

36th ACSB Meeting Report & ACA Update/Next Step
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Link to updated Annexes: <https://drive.google.com/drive/folders/1mUmQ0FwVvWjKhxjOwoxXBjbNU-5yJp9h?usp=sharing>



Link to Appendix/Presentations: <https://drive.google.com/drive/folders/1BAatOpjgnWY8wAN3P9WEA2PFd-MIN94mY?usp=sharing>



ACSB Meeting Agenda (final):









36thACSB-Final
Agenda.pdf




36 th ACSB Meeting Agenda	36 th ACSB Outcome	ACA Update/Next step
4: CONTINUING DISCUSSIONS FROM the 35th ACSB MEETING		
4.1 Matrix of Follow-up Actions	 Matrix Follow Up Action from the 36 th	
4.2 Consolidated List of Banned Ingredients from EU Amendment of Annex II (EU 2019/831, EU 2019/1966, EU 2021/850 and EU 2021/1902)	<p>The ACSB Secretary presented the summary of consolidated list of banned ingredients to the Meeting and informing that the EU Annex II (EU 2019/831, EU 2019/1966, EU 2020/1683, EU2021/850, EU 2021/1902) were continuously consolidated, reviewed and considered by ACSB in the 32nd ACSB, 33rd ACSB, 34th ACSB, and 35th ACSB Meetings.</p> <p>The Meeting agreed to the ACSB Secretariat’s proposal that the identified 37 entries in the list which were not used in ASEAN are to be moved to ACD Annex II with the grace period of 24 months – Effective 21 November 2024, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.</p> <p>For the 27 entries with reported use in ASEAN, the Meeting agreed to Brunei Darussalam’s proposal and adopted to move entries #1428 and #1490 into Annex II with a grace period of 24 months – Effective 21 November 2024, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. Cambodia and Thailand informed the Meeting that they will seek consultation with their local industry and provide updates in the next Meeting.</p> <p>ACSB Secretary also informed the Meeting that the Ref# 1669 was removed from EU Annex II (EU 2022/1531). The background on the removal of Ref# 1669 from EU Annex II was presented under Agenda Item 5.3 New Issuance of EU Regulation of the 36th ACSB Meeting.</p>	<p>No action from ACA, other than making its members aware of the changes.</p> <p>Reference:</p>  APPENDIX 4-36thACSB-Update





<p>4.2.1 Perboric Acid, Sodium Perborate compounds and some Boron compounds listed in EU Annex III 1a and 1b</p>	<p>The Meeting agreed to include Perboric acid, Sodium Perborate and Boron compounds as a new entry to ACD Annex II with a grace period of 24 months – Effective 21 November 2024 only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.</p>	<p>No action from ACA, other than making its members aware of the changes.</p>
<p>4.2.2 Octamethylcyclotetrasiloxane (D4)</p>	<p>ACA presented the updated D4 assessment incorporating the review of the EU Commission Regulation 2018/35. The Meeting agreed to the proposal to include D4 as a new entry in ACD Annex II, with a 24 months grace period – Effective 21 November 2024, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.</p>	<p>No action from ACA, other than making its members aware of the changes.</p> <p>Reference: ACA presentation</p>  <p>APPENDIX 5-36ACSB_4-2-2_ACA</p>
<p>4.2.3 Silver Zinc Zeolite (SZZ)</p>	<p>ACA presented the safety assessment including the CIR review for the Silver Zinc Zeolite (SZZ) showing a margin of safety (MOS) of 1,301. In addition, as per CIR safety review on silicates, it also indicated that SZZ is safe for use in cosmetics. On this basis, ACA proposed for the addition of a new entry for SZZ in ACD Annex III for the following; (a) Foundation (b) Deodorant up to 1%, with 24 months grace period.</p> <p>The AMS, except for Indonesia, Singapore and Philippines agreed to the proposal from ACA to add the new entry for SZZ in ACD Annex III with a grace period of 24 months – Effective 21 November, 2024, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.</p> <p>Indonesia could not agree yet with ACA proposal and proposed the discussion to be pending until SCCS issued their Opinion on Silver Zinc Zeolite safety in cosmetics (SCCS opinion is expected to be available next year). The Philippines and Singapore sought for more information on the SCCS assessment of Silver Zinc Zeolite and additional safety data in the next ACSB Meeting.</p>	<p>ACA to monitor the progress of the SCCS review and publication of the official opinion on SZZ. ACA to present the findings of the same once available, at the next ACSB.</p> <p>Reference: ACA presentation on SZZ</p>  <p>APPENDIX 6-36ACSB_4-2-3_ACA</p>
<p>4.2.4 2-(4-tert-butylbenzyl) propionaldehyde (p-BMHCA)</p>	<p>ACA presented the safety assessment review on p-BMHCA which indicated p-BMHCA is safe for each product type of both leave-on and rinse-off products based on RIFM safety assessment review and SCCS opinion. ACA requested the Meeting for an appropriate grace period since the substance is widely used as fragrance in ASEAN.</p>	<p>No action from ACA, other than making its members aware of the changes.</p>





