

**Summary report on the 10<sup>th</sup> meeting of the ASEAN Cosmetic Scientific Body (ACSB)**

The meeting was held on November 19, 2008 in Singapore

The following issues were discussed.

Item	Content	Conclusion
Update of EU Annexes	<p>The meeting considered the following changes to the EU Annexes</p> <ul style="list-style-type: none"> <li>- Banning of the use of 40 ingredients as hair dyes by moving them from Annex III Part 2 to Annex II (they may still be used for other purposes)</li> <li>- Deletion of the hair dye usage of hydroquinone in Annex III, leaving only the allowance for it's use in artificial nail systems</li> </ul>	<p>The changes were adopted by the ACSB into the ASEAN Annexes.  <b>This was agreed by the ACC.</b></p>
AHA Labeling	<p>In continuation to the discussions held at the previous ACSB meeting, the meeting further discussed on the scope of the mandatory warning statement for products containing AHAs.</p>	<p>It was agreed that a guidance document is to be developed to clarify the circumstances under which the warning statement is not required.  <b>ACC agreed. Singapore and Malaysia will develop and circulate the draft guideline to ACSB Members for comments by 11 February 2009.</b></p>
Botanical ingredients	<p>The meeting has gathered available data on botanical ingredients that are banned for topical use in countries within and outside ASEAN.</p>	<p>It was agreed that the ASEAN regulatory agencies would then check the notified products in their countries against the banned list in China and UK to identify botanical ingredients commonly used before the meeting discusses the next step.  <b>ACC agreed.</b></p>
Alpha Arbutin	<p>The meeting considered the currently available safety data and concluded that there are no specific safety issues around the use of this ingredient.</p>	<p>The meeting agreed that there is no need to regulate the use of this ingredient in cosmetics. This means that the ingredient will be subjected to the normal safety assessment requirements covering all other ingredients.  <b>ACC agreed.</b></p>
IFRA Guidelines	<p>The meeting considered the proposal to incorporate IFRA guidelines into the ASEAN Cosmetic Directive.</p>	<p>The meeting concluded that this would be impractical and unnecessary as the compliance to IFRA guidelines already forms part of the safety assessment of the product.  <b>ACC agreed.</b></p>
Regulation of Methanol in Ethanol for	<p>Based on a standard implemented by the Thai Industrial Standards Institute, the Thai delegation submitted a proposal to restrict</p>	<p>Thailand agreed to present this information to the Standards for further discussion.</p>

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products used around the eyes	the level of methanol in ethanol for refreshing towels used around the eyes. In response to this, a CIR review report was circulated to highlight the fact that the toxicity of methanol is impeded when used as a denaturant for ethanol.	The meeting agreed to consider this item in depth at the next ACSB meeting when more information from Thailand becomes available. <b>ACC agreed.</b>
Zinc Pyrithione	The meeting considered ACA's proposal to include an additional usage for Zinc Pyrithione in rinse off hair products at concentrations up to 2%.	Upon review of the safety package circulated by ACA, the meeting agreed with the proposal. <b>ACC agreed.</b>
Tranexamic acid	The meeting reviewed the need to regulate Tranexamic Acid under the ASEAN Cosmetic Directive. Tranexamic Acid is not specifically regulated in EU, and is approved as a whitening active at 2-3% in Taiwan and 1.5-2% in Japan. Malaysia on the other hand classifies the ingredient as a Poison while Thailand has products in the market containing up to 7% Tranexamic Acid.	Due to the differing permitted levels of usage in different countries, the meeting agreed to include Tranexamic Acid in Annex III part 2 (provisionally restricted list), with a max concentration of 3% in leave on products and a prohibition for use in products coming into contact with the mucous membrane. This is to be implemented on <b>30 November 2009</b> . <b>ACC agreed and requested ACSB to look into the limits for rinse-off products at the next meeting.</b>
Borderline products – Dry mouth products	The meeting considered the classification of dry mouth products using the decision process under the ASEAN cosmetic claims guidelines.	The meeting agreed that dry mouth products can be considered as cosmetic products provided that the primary purpose is to moisturize the mucous membrane and not to stimulate the salivary glands. <b>ACC agreed.</b>
Borderline products – Perineal massage products	The meeting considered the classification of perineal massage products using the decision process under the ASEAN cosmetic claims guidelines.	The meeting agreed that perineal massage products can be considered as cosmetic products provided that the site of application is specifically the external genitalia and skin area. <b>ACC agreed, Thailand will provide further clarification on the instructions of use at the next meeting.</b>
Ingredient labeling with INCI name /CI numbers	The meeting considered the preferred name to use in the product labeling for ingredients that have both INCI and CI nomenclature.	The meeting agreed that the nomenclature used should be in line with the purpose the ingredient serves in the product, i.e. CI number when used as a colorant, and INCI name when used for other purposes. The meeting also added that this is a minor labeling issue and non-compliance to this should not lead to rejection or revocation of the product

