**APPENDIX IV**
**ASEAN COSMETIC PRODUCT REGISTRATION REQUIREMENTS**
**Technical Document**

## A. Introduction

The ASEAN Product Registration Requirements/Procedures shall be reduced to their simplest form. This scheme shall be reviewed to evaluate if it can already be replaced by the ASEAN Cosmetic Directive scheme for all cosmetic products with focus on post-marketing surveillance system.

## B. Coverage

The following shall apply to all cosmetic products that are currently required to be registered in the respective ASEAN countries. Registration is defined as the submission of information on the product and undergoing an evaluation and approval process prior to marketing the product. The ASEAN member countries, based on their existing laws, shall designate the cosmetic products that need to undergo the requirements of registration. The ASEAN member countries shall, within their own competence, may accept product registration approvals of any of the ASEAN member countries, which regulate cosmetic products. This process of mutual acceptance of each others product registration approvals mean that, where an ASEAN member country product registration approval that complies with this ASEAN Cosmetic Product Registration Requirements is obtained , the other ASEAN member countries may agree to such approval and may allow the corresponding cosmetic products to be marketed in their respective countries.

The above shall also apply to imported products from non-ASEAN countries and marketed within the ASEAN region. However, the country issuing the product registration shall take necessary steps to ensure that the imported product being registered complies with the ASEAN Harmonized Cosmetic Regulatory Scheme Technical Documents.

## C. Registration Leadtime

Registration leadtime is preferably 30 working days maximum.

## D. Validity of Product Registration

The Product Registration shall be valid for 5 years subject to renewal. Any change in the formulation which affect the function of the product and any change in the product claims shall require a new product registration.

## E. Registration Requirements

**1.** ***Language Requirement:*** English and/or the most common language used in each of the countries where the product is to be marketed.

**2.** ***Technical Requirements***:

2.1 Qualitative composition of the product with INCI nomenclature of ingredients or any approved nomenclature as given in any standard references that may be approved from time to time. Quantitative composition is required for substances with restrictions for use. The master formula of the product shall be made available to the cosmetic regulatory agency when requested or necessary.

2.2 Finished Product Description. Finished Product Specifications as required by the country.

2.3 Test Methods as required by the country.

2.4 (i) Certificate of Free Sale and License to Operate /Manufacture[11]; or

(ii) Certificate of Free Sale and Certificate of Good Manufacturing Practice ; or

(iii) Certificate of Origin[1] ; or

(iv) Certificate issued by the Board of Health or competent authority stating that the manufacturing plant meets the national requirements in terms of hygiene, safety and quality.

Certificate of Free Sale shall be issued by the Board of Health or any compenent authority of the country where the product is marketed stating the country of manufacture.

License to Operate/Manufacture shall be issued by the Board of Health or cosmetic regulatory agencies from the country of manufacture.

Certificate of Good Manufacturing Practice shall be issued by the Board of Health or cosmetic regulatory agencies from the country of manufacture.

Certificate of Origin shall be issued by the Board of Health or cosmetic regulatory agencies from the country where the finished cosmetic product has been manufactured (i.e. cream, gel, pencil, stick.).

In the event that there is no issuing regulatory agency in all cases, the document may be issued by recognized associations. Qualification of these associations rests with the industry or any country agency and a list shall be made available to all ASEAN Member Countries.

2.5 Technical data or clinical data (when appropriate) to support special product claims.

2.6 Information sheet containing the product decsription/use, methods of administration, necessary precautions to be observed during use of the product, declaration of shelf life and method of decoding batch reference, pack sizes available, information on the product owner, manufacturer or assembler.

2.7 Company's declaration of absence of prohibited substances and compliance with the content limits of restricted substances.

2.8 Business License of the registrant or the company/person responsible for placing the product in the market.

2.9 Label copy

2.10 Samples as required by the country

**3.** For a product that has an existing product registration approval issued by any ASEAN member country, the following shall be submitted to the cosmetic regulatory agency in the other country/ies where the product is to be marketed:

3.1 Notification Letter advising the cosmetic regulatory agency that the product will be marketed in the country. The Notification shall consist the following information:

[1] The License to Operate/Manufacture or Certificate of Origin shall indicate that the manufacturing plant have met the national requirements in terms of hygiene, safety and quality. This statement is made with the end view that the ASEAN Cosmetic GMP shall be the reference guideline for manufacturing standards in ASEAN within the agreed implementation timing of the Member States.

i. Name of Product
ii. Product Brand
iii. Product Description
(*Describe the form of cosmetics such as cream, gel, powder, pencil, stick etc)*
iv. Purpose of Cosmetic (intended use)
*(Describe the purpose of the cosmetic such as baby product, deodorant, eye lotion, hair dye, hair shampoo, skin moisturizer, etc.)*
v. Product Formula
*(Shall consist of full ingredients listing and indicate percentage of restricted ingredients)*
vi. Packaging particulars
*(Describe the packaging and their pack sizes, e.g. glass, 10ml, 30ml & 100ml)*
vii. Name and address of person responsible for putting the product on the market
viii. Name and address of manufacturer or contract manufacturer
ix. Name and address of importer
x. A copy of the product label

3.2 Certificate of Product Registration certified true copy by the issuing agency.