	<p>There was a discussion on the scientific evidence presented by ACA, which was earlier received from IFRA – RIFM. The Chair cited the SCCS opinion (SCCS/1591/17), which concluded that the MOS was not adequate considering the deterministic aggregate exposure. Hence p-BMHCA cannot be considered safe as per the SCCS opinion conclusion.</p> <p>The ACSB agreed to include p-BMHCA in ACD Annex II, including the 24 months’ grace period – Effective 21 November 2024, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.</p>	 <p>APPENDIX 7-36ACSB_4-2-4_ACA</p>
<p>4.2.5 Zinc Pyrithione (ZPT)</p>	<p>ACA presented the safety assessment for ZPT which indicated that it is safe for both leave-on and rinse-off hair products, based on the SCCS opinions. ACA proposed to maintain the ACD Annex III entry with restricted concentration. For rinse-off hair products, the allowed concentration is up to 1.0% while leave-on product is up to 0.1%. For preservative purposes, as ACD Annex VI, ACA proposed to maintain the current ACD entry with restricted concentration for rinse-off hair products is up to 1.0% and rinse-off non-hair products up to 0.5%.</p> <p>ACA further strengthened its argument in defence of ZPT citing:</p> <ul style="list-style-type: none"> - Consecutive safety reviews from SCCS, and also safety review from the US EPA - Approved food contact use in the US and Germany - Global use due its safety profile and long history of safe use <p>In response to a question from the AMS, ACA did acknowledge the availability of few other alternatives to ZPT. However ACA emphasized that banning ZPT will eliminate innovation opportunities.</p> <p>Singapore requested the Meeting to discuss first the Agenda item on carcinogenic (C), mutagenic (M) and reprotoxic (R) or CMR substances to clarify the ACSB’s decision-making process in adopting the EU Regulations for CMR substances with Categories 1A, 1B and 2 into the ASEAN Cosmetics Directive.</p> <p>ACA presented its proposal for the ACSB to consider in its decision-making process for CMR substances listed under the EU Regulations.</p> <p>The Meeting agreed with the proposal of the Chair for the creation of a Technical Working Group composed of ACA, Singapore, Brunei Darussalam, and the Philippines to review the criteria provided by the Article 15 of the EU Cosmetics, and ACA on the issue of CMR</p>	<p>ACA to follow-up and participate in the TWG. SAT to identify key participant in the TWG from their team. The TWG consists of ACA, Singapore, Brunei Darussalam, and The Philippines</p> <p>Reference ACA presentation on ZPT.</p>  <p>APPENDIX 8-36ACSB_Agenda4-</p>





