The Report of the Eighth Meeting of the
ASEAN Consultative Committee for Standards and Quality (ACCSQ)
The ASEAN Cosmetic Committee (ACC)
THE ASEAN Cosmetic Scientific Body (ACSB)
10 - 11 December 2007,
Ho Chi Minh City, Viet Nam

INTRODUCTION

The Eighth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) ASEAN Cosmetic Scientific Body (ACSB) was held on the 10 - 11 December 2007 in Ho Chi Minh City, Viet Nam.

ACSB Members Present

Brunei Darussalam	Mr Chong Chee Kiong Ms Jamilah Metusin
Cambodia	Dr Chhieng Phana
Indonesia	Dr Purwantyastuti Ms Nuning Barwa
Lao PDR	Mr Vongtavanh Chiemsisourath
Malaysia	Ms Anis Talib (Co-Chair) Ms Hamidah B Minhaj
Myanmar	Not present
Philippines	Ms Celia Ong Ms Esperanza Moya
Singapore	Dr Alain Khaiat Ms Marie Tham
Thailand	Mrs Narupa Wongpiyarattanakul Dr Simon Young (Secretary)
Vietnam	Dr Nguyen Van Loi Mr Nguyen Xuan Tien
ACA	Mr Tonny Pranatadjaja (Chair) Ms Zeny Soriano

Welcome, introduction & adoption of the agenda– Chair

The Chair welcomed the delegates and thanked the government of Vietnam for the arrangements and their hospitality. He also thanked the Ms Anis Talib for Chairing the previous meeting in his absence. The agenda was adopted with the following modifications,

1. The update on EU ingredient reviews by COLIPA was deferred.
2. Discussions on henna, azelaic acid, thiolactic acid, ethyl-4-bis hydroxypropyl aminobenzoate and grace periods were added under any other business.

Business arrangements & Actions from previous meeting – Secretary

The secretary confirmed that all actions from the previous meeting would be covered under the agenda.

Regulation of tranexamic acid

This ingredient is used as a skin whitening agent in leave-on skin products on the basis of a high margin of safety (Approx 547,400). The proposal from Malaysia to add tranexamic acid to Annexe III, Part 1 was unanimously adopted for proposal to ACC as follows.

Ref #	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warning which must be printed on the labels
A5	Tranexamic acid	Leave on products	2%		Keep out of reach of children

Recommended grace period – Products shipped to market from 01/01/2010 must comply (24 Months)

Regulation of royal jelly in cosmetics

Malaysia currently has a mandatory allergen warning for this ingredient. The key points of the discussion were that the allergenic potential of royal jelly is due to the presence of pollen, also present in all honey-based ingredients, and that different consumers may have allergies to pollen from different plant species. No other country in ASEAN or in a scan of international regulatory regimes has allergen labeling for royal jelly. The ACSB concluded that allergen labeling was not appropriate in this case and that consumer safety would be adequately addressed by the fact that royal jelly must be included, along with all other ingredients, in the INCI list mandated on the product label by the ACD. This will allow consumers with known allergies to avoid purchase and use of products containing ingredients to which they are allergic.

Regulation of menthol

Menthol is currently listed in Annexe III of the ACD with usage and labeling restrictions for leave-on products for children under the age of three years. ACSB Discussed need for regulation of menthol, with several countries proposing that menthol be deleted from Annexe III and regulated as being free to use provided that the resulting product meets the safety requirements of the ACD. A scientifically supported position for ASEAN will be developed for the next ACSB meeting using support data to be supplied by ACA (For oral hygiene products) and Thailand (Body powder).

Regulation of camphor

No scientific support data was available to ACSB to make a proposal on regulation of camphor. It is known that there were product recalls in France during 2007 due to alleged adverse effects in infants. The ACSB Secretariat will follow up with COLIPA to clarify the results of these recalls and will compile a safety package to enable a proposal for regulation to be made to ACC. It should be noted that the lack of specific EU regulation of camphor may be a result of the relative scarcity of camphor-containing products in the EU markets. Products with high levels of camphor are more prevalent in some ASEAN countries (e.g. body powders in Thailand) and may require control measures to be put in place.

