulfil the Annex III restriction. This will then be declared as Acid Orange 7 in the ingredient listing. If the material is used as a colorant, then the restriction in Annex IV will apply. CI 15510 is approved for use as "Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of eyes, in particular eye make-up and eye make-up remover", therefore cannot be used as a colorant for products that are applied around the eye area. This will be declared as CI15510 in the ingredient listing. Other examples with similar conditions are Acid Violet 43 in Annex III (Ref: 306) and CI 60730 in Annex IV.	
5.3 Amendment of EU Annex VI (EU 2020/1684)	ACA presented the safety data on UV Filter 2-ethoxyethyl (2Z)-2-cyano- 2-[3-(3-methoxypropylamino) cyclohex-2-en-1- ylidene] acetate (otherwise known as, Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate) or BC-3 to support the proposal to adopt the EU Regulation and add this ingredient into ACD Annex VII (UV Filter). In summary, at 3% there is no local and systemic safety issue anticipated for using BC-3 in cosmetic product as a UV filter and BC3 is a secondary amine which makes the control of generating nitrosamine to be reasonable. The Meeting agreed to adopt the revision and add the ingredient into ACD Annex VII effective immediately. The ACSB Secretary will revise Annex VII to reflect this addition.	
5.4 Amendment of EU Annexes II, III and V (EU 2019/831) <addendum: pending from 31st ACSB Meeting> Amending Annex II, III, V (EU 2019-831)_A	The Secretary presented the proposal template, appearing as APPENDIX 14, from the last 31st ACSB Meeting for the review of the balance substances classified as CMR Three substances category 2 under EU 2019/831 namely trimethylbenzoyl diphenylphosphine oxide (Annex III-restricted ingredient), furfural (Annex III-restricted ingredient) and polyhexamethylene biguanide hydrochloride (Annex V-preservative). While these substances were classified as CMRs under Regulation (EC) No 1272/2008, there are SCCS Opinions which support that these ingredients can be used for certain types of cosmetic products within specific restrictions establishing the conditions laid down for CMRs are fulfilled. Therefore, these substances were incorporated into the EU Annexes as follows: (a) EU Annex III - Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide (Trimethylbenzoyl diphenylphosphine oxide (TPO) is safe when used as a nail product and added to the	

	list of restricted substances in Annex III for professional use in artificial nail systems with a maximum concentration of 5%. (b) EU Annex III - 2-Furaldehyde (Furfural) added to the list of restricted substances in Annex III with a maximum concentration of 0.001 %. (c) EU Annex V - Polyhexamethylene biguanide hydrochloride (PHMB), (Polyaminopropyl Biguanide) added as a preservative in all cosmetic products, except in applications that may lead to exposure of the end-user's lungs by inhalation, with a maximum concentration of 0,1 %. The conditions set out in Annex V to Regulation (EC) No 1223/2009 should be adapted accordingly. ACA presented the safety data on PHMB which basically supports the SCCS Opinion on this ingredient, and in turn, requested sufficient grace period for implementation. The AMS except for Indonesia agreed to adopt the revisions into the ACD Annexes III and VI respectively with the grace period of 18 months - Effective 06 April 2023, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. Indonesia will defer her decision until the EU workshop. The Secretary will update the Annex II and III accordingly.	
5.5 Silver Nitrate <addendum - pending from 31st ACSB Meeting>	The AMS except for Thailand agreed to include Silver Nitrate in Annex II with a grace period of 12 months - Effective 06 October 2022, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. Thailand will make internal consultations on the time frame and inform in the next ACSB Meeting. The Secretary will update the Annex II to incorporate this substance	
AGENDA ITEM 6: NEW ISSUANCE OF EU REGULATIONS		
6.1 Amendment of EU Annexes II, III, IV and VI (EU 2021/850)	The Secretary presented the proposal template, appearing as APPENDIX 16, for the review of EU regulation No. 2021/850 with subject on the revision of entries in Annexes II (Prohibited Ingredients) III (Restricted Ingredients), IV (Colorants) and VI (UV Filters). In light of the SCCS Opinions and adoption of Commission Regulation (EU) 2019/1966(6) to uniformly implement the prohibition of substances classified as CMR, the EU Annexes are revised as follows- Titanium Dioxide in powder form - In light of the SCCS conclusions, titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10µm should not be authorised for use in applications that may give rise to inhalation exposure by the end user and added to the list of restricted substances in Annex III for use as face products in loose powder form and in hair aerosol spray products. The use of titanium dioxide as colorant (entry 143 of Annex IV) and as UV filter (entry 27 of Annex VI) are updated to reflect the restricted use. Benzoic acid, 2-hydroxy- (INCI name: salicylic acid)- added for purposes of use as body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant in a concentration of up to 0.5 % in Entry 98 of Annex III. Additionally, the following CMR substances are added to Annex II - cobalt, metaldehyde (ISO), methylmercuric chloride, benzo[rst] pentaphene, dibenzo[b,def]chrysene; dibenzo[a,h]pyrene, ethanol, 2,2'-iminobis-,N-(C13-15-branched and linear alkyl) derivs,	Industry review the list of revisions from EU 2021/850 and share with ACA before the next ACSB if any need to prioritizematerial for defense.

