

Summary report on the 7th meeting of the ASEAN Cosmetic Scientific Body (ACSB)

The meeting was held on June 12, 2007 in Vientiane, Lao PDR.

ASEAN Cosmetic Claim Guideline

- The new version of the claim guideline proposal that focuses on the decision making process when assessing a product claim (as outlined in Proposal 1 of the Report of the 7th ACSB Meeting), was discussed.
- It was also decided to include the following to the document
 - >Some examples of unacceptable claims commonly observed for cosmetics under different product types (based on the format, i.e. a simplified list of examples of unacceptable claims, proposed by Singapore at the last ACSB meeting).
 - > A clause stating that the list of examples of unacceptable claims is not exhaustive.
 - > Reference that claims can be softened, e.g. by using words like “helps to”.
- *At the 8th ACC Meeting:*
 - *The revised ASEAN Cosmetic Claim Guideline was adopted by the ACC.*

Review of Product Categories

- Recap on Borderline Products: A recap was conducted on the following 11 borderline product categories to finalize their classification. The meeting agreed on a proposal to include these product categories to Annex I of the ASEAN Cosmetic Directive (ACD). A draft revision for Annex I was prepared (outlined in Proposal 2 of the Report of the 7th ACSB Meeting).
 1. Mouth wash
 2. Anti-caries toothpaste
 3. Anti-dandruff products
 4. Skin wash products
 5. Anti-bacterial, including rinse off
 6. Sunscreens
 7. Skin whitening products
 8. Anti-acne products*
 9. Anti-hair loss products*
 10. Anti-cellulite products*
 11. Bust contouring products

Note: * Use of the word “anti” is subject to confirmation by Thailand

- The entries of product categories containing the word “anti” are subject to confirmation/agreement by Thailand by 31 July 2007 as Thailand was concerned about the use of the word “anti” and its translation into local language.
- Ice Drops-Breath Fresheners: It was proposed that these products should be considered as cosmetic products.
- Eye-lash Perming Products: It was proposed that eye-lash perming products may be banned in ASEAN. This product category (usually containing thioglycollic acid or mercaptans) is currently banned in several US states because of eye safety concerns. It

was also decided that proposals to ban certain categories of products should be recorded to act as a summary of past decisions.

- Chemical Peels: In response to a request by the Heads of Delegations meeting, the following clarification would be given to ACC regarding chemical peel face masks that are currently listed in Annex I as outside the scope of cosmetic products: “Chemical peel face masks are skin treatments consisting of high concentrations of chemicals such as alpha-hydroxy acids (AHAs), chloracetic acid or resorcinol. They are used by dermatologists under clinical conditions to remove spots, acne or other blemishes”.
- *At the 8th ACC Meeting:*
 - *Based on the decision making process in the adopted ASEAN Cosmetic Claim Guideline, the ACC agreed to incorporate the following product categories into ACD Annex I:*
 - *Mouth wash*
 - *Anti-caries toothpaste*
 - *Anti-dandruff*
 - *Skin wash*
 - *Anti-bacterial*
 - *Sunscreen*
 - *Skin whitening*
 - *Anti-acne*
 - *Anti-hair loss*
 - *Bust contouring cream*
 - *Breath fresheners – liquid or spray*
 - *The ACC clarified that the word “anti” refers only to product categories and not to product claim. ACC agreed with Thailand’s proposal that the word “anti” should not be allowed to be translated by the industry into Thai language or to be put on labels for anti-acne and anti-hair loss products in Thailand.*
 - *With the exception of Thailand, all countries agreed that anti-cellulite products are to be considered as cosmetic products. Thailand clarified that anti-cellulite products are not considered as cosmetic products under current Thai legislations. Thailand would have to consult its national cosmetic committee before reverting to ACC.*
 - *ACC agreed that Eye-Lash Perming Products should be recorded in a forbidden product list to be set up by the ACSB.*
 - *ACC noted ACSB’s clarification of Chemical Peel Products referred to in ACD Annex I under “face masks (with the exception of chemical peeling products)”.*

ASEAN Microbiological Limits

- It was agreed that the guideline is to be used by the industry for ensuring safety, and by the regulators when conducting post-marketing surveillance testing.
- The limits that have been finalized and agreed upon by the meeting are given below (as outlined in Proposal 3 of the Report of the 7th ACSB Meeting).
- Thailand FDA however will retain testing for *Clostridia* species as a local test item for products containing crude herbal extracts.
- It was noted that regulatory authorities may carry out additional tests when they have specific concerns.

	Products for children under 3 years, eye area and mucous membrane	Other products
Total Plate count (Bacteria, Yeast and Moulds)	=< 500 cfu/g	=< 1000 cfu/g
<i>P. aeruginosa</i>	-ve per 0.1g or 0.1ml test sample	-ve per 0.1g or 0.1ml test sample
<i>S. aureus</i>	-ve per 0.1g or 0.1ml test sample	-ve per 0.1g or 0.1ml test sample
<i>C. albicans</i>	-ve per 0.1g or 0.1ml test sample	-ve per 0.1g or 0.1ml test sample

- *At the 8th ACC Meeting:*
 - *The ASEAN Microbiological Limits were adopted by the ACC.*

Adoption of Latest Changes to Annex II of the EU Cosmetics Directive (CD)