	substances and provide updates in the next meeting. Hence, the Meeting deferred the discussion on ZPT until the next meeting.	
4.3 Amendment of EU Annexes III, IV and VI (EU 2021/850)		
4.3.1 Titanium Dioxide	<p>The ACSB Secretary provided the background information that the previous decision of the AMS in the 35th ACSB Meeting adopted to amend the entry of TiO₂ in Annex III only. ACA updated its presentation on the safety information on Titanium Dioxide.</p> <p>AMS agreed to adopt the revisions and amendment on the entries of Titanium Dioxide in EU Annexes IV and VI into ACD Annexes IV and VII, except for purity criteria, with a 24 months grace period - Effective 21 November 2024, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.</p> <p>ACSB Secretary was asked to clarify regarding the discussions during the 24th ACSB Meeting where the purity criteria for CI 77266 & CI 26100 was decided (25th ACSB meeting for CI 77266 and since 2005 for CI 26100). The ACSB Secretary will provide clarification regarding the background of the decision in the 24th ACSB Meeting and will be discussed in the next meeting.</p>	<p>No action from ACA, other than making its members aware of the changes.</p> <p>Reference: ACA presentation</p>  <p>APPENDIX 9-36ACSB_4-3-1_ACA</p>
4.3.2 Salicylic Acid	<p>ACA made a scientific presentation on Salicylic Acid relative to the additional products included in the EU Annex III entries, incorporating the information from AMS on their check on the usage of Salicylic Acid in their markets in terms of notified product types and applications.</p> <p>The Meeting agreed to adopt the corresponding entries for Salicylic Acid into ACD Annexes III and VI with a 24 month grace period - Effective 21 November 2024, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.</p>	<p>No action from ACA, other than making its members aware of the changes.</p> <p>Reference: ACA Presentation</p>  <p>APPENDIX 10-36ACSB_4-3-2_AC</p>
4.4 Amendment of EU Annex III (EU 2022/135)		
	<p>ACA presented the safety assessment on the fragrance raw material of Methyl-N-methylantranilate (MNMA) and proposed its inclusion in ACD Annex III, allowing the use of Methyl-N-methylantranilate (MNMA) with restricted concentration, with a grace period of 24 months.</p> <p>There was a discussion around the condition of use which states – “not to be used in sunscreen product and products marketed for exposure to natural or artificial UV light”. ACA clarified that MNMA would be banned only in primary sunscreens and not in secondary sunscreens. Singapore was specifically concerned about the definition of primary vs secondary</p>	<p>ACA to get more clarification from EU on the interpretation and implementation of this regulation. This will enable us to have a good discussion at the next ACSB and help close the topic.</p>



	<p>sunscreens. After a discussion it was agreed to seek further clarification from the EU commission about the condition of use. The Meeting deferred the decision to amend the ACD Annex III, Methyl-N-methylantranilate (MNMA) in the next ACSB Meeting.</p>	 APPENDIX 11-36ACSB_4-4_ACA
<p>4.5 Acid Orange 7 (ACD Annex IV)</p>		
	<p>ACA presented the safety review on acid orange on lip products and on other usage/product types other than its current allowed use based on the information provided by the AMS.</p> <p>The Meeting requested ACA to present the safety assessment of Acid Orange 7 as a coloring agent and provide feedback in the next ACSB Meeting.</p>	<p>ACA to prepare the safety assessment of Acid Orange 7 as a coloring agent for the next ACSB meeting. The important point is most of the coloring agents are based on food use also.</p>  APPENDIX 12-36thACSB_4-5_AC
<p>4.6 Cosmetic Refilling and Cosmetic Forms</p>		
<p>4.6.1 Cosmetics Refilling</p>	<p>The TWG presented the current draft (options 1 and 2) of the Information Sharing Paper on Cosmetics Refilling.</p> <p>All AMS, except Singapore agreed to use option 1. Singapore agreed to review their position and inform their final decision within 1 month.</p>	<p>No further action from ACA.</p> <p>References: Draft versions of option 1 & 2</p>  COSMETIC REFILLING_Option 1
<p>4.6.2 Cosmetics in vials and ampoules</p>	<p>Since the draft was circulated only just prior to the meeting, the Meeting agreed to a one month period for ACSB members to review the revised document. This agenda item will be discussed in next ACSB meeting.</p>	<p>ACA to inform the TWG lead of their final inputs and decision.</p> <p>Reference: Draft version of the information process</p>  Information Sharing Paper on Cc