	cyflumetofen (ISO), diisohexyl phthalate, halosulfuron-methyl (ISO), 2-methylimidazole, metaflumizone (ISO), dibutylbis(pentane-2,4-dionato-O,O')tin, nickel bis(sulfamidate), 2-Benzyl-2-dimethylamino- 4′- morpholinobutyrophenone and ethylene oxide. Further, the substance nickel bis(tetrafluoroborate) (CAS number: 14708-14-6) is corrected as it has been introduced twice by error in Annex II. This double entry has been corrected in the Consolidated List of Banned Ingredients under this Meeting Agenda Item 4.3. Related to Titanium Dioxide, the ACSB Chair informed the Meeting that the ACSB Chair and ACTLC Chairs pre-met to discuss possible testing methods for titanium dioxide noting the specific requirement on particle size. This is in consideration that there are several products in the market that are containing titanium dioxide. ACTLC Chair informed the Meeting that there is a standard method for quantification and qualification of nano ingredients as raw material and in finished goods that may be used for testing if needed. ACA informed the Meeting that the specification requirement on Titanium Dioxide is on raw material. This is reviewed via Post Marketing Surveillance on the PIF documentation on the raw material. The ACTLC Chair advised in turn that the available method can detect the specific requirements in the finished product. Following the discussions, the Meeting agreed for AMS to check with their local industry on the available methods for Titanium Dioxide, whether in raw materials or in finished product. Related to T Benzoic acid, 2-hydroxy- (INCI name: salicylic acid)-, Thailand raised a query on the additional use under its entry in Annex III (c) whether body creams would be part of the body lotion and eyeliners would include all eye products. ACA clarified that the SCCS Opinion will reflect the certain types of products requested for assessment, and in turn will be carried in the EU Cosmetic Regulation. The Meeting requested the Secretary to review the SCCS Opinion related to this matter and report in the next ACSB Meeting. Further, the Meeting agreed to defer the discussions for the substances under this EU regulation in the next ACSB Meeting, and also to the Secretary's proposal to include the substances added in EU Annex II under this Regulation to the Consolidated List of Banned Ingredients for review of the AMS and ACA	
6.2 Amendment of EU Annex V (EU 2019/1858)	The Philippines presented the the template for the review of EU regulation No. 2019/858 on the revision of Annex V to add the substance 4-(3-ethoxy-4-hydroxyphenyl) butan-2-one as a preservative. The Meeting agreed to defer the discussion on this ingredient and requested ACA to make a presentation on the ingredient safety in the next Meeting	
AGENDA ITEM 7: OTHER MATTERS		
Per the request of the 33rd ACC Meeting, the Meeting may wish to	Following the request of the 33rd ACC Meeting arising from the 16th ACTLC Meeting on prioritization of substances for ASEAN Cosmetic Methods (ACM), the ACTLC Chair informed the Meeting that ACTLC is looking at 3 substances out of the 5 identified high-	

