I. BACKGROUND OF THE ASEAN HARMONISED COSMETIC REGULATORY SCHEME

ASEAN is a very important player in the global trade, regardless of product category, with a market of >500 million people as compared to EU's only >300 million. ASEAN with its 10 Member Countries namely; Brunei Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, Lao PDR, Philippines, Singapore, Thailand and Viet Nam, has always been focused on its economic and social growth. The region has a very strong economic alliance with the ASEAN Secretariat in Jakarta, Indonesia that has been working to meet its key goals of economic integration in the region. The vision of regional economic integration was conceptualised in recognition of the importance and potential of trade liberalisation and facilitation and in desiring to increase regional competitiveness.

However, market integration is not just about cutting or removing tariffs on trade. ASEAN countries have to make sure that non-tariff barriers including technical barriers created by standards, technical regulations and conformity assessment are removed. ASEAN has recognised the need to conclude Mutual Recognition Arrangements and harmonise standards and technical regulations in order to facilitate the movement of goods within the region.

In December 1998, ASEAN decided to meet this problem head-on by signing the Framework Agreement on Mutual Recognition Arrangements and the ASEAN Cosmetic Association was the driving force for this. In July 1997, the ASEAN Cosmetic Association officially asked the ASEAN Secretariat and the ASEAN Consultative Committee on Standards and Quality for help in removing barriers to cosmetics, specifically by harmonising technical regulations governing the cosmetic industry in ASEAN. Since then ASEAN cosmetic regulators and the cosmetic industry in the ASEAN region have been working together to address the issues associated with barriers.

As a result of this collaboration, the Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme (AHCRS) was signed on 2 September 2003. The AHCRS lays down the requirements for cosmetic products for all signatory ASEAN Member Countries starting from 1 January 2008. A product produced or marketed in any signatory country and meeting the requirements of AHCRS would be able to enter other signatory countries. The most significant aspect of this harmonised scheme is that all ASEAN Member Countries will move from the traditional and preferred approach of "pre-market approval" to the new approach of "post-market surveillance" for cosmetic products, considered being more effective.

The harmonisation of cosmetic regulations in the region will benefit all stakeholders: the consumers (a wider choice of safe cosmetic products), the regulatory bodies (one simplified regulatory system) and the cosmetic industry (open ASEAN as one single market for manufacturers, with more than 500 million consumers).

A. Coverage

Schedule A: Mutual Recognition Arrangement of Product Registration Approval

The product registration approval in an ASEAN country is recognised in Member Countries, where a mutual recognition arrangement has been agreed upon. Schedule A is a preparatory stage for Member Countries to proceed to Schedule B but a Member Country can opt to proceed directly to Schedule B.

Schedule B: The ASEAN Cosmetic Directive: Product Notification

The manufacturer or the person responsible for placing cosmetic products on the ASEAN market, shall notify the cosmetic regulatory authority of each Member State where the product will be marketed of the place of manufacture or of the initial importation of the cosmetic product before

it is placed on the ASEAN market. In most ASEAN countries, this is a transition from a pre-market approval (registration) system to post - market surveillance. All ASEAN countries are committed to implement Schedule B – the ASEAN Cosmetic Directive by January 2008.

B. Technical Documents

The following are the highlights of the ASEAN Harmonised Cosmetic Regulatory Scheme Common Technical Documents. These have been the result of close collaboration between the ASEAN governments and the cosmetic industry with the objective to harmonise cosmetic technical requirements among ASEAN Member Countries for the marketing of safe and quality cosmetic products.

i. **Illustrative List by Categories of Cosmetics**

The current EU illustrative list has been adopted with emphasis that this list is not exhaustive. Products satisfying the definition of cosmetic in the ASEAN Directive (similar to the EU definition) shall be allowed as a cosmetic.

ii. **Cosmetic Ingredient Lists**

The ASEAN Cosmetic Directive has the following Annexes:

Annex II : List of Substances which must not form part of the composition of cosmetic products.

Annex III : List of Substances which cosmetic products must not contain except subject to restriction and conditions laid down.

Annex IV : List of Colouring Agents allowed for use in cosmetic products.

Annex V : List of Excluded from the scope of the Directive.

Annex VI : List of Preservatives which cosmetic products may contain.

Annex VII : List of UV filters which cosmetic products may contain.