<p>4.6.3 Customized cosmetic products and products in tablet forms</p>	<p>The Chair requested the TWG to provide the AMS with a copy of the updated draft of the Information Sharing Paper. The Meeting agreed to further discuss this topic in the next ACSB meeting.</p>	<p>ACA has already provided its inputs and is satisfied with the current version. ACA has stated its concern during the meeting that all AMS should adhere to this information paper and not create their own guidelines. This will become very difficult for industry to follow.</p> <p>Reference: Draft version of the Information sharing paper</p>  <p>APPENDIX 17- Information Sharing</p>
<p>5. NEW ISSUANCE OF EU REGULATIONS</p>		
<p>5.1 EU 2022/1176: Amending Regulation (EC) No. 1223/2009 for the Use of Certain UV Filters in Cosmetic Products; Benzophenone-3 and Octocrylene</p>	<p>ACA will present the safety review of BP3 and Octocrylene in the next ACSB meeting. The Chair also requested the AMS to review the cosmetic products containing Benzophenone-3 and Octocrylene in their markets for further discussion in the next meeting. The Meeting agreed to continue the discussion on EU 2022/1176 Benzophenone-3 and Octocrylene in next ACSB meeting.</p>	<p>ACA to prepare the safety of these sunscreens at the next ACSB.</p> <p>Reference: Proposal from ACSB</p>  <p>APPENDIX 18A-EU 1176-ACSB Proposal</p>  <p>APPENDIX 18-New Issuance of EU Regu</p>
<p>5.2 EU 2022/1181: Amending the Preamble of Annex V to Regulation (EC) No. 1223/2009</p>	<p>The ACSB Secretary presented the review of EU regulation No. 2022/1181 with subject on the Amending the Preamble of Annex V to Regulation (EC) No. 1223/2009. Given the fact this is a complex regulation due to lowered threshold of formaldehyde for labelling, etc., the Meeting agreed to defer a decision on this and further discuss this new regulation in the next ACSB Meeting.</p>	<p>ACA needs to follow-up with industry on this labelling requirement and also the challenges with analytical methods to test for formaldehyde at 10 ppm.</p>

		<p>References: Proposal and new regulation documents</p> <p> APPENDIX 19A-1181-ACSB Prop</p> <p> APPENDIX 19-New Issuance of EU regu</p>
<p>5.3 EU 2022/1531: Amending Regulation (EC) No. 1223/2009 for the Use in Cosmetic Products of Certain Substances Classified as Carcinogenic, Mutagenic or Toxic for Reproduction and Correcting that Regulation</p>	<p>The Secretary presented the review of EU Regulation No. 2022/1531 with the subject on the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction and correcting that Regulation.</p> <p>ACA stated the difficulties in adopting this regulation and requested more time for discussion within the industry. The Meeting agreed to further discuss the scientific basis on this new regulation in the next ACSB Meeting.</p>	<p>ACA to update members and get feedback on this regulation and the ingredients included therein.</p> <p>Reference: ACSB proposal and EU regulation docs.</p> <p> APPENDIX 20A-1531-ACSB Prop</p> <p> APPENDIX 20-New Issuance of EU regu</p>
<p>6: NEW PROPOSAL FROM AMS</p>		
<p>6.1 Proposal to Change Article 2 in the Terms of Reference (TOR) of ACSB</p>	<p>Indonesia presented her proposal to amend Article 2 of the TOR of the ACSB. Indonesia proposed to revise Article 2 (c) "Review the cosmetic ingredients listing in ACD Annexes by referencing ASEAN region as well as other regions and provide recommendations to the ACC on the adoption of the amendments."</p>	<p>ACA welcomes the statement suggested by Singapore as it is part of the current process of review for regulatory changes. ACA will provide their agreement within the stipulated time.</p>