discuss on what's constitute the prioritization of high-risk substances from the perspective of the Regulatory Authority.	risk substances namely methanol, isopropyl parabens/isobutylparabens. These substances have available methods in the ASEAN method database for AMS consideration for ACM. Upon the comment of ACA that the term 'High Risk Substances' may have different connotation, the Meeting requested the ACTLC to consider other terminologies for these substances. The Meeting agreed for ACSB and ACTLC to continue to collaborate on the prioritization of substances for ACM, mainly based on the safety concerns on the ingredients particularly on the banned and restricted ingredients. ACA informed the Meeting that they can conduct safety assessments on these identified ingredients to help in the prioritization.	
Following the receipt of the letter from the Humane Society International (HSI) to brief ASEAN on their advocacy for non-animal testing for cosmetic products, and with the agreement of the ACC HOD Meeting of 29 September 2020, HSI will present information about animal testing and developments on non-animal technologies and approaches. The Meeting may wish to discuss further.	As a follow through on the letter of the Humane Society International (HSI) and with the agreement of the ACC HOD Meeting of 29 September 2020, the HSI presented to the Meeting their brief on Advancing Animal-Free Safety Assessment and Cosmetics Policy. The presentation consists of Introduction, Global Landscape, Building Capacity, the ASEAN context and recommendation to ACSB. Thailand commented that it is important to determine the level of expertise and facilities for ASEAN in terms of conducting the non-animal testing methods. ACA reinforced the same for the industry with regard to understanding the local capability particularly the SMEs, and that this needs to be pursued within the AMS-industry partnership. The Meeting agreed for HSI to engage at the ASEAN level via the ASEAN Secretariat versus individual countries as all AMS have obligations under the ASEAN Cosmetic Directive (ACD). The Meeting agreed for the ACSB Chair to bring the discussion to ACC and determine the direction and next steps.	
Referring to Section 2.9 of the WTO Agreement on Technical Barriers to Trade (TBT), where Members are required to notify proposed regulations for a relevant international standard that does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the	Removed from agenda and to be discussed with ASEAN Secretariat	

technical regulation may have a significant effect on trade of other Members, the Meeting may wish to seek guidance from the ACC on the process of notification whether this is done by each AMS or by the ASEAN Secretariat on behalf of the AMS under the ACC umbrella.		
AGENDA ITEM 8: HANDOVER OF CHAIRMANSHIP AND CHANGE OF ACSB Secretary	As provided by the ACSB TOR Article 7 – Term of Office, the Meeting requested the Philippines to renew her term as Chair of the ACSB subject to the agreement of ACC. The Philippines informed the Meeting that she will need to do internal consultations and will inform ACSB of her decision accordingly. The Meeting agreed to defer the discussion in the next Meeting.	

34th ACC Meeting Agenda & ACA Summary (15-16 Nov 2021)
For ACA and ACA Members use only

34th ACC Meeting Agenda	34th ACC Meeting Outcome	ACA Update
Agenda Item 3: HANDOVER OF CHAIRMANSHIP AND VICE-CHAIRMANSHIP	The Meeting witnessed the handover of the Chairmanship of ACC from Brunei Darussalam to Cambodia and the handover of the Vice-Chairmanship from Cambodia to Indonesia.	
AGENDA ITEM 4: Progress Of The Implementation Of The Asean Cosmetic Directive (ACD)		
ASEAN Comprehensive Recovery Framework (ACRF)	The ASEAN Secretariat presented the updates on ASEAN economic integration specifically on the progress of implementation of the ASEAN Comprehensive Recovery Framework (ACRF) under the ASEAN Economic Community The Meeting noted that one of the key initiatives of the ACRF is the Memorandum of Understanding on the Implementation of Non-Tariff Measures on Essential Goods under the Hanoi Plan of Action on Strengthening ASEAN Economic Cooperation and Supply Chain Connectivity in Response to the COVID-19 Pandemic. Appended to the MOU is the list of essential goods where trade restrictive NTM will be eliminated to combat the COVID 19 pandemic and providing availability of essential goods during COVID 19 and post pandemic era. noted the three (3) key priorities of the ACRF which fall under the ambit of the ASEAN Consultative Committee for Standards and Quality ACCSQ) and its Working Group (WG)/Product Working Group (PWG), namely: (i) Key Priorities 2b. Ensuring food securities, food safety and nutrition; (ii) Key Priorities 3c. Enabling trade facilitation in the new normal; and (iii) Key Priorities 4b. Promoting E-commerce and the digital economy. Specifically under "Enabling trade facilitation in the new normal", an initiative on expanding the harmonisation of standards has been identified to eliminate NTMs. 12. From among the List of Essential Goods, ASEAN Harmonised Tariff Nomenclature (AHTN) 34.01 and its associated sub-products fall under the category of cosmetics products, as shown in the table below. The Meeting noted that identifying the relevant international/ published standards for these cosmetics products and their subsequent harmonisation among the AMS would contribute to the elimination of trade restrictive NTMs	ACA to monitor to development closely and shared input that this is further incentive for AMS to harmonize completely the notification and labelling requirement of cosmetic products which are important for hygiene and health of consumers. ACA commented that existing ACD is a harmonized standard for application to finished cosmetic product while it welcomes ACTLC effort to harmonize testing method across AMS on certain specifications.