Additionally the Directive contains an ASEAN Handbook of Ingredients which lists the differences between current regulations and the Cosmetic Directive. The ASEAN Cosmetic Scientific Body (ACSB) is tasked with making a decision as to the status of the ingredients contained in the Handbook no later than January 2011.

iii. **ASEAN Guidelines for Cosmetic GMP**

This document has been the result of close collaboration between the regulatory authorities and the cosmetic industry with the objective to provide a simple guideline on Cosmetic GMP that addresses the needs of both the industry and government.

iv. **ASEAN Cosmetic Labeling Requirements**

Full Ingredient Listing will become mandatory. The International Nomenclature of Cosmetic Ingredients names (INCI) would be the primary reference for ingredient names on the label. Please refer to the ASEAN labeling requirements for details.

v. **ASEAN Cosmetic Claims Guidelines**

There will be no negative or positive list of claims. Claims will be subject to local country control because of difference in languages, interpretations, culture and religions. The definition of a cosmetic product, illustrative List by Category of Cosmetic Products, Ingredient Lists and and the ASEAN Cosmetic Claims Guideline shall be the technical documents that will guide the countries in the review of the acceptability of a cosmetic claim.

vi. **ASEAN Cosmetic Product Registration Requirements/ Procedure (Schedule A)**

This applies to all cosmetic products that are currently required to be registered in the respective ASEAN countries that have entered into

mutual recognition arrangement with another ASEAN country. Target registration processing period is 30 days maximum.

vii. **ASEAN Requirements for Import/Export of Cosmetic Products**

All cosmetic products manufactured in or imported from non-ASEAN Member Countries or ASEAN Member Countries have to comply with the ASEAN Harmonised Cosmetic Regulatory Scheme and its technical documents. Licensing and its requirements shall be regulated by each country's regulatory authority.

II. ASEAN COSMETIC REGULATORY HARMONISATION: FREQUENTLY ASKED QUESTIONS

A. General

1. What is the ASEAN Harmonised Cosmetic Regulatory Scheme? Who are affected by this Scheme and when is it effective?

A. The ASEAN Harmonised Cosmetic Regulatory Scheme is the agreed one standard scheme for regulating cosmetic products among the ASEAN countries. It is composed of:

(i) Schedule A – The Mutual Recognition Arrangement of Product Registration Approval (MRA) where a product registration processed and issued by one country is recognised by the ASEAN countries, who have signed the MRA.

(ii) Schedule B – The ASEAN Cosmetic Directive which is Product Notification scheme does not require registration. The company shall file the Product Notification with the regulatory agency in the country prior to placing the cosmetic product in the market.

ASEAN countries that accede to Schedule A can implement MRA between now and 1 January 2008. The cosmetic products marketed in these countries need to comply with the Schedule A – MRA requirements.

ASEAN Member Countries are committed to implement Schedule B – The ASEAN Cosmetic Directive by January 2008. Therefore, all cosmetic products marketed in the 10 ASEAN countries need to comply with the Directive requirements by 1 January 2008.

2. Why is ASEAN moving to this scheme? What are the benefits we can derive from this?

A. The Scheme aims to remove technical barriers to trade by harmonising regulatory and technical requirements across ASEAN without compromising product safety and quality. This would facilitate the flow of cosmetic products across ASEAN Member Countries to increase ASEAN's competitiveness in the region

3. How can I make ASEAN Harmonised Cosmetic Regulatory Scheme work for me? Who can I contact if I have questions? Where can I get help?

A. It is encouraged that the company/industry actively participates in all information dissemination campaigns and activities e.g. training, seminars, workshops, etc. to promote awareness and understanding of the scheme. Preparations for compliance with the regulatory scheme should start now and any concerns/ difficulties should be raised so that they can be properly addressed. The companies should also start to look for opportunities to expand marketing of products within the ASEAN region. Seek the help of your local regulatory authorities and industry associations if you have queries or concerns on the scheme.
(Please refer to Appendix 2)

4. Where can I get more information about the ASEAN Harmonised Cosmetic Regulatory Scheme?

1. Information about the ASEAN Harmonised Cosmetic Regulatory Scheme can be obtained from the following websites:
   a. ASEAN Secretariat (www.aseansec.org/4951.htm)
   b. ASEAN Cosmetics Association (www.ASEANcosmetics.org)
   c. Please refer to Appendix 2.

2. Information could also be obtained from the contact person in each Member Country and local cosmetics associations. (Appendix 2)

Schedule A - Mutual Recognition of Product Registration Approval

5. When do I need to comply with the ASEAN Cosmetic Product Registration Requirements? What will happen with the local registration requirements/timing?

A. If the country accedes to Schedule A – MRA, the cosmetic products marketed in these countries will need to comply with the ASEAN Cosmetic Product Registration Requirements when the country starts implementing the scheme. When this happens, the existing local requirements/timing will be superseded by the ASEAN requirements.

6. If my country implements Schedule A, what do I need to comply with? What do I need to do to ensure that I can comply with the requirements?

A. When Schedule A is implemented, the cosmetic product will need to comply with all the ASEAN Technical Documents on Cosmetic Product Registration Requirements, the ASEAN Cosmetic Labeling Requirements, the ASEAN Cosmetic Claims Guidelines and Cosmetic GMP and Annexes of prohibited and restricted ingredients.

The company should be aware and understand the ASEAN Common Technical Documents. The company's system and technical documentations would also need to be aligned with the MRA requirements. Seminars, trainings and workshops will be conducted and will be made available to the industry so we encourage that you actively participate in these activities.