	<p>Singapore proposed to maintain Article 2(c) of the TOR with the addition of the following; “Scientific opinions from other regions and countries could also be considered for amendments to the annexes.” The Meeting agreed with the proposed statement except for Malaysia.</p> <p>ACA’s position is to maintain the current TOR statement. In addition, ACA and Malaysia informed the Meeting that they will review the proposal and provide their comments after one month.</p>	<p>References Indonesia proposal document</p>  <p>APPENDIX 21-Indonesia Propo:</p>
<p>6.2 Cosmetic Packaged and/or Used Along with Microneedle</p>	<p>Indonesia presented the template for Cosmetic Products which were packaged and/or used along with microneedle.</p> <p>Taking into consideration that more research is required for such products, the Chair proposed to create a Technical Working Group to discuss on its innovation, the safety of these products, manner of application, its mechanism of action, and classification of these products in ASEAN. The TWG is composed of Indonesia, Thailand, and ACA. TWG will present their findings at the next ACSB meeting.</p> <p>Brunei Darussalam also commented that the TWG need to review whether notification system is enough to ensure the safety of such product, if it will be classified as cosmetics.</p>	<p>ACA to follow-up with its members to get more information on such products. ACA to nominate relevant representatives to also take part in the TWG proceedings.</p> <p>Reference: Indonesia proposal document</p>  <p>APPENDIX 22-Indonesia Propo:</p>
<p>6.3 Review the Safety of Plant Extract Containing Furocoumarines</p>	<p>Indonesia presented the proposal on this topic seeking clarification on:</p> <ul style="list-style-type: none"> - the proper interpretation and context of the entry “except for normal content in natural essence used” under ACD Annex II Ref. No. 358. - “What is the definition of normal content in this case and which plant extracts/oils containing furocoumarines can be used in cosmetic”. <p>ACA presented its views on the Furocoumarines (FCs) restriction and explained that the natural presence of FCs should be managed within GMP limits as described in article 17 of the EU regulation.</p> <p>The ACSB Secretary was requested to seek clarification from EU on the statement of Article 17 of EU Cosmetic Regulation related to proposal from Indonesia and provide feedback on normal content in natural essences used in the next ACSB Meeting.</p>	<p>ACA to follow up with EU industry on the possible explanations for this statement.</p> <p>References: Indonesia proposal & ACA Presentation</p>  <p>APPENDIX 23-Indonesia Propo:</p>  <p>APPENDIX 24-36ACSB_6-3_ACA</p>
<p>6.4 Review the Safety of Verbena Essential Oils</p>	<p>Indonesia presented the proposal for the review of the safety of verbena essential oils and derivatives, other than absolute (ACD Annex II Ref. No. 450) as non-fragrance ingredients.</p>	<p>ACA to prepare safety assessment of Verbena Essential Oils after getting relevant data from AMS.</p>

<p>and Derivatives other than Absolute (ACD Annex II Ref No. 450) as Non-Fragrance Ingredients</p>	<p>For the safety assessment, ACA requested the AMS to provide the product type and percentage of usage in products containing Verbena Essential Oils in their respective markets and the maximum concentration in the notified product, if possible. ACA will provide safety assessment on the Verbena ingredient in next ACSB Meeting.</p>	<p>Reference: Proposal document</p> <p> APPENDIX 25-Indonesia Propo:</p>
<p>6.5 Regulatory Deep Dive Clarification Among Member States in the Use of Cannabis Plant in Cosmetic Formulations</p>	<p>The Philippines presented the proposal for regulatory deep dive clarification among Member States in the Use of Cannabis Plant in Cosmetic Formulations.</p> <p>The AMS except for Thailand does not allow the use of products containing hemp and cannabis as cosmetic ingredients.</p> <p>No further requests for follow-up action were made by The Philippines.</p>	<p>No further action for ACA.</p> <p>References: Proposal document and Thailand presentation</p> <p> APPENDIX 26-Proposed Topic f</p> <p> APPENDIX 27-Cannabis-Thailar</p>
<p>6.6 Cosmetics Containing Microneedle-like Ingredients</p>	<p>Indonesia presented the proposal for the review of the safety of microneedle-like ingredients and the usage of the “microneedle” term as cosmetic products within ASEAN.</p> <p>ACA proposed to initiate a technical discussion on such materials and reminded the Meeting of the framework for reviewing new ingredients in ASEAN which are not in the EU regulations.</p> <p>The ACSB agreed to create a technical working group (TWG) to review several aspects of such materials and the technology. The TWG, comprising of Indonesia, Thailand and ACA will present their findings at the next ACSB.</p>	<p>ACA to work with the TWG to discuss the technology and review any data that may come from suppliers of such ingredients. ACA should also actively ask amongst its members if anyone has any specific technical knowledge about this technology.</p> <p>Reference: Proposal document</p> <p> APPENDIX 28-Indonesia Propo:</p>
<p>6.7 Clarification Regarding Hair Dye Ingredient</p>	<p>Indonesia presented the proposal for the review and clarification regarding hair dye ingredients which are listed in both ACD Annex III and ACD Annex IV (field of application 1).</p>	<p>No follow-up from ACA, other than informing its members of the discussion.</p>