	<table><tr><th>NO</th><th>AHTN 2017</th><th>PRODUCT DESCRIPTION</th></tr><tr><td></td><td>34.01</td><td>Soap; organic surface-active products and preparations for use as soap, in the form of bars, cakes, moulded pieces or shapes, whether or not containing soap; organic surface-active products and preparations for washing the skin, in the form of liquid or cream and put up for retail sale, whether or not containing soap; paper, wadding, felt and nonwovens, impregnated, coated or covered with soap or detergent.</td></tr><tr><td></td><td></td><td>- Soap and organic surface-active products and preparations, in the form of bars, cakes, moulded pieces or shapes, and paper, wadding, felt and nonwovens, impregnated, coated or covered with soap or detergent :</td></tr><tr><td></td><td>3401.11</td><td>- - For toilet use (including medicated products) :</td></tr><tr><td>84</td><td>3401.11.40</td><td>- - - Medicated soap including disinfectant soap</td></tr><tr><td>85</td><td>3401.11.50</td><td>- - - Other soap including bath soap</td></tr><tr><td>86</td><td>3401.11.60</td><td>- - - Other, of felt or nonwovens, impregnated, coated or covered with soap or detergent</td></tr><tr><td></td><td>3401.19</td><td>- - Other :</td></tr><tr><td></td><td>3401.20</td><td>- Soap in other forms :</td></tr><tr><td>87</td><td>3401.20.20</td><td>- - Soap chips</td></tr><tr><td></td><td></td><td>- - Other :</td></tr><tr><td>88</td><td>3401.20.99</td><td>- - - Other</td></tr><tr><td>89</td><td>3401.30.00</td><td>- Organic surface-active products and preparations for washing the skin, in the form of liquid or cream and put up for retail sale, whether or not containing soap</td></tr><tr><td></td><td>3808.94</td><td>- - Disinfectants :</td></tr></table> The Meeting noted that complementing the harmonisation of standards on cosmetics products under the list of essential goods, the ACC could further strengthen the elimination of NTM in the cosmetics sector through the effective implementation of the AAHCRS and the elimination of country-specific requirements that are not consistent with the ACD and its harmonised technical requirements. On the harmonisation of standards of cosmetics products identified in the list of essential goods in the table above, the Meeting requested the AMS to submit the list of relevant international/published standards of those products to the ASEAN Secretariat by 31 January 2022 for consolidation and consideration in the harmonisation initiative in ASEAN. The Meeting noted that the ACTLC have identified ISO test methods standards which had been submitted to the ACCSQ Working Group on Standards (WG 1) for harmonization. Meeting noted that the above soap products fall under the definition of cosmetics in the ACD	
AGENDA ITEM 5: Follow-Up From The 33rd Asean Cosmetic Committee Meeting)		
AGENDA ITEM 6: PROGRESS OF THE IMPLEMENTATION OF THE ASEAN COSMETIC DIRECTIVE (ACD)		

6.2: Update from the Industry Following the Implementation of the ACD	The representative from ACA informed the Meeting on ACA's activities since the last ACC Meeting and highlighted series of webinars/trainings conducted by ACA and her Members in 2021. The Meeting noted the recently conducted ASEAN Cosmetic Safety Assessment Workshop on 10-11 November 2021 which was attended by 125 participants from Industries and regulators across ASEAN Member States. The Meeting also noted ACA Office Bearers for the period of July 2021 to June 2023 ACA also presented the outcomes of its bilateral discussion with Cambodia, Indonesia, Lao PDR, Myanmar and Thailand regarding Country Specific Requirement (CSR) issues. ACA highlighted that the productive discussion between AMS and ACA as well as the conduct of bilateral discussion with relevant AMS have contributed to the conclusion of the following CSR issues: *Product Notification Requirements* (i) 1.2 GMP certificate or equivalent document; (ii) 1.3 GMP Inspection required before product notification (domestic product) (iii) 1.6 Product sample (iv) 1.8 Product notification required before starting production; (v) 1.10 Product name/tradename reviewed and approved by authority (vi) 1.11 Letter of Authorization (LOA)/Letter of Appointment and Acceptance of 3rd party manufacturer. *Labelling Requirement* (i) 2.6 Valid contact number/hotline number of the cosmetic notification holder; (ii) 2.7 Over-labeling is not allowed. Only original packaging is acceptable. *Others* (i) 3.1 Heavy metal testing is required as supporting data to get import license (SKI) of imported product or as supporting data in Product Information File (for domestic products). (ii) 3.2 Microbiology testing is required as supporting data to get import license (SKI) of imported product or as supporting data in Product Information File (for domestic products). The Meeting noted that ACA will conduct workshops with industry and regulators to address concerns around product artwork and quality of notification application for Lao PDR and Myanmar The Meeting noted the request of ACA for Cambodia, Indonesia and Thailand to share updates on the (i) the submission of bilateral meeting minutes to the Minister for Cambodia; (ii) stakeholder consultation and feedback on the notification paper in Thailand; (iii) the changes to the system and feedback on the notification paper by Indonesia Following ACA's presentation, the Meeting noted the responses from Member States, as follows: (i) Lao PDR still requires product artwork since there is inconsistency of product artwork submitted during notification and product artwork in the product marketed. Lao PDR will consider removing the requirement on product artwork during notification after the conduct of ACA's workshop with	