Regulation of fluoride in children's oral care products

Following a discussion of the EU SCCNFP report on The safety of fluorine compounds in oral hygiene products for children under the age of 6 years (SCCNFP/0653/03) it was agreed to modify the wording of Annexe III, Part 1 entries 26-43 inclusive, 47 and 56 (fluorine compounds for oral hygiene products) as follows

Add to column e (Other limitations and requirements)

The amount of total fluoride in a single unit container shall not exceed 300 mg[1]

Footnote 1 - This requirement does not apply to containers of dentifrice to be dispensed under supervised conditions in community based caries prevention programs such as school toothbrushing programs

This wording is as per the ISO Standard 11609 and is intended to limit harmful effects to children who consume an entire tube of toothpaste. ACSB Discussed the relative merits of industry voluntary compliance with, and regulation of this maximum level. Products exceeding this limit are currently on the market in ASEAN and it was agreed that if responsible industry will comply with the limit then mandating the 300mg total F per pack will make it simpler for regulators to identify and control non-compliant products.

Add to column f (Conditions of use and warning which must be printed on the labels)

'For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. "for adult use only") the following labelling is obligatory:

"Children of 6 years and younger: Use a pea sized ● amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor."

ACSB also discussed whether ASEAN consumers would readily understand what a 'pea-sized amount' was, and whether an alternative, clearer example could be found. The final recommendation was that the wording in column f which must appear on the product label should be accompanied by a 6mm circle to graphically demonstrate the size of the bead of paste to be used for children under the age of 6 years.

Recommended grace period – Products shipped to market from 01/01/2010 must comply (24 Months)

Testing and labelling of sunscreen products

This subject was raised by Thailand with the aim of agreeing a harmonized ASEAN position on mandatory sunscreen labeling.

European Commission Recommendation 2006/647/EC on the efficacy of sunscreen products and their claims was discussed by ACSB. This recommendation covers all preparations (creams, oils, gels & sprays) intended to be placed in contact with the human skin with a view exclusively or mainly to protecting it from UV radiation by absorbing, scattering or reflecting radiation. Note that products providing UV protection for hair are not covered by this document, neither are products where UV protection is a secondary function e.g. skin lightening products with sunscreens. The guideline covers testing methods, claims, precautions for use and usage instructions and although it is not mandatory it has been agreed by the EU, US, Japanese and other international Industry Associations.

ACSB Propose that this document is accepted by ACC as a guideline for ASEAN regulators and industry. It was agreed that the guideline would help ASEAN industry, particularly SMEs, to improve the quality of their products and support materials.

ACSB Also propose that the mandatory statement "Do not stay too long in the sun, even while using a sunscreen product" be added to all entries in the UV Filter positive list (ACD Annexe VII).

Recommended grace period – Products shipped to market from 01/01/2010 must comply (24 Months)

Guidelines for use of Alpha-Hydroxy Acids (AHAs)

ACSB Discussed a proposal for regulation based upon the US FDA guidelines for the usage and labeling of products containing AHAs, which in turn was based on a review by the US Cosmetic Ingredient Review committee. These recommend limits on concentration and pH, and mandate sunburn warnings. The EU SCCP has also issued an opinion recommending much lower maximum concentrations of AHAs than those used in the USA, this opinion has not yet been translated into regulation.

The ACSB discussed that fact that ASEAN consumers are reportedly more sensitive to irritation by AHAs than caucasian consumers. It is proposed that the US CIR review, the US FDA Guideline and the EU SCCP opinion be shared by ACSB members with local dermatologist associations to develop a proposal for uniform regulation of products used by the general public, by professionals in salons and by dermatologists.

Note that current National cosmetic regulations in Indonesia and Thailand have specific requirements for AHA-containing products. Although these current regulations will be replaced by the ACD on January 01 2008 Thailand and Indonesia have confirmed that their National regulation of AHA products will continue between 01/01/2008 and the implementation of a single ASEAN position. Note also that all other ASEAN members will regulate AHAs under the ACD regulations only until an ASEAN AHA regulation is agreed.

Hydrogen peroxide in oral care products

Final discussion of this issue has been deferred several times while ACSB awaited resolution of the EU regulations. Discussions on post market monitoring, usage restrictions and specific warnings for products containing higher levels of hydrogen peroxide are still ongoing and so the aim of this discussion was to agree a proposal for ASEAN.

It is proposed that oral care products containing hydrogen peroxide will be regulated under three groupings based upon concentration as follow.