		<p>notification. Mica (C177019) will also be added to the Annex IV to prevent misunderstandings on whether it is an approved colorant. <b>ACC agreed.</b></p>
Sunscreen Guideline	<p>A proposal on the labeling requirements for primary sunscreens was presented to the meeting. The guidelines include a series of warning statements that sunscreen products should include in their labels.</p>	<p>The meeting agreed to adopt the guidelines with the following clarifications: 1) That the guidelines are not strictly mandatory but strongly recommended; 2) The guidelines are applicable only to primary sunscreens; 3) There would be a 2 year grace period till <b>end November 2010</b>; <b>ACC adopted the guidelines and agreed on the grace period.</b></p>
Use of Silver Nitrate in hair dyes	<p>A proposal was made to extend the scope of usage for silver nitrate from the current scope of eyebrows and eyelashes to the whole head.</p>	<p>Upon review of the current safety data, the meeting concluded that this extension cannot be supported. The current ASEAN regulations would thus remain unchanged. Current hair dye products containing silver nitrate can thus remain on the market on up to end 2010. <b>ACC agreed.</b></p>
Labeling of period after opening (PAO)	<p>A presentation was made on the PAO labeling requirements in Europe.</p>	<p>Upon discussion, the meeting decided that PAO labeling should not be accepted in place of the current manufacturing/expiry date labeling required under the ASEAN Cosmetic Directive. However, the labeling of PAO on top of the current requirements is permitted. <b>ACC agreed.</b></p>
ISO updates	<p>Indonesia gave an update of progress on ISO/TC 217 &amp; 106, which may have an impact on cosmetic products.</p>	<p>The meeting agreed that Indonesia and Thailand would provide updates on the progress in these technical committees in the future and any proposal can be escalated through the ACC delegation. <b>ACC agreed.</b></p>
Mercury limit	<p>The Secretary made a proposal to adopt the US position on mercury, i.e. to set an upper limit of 1ppm (calculated as metal) for mercury in cosmetic products, with the exception of products for the eye area, where mercury can be allowed up to 65ppm (calculated as metal) if no other effective and safe preservative is available for use.</p>	<p>The meeting confirmed the previous agreed limit of 1ppm; <b>ACC agreed.</b></p>
Use of the “+”	<p>For clarification purposes, the Secretary</p>	<p>The meeting agreed.</p>

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symbol in the preservative annex	proposed for the preamble to Annex VI to be rewritten.	ACC agreed.
Camphor and menthol entries in Annex III	As it was not the original intention of ACSB to prohibit usage of camphor and menthol in products other than those currently mentioned in Annex III, the Secretary proposed for the Annex III to be amended to include a comment stating so.	The meeting agreed for the Secretary to draft the change for presentation at the next ACSB meeting ACC agreed.
Cosmetic products presented in eyedrop packaging	Malaysia presented to the meeting a misuse that has occurred on such a product.	The meeting agreed that such products should be considered medicinal by presentation. Where marketed, there should also be data supporting the safety of such products when applied to the surface of the eye, as such an application would be a <i>reasonably foreseeable</i> condition of use. ACC agreed and requested ACSB to make formal recommendation on the regulation of such products at the next meeting.
Regulation of caffeine	A proposal was made to look into the regulation of caffeine usage in cosmetic products	The Secretary agreed to gather further information on caffeine use in cosmetic products for discussion at the next meeting. ACC agreed.