	industry and regulators and the number of the inconsistency has declined. (ii) Lao PDR requires the GMP certificate or equivalent document only for the high risk product. Lao PDR has prepared the definition and list of the high risk cosmetic product. Lao PDR is now drafting the Drug Law whereby cosmetic is included under this law. Lao PDR has requested the law to be aligned and comply with the ACD. (iii) Indonesia clarified that Indonesia do not require CFS for cosmetic products from ASEAN countries as stated in the summary table from ACA's presentation. (iv) Cambodia informed that the notification number to be printed on label is mandatory and part of post market surveillance system in Cambodia as stipulated in Cambodia's legislation which entered into force in 2010. Should there is any adjustment made to this requirement, Cambodia will update ACC through the ASEAN Secretariat. The Meeting noted the information from Cambodia at the ACC HODs Meeting in 2012 that the requirement for notification number labelling would be a short term interim measure for Cambodia. ACA noted AMS responses notably on the different treatment on product traded and product manufactured in ASEAN and encouraged Member States to treat all products equally regardless where the product manufactured. ACA shared that during bilateral discussion with Indonesia, Indonesia shared that they do not require CFS for ASEAN made product, however there are differentiation based on where the principal company is located. ACA proposed Indonesia to simplify the CFS requirement to be for two conditions: (i) ASEAN made – regardless of the location of the principal company – No CFS and no proof of notification is required. (ii) Non-ASEAN made – regardless of the location of the principal company –Proof of notification from other ASEAN markets to substitute the CFS. Indonesia will further deliberate on the above proposal and will update the industry. With regard to the notification requirement based on low and high risk product, ACA encouraged AMS to treat the product based on the Annexes of the ACD	
6.3 Information on Country Specific Requirements	The Chair informed the Meeting of the outcomes of the Meeting of the Heads of Delegations (HODs) for the 34th ACC Meeting held on 13-14 October 2021. *CSR Issues* The Meeting noted AMS feedback, as follows: (i) Indonesia is in the process of redesigning her e-notification system which planned to be ready by end of 2022; (ii) On the product artwork, Cambodia informed the company can upload the picture of actual product/photo of the product in terms of labelling/artwork; (iii) Thailand is trying to solve the issue on notification number on product labelling and will need a budget to develop an alternative tool/method and prepare a database. Thailand will need to	ACA Presentation to ACC as summary of the country specific requirements appears as attached below Refer attachment here: https://bit.ly/3cKGIdH *File Name: 34th ACC Annex 10 - ACA Updates on Bilateral Meeting.pdf* This topic was discussed extensively and it was recognized that there are still several country specific requirement that are not in line with ACD due to various reasons at the country level.

	publish periodically reach out to the stakeholders to gain their acceptance and anticipate to complete this transition within a few years. (iv) Indonesia still need 2D Barcode and Notification Number included in the label of cosmetic product to prevent the circulation of illegal cosmetic. (v) With regard to notification number, Brunei Darussalam shared that having the notification number may not necessary make an easy solution during post market inspection activities in ensuring the product is safe. It can create a false assurance to the public that the product has been fully assessed for its quality and safety, when cosmetic notification is merely an upfront declaration of compliance by the company placing the cosmetic product in the market. Brunei Darussalam further shared that, during inspection activities, the enforcement officers have come across product printed with other AMS notification number, however, the notification number could not be found on the respective AMS website. Having the notification number would also create another task for regulators whereby regulators will need to ensure and check that the notification number stated on each of the cosmetic product package is the actual notification number on the system. (vi) Singapore shared on her experience on making available the information on notified cosmetic products on HSA website for the public to check on the product's notification status. With smartphones and internet enabled devices gaining popularity globally and in AMS, it would be easy and convenient for members of public in AMS to check if a cosmetic product is notified on a regulatory authority's website. (vii) The Meeting noted the request of Philippines to Singapore to share information on use of Robotic Process Automation (RPA) for post-market surveillance on noncompliant cosmetic products implicated in safety alerts. The Meeting noted that Singapore would be able to share its policy on the control of cosmetic product at the next ACC Meeting. *<u>Legal Services and Agreements Directorate (LSAD) of ASEAN Secretariat opinion on whether the ACD applied to product traded in ASEAN or product manufactured in ASEAN</u>* With regard to ACC's request for LSAD of ASEAN Secretariat to provide opinion on whether the ACD applied to product traded in ASEAN or product manufactured in ASEAN, LSAD shared the following: (i) In order to understand the scope of the ACD, there are a number relevant provisions in the ACD that need to be examined: *Article 2: Definition and Scope of Cosmetic Product Paragraph 2* *"A 'cosmetic product' shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."* *Article 1: General Provision (Paragraphs 1 and 2)*	ACA to follow up with specific workshop with Laos and Myanmar while be ready to address the feedback on the not ACA to review the feedback on information paper and share perspective on the inputs received.