Ref #	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warning which must be printed on the labels
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	d) Oral hygiene products	d) 0.1% of H_2O_2 present or released		
		e) Tooth whitening products for application by the consumer under the supervision of a dentist	e) 6% of H_2O_2 present or released	For supply only through a dentist. Not for direct sale to the general public.	Not for direct sale to the general public. For supply only through a dentist. Use only under the supervision of a dentist Read and follow the instructions and use the product accordingly Do not use the product within 2 weeks prior to, or immediately after dental restoration Not for use by pregnant women or habitual tobacco and/or alcohol users Stop using immediately if you experience any tooth sensitivity, gum irritation, toothache, defective restorations, gingivitis, nausea etc. Store out of reach of children.
		f) Tooth whitening products for application by a dentist only	f) 35% of H_2O_2 present or released	Only to be used by a dentist. Not for direct sale to the general public.	Not for direct sale to the general public. Only to be used by a dentist Read and follow the instructions and use the product accordingly Do not use the product within 2 weeks prior to, or immediately after dental restoration Not for use by pregnant women or habitual tobacco and/or alcohol users Store out of reach of children

Recommended grace period – Products shipped to market from 01/07/2008 must comply (6 Months)

ACSB Also requests clarification from ACC on whether products containing >6% hydrogen peroxide for application by dentists only might be more effectively regulated under other regulatory regimes i.e. not as cosmetics at all. In this case the entry (f) above could be deleted and products containing >6% hydrogen peroxide would fall outside the scope of the ACD and would need to be regulated elsewhere.

Progress on ASEAN Inventory of Botanical Ingredients

Indonesia is making progress compiling the lists of natural ingredients but is still awaiting lists from some member countries. It was agreed that all countries will send soft copies of the lists of natural ingredients used for cosmetics in their markets to Indonesia by end of April 2008. Priority will be given to those ingredients which give a functional benefit e.g. whitening agents, colourants, anti-dandruff agents, preservatives etc. Indonesia will send out a template for data collection and industry will assist regulators in compiling national lists of ingredients actually used for cosmetic products.

Review of product categories for a recommendation on cosmetic status

ACSB Discussed whether the following product categories should be considered to be cosmetics under the ACD. The decision tree from the ACD Claim Guideline was used. Proposals to ACC are given below.

Bust creams	Cosmetic (Individual claims should be assessed to ensure that they comply with the cosmetic claim guideline).
False eyelashes	Not cosmetic. Not a substance or preparation.
Automatic fingernail painting systems	Paints applied to fingernails are cosmetic products
Face paints (For children or adults)	Cosmetic
Temporary tattoos	Cosmetic
Permanent tattoos	Not cosmetic (Injected under the skin and permanent effect)
Denture cleansers	Products applied to dentures outside the mouth are not cosmetic. Dentifrices intended for use in the mouth by denture wearers are cosmetics
Moist wipes	The liquid component of wipes making cosmetic claims (e.g. skin cleansing, refreshing, perfuming etc.) is cosmetic.
False eyelash glue	These do not strictly comply with the definition of a cosmetic product as they do not themselves change the appearance. However, ACSB looks to ACC for a view on whether the safety of these cosmetic-related products would be best assured by inclusion in the scope of the ACD

Recommended grace period – To be determined by individual countries

Restrictions on heavy metals in finished products

ACSB Reviewed International regulations on heavy metal limits for finished cosmetic products. There are very few of these. Philippines (BC2006-12) has limits for Pb (20ppm), As (5ppm) which are based upon those of Singapore, and Cd (1ppm). Thailand has limits for Pb (20ppm), As (5ppm) and Hg (0.5ppm). USA has a limit for Hg only (1ppm) and China has limits for Pb (40ppm) and As (10ppm).

Key points of agreement were that,

- Any limits set should be guidelines for regulator use only during the finished product analyses performed as part of in-market inspection i.e. they should not be imposed as a standard finished product test for industry to perform.

- Limits should only be applied when the ASEAN harmonized test methods are used.
- Limits should take into account the variability of the laboratory performing the assay.
- Whatever limits are agreed, heavy metals cannot be deliberately added as they are individually listed in Annexe II.
- In the absence of internationally agreed standards, limits might be seen as being non-tariff trade barriers unless they have a sound scientific basis.
- We do not currently have a sound scientific basis for heavy metal limits with the exception of a 1ppm limit for Hg.
- It is proposed that broad guideline limits be set to act as triggers for investigation of safety assessment, ingredient control and GMP and that these limits should be as follow

Mercury	1 ppm when tested by the PMS 1 ASEAN Standard Method
Lead	20 ppm when tested by the PMS 1 ASEAN Standard Method
Arsenic	5 ppm when tested by the PMS 1 ASEAN Standard Method

ASEAN Handbook Outstanding Issues

Henna

It was confirmed that henna has already been reviewed and added to Annexe IV (CI 75480).