<p>which are Listed in both ACD Annex III and ACD Annex IV (field of application 1)</p>	<p>The Meeting agreed further that a warning label should be required for all hair dye products in ASEAN. The Secretary was also directed to update Annex III, column f to include the required warning statement "Do not use to dye eyelashes or eyebrows" in all hair dye entries and also to revise Annex III to exclude the use for dyeing eyelashes and eyebrows from column c - the Field of Application.</p> <p>The AMS provided feedback to Indonesia that they allow the use of hair dye ingredients listed in Annex III and also in Annex IV as colorants (with field of application column 1) to be used in products to color eyelashes and eyebrows.</p> <p>No further requests for follow-up action were made by Indonesia.</p>	<p>Reference Proposal document from Indonesia</p>  <p>APPENDIX 29-Indonesia Propo:</p>
<p>6.8 Use of Diethyltoluamide (DEET) and Its Possible Banning in ASEAN</p>	<p>The Philippines presented the proposal for the review on the use of DEET and its possible banning in ASEAN. Since DEET is a popular insect repellent and used widely in such products, its status as a cosmetic ingredient was discussed in the meeting.</p> <p>Indonesia has stated in the meeting that product containing DEET cannot be accepted as cosmetics in Indonesia. Other AMS except Vietnam confirmed DEET can be used as cosmetic ingredient. Vietnam will provide feedback in next meeting.</p> <p>DEET is currently not included in EU and ACD Annex II, and listed in the EU CosIng directory. The ACSB will further discuss the status of this ingredient in the next meeting.</p>	<p>ACA should collect information from its members on the use of DEET. If industry is not able to defend the use of DEET as a cosmetic ingredient, possibly ACSB will ban the ingredient in the next meeting. ACA should review the safety of this ingredient for cosmetic use.</p> <p>Reference: Proposal document from Philippines</p>  <p>APPENDIX 30-ACSB Proposal - Diethylto</p>
<p>7: UPDATES FROM ACA</p>		
<p>7.1 Safety Evaluation of Cosmetic Ingredients</p>	<p>ACA reported the seminar on the Probabilistic approach for cosmetic combination use at the ASEAN Cosmetics Safety Assessment Workshop on September 2022. The Chair proposed that additional seminars can be conducted for the AMS.</p>	<p>ACA was happy to note the appreciation for the previous webinar organized in partnership with IFRA-RIFM. ACA will work closely with IFRA to organize more such webinars.</p>

		 APPENDIX 31-36ACSB_7-1_Prob
7.2 CMR Substances	<p>This agenda was firstly about a survey of the use of CMR substances in ASEAN, which the 35th ACSB had requested ACA to conduct, with the objective of establishing some “safe history of use” of such CMRs.</p> <p>ACA conducted a survey to obtain information on the CMR use from industry. However, very few industry members provided the response to ACA survey which may be attributed to confidentiality concerns.</p> <p>The Meeting requested the TWG to look into this issue. (TWG includes: <i>Singapore, Brunei Darussalam, Philippines, and ACA</i>)</p>	ACA to work with the TWG to propose a scheme for evaluating CMRs in ASEAN.
8: OTHER MATTERS		
	<p>Indonesia sought clarification about CI 45430, which has some requirements listed in Annex IV of the ACD - “Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 3% 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid”. The same requirement is not listed in the EU Annex IV for this CI.</p> <p>The ACSB Secretary will provide the background of the adoption of the entry under ACD Annex IV for this colorant in the next meeting. ACA will review and present this topic in the next meeting.</p>	<p>ACA to seek clarification – maybe from CosEU – about such requirement or wait for ACSB Secretary to provide more background. And then review the inputs received.</p> <p>Reference: Proposal form Indonesia</p>  APPENDIX 32-Clarification for C