	"Member States shall undertake all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive, its Annexes and Appendices may be placed in the market." *"Notwithstanding to Article 4 and without prejudice to Article 5 and Article 10, a Member State may not, for reasons related to the requirements laid down in this Directive, its Annexes and Appendices, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive, its Annexes and Appendices thereto."* (ii) The above provisions suggested that AMS must take all necessary measures to ensure that the cosmetic products (as defined in Article 2 of the ACD) to be marketed must comply with the requirements of the ACD. These provisions also suggested that cosmetic products that meet the requirements of the ACD will have access to the ASEAN market or are allowed to be marketed in ASEAN. Furthermore, the ACD only concerns about the placement of the cosmetic products and do not differentiate between products manufactured in ASEAN and product traded in ASEAN. As long as the products comply with ACD, they could enter the ASEAN market. (iii) The ACD provides no definition on "ASEAN made cosmetic product" or "non ASEAN made cosmetic product", hence there is no reference found on what constitutes "ASEAN made cosmetic product" and "non-ASEAN made cosmetic product". (iv) Furthermore, other than the above legal instrument, LSAD also made reference to the General Information Booklet on ASEAN Harmonized Cosmetic Regulatory Scheme, background section that mentioned as follows: *"A product produced or marketed in any signatory country and meeting the requirements of AHCRS would be able to enter other signatory countries."* *<u>Way Forward:</u>* The Meeting agreed on the following course of actions: (i) The ASEAN Secretariat to work with ACA in developing the latest status of CSR issues with reference to the outcomes from ACC HODs Meeting, ACA presentation on the outcomes of bilateral discussion with relevant AMS (Cambodia, Indonesia, Lao PDR, Myanmar, and Thailand) and updates shared by AMS at this Meeting; (ii) The latest status of CSR issues will be tabled and deliberated further at the next ACC HODs Meeting, including the discussion of long standing CSRs that may need the intervention of high level meetings. (iii) Outcomes of discussion at the ACC HODs Meeting will be shared with ACA at the next ACC Meeting. The Meeting noted the offer of ACA to provide detailed information and discuss the pending CSR issue with HODs at the next ACC HODs, where necessary. The Meeting noted that following the circulation of ACA's information paper on labelling of notification number of 2D Barcode/QR Code, Brunei Darussalam, Indonesia and Singapore have provided their	