Azelaic acid

ACSB Propose that this ingredient be banned by addition to Annexe II.

Recommended grace period – Products shipped to market from 01/01/2008 must comply (Immediate)

Thiolactic acid

ACSB Propose that this ingredient is added to Annexe III as follows

Ref #	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warning which must be printed on the labels
A6	Thiolactic acid and its salts	Hair waving or straightening products:	8.5% ready for use at pH <9.5 Percentage calculated as thiolactic acid.	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: - Avoid contact with eyes. - In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice. - Wear suitable gloves	- Contains thiolactic acid. - Follow the instructions - Keep out of reach of children.

Recommended grace period – Products shipped to market from 01/01/2009 must comply (12 Months)

Ethyl-4-bis hydroxypropyl aminobenzoate as a sunscreen

This ingredient is reportedly used as a sunscreen by one company only in Philippines, Indonesia, Thailand & Japan. It is not approved for use as a sunscreen in the EU or US. In the absence of any international support data the ACSB propose that this ingredient be removed from the ASEAN Handbook and not added to Annexe VII of the ACD. It is proposed that ACC should grant a one year grace period for the company to either reformulate or submit a safety assessment package to ACSB to enable them to propose its addition to Annexe VII. Once under review the ingredient could be added to Annexe VI, Part 2 until the review is completed. ACA will contact the concerned company and explain the situation to them.

Note that the ASEAN Handbook of Cosmetic Ingredients is now empty.

Bimatoprost

ACSB Propose that bimatoprost (CAS 155206-00-1) be added to Annexe II due to the fact that it is a significant risk to consumer health when used in cosmetic products. Note that this decision was not taken due to the fact that bimatoprost is a molecule with drug applications. ACSB Agreed that there could be circumstances where molecules with drug applications could safely deliver cosmetic benefits when used at different levels or by different routes of application e.g. tranexamic acid.

Recommended grace period – Products shipped to market from 01/01/2008 must comply (Immediate)

Grace Periods

ACSB Discussed the Philippines proposal for grace periods and agreed the following proposal

For ACSB proposals approved before 14 June 2007

These will become effective with implementation of the ACD on 01/01/2008

For ACSB proposals approved between 14 June 2007 and 09 December 2007

Additions to Annexe II will become effective with implementation of the ACD on 01/01/2008. All other changes will become effective no later than 01/01/2010. Note that member countries can elect to implement these changes earlier than this date.

For ACSB proposals approved after 09 December 2007

All ACSB proposals will be delivered to ACC with a recommended grace period based upon the assessed balance of risk to consumer health and the ability of industry to comply.

Adoption of Changes to EU Ingredient Lists

ACSB has now used the procedure for automatically updating the ingredient annexes following the issue of EU Technical Adaptation 2007/54/EC which added a number of hair dye ingredients to Annexe II. A copy of the directive was circulated to ACSB and ACC members by the ACSB Secretariat. No objections or requests for further discussion were received within the allocated response time and the ACD Annexe II was accordingly updated and sent to the ASEAN Secretariat. ACSB Members requested that in future, copies of the updated Annexes should also be sent to all members to enable the updating of National Authority and Industry Association websites.

Mechanism for Managing Public Safety Concerns

It was agreed at the last ACSB meeting that ACSB members would monitor their own markets and the media to detect potential public safety concerns regarding cosmetic products. An example of this mechanism at work is the identification and circulation of the bimatoprost issue which has now been addressed. It was noted that there are many other potential public safety issues occurring around the world e.g. lead in lipsticks that are not being discussed by ACSB.

Any other business

Red 2G

This colourant has recently been banned for food use in many markets due to concern that it is metabolized in the intestine to aniline, a known carcinogen. Red 2G is permitted for use in cosmetic products in Annexe IV of the ACD as CI 18050, and as such it is restricted for use to products intended not to come into contact with the mucous membranes. This means that it is not for use in oral care products and lipsticks which might enter the gastrointestinal tract. The ACSB Secretary will monitor any concerns raised for the use of Red 2G in topical products and will report back to the next ACSB meeting.

Next Meeting

The next meeting of the ACSB will be held back to back prior to the next meeting of the ACC and it is proposed that it should be a two day meeting to address the increasing workload of the ACSB.

Meeting Close

The Chairman then summarised the meeting and thanked the ACSB members, ACA, and observers for their valuable inputs, comments and attention. All present expressed their gratitude and appreciation to the host country for their arrangements and warm hospitality before the meeting was closed by the Chair.