## COSMETICS & SKINCARE PRODUCTS TESTING

Cosmetic products in Malaysia are regulated under the Control of Drugs and Cosmetic Regulations 1984. In conformance with the harmonization of cosmetic regulations in the ASEAN region, starting 1 January 2008, instead of registration, the companies will now be required to only notify / declare their compliance to the ASEAN Cosmetic Directive to the NPCB. Article 8 d of the ASEAN Cosmetics Directive 1 requires “Assessment of the safety for human health of the finished product, its ingredients, its chemical structure and its level of exposure”. This safety assessment is to be performed by a qualified professional defined as the “Safety Assessor”.

All cosmetics and skincare companies, whether they manufacture, import, or distribute cosmetic products must address the critically important issue of assuring the safety of their products and protect the consumers. General toxicological profiles for ingredients must be addressed. Potential irritancy of ingredients or mixtures of ingredients in finished products should be identified.
As far as skin is concerned, the two main untoward reactions to be avoided are skin irritation and skin sensitisation. Potential sensitizing ingredients or mixtures of ingredients should undergo predictive testing. Human data from skin compatibility tests ethically performed on the skin of human volunteers, supporting data for claimed benefits of cosmetic products should be made available to justify the nature of its effect.

Therefore, evaluation of any device intended for human use should provide data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by the device materials. The US Food and Drug Administration (FDA) 1995, in ensuring the safety of medical devices has enacted guidance for biological evaluation of medical devices incorporating the ISO 10993 testing matrix comprising in vitro and in vivo evaluations