	comments to the paper	
6.4 Post Market Alert System	Cambodia presented the progress report of ASEAN PMAS as of 30 September 2021) The Meeting noted that a total of 160 alerts were raised for cosmetics, pharmaceuticals/biologics, health supplements, traditional medicines and others where 33 alerts received for cosmetic product were submitted by Brunei Darussalam, Malaysia, Myanmar, Philippines, Singapore and Thailand. The Meeting noted that in 2021 (up to 30 September 2021), 19 cosmetic products were found to be adulterated with 7 different pharmaceutical/banned ingredients namely (i) Betamethasone; (ii) Clotrimazole; (iii) Hydroquinone; (iv) Mercury; (v) Methanol/Methylalcohol; (vi) Tretinoin and (vii) CI 15585.	
AGENDA ITEM 7: REPORT OF THE 17th MEETING OF THE ASEAN COSMETIC TESTING LABORATORY COMMITTEE	The Chair of the ASEAN Cosmetic Testing Laboratories Committee (ACTLC) reported the outcomes of the 17th ACTLC Meeting held on 11-12 October 2021. The Meeting noted the following outcomes of the 17th ACTLC Meeting: Follow-up from the 16th Meeting of the ASEAN Cosmetic Testing Laboratories Committee (ACTLC) and the Pre-Meeting of Chair ASEAN Cosmetic Scientific Body (ACSB) – Chair ACTLC (i) The Pre-meeting between the Chair of ASEAN Cosmetic Scientific Body (ACSB) and Chair of ACTLC was held on 22 September 2021. Several issues were discussed during the Pre-meeting, among others, ACTLC's work on the prioritisation of high-risk substances; testing method for Titanium dioxide considering EU2021/850 amendment; if ACTLC have the capacity of laboratory methods to identify and quantify nanomaterials as well as topics from the previous discussions on 1,4-Dioxane, TTP in tagetes and methanol in cosmetic products. (ii) ACTLC discussed the interests of some ACTLC Members to participate in the ACSB Meeting as observer, and may need additional connection point from the host of ACSB Meeting. ACTLC agreed to seek ACC HODs' consideration in accommodating the participation of ACTLC Members in ACSB Meeting where additional connection points would be allocated. Determination of 1,4-Dioxane by Gas Chromatography Mass Spectrophotometry (GCMS) – HSS by Indonesia (iii) With regard to the study on 1,4-Dioxane by Gas Chromatography Mass Spectrophotometry (GCMS), ACTLC noted that Indonesia will complete the 1,4-Dioxane method using 1,4-Dioxane-d8 as internal standards by the end of 2021. ACTLC further agreed to establish a technical working group (TWG) on 1,4-Dioxane, with members from Indonesia, Singapore and Thailand who will continue with study. The TWG will update ACTLC Members on the progress of the study at the next ACTLC Meeting. (iv) On the request from the 33rd ACSB Meeting for the 1,4-Dioxane methods from Indonesia, Singapore and Korea, Indonesia agreed to share the method after the completion of ACM, Singapore has shared the method with ACTLC Members and agreed to share the method with ACSB Members. Korea agreed to share the method to ACSB Members. . Exploration of Methods for High Risk Prohibited Substances	ACA members may wish to take note of the development on testing related to 1,4-Dioxane as impurity. ACA members may also wish share any comment on the methods being discussed for testing of iso-butyl & iso-propylparaben.

	(v) ACTLC agreed to establish a TWG on Isobutyl paraben and Isopropyl paraben. The TWG is led by Viet Nam with Indonesia and Thailand as members. (vi) With regard to the method comparison for methanol, ACTLC agreed for Philippines, Brunei Darussalam and Viet Nam to further analyse the available methods before selecting one method as the possible ACM candidate. Philippines will report the outcome of comparison test at the next ACTLC Meeting. Handover of ACTLC Chairmanship (vii) On the handover of the Chairmanship of ACTLC from Thailand to Brunei Darussalam, ACTLC noted that the handover will be effective starting from 24 October 2021. ACTLC, through ASEAN Secretariat will follow up Cambodia on the vice-chairmanship position and seek confirmation by 23 October 2021. While waiting for Cambodia's confirmation, ACTLC requested Indonesia to consider the vice-chairmanship of ACTLC, as the next AMS in alphabetical order requested Indonesia to consult internally and inform ASEAN Secretariat on their decision by 23 October 2021. Workshop on Updating the ASEAN Guidelines for Harmonisation of Standards (viii) On the Workshop on Updating the ASEAN Guidelines for Harmonisation of Standards" organised by ACCSQ Working Group on Standards (WG 1), ACTLC requested ASEAN Secretariat to share outcome of the Workshop to ACTLC Members. ACTLC Online Training Courses and Expert Exchange Programme (ix) ACTLC agreed to set up ACTLC Online Training Courses and Expert Exchange Programme (EEP) and agreed for AMS to conduct internal consultation on (i) their representative for TWG and (ii) list of training needs AMS wish to have under this activity and provide their information to ASEAN Secretariat by 31 October 2021. The nominated TWG will report the progress at the 18th ACTLC Meeting. (x) The Meeting noted that during the Meeting of the HODs for the 34th ACC Meeting, Singapore and Philippines (in her capacity as ACSB Chair) had expressed their support for ACTLC Members to attend ACSB Meeting. The HODs further agreed to provide additional link for ACTLC Members.	
AGENDA ITEM 8: REPORT OF THE 34th ASEAN COSMETIC SCIENTIFIC BODY MEETING	Refer update in the table above: Specific to HSI presentation: The Meeting discussed HSI's recommendation notably for ACSB to form a TWG to gather baseline regarding cosmetic animal testing and animal free-safety assessment capacity across ASEAN countries and recalled the agreement of the ACC HODs to revisit this issue at a suitable time. The Meeting further agreed that if any action taken on this matter, ACC will consider the involvement of the industry. The ASEAN Secretariat informed the Meeting that following her presentation at the 34th ACSB Meeting, HSI has inquired of a decision, concern or next steps moving forward that has been agreed by the ACSB. In consultation with ACSB Chair, the ASEAN Secretariat shared the outcomes from the 34th ACSB and ACC HODs discussion to HSI that the ACSB was of the view that it is important to determine the level of expertise and facilities for ASEAN and understanding the local capability	ACA noted the update from ACC and requested ACC to revert back with the feedback on HSI proposal. ACA also shared that industry would be interested to participate in the TWG proposed.