7. Does change of any packaging materials of an existing product in the market require new product registration?

A. For those in Schedule A, no. For those not in Schedule A, please refer to the regulations on registration of your country and/or the country where you wish to market the product.

8. Does change of brand name of an existing product in the market require new product registration?

A. For those countries that accede to Schedule A, a change in brand name requires an amendment application. However, products that incur changes in the formulation which affect the product function and/or claims require new registration. For countries not implementing Schedule A, please refer to the regulation on registration of the country where you wish to market product.

9. How does the ASEAN Cosmetic Product Registration Requirements impact the current Product Notification or registration system existing in some countries?

A. In the country that choose to implement Schedule A, the ASEAN Cosmetic Product Registration Requirements shall only apply to all the cosmetic products to be marketed in the country. For countries that choose to proceed directly to Schedule B but have not yet implemented the ASEAN Cosmetic Directive (Schedule B) the existing regulatory requirements applies. But once the ASEAN Cosmetic Directive is implemented, notification of product will apply.

Schedule B - ASEAN Cosmetic Directive

10. What is Schedule B - the ASEAN Cosmetic Directive?

A. Schedule B or the ASEAN Cosmetic Directive shifts from a pre-market approval system (product registration) to a post marketing surveillance system, that will be implemented by all ASEAN Member Countries by January 2008 or earlier. The company or person responsible for placing the cosmetic products in the market, shall notify the cosmetic regulatory authority responsible for cosmetics of each Member Country where the product will be marketed of the place of manufacture or of initial importation before the product is placed in the market. The existing Product Registration system will be replaced by a Product Notification System where it involves an upfront declaration of compliance by the company responsible for the product. As the ntention of the Directive is to place the responsibility of ensuring product safety on the company that markets the product, self regulation by the cosmetic industry to ensure compliance with the safety and quality criteria, becomes an important part of the regulatory scheme.

11. What are the benefits we can derive from the implementation of the Directive?

A. As the Directive requires only product notification, the product to trade cycle will be shortened. Research breakthroughs and new product technologies can be made available to consumers faster. This will provide consumers with a wider choice of cosmetic products as well as help build cosmetic/ingredient safety database for the industry.

12. How will the Directive affect my company? How do I prepare for the implementation of the Directive?

A. The Directive identifies the company or person placing the cosmetic products in the market to be ultimately responsible for the safety and quality of cosmetic products. The company should take all necessary steps to understand fully and comply with all the requirements of the Directive. You should work with your cosmetic regulatory authority and industry associations to help prepare for the implementation of the Directive.

13. What are my responsibilities under the ASEAN Cosmetic Directive after it has been implemented?

A. You and your company will be fully responsible for the safety and quality of cosmetic products placed in the market. The following is a guide of what you will need to do when you intend to market a cosmetic product in ASEAN:

i. Be conversant with the all requirements of the Directive and the Annexes of ingredient listings (i.e banned, restricted and permitted

substances). Seek the help of the local regulatory authority and industry association.

ii. Take steps to ensure full compliance with the Directive's requirements and technical documents, particularly the requirement on the safety and quality of the cosmetic product.

iii. File Notification with the cosmetic regulatory authority in the country where you intend to market the product. Pay the necessary notification fee as required.

iv. Ensure that the technical and safety information required in Article 8 of the Directive (Product Information File) is ready anytime for inspection by the cosmetic regulatory authority.

v. Monitor products in the market for product quality or adverse cosmetic event. Report any serious adverse cosmetic event to the regulatory authority.

14. What is Post Marketing Surveillance (PMS)?

A. The Regulatory Authorities will conduct an on-going post-market surveillance programme on cosmetic products to ensure that they comply with the Directive's requirements. This may involve any or all of the following activities:

- Audit of Product Information File for compliance with the regulations, in particular, but not exclusively, on product safety.
- The Regulatory Authorities may, take products samples from manufacturers, importers and distributors to analyse them for compliance.

- The Regulatory Authorities may request for laboratory test reports from the company as and when necessary.

15. When the Directive is implemented, will the industry still need to label registration numbers on the product?

A. No. Product labels will no longer be required to reflect registration numbers.

16. What if I change formulation or packaging or claims of an existing product in the market? What do I need to do under the Directive?

A. Check if your formula changes comply with the ASEAN Cosmetic Ingredient Listings, the ASEAN Cosmetic Labeling Requirements, the ASEAN Cosmetic Claims Guidelines. You will also need to check if the change would require a new notification or amendment and file for the change accordingly.

17. What is the role of the cosmetic regulatory authority under the Directive?

A. The cosmetic regulatory authority has the authority to enforce post-marketing surveillance to ensure compliance with the ASEAN Cosmetic Directive. They can visit the company anytime, with or without prior notice, to audit the Product Information File as well as take samples for analytical testings. In the event of non-compliance with requirements of the ASEAN Cosmetic Directive, the regulatory authority can impose sanctions for the violation as defined in the local laws and issue a product recall if deemed necessary to protect public health.