

**5th ASEAN Cosmetic Committee Meeting
7-8 December 2005, Bandar Seri Begawan, Brunei Darussalam**

Thailand Country Report

Implementation of ASEAN Harmonized Cosmetic Regulatory Scheme

The Progress in Implementing ASEAN Cosmetic GMP

After the ASEAN GMP Guideline and the Modules had established, many challenges have occurred in the countries. As schedule in the year 2008 ASEAN GMP Guideline will be the guideline for all cosmetic manufacturers in Thailand, which is the most important thing since all cosmetic manufacturers whether they are big, medium, small or household business, they all have to follow ASEAN GMP Guideline.

Just like in our neighbor ASEAN countries, Thailand has different sizes of cosmetic business most of them are SMEs and household business so we have to concern more on how to educate them and how to make them understand thoroughly on ASEAN GMP Cosmetic Guideline and GMP Modules. Hence these kind of manufacturers require time and encouragement to understand all GMP guideline and modules to improve their capacity to reach the goal.

Addition to Cosmetic GMP in Thailand, we are now introducing quality system program to strengthen the capacity building of GMP auditors.
(Thailand GMP Roadmap is attached)

The progress in Post Marketing Surveillance

PMS 1

1. Responsible by Division of Cosmetic and Hazardous Substances, Department of Medical Sciences

2. Activities

The following activities have been carried out

2.1 Activities for the laboratory expertise, which covering :

2.1.1 As a working group established 8 ASEAN harmonized methods for cosmetic products i.e

- ACM SIN 01 Identification of tretinoin in cosmetic products by using TLC and HPLC
- ACM SIN 02 Identification of prohibited colorants in cosmetic products by TLC and HPLC
- ACM INO 03 Identification and determination of hydroquinone in cosmetic products by TLC and HPLC
- ACM INO 04 Identification and determination of 2-phenoxyethanol, methyl-,ethyl-, propyl- and butyl-4-hydroxy benzoate in cosmetic products
- ACM THA 05 Determination of heavy metals (As, Cd, Pb and Hg) in cosmetic products
- ACM THA 06 Microbial limit test for cosmetic products

- ACM MAL 07 Identification of hydrocortisone acetate, dexamethasone, betamethasone and triamcinolone acetonide in cosmetic products

- ACM MAL 08 Preservative efficacy test for cosmetic product.

2.1.2 Host trainer providing training course for two harmonized methods i.e ACM THA 05 and ACM THA 06 which was held at the Division of Cosmetics and Hazardous Substances during 29 November -3 December 2004. Seventeen delegates from 9 ASEAN countries attended the training course

After training Video CD with the practical actions for testing were also produced and submitted to CEN Team Leader (Mr. Alain Decharnat)

2.1.3 Training in EU statistics, measurement uncertainty, method validation, traceability, quality systems and proficiency testing, Ten delegates from 5 ASEAN countries including 2 delegated from Thailand attended the training course

Place : England and France

Time : 16-28 May 2005

2.1.4 Regional training for reviews and finalizing testing methods

It was organized by Brunei during 30-31 August 2005. Eight harmonized methods were reviewed and corrected. Interlaboratory comparison programme was discussed and finalized the protocol. Minutes and draft methods are under commented by all participants

2.1.5 Interlaboratory comparison programme

Proficiency testing for 2 harmonized method (ACM INO 03 and ACM INO 04) and collaborative study for the remain 6 methods were organized by ISIPCA in France. Ten samples were submitted to the laboratory of Division of Cosmetics and Hazardous Substance and also to other 8 ASEAN laboratories.

The samples are under testing by laboratories.

Test results will be sent to ISIPCA to evaluate the performance of all participating laboratory.

Regarding to EU Expert, Thailand will submit the result to EU Expert by next week, for ACM MAL 08 – the result will be submitted by the end of January 2006

2.2 National programme :

2.2.1 Training on ISO Guide 34, ISO Guide 43 and Technical assistance for data base information center.

2.2.2 National testing Laboratory for Indigenous materials.

Until now, there is no activity.

PMS 2-3

For Post-Marketing Surveillance ,Thailand has already established many activities beside the routine marketing surveillance such as setting alert system and hotline number 1556 for complaint service and inspection of advertisement.

Thailand has sent 2 representatives to participate in the training of PMS 3 in EU (in Germany and Hungary). After the training, we have gained lots of idea on PMS System in EU which happened long ago and was successful like in Germany and for the country as Hungary which just introduced this PMS system to the cosmetic industry. All this will become the reference for us when developing the PMS system to be in line with ASEAN Cosmetic Directive.

The progress in ACSB

ACSB sub-committee in Thailand has done 6 meetings so far , its aimed to set standard for the consideration of cosmetic ingredients safety evaluations among the group and it was very satisfied. We came out with lots of solutions ,ready for the 4th ACSB Meeting in Brunei.

The progress of transposition of ACD into national law.

As mentioned in the last meeting, we are now in the process of revision the Cosmetic Control Act. There has been many brainstorming meeting set up for both regulatory and industry including representative from Office of the Royal Decree Commission, they are reviewing and clarifying all relevant definitions of a New Cosmetic Bill to be in line with ASEAN Cosmetic Directive.

All this, cosmetic which (at the moment) divided into 3 categories namely

- Specially Control Cosmetic (high risk: have to be registered)
- Control Cosmetic (moderate risk: need notification)
- General Cosmetic (rather safe: no need for registration and notification but the label must meet rules and regulation before placing in the market)

will be no longer existed, but all of them have to be notified to the regulator. To support this activity the pre-marketing has set data base system contained all relevant information which will help serving both regulator and industry in running the process of Cosmetic Notification.

Beside, in the New Cosmetic Bill, the provisions of cosmetic advertisement, notification guideline, adverse cosmetic report and all relevant documents will be added according to ASEAN Cosmetic Directive.

Other matters

For the preparation to facilitate the Notification template, we are now setting the data base line contained information of cosmetic ingredients so that when we are started to implement the notification template all information are ready.

(Thailand Roadmap for development of Notification system is attached)