	particularly the SMEs in terms of non-animal testing methods, and for HSI to engage at the ASEAN level via the ASEAN Secretariat and that ACC HODs will look into the issue at suitable time. In relation to the above, the ACC may look into the issue of the appropriate time after the resolution of priority issues.	
AGENDA ITEM 9: PROJECT PROPOSAL ON "CYBER POST MARKET SURVEILLANCE**"**	The ASEAN Secretariat updated the Meeting on the progress of the submission of the Concept Paper on "Cyber Post Market Surveillance" to AADCP and highlighted AADCP's queries on the concept paper. The Meeting noted the clarification forwarded by the AADCP and requested the ASEAN Secretariat to assist in providing responses on items (i) and (iv) to Indonesia and Philippines as proponents of the project.	ACA supports effort to do post market surveillance on e-commerce/online sales that is based on the same principle as on-shelf post market surveillance.
AGENDA ITEM 12: OTHER MATTERS **12.1 AANZFTA SC-STRACAP Program**	The ASEAN Secretariat updated the Meeting on the progress of the projects under the AANZFTA SC-STRACAP related to cosmetics: Stream 1: GRP on Cosmetics The Meeting noted that the Workshop on Good Regulatory Practice (GRP) - Cosmetics Sector was held on 20-22 October 2021 where majority of AMS and ACA attended. The Meeting noted that the final desk-based research report and the report of the workshop will be submitted to SC-STRACAP for consideration and endorsement as part of the milestone required of the project. The report of the workshop, which is focused on the recommendations identified from the desk-based research report, will be considered by the SC-STRACAP whether the recommendation merits taking each recommendation forward. The Meeting noted the request of ACC to be given an opportunity to provide inputs to ASEAN SC-STRACAP when deliberating on the recommendation of the GRP workshop, to ensure that the recommendations related to technical requirements (if any) are in line with ACD. Stream 2 Project on International Standards Engagement The Meeting noted that the Stream 2 project was approved by the AANZFTA Joint Committee (FJC) on 27 October 2020. The Project Implementation Plan (PIP) is being updated while the Monitoring & Evaluation (M&E) Plan and Project Adjustment Proposal is at finalisation stage. The upcoming activity "Standards Mapping and Gap Analysis Study" will facilitate the development of a report on standards harmonisation in the Cosmetics Sector across AANZFTA Parties. The implementation will include the following: (i) Obtaining standardization data, including published and yet-to-be published standards in the cosmetics sector; (ii) Obtaining data on project beneficiaries and relevant stakeholders; (iii) Data on participation in international standardization activities in the Cosmetics sector; (iv) Desk research and data analysis, incorporating industry economic and trade data. Following the Standards Mapping and Gap Analysis Study, a virtual workshop that will engage broad cross sector of stakeholders relevant to standardization in the cosmetics sector will be held in February 2022. With regard to the organisation of the Workshop, the ACC agreed on the proposal to hold the workshop on 17 February 2022	ACA continues to participate in the dialogues related to cosmetic with AANZFTA SC-STRACAP to find opportunities that will enable simplification of standards/requirement across ASEAN-AU-NZ. ACA will participate in discussion on Stream 2 in Feb 2022.
AGENDA ITEM 13: DATE AND VENUE OF THE FUTURE MEETINGS	The Meeting agreed to convene the 35th ACC Meeting and its related Meetings through online platform hosted by the ASEAN Secretariat on the following dates **Meeting** — **Tentative Schedule** 35th ACSB Meeting — 10 – 11 May 2022	ACA members to take note of the upcoming meeting dates including the proposed workshop with EU.

		18th ACTLC Meeting	11 – 12 May 2022
		ACC HODs Meeting	23 – 24 May 2022
		35th ACC Meeting	25 & 27 May 2022
	The Meeting also agreed to propose 9 May 2022 to EU as the tentative schedule for the Workshop on EU criteria and the process for categorizing cosmetic ingredients as Banned/Prohibited and CMR (Annex II).		