- It was proposed that ACD Annex II should be updated to include latest additions to the EU CD Annex II. Entries 423 to 1136 of EU CD Annex II would be included in ACD Annex II, in addition to the 3 banned ingredients from the ASEAN Handbook of Cosmetic Ingredients.
- In response to a request from the Heads of Delegations Meeting (Jakarta, 9-10 May 2007), the procedure outlined below will be adopted by ACSB to respond to changes to EU CD Annex II:
 - ACSB secretary will inform ACSB members of changes to Annex II and grace periods involved.
 - ACSB members are to respond within 2 weeks if there are issues requiring further clarification.
 - ACSB secretary will send the agreed proposal and updated ACD Annex II to the ASEAN Secretariat and ACC Chair for implementation.
- *At the 8th ACC Meeting:*
 - *The ACC agreed to the updating of ACD Annex II, to include the addition of the extra 107 ingredients.*

Hydrogen Peroxide in Tooth Whitening Products

- As a follow up from the previous meeting, Indonesia made a proposal based on input from the Indonesian Dental Association to stipulate the maximum concentration of hydrogen peroxide in home use tooth whitening products as 3%.
- It was thus agreed to retain the original ACSB agreement to allow hydrogen peroxide use in concentrations 0.1% to 6% under dentist supervision, as part of the national regulations. The final levels to be adopted into the ACD however will be pending the final decision in EU.

Adoption of Changes to the EU Restricted List Annexes

- Annex III Part 1 entries 66 - 97: All additions with the exception of the 26 fragrance raw materials were agreed upon for adoption to ACD Annex III Part 1.
- Annex III Part 2 entries: All additions (entries 1-62) were agreed upon for adoption into ACD Annex III Part 2 (provisional restricted list).
- Annex IV, VI & VII: All countries, with the exception of Philippines and Indonesia, agreed to adopt the changes per EU CD. Philippines and Indonesia are to review and revert before September 2007.
- It was also decided that updates to the ACD Annexes would be accompanied with an ACSB recommended grace period.
- *At the 8th ACC Meeting:*
 - *The ACC agreed to the proposal of not adopting entries 67-92 (26 fragrance ingredients) into ACD Annex III Part1.*

Fluoride Levels in Children's Oral Products

- Scientific evidence from SCCP, and ISO toothpaste standard child safety provision (total fluoride content of less than 300 mg per pack) were presented and a proposal was made to adopt the 1500 ppm (or 1100 ppm for Thailand under Article 11) limit in adult products for children's oral product as well, but to include advisory statements on pea-sized amount usage and adult supervision.

ASEAN Heavy Metal Limits

- ACSB secretary would be circulating a proposal based on current ASEAN National standards.

US Nomenclature for Labeling of Colorants

- A question was raised by Singapore on whether US FDA nomenclature for colorants should be accepted in addition to the currently accepted CI number labeling system.
- As there was no safety or technical issue over this question, ACSB agreed to refer the question to the ACC Heads of Delegation for a decision.
- *At the 8th ACC Meeting:*
 - *The ACC opined that use of EU INCI or US INCI names could be considered acceptable by the regulatory authorities.*

Whitening Ingredients and Natural Ingredients

In response to a request from the Heads of Delegations meeting to look into the safety assessment of ingredients that are used primarily in ASEAN but not assessed in the US, EU or Japan, ACSB decided that the first step would be to set up an inventory of botanical ingredients specific to the ASEAN region. Indonesia was tasked to collate and compile the lists of botanical ingredients regulated (banned, restricted or positively-listed, including banned herbal medicines) for ACSB's assessment of scope and further steps to be taken for action.

Responses to Public Safety Concerns on Cosmetics Products

Following a request from the Heads of Delegations meeting, the ACSB secretary was tasked to draft a one page process chart summarizing ACSB work methods for providing rapid information and support to ASEAN regulatory authorities and industry.

Other Matters Discussed

- Diethylene Glycol: The meeting noted the proposal made by Singapore to include Diethylene Glycol in the ACD Annexes. All countries will consider products containing this ingredient with caution while awaiting the final recommendation by the ACSB. The meeting discussed the addition of Diethylene Glycol to Annex III Part 2 (provisional restricted list). Following the meeting the ACSB made the recommendation to include DEG in Annex III part 2: not allowed in oral care products
- Royal Jelly: A request was made by Malaysia for assistance in evaluating the requirement for mandatory labeling of topical products containing royal jelly. Malaysia would be circulating a copy of the proposed labeling and scientific data for comment.
- Tranexamic Acid: Tranexamic acid is one of the remaining ingredients in the ASEAN Handbook of Cosmetic Ingredients for review. Malaysia would be contacting companies that market this ingredient to request sharing of safety data. It was noted that evidence of approval as a quasi-drug ingredient in Japan, could assist in the review process.
- Alpha-Hydroxy Acids (AHAs): In response to Indonesia's request for assistance in the regulation of AHA products, ACSB secretary would be circulating EU AHA guidelines for consideration. It was noted that while there is currently no legislative regulation in the EU and US for AHAs, there are industry voluntary limits on pH, concentrations, use of sunscreens and warning statements.
- Editorial Process: Several errors have been found in the ACD Annexes. ACSB would be continuing work on updating the ACD annexes.

Next Meeting: Due to ACSB's increasing workload, it was proposed that the next meeting should be extended from one to two days. The next meeting will be held in December 2007, in Viet Nam. Venue and date will be communicated in due course.

Comment [C1]: Whether to include limit proposed in Vientiane (with concentration limited to a maximum of 0.1% in oral care products/products intended to come into contact with oral mucous membranes)?

There was to be further discussion on this topic after Vientiane.

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