

## **The ASEAN Harmonized Cosmetic Regulatory Scheme**

The ASEAN Economic Ministers signed the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme at the 35th ASEAN Economic Ministers Meeting in Cambodia in September 2003.

The Scheme is the culmination of 4 years of work by the ASEAN Consultative Committee on Standards and Quality (ACCSQ) Cosmetic Product Working Group (CPWG), formed in 1998 in response to a request from the ASEAN Cosmetic Association (ACA) to harmonise regulations across the region to reduce technical barriers to trade.

The Scheme, which has been co-developed with the cosmetic industry, comprises the signed Agreement and its 2 Schedules as follows:

- a. Schedule A (Phase 1): ASEAN Mutual Recognition Arrangement (MRA) of Product Registration Approvals for Cosmetics; and
- b. Schedule B (Phase 2): The ASEAN Cosmetic Directive

Phase 1 is an interim voluntary phase whilst Phase 2 (ASEAN Cosmetic Directive) must be implemented by all member countries by January 2008. Member countries can choose to proceed directly to Phase 2 without going through Phase 1. Phase 1 has not been implemented by any country and, as we approach January 2008, is now obsolete

The common technical requirements under the ASEAN Harmonized Cosmetic Regulatory Scheme provide for a common definition for cosmetics, common labeling requirements, and detail the ingredients that cannot be used in cosmetics, those which can be used with restrictions, as well as the preservatives, UV absorbers and colorants which are permitted.

Basic principles of the ASEAN Cosmetic Directive are as follows:

No pre-market approval or licensing requirement. Company is to notify the authority of each Member Country before putting the product in the respective market place.

Company is responsible for safety of the products.

Compliance with all the requirements of the Directive is mandatory and must be certified in the notification form. A Product Information File (PIF) is to be prepared according to the Directive and kept at the address of the Company placing the product in the market. Products must be manufactured following the ASEAN Cosmetic GMP Guidelines.

Post-marketing surveillance system to monitor compliance. Company is to keep the product's technical and safety information readily accessible to the regulatory authority.

Trade implications by the ASEAN Cosmetic Directive are as follows:

Ease of doing business in the ASEAN countries as all the technical requirements are the same.

Facilitate export to EU countries as the ASEAN Cosmetic Directive is similar to EU Cosmetic Directives. The EU directive has some additional requirements which would need to be fulfilled.

Shifting from pre-market approval to post-market surveillance speeds up product launch in the ASEAN countries.

Greater reliance on market forces and industry self-regulation to ensure products meet the standards set out in the Directive.