Text in red: Final conclusions made at the ACC meeting.

## Summary report of the 11<sup>th</sup> meeting of the ASEAN Cosmetic Committee (ACC)

The meeting was held on November 20-21, 2008 in Singapore

### Update and highlights for ASEAN Meeting

- The ASEAN Secretariat gave the meeting an update on the ASEAN Economic Integration Initiatives, for supporting the establishment of the ASEAN Economic Committee (AEC) by 2015
- ACA thanked the ASEAN secretariat for the presentation and raised an issue regarding the ASEAN-China TBT agreement. As there are differences between cosmetic regulations in the 2 regions, ACA suggested for cosmetics to be considered as a priority area and seeks harmonization of cosmetic regulation so as to ease cosmetic trade between ASEAN and China. The ASEAN Secretariat assured that this is an area that will be taken into consideration once the process for communication of information is set up.

### Update on status of the implementation of the ASEAN Cosmetic Directive at National Level

- The Meeting noted that all Member States except Cambodia, Myanmar and Indonesia have transposed the ACD into the national legislation. The Meeting was informed that Cambodia and Myanmar are awaiting the approval of the draft legislation by the end of 2008.
- Cambodia further informed the Meeting that the notification will be fully implemented by 1 January 2009.
- Indonesia informed the Meeting that due to the internal processes, she is unable to provide an indication on when the notification system will be implemented. Member States urged Indonesia to take the necessary steps to implement the notification system soonest possible as their respective industries have raised concerns on the stringent registration requirements posed by Indonesia despite the entry into force of the ACD.
- The ASEAN Secretariat would look into the possibility of assisting Indonesia to expedite the transposition of the ACD into the national legislation.

### Update from Member States on the enforcement issues of the ACD

- The Meeting discussed the challenges faced by the regulators and enforcement authorities of the Member States with the full implementation of the ACD. The Meeting noted the problems faced by Member States and the key challenges were identified as follows:
  - a) Notification systems need to be further improved and should include measures to discourage the placing of unsafe products in the ASEAN market;
  - b) Further trainings to facilitate common interpretation of the ACD including the PIF and safety assessment for both the regulators and industries;
  - c) Further trainings on GMP for SMEs to enhance their capabilities;
  - d) The need to raise consumer awareness as well as to empower them as key partners in post-market surveillance activities;
  - e) Timely exchange of information among ASEAN regulators on the challenges and issues faced in the implementation of the ACD;
- The Meeting agreed to organise Heads of Delegation Meeting intersessionally to address the above concerns and further requested the ASEAN Secretariat to organize a meeting prior to the 12<sup>th</sup> ACC Meeting.

ASEAN Post Marketing Alert System

- Singapore presented an update of all the PM alerts done from Jan-Oct 2008
- The number of alerts received was 113 products with 46.9% for cosmetic products, 31% for pharmaceutical/biological products, 15% for traditional medicine and 4.4% for health supplements. The alerts were received for products containing banned ingredients, restricted ingredients, exceeding heavy metal limits, exceeding microbial limits, exceeding preservative limits and/or containing non-permitted colorants.
- The Meeting urged all Member States to participate actively in ASEAN PMAS as it serves as an important communication tool between Member States to alert each other on regulatory issues.

The 12<sup>th</sup> ACC meeting is tentatively to be held in last week of May 2009 in Malaysia, pending confirmation from the Malaysia delegation.

Compiled by Tan Kah Leng, January 2009