

**The Report of the Regional Workshop on the development of
Safety Assessment Guidelines
Bohol, Philippines 4-5 December 2006**

Introduction:

1. Following up from the first Workshop on the development of safety assessment guidelines held on 12-13 June 2006 in Siem Reap, Cambodia, the second regional workshop was held on 4-5 December to finalize the Guidelines for submission for adoption to the ACC.
2. The Regional Workshop was facilitated by Mrs. Marie Tham, Deputy Director, International & External Programmes, Health Sciences Authority, Singapore assisted by Dr. Alain Khaiat, PTB expert.
3. The Meeting was attended by representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam, ASEAN Cosmetic Association and the ASEAN Secretariat. Industry observers were also present.
4. The Agenda of the Workshop is attached as Appendix 1.

Review of the output of the first workshop:

5. A brief review of the output of the first workshop was presented in order to facilitate the discussion. The presentation as well as the first draft is attached as Appendix 2.

Discussion:

5. The workshop considered the input submitted by Member Countries and agreed to revise the first draft. The final proposal is attached as Appendix 3.
6. Main changes were made under the following headings:
 - Objective: addition of a sentence regarding the Safety Assessor
 - General approach:
 - Addition of consideration for “approved equivalent” of the GMP guidelines
 - Addition of stability studies
 - Raw Material supplier responsibilities:
 - Addition of toxicity studies under Animal extracts
 - Addition of a paragraph on fragrances and flavours

Conclusion:

7. The Workshop was held in the ASEAN spirit, and was very fruitful. The Meeting considered and adopted the Report of the Regional Workshop on the development of Safety Assessment Guidelines.

8. The participants also agreed to submit the final guidelines for consideration and adoption by the ASEAN Cosmetic Committee at the 7th meeting to be held on 7-8 December in Bohol, Philippines.

9. The workshop also agreed that upon adoption by the ACC, the Guidelines should serve as a reference document.

Follow-up:

10. The Workshop discussed the assistance required by Member Countries for implementation of the Safety Assessment Guidelines and agreed to recommend to the ACC the following:

- Identification of the gaps and training need analysis,
- More training and workshops at Regional and National levels to be provided to narrow the gap among and within ASEAN Member Countries,
- Training and workshops to be customized according to the needs of the regulatory authorities and industry focusing on:
 - PIF auditing (including safety assessment) for the regulators,
 - PIF development (including product safety assessment) for industry,
 - Pilot program to provide hands-on training to regulators and industry: submission of notification forms by selected companies (MNC, SME manufacturers and importers), development/compilation of PIF, audit of PIF and product audit in the market by regulators
- Development of a training booklet on “how to develop a PIF”, including a PIF mock-up and FAQ

Acknowledgement:

11. The delegates participating in the Workshop expressed their appreciation to the PTB for their kind assistance and to Philippines host country for their kind hospitality.