

Summary report on the 11th meeting of the ASEAN Cosmetic Scientific Body (ACSB)

The meeting was held on June 23, 2009 in Kuala Lumpur

The following issues were discussed.

Item	Content	Conclusion
Update of EU Annexes	<p>The meeting considered the following changes to the EU Annexes</p> <p>Annex II</p> <ul style="list-style-type: none"> - Replacement of entry 167 with '4-aminobenzoic acid and its esters, with the free amino group'. - Addition of diethylene glycol - Addition of Phytonadione <p>Annex III</p> <ul style="list-style-type: none"> - Addition of 17 entries under hair dye strategy - Addition of Toluene, Butoxydiglycol and Butoxyethanol - Addition of diethylene glycol with a 0.1% maximum limit (for trace levels from other ingredients) <p>Annex VII</p> <ul style="list-style-type: none"> - Deletion of 4-aminobenzoic acid - Deletion of words "in sunscreens" from column c for Diethylamino Hydroxybenzoyl Hexyl Benzoate 	<p>The changes were adopted by the ACSB into the ASEAN Annexes. This was agreed by the ACC.</p>
Camphor and menthol entries in Annex III	<p>In continuation to the discussions held at the previous ACSB meeting, the secretary presented to the meeting EU's decision to let camphor and menthol remain under the regulation of national laws. Indonesia and Thailand were then consulted on whether they intend to continue regulating camphor and menthol as national regulations.</p>	<p>As Indonesia and Thailand intends to continue regulating these 2 ingredients, the meeting agreed for them to come up with a proposal for adoption into the ACD, together with arguments on why the 2 ingredients need to be regulated. ACC agreed.</p>
Mechanism for communication of implementation dates for new additions to ACD Annexes	<p>The secretary proposed to establish a tracking spreadsheet of pending implementation dates for regulators and industry reference, The intention is to have the spreadsheet published on ASEAN and ACA websites.</p>	<p>The meeting agreed and further suggested that the same be established for initiatives passed during the ACC meeting. The updated template will be uploaded in the ASEAN and ACA websites for public reference. ACC agreed.</p>

<p>AHA Labeling guidelines</p>	<p>In continuation to the discussions held at the previous ACSB meeting, the meeting considered the draft guidelines developed by Singapore, which are as follows:</p> <ul style="list-style-type: none"> - Labeling mandatory for products containing glycolic and/or lactic acids at a concentration $\geq 2.5\%$ (i.e. for exfoliation purpose) and do not contain a sunscreen - Not required for products intended to be applied to non sun exposed areas, contains a sunscreen or a lower concentration of AHA 	<p>It was agreed that the conditions proposed be incorporated into Annex III of the ACD. ACC agreed.</p>
<p>Botanical ingredients</p>	<p>As a follow up from the previous meeting, Malaysia reported their findings on notified products containing the botanical ingredients listed in the China and UK lists.</p> <p>Philippines and Brunei reported no local notified product containing these ingredients.</p> <p>The meeting is pending feedback from the other member countries.</p>	<p>The meeting agreed to come up with a consolidated list of locally notified products containing ingredients in the China and UK lists by 1st October 2009.</p> <p>The meeting also agreed that the ACSB secretary would work with the ASEAN secretariat to extend an invitation to the China SFDA for review and control of botanicals in cosmetics.</p> <p>Singapore and Malaysia volunteered to conduct safety assessment for the 2 top ingredients in the Malaysian list. ACC agreed.</p>
<p>Methanol</p>	<p>The Meeting noted that Thailand had concluded her process to consider and amend control of methanol in ethanol specifically for use in refreshing tissues and product use around the eyes, and will further follow the requirements of the ACD.</p>	<p>-</p>
<p>Tranexamic acid</p>	<p>Per ACC's request, the meeting looked into the limits that need to be implemented for rinse-off products.</p> <p>As no supporting data or proposals were received from countries or industry, there is a choice of not restricting at all for rinse-off use or to adopt the same limits as leave-on products.</p>	<p>The meeting agreed to amend the previous agreement in conjunction with the consideration for rinse-off products such that there would be a common limit of 3% for both rinse off and leave on products. The prohibition for use in products coming into contact with the mucous membrane would be retained. ACC agreed.</p>
<p>ISO updates</p>	<p>The secretary presented an update of the progress on ISO/TC 217 cosmetic committee.</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. ACC agreed.</p>

<p>Preamble to the preservatives annex</p>	<p>As agreed in the last meeting, the Secretary presented the proposed amendment to the preamble to Annex VI. The proposal is as follows: “The substances marked with the symbol (+) may also be added to cosmetic products in concentration other than those laid down in this Annex for other purposes as specified in Annex III (List of Substances which Cosmetic Products must not contain except subject to restrictions and conditions laid down).”</p>	<p>The meeting agreed. It was also noted that many ingredients have their (+) sign removed in the EU Annexes due to the establishment of biocidal regulations in the EU.</p> <p>The meeting agreed that these should be retained in the ACD as there is no parallel regulation in ASEAN.</p> <p>The ACSB Secretary will provide a review of the borderline between the EU Cosmetics Directive and Biocidal Products Directive with particular reference to the impact of this borderline on continued use of substances currently in Annex 6 of the ACD by the next ACSB meeting.</p> <p>Malaysia and ACA agreed to assess the impacted ingredients and make proposals by end October 2009. ACC agreed. ACC requested ACSB to assess the EU Biocidal regulations to ensure that the interpretation on the removal of (+) is correct.</p>
<p>Regulation of caffeine</p>	<p>Based on information received, the proposal was for no specific regulations for caffeine.</p>	<p>The meeting agreed. ACC agreed.</p>
<p>Cosmetic products presented in medicinal packaging</p>	<p>The meeting considered the following types of packaging</p> <ul style="list-style-type: none"> - Eye dropper bottles - Blister packs - Syringes <p>Using the decision tree for borderline products, the secretary identified potential confusion in the areas of site of application and product presentation.</p> <p>There are also safety concerns as a cosmetic product must not cause damage to human health when used under normal or reasonably foreseeable conditions of use.</p> <p>As the risk and concerns would differ from product to product, the proposal is to avoid an umbrella regulation for all such products and to encourage the industry to consult local regulators on a case-by- case basis.</p>	<p>The meeting agreed on the proposal. To ensure alignment across ASEAN countries, the meeting also agreed that the country authorities would survey products on their local market and exchange information their own assessment outcome before the next ACSB meeting. ACC agreed</p>

Annex III Part 2 Deadlines	The ACD Annexes have been updated accordingly to reflect new EU review deadlines	ACC agreed
Updates on EU recast	<p>The secretary updated the meeting on progression of the EU recast.</p> <p>EC will create 4 new ad hoc working parties</p> <ul style="list-style-type: none"> - Nanomaterials - Guidelines on safety assessment - Definition/reporting of serious undesirable effects - Claims 	-
Thiolactic acid field of application	<p>Under the ACD, thiolactic acid is allowed for use only in hair waving and straightening products. This stipulation does not account for other known uses of thiolactic acid, such as anti-oxidant in hair dyes.</p> <p>As there are no restrictions on the usage of thiolactic acid in cosmetics in the EU and US, ACSB has been requested to consider an extension of field of application for thiolactic acid.</p>	<p>The meeting agreed that Malaysia and ACA would come up with a proposal for extending the use of thiolactic acid to a similar level as thioglycolic acid, including a limit for total thioacids by the end of August.</p> <p>ACC agreed</p>
Use of the word antiseptic in cosmetic products	<p>A motion was initiated to obtain opinion from each member country on the use of the word “antiseptic” for cosmetic products such as mouthwash, soaps, body wash, wipes.</p> <p>Examples of ingredients used for such claims are triclosan, chlorhexidine, chloroxylenol and alcohol.</p> <p>This was exclude antiseptic products for other purpose such as for pre-operative surgery, wound/cut cleansing, treatment/prevention of diseases or other medicinal purposes.</p> <p>While the scope of “antiseptic” is broader than “antibacterial”, the purpose is the same, i.e. prevention of contamination.</p> <p>With this, the proposal is to accept the use of the words ‘antiseptic’, “antibacterial” and “germicidal”, on condition that it is used as a secondary claim and that it is not associated with a disease state.</p>	<p>The meeting agreed</p> <p>ACC agreed</p>

FOR CTFAS MEMBERS ONLY

<p>Clarification for conditions in Annex II</p>	<p>Thailand sought clarification from ACSB on the correct interpretation of “when used as a substance in X products” in Annex II of the ACD.</p> <p>The secretary volunteered to make a proposal on the options and implications for revisions to the Annex II and III structure and function at the next ACSB meeting.</p>	<p>The meeting agreed ACC agreed</p>
---	---	---

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

Summary report of the 12th meeting of the ASEAN Cosmetic Committee (ACC)

The meeting was held on June 24 -25, 2009 in Kuala Lumpur

Update and highlights for ASEAN Meetings from the ASEAN Secretariat

- All 10 member countries have ratified the ASEAN Charter
- The AEC scorecard is one of the tools used to monitor implementation of the AEC Blueprint. SEOM will be taking stock of the challenges faced with the implementation of the measures in the blueprint.
- ASEAN Trade in Goods Agreement (ATIGA) has also been signed by all member states. Outreach programs for its effective implementation have been proposed.
- The updated ASEAN Trade Facilitation Work Program was endorsed by the 53rd CCCA.
- ASEAN FTA negotiations underway include the ASEAN-China MOU, the ASEAN-Japan Comprehensive Economic Partnership, the ASEAN-Republic of Korea Trade in Goods Agreement and the ASEAN-Australia/New Zealand FTA. The ASEAN-EU FTA is still in early stages of negotiation.

Update on status of the implementation of the ASEAN Cosmetic Directive (ACD) at National Level

- Cambodia informed the Meeting that ACD has been transposed to local regulations as of January 1, 2008. Product notification has however not been fully implemented as the Joint Declaration on notification fees between the Ministry of Health and Ministry of Economy and Trade is yet to be approved by the latter.
- Myanmar informed the Meeting that the local transposition of the ACD has been finalized and is expected to be approved by Q3 2009 for implementation by the end of 2009. In the meantime, the current cosmetic regulations will be active.
- Indonesia also shared with the Meeting the reasons that are resulting in the delay in implementation of the ACD. The Meeting noted that the main concerns faced by Indonesia were the lack of traceability mechanisms which place heavy burdens on the post market surveillance activities.
- The Meeting requested Indonesia to provide a firm indication of the timeframe for the implementation of the ACD, in particular the notification procedure. Indonesia informed the Meeting that she was unable to provide any timeframe at this point of time.
- Malaysia and the Philippines informed the Meeting that the business stakeholders have raised concerns on the trade restrictive measures imposed by Indonesia which is not in line with the ACD and urged Indonesia to provide an interim solution to this problem.
- Singapore proposed that Indonesia should consider a parallel voluntary notification procedure for low-risk products such as rinse-off products to start off with. Indonesia agreed to consider the proposal from Singapore and will discuss the matter internally and will revert back to the ACC as soon as possible.
- The Meeting agreed to update the SEOM on status of the implementation of the ACD together with the problems faced, noting that Indonesia was unable to provide any indication of the timeframe for the implementation of the ACD.

Updates on efforts take to ensure a common interpretation of the ACD by ASEAN Member States

- The Meeting noted that the HoDs had discussed the efforts taken at the national levels to ensure that there is a common understanding of the ACD which included the organization of training programmes, dissemination of information through the media and campaigns and inclusion in the tertiary education curriculum

Enhancing the capability of SMEs to comply with the ACD

- The ASEAN Secretariat updated the Meeting on the recommendations of the HoDs to enhance the capability of SMEs to comply with the ACD, which includes organization of trainings for the SMEs through collaborative initiatives with ACA and Dialogue Partners in terms of provision of experts as well as organize “Train the Trainers” programmes at the national and regional level.
- The Meeting also recalled the decision of the HoDs during their meeting in September 2007 on the flexibility and due consideration to be given to the SMEs through a progressive approach for compliance with GMP requirements, safety assessments and PIF.
- ACA will develop a training strategy and action plan to provide support to the SMEs and local industries.

Consumer Awareness Program

- The ASEAN Secretariat updated the Meeting on the recommendations of the HoDs on cooperation with the ASEAN Coordinating Committee on Consumer Protection (ACCCP) to raise consumer awareness and encourage safe cosmetic products purchases and enhance safe use.
- Thailand presented the Consumer Awareness Program that they have launched locally to the Meeting.

Achieving free movement of cosmetic products in ASEAN

- The ASEAN Secretariat urged the member countries to consider the degree of achievement of free movement of safe cosmetics in ASEAN with the implementation of the ACD.
- The ASEAN Secretariat agreed to come up with a proposal for circulation to member countries

Post-market surveillance

- Malaysia, Philippines, Singapore and Thailand updated the meeting on the efforts taken by their respective enforcement authorities on post market surveillance and the key problems encountered
- Malaysia delivered a report on the surveillance activities that were initiated and conducted based on risk. Products surveyed included products containing hydroquinone, baby products and products that have received complaints from consumers.

ASEAN Cosmetic Testing Laboratory Network

- Singapore updated the Meeting on the progress of the establishment of the ASEAN Cosmetic Testing Laboratory Network as a post-market initiative to support the implementation of the ACD.

ASEAN-China TBT MoU

- The Meeting noted the finalisation of the MoU and the implementation of the Joint Implementation Plan, which may include the cosmetic as one of area for cooperation.

ASEAN Post Marketing Alert System

- Singapore expressed difficulties in consolidating alerts for all ASEAN countries when the reports issued to them are in local languages and requests for alerts to be sent to in English when it is for consolidating and forwarding purposes

The 13th ACC meeting is tentatively to be held on 1-3 December 2009 in Chiang Mai